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Original Paper

Data-Driven User-Type Clustering of a Physical Activity Promotion App: Usage Data Analysis Study

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Abstract

Background: Physical inactivity remains a leading risk factor for mortality worldwide. Owing to increasing sedentary behavior (activities in a reclining, seated, or lying position with low-energy expenditures), vehicle-based transport, and insufficient physical workload, the prevalence of physical activity decreases significantly with age. To promote sufficient levels of participation in physical activities, the research prototype *Fit-mit-ILSE* was developed with the goal of making adults aged ≥ 55 years physically fit and fit for the use of assistive technologies. The system combines active and assisted living technologies and smart services in the *ILSE* app.

Objective: The clustering of health and fitness app user types, especially in the context of active and assisted living projects, has been mainly defined by experts through 1D cluster thresholds based on app usage frequency. We aimed to investigate and present data-driven methods for clustering app user types and to identify usage patterns based on the *ILSE* app function *Fit at home*.

Methods: During the 2 phases of the field trials, *ILSE* app log data were collected from 165 participants. Using this data set, 2 data-driven approaches were applied for clustering to group app users who were similar to each other. First, the common approach of user-type clustering based on expert-defined thresholds was replaced by a data-driven derivation of the cluster thresholds using the Jenks natural breaks algorithm. Second, a multidimensional clustering approach using the Partitioning Around Medoids algorithm was explored to consider the detailed app usage pattern data.

Results: Applying the Jenks clustering algorithm to the mean usage per day and clustering the users into 4 groups showed that most of the users (63/165, 38.2%) used the *Fit at home* function between once a week and every second day. More men were in the *low* usage group than women. In addition, the younger users were more often identified as *moderate* or *high* users than the older users, who were mainly classified as *low* users; moreover, the regional differences between Vienna and Salzburg were identified. In addition, the multidimensional approach identified 4 different user groups that differed mainly in terms of time of use, gender, and region. Overall, the younger women living in Salzburg were the users with highest average app usage.

Conclusions: The application of different clustering approaches showed that data-driven calculations of user groups can complement expert-based definitions, provide objective thresholds for the analysis of app usage data, and identify groups that can be targeted individually based on their specific group characteristics.

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KEYWORDS

active and assisted living; app usage; cluster analysis; Jenks natural breaks algorithm; Partitioning Around Medoids algorithm; physical activity promotion; usage groups

Introduction

Background

Around 1.65 million people ≥ 65 years old were living in Austria in 2018. This number will increase to 2.5 million in 2040 according to the 2018 population forecast of the Austrian Conference on Spatial Planning [1]. The increasing number of older adults highlights the need for health-promoting measures to prevent immobility and ensure a good quality of life for this growing segment of society.

To date, the recommended physical activity dosage for healthy insufficiently active adults consists of 150 minutes of moderate to vigorous physical activity per week [2,3]. In addition, according to the World Health Organization (WHO) [4], people ≥ 65 years old with poor mobility should be physically active for ≥ 3 days per week, focusing on functional balance to prevent falls. However, every exercise session, whether short (seconds to minutes) or long (minutes to hours), counts toward reducing the risk of cardiometabolic morbidity and mortality [5].

To promote physical activity, the fitness program *Fit-mit-ILSE* was introduced as part of the Austrian Active and Assisted Living (AAL) research project, *fit4AAL*. The project aimed to make the increasingly technology-familiar generation of ≥ 55 years fit and *fit for the use of assistive technologies*. Within the program, an app called *ILSE* was developed to support and encourage the older adult population to exercise at home or outdoors through videos and courses on a tablet or 3D camera system.

In particular, the analysis of app usage is of interest in determining the acceptance of apps in general and fitness apps. Actual app usage can be monitored by analyzing the questionnaire or app usage log data, which may include exercise frequency tracking. App usage and reasons for fitness and health apps have been addressed in various studies. For example, the study by Dadaczynski [6] analyzed the user experience and the actual use of the web-based intervention *Healingo Fit* with a user experience questionnaire and usage data. The results showed particularly high satisfaction values for the dimensions of attractiveness, stimulation, and originality. Analysis of the log data revealed that the app was visited on average 65 times a day within 6 weeks [6]. The study by Schneider et al [7] discussed the use of the AAL prototype CARIMO and found from the analysis of the log data that the use of the CARIMO app remained quite stable during the test months. The study by Meyer et al [8] analyzed the use of activity trackers and described their general use, changes over time, and characteristic patterns of activity tracker usage in the long term.

The definition of app usage groups characterizes users and can be used as a grouping variable in statistical tests. From an exercise prescription perspective, identifying user types is important for creating a personalized fitness training program. Such personalization aims to engage in health-promoting physical activity, improve physical fitness levels, and maintain users' exercise fidelity [9]. A wrongly tailored exercise program, that is, if the exercises are too difficult and too intense, will not be adopted by the user [9,10]. By analyzing app usage and

identifying the types of usage, app limitations can be identified. For example, it is possible to investigate which user groups are using the app and which groups may not yet be addressed and therefore may need other engagement strategies.

Thus far, different approaches have been used to identify and group app usage groups. Meyer et al [8] and Schneider et al [7] used expert or predefined categorization limits to define different use patterns or user types. Data-driven clustering of users was performed by Lim et al [11], who used daily step counts from activity trackers of 140,000 individuals and clustered them into 16 user segments.

However, to the best of our knowledge, no common definition exists for classifying fitness app users into user groups. Groups of app users can be clustered based on either expert knowledge [7,8] or data-driven methods [11], which offers a less subjective grouping option and can help experts identify an objective classification.

Objective

This paper proposes 2 data-driven usage-type clustering approaches that can be used to characterize the users of the training module of the *ILSE* program. We aimed to answer the following 2 research questions: How can *ILSE* app user types be defined in a data-driven manner? How are these user types characterized?

Log data from the *ILSE* app's *Fit at Home* training module were used for the analysis, and users were categorized in 2 different ways. The 1D clustering approach was based on usage frequency, and the classes were defined using the Jenks natural breaks (Jenks NB) [12] algorithm, with the number of groups and the lower bound set manually. The second multidimensional clustering approach was based on multiple features of app usage, and the Partitioning Around Medoids (PAM) [13] clustering algorithm was applied to identify app usage patterns.

Methods

Overview

The analysis was based on *ILSE* app usage data from the AAL project *fit4AAL*. The *ILSE* system combines smart home components and smart services such as the *ILSE* fitness app. The fitness app aimed to encourage and support elderly exercise at home or outdoors via prerecorded videos and courses on a tablet or 3D camera computer. Participants in the program used the *ILSE* app in a field study for several weeks. There were 2 field trial phases in the Austrian cities of Vienna and Salzburg as well as in the surrounding area of Salzburg. The participants were able to use the system for 13 consecutive weeks before they returned the systems in either trial phase 1 or trial phase 2. The first trial phase was from April to September 2019. The second phase began in September 2019 and ended in March 2020.

Study Design

Overview

A prospective controlled trial using a wait-list protocol was conducted. To analyze the usage of the *ILSE* app, usage data from the first and second field tests were collected.

The developed system included 2 *ILSE* app versions (1 for the tablet and 1 for the 3D camera system). The app received physical activity data from a fitness tracker (eg, steps, duration, and type of activity) and additional smart home components. The *ILSE* app consisted of 4 different modules for German-speaking participants (see Figure 1 for an overview of the system).

Figure 1. The *ILSE* app and its modules provided on the tablet version and the 3D camera system version. e-Learning: electronic learning.



Exercise Module

In *Fit zu Hause* (translated as *Fit at home*), the users could access their training plan tailored to their fitness level. Each day, a different workout session of 10, 20, or 30 minutes could be selected, which consisted of exercises to improve strength and balance.

The *ILSE* app version on the 3D camera system, namely the Orbbec Persee [14], supported an overview of the training sessions performed and an advanced exercise module by using skeletal tracking to detect starting positions, counting repetitions, and notifying the trainees when unfavorable positions for selected exercises occurred.

Before the participants received the system, the *ILSE* coaches, who were specifically trained sports scientists, assessed the functional fitness of each participant and configured the functional training plan tailored to the fitness level of the participants.

Physical Activity Module

Within *Fit unterwegs* (translated as *Fit on the move*), users could keep an outdoor activity diary by entering their activities manually or by wearing the fitness tracker using the integrated activity recording. Furthermore, a connection to the outdoor platform *outdooractive* [15] enabled users to plan their next outdoor activities (such as hiking or cycling).

e-Learning Module

The module *Fit durch Wissen* (translated as *Fit by knowledge*) offered a total of 24 e-learning topics that focused on health- and fitness-promoting exercise training and physical activity for adults ≥ 55 years old.

Motivation Module

The *Erreichtes* (translated as *Achievements*) module displayed the activities performed and the goals achieved in terms of

physical activity engagement. The exercise module allowed users to check how much exercise they had performed and the duration of training sessions. In terms of behavior change concepts, all engagements were summarized, and users received weekly medals.

For the following analyses, only those participants who used the *ILSE* app at least once during the field study were included in the analysis. In total, 79% (79/100) of participants from the first test phase and 79% (86/109) of participants in the second test phase used the system. As there were no notable differences in *ILSE* app usage and demographic characteristics between the 2 field test phases [16], the 2 phases were analyzed together to obtain a larger sample size of 165 users.

For each participant, the test week was defined as the week beginning with the day of the week in which they received the system. For example, if they received the system on a Thursday, their test weeks started on Thursdays and ended on Wednesdays. The first test week was assumed to be the familiarization phase for participants; therefore, the first test week was excluded for all. The subsequent analysis of app usage was based on 12 continuous test weeks (test weeks 2-13) for each participant. For the analysis, visits were aggregated per test week and participant.

Data Collection and Aggregation

Usage data of the *ILSE* app were collected via *Matomo*, an open-source web analytics tool [17]. Usage data describe the log data of the *ILSE* app visits, such as date, time, and visit duration. The main metric of interest for *ILSE* app usage is a *visit*. A visit is defined as the access of a webpage (in our case, the *ILSE* app) by a visitor more than 30 minutes after their last opening of *ILSE* (see the glossary of *Matomo* for detailed descriptions [17]). For the analysis, this definition of a visit was further narrowed so that it consisted of at least 2 actions within

30 minutes; that is, if someone only opened the app, the visit would not be counted.

To identify the *ILSE* app user types, the analysis focused on those visits that opened the exercise module *Fit at home*. Visits that contained only the other 3 modules were not considered in the following analyses.

Apart from usage data, demographics (age, region, gender, education, and household size) were added to describe app users and find usage patterns. For the analysis, Austrian education levels were grouped according to the International Standard Classification of Education classification [18].

Furthermore, information on fitness level and subjective stated amount of daily exercise and sports was collected at the

beginning of the field test to include participants' previous experience in relation to movement in the analyses. The fitness level as a score between 1 (not fit) and 4 (very fit) was assessed by sports scientists at the beginning of the field test. In addition, participants indicated how much time they spent on average during a typical exercise session. They also indicated how many days per week, on average, they do fitness exercises and how many days they ride a bicycle. Furthermore, the self-reported number of hours they sat on an average day was included in the analysis. As demographic- and exercise-related variables were not available for all participants, Table 1 provides an overview of these variables and the availability of given information based on the number of observations.

Table 1. Overview of the demographic- and sports-related variables included in the analysis (N=165).

Characteristics	Observations, n (%)
Variables	
Region	165 (100)
Age (years)	165 (100)
Gender	165 (100)
Household size	165 (100)
Education level	165 (100)
Fitness level	129 (78.2)
Subjective variables	
Sports duration	138 (83.6)
Number of days with fitness exercises performed	163 (98.8)
Hours in sitting position	163 (98.8)
Number of days on which they ride a bicycle	78 (47.3)

Ethics Approval

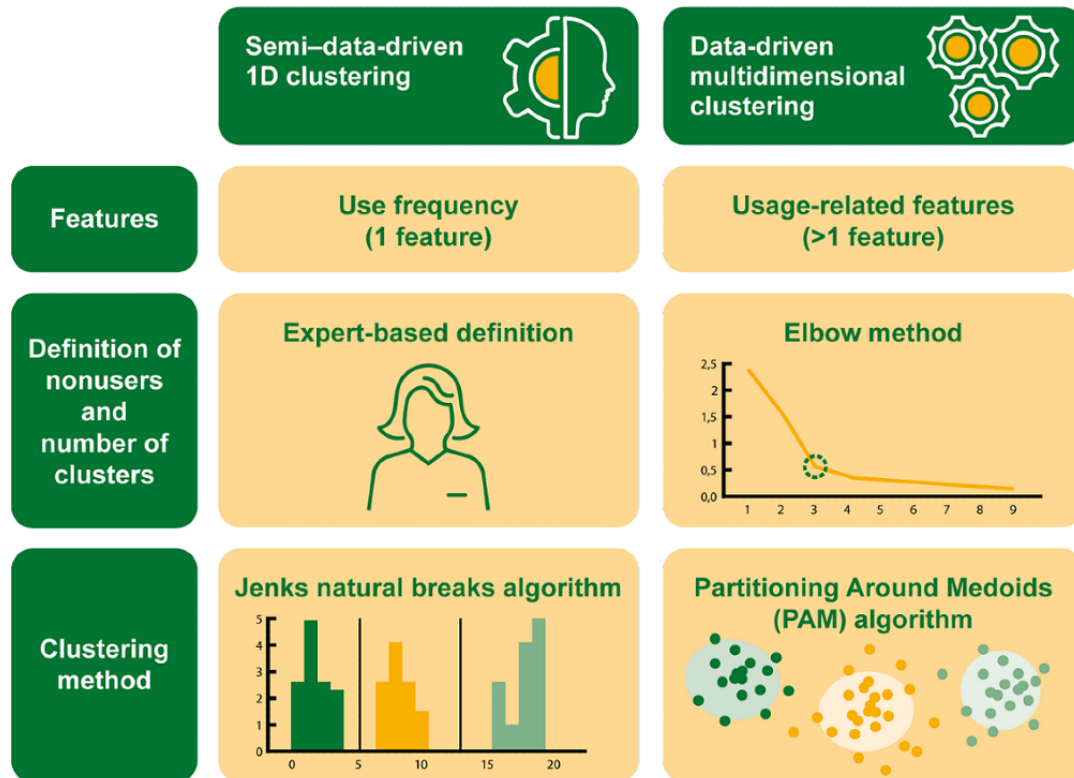
All participants provided written informed consent before their participation in the study. The study was conducted in accordance with the guidelines of the Declaration of Helsinki and was approved by the ethics committee of the University of Salzburg (protocol code EK-GZ:09/2018).

Data Analysis

Statistical analysis was performed using R (R Foundation for Statistical Computing; version 4.1.0) [19]. The clusters based

on the 1D algorithm were calculated using the package `classInt` [20], the multidimensional clustering algorithm with the package `cluster` [21]. For the generation of plots and data preparation, several packages [22-27] were applied. To test the statistical relationship between app usage types and demographic- and sports-related variables, a chi-square test was applied for categorical variables and a Kruskal-Wallis test was applied for numerical variables. The significance level was set at .05 in both cases. To determine app usage types, 2 data-driven approaches were presented and explored. Figure 2 presents an overview of the 2 clustering approaches.

Figure 2. Overview of the 2 user-type clustering approaches.



Semi-data-Driven Usage Frequency-Based Clustering Approach

This 1D approach is similar to the usual clustering approach for user types, where experts use the usage frequency as a basis to categorize user groups by means of thresholds and, hence, identify subgroups, called clusters, that have cases that are similar to each other but different from other groups in a data set [28]. As in the work of Schneider et al [7], we defined a total of 4 groups but calculated the cutoff points in a data-driven manner with nonequal length based on the Jenks NB [12] clustering algorithm, which identifies the interval thresholds of the groups in a data-driven manner. Jenks NB was developed for the analysis of geographic data and has the additional requirement of a predefined number of clusters [29]. It is similar to the k-means algorithm as it minimizes the within sum of squares of the classes [30].

Furthermore, in the first approach, the lower threshold that defined *low* was set manually. *Low* users were defined as those that did not use the app at least once per week. A single visit was assumed to equate to a training frequency of once per week. There are indications that positive health results can already be expected from a frequency of once per week in the target group of >65 years old [31,32].

Data-Driven Multidimensional Clustering Approach

As *ILSE* app usage is not only characterized by the pure usage frequency, the second approach took several features into account. The app users were clustered not only by the frequency of the *ILSE* app usage but also by app usage patterns such as *When did they use ILSE?*, *For how many days did they use ILSE?*, *Did they use the tablet or the camera system?*. Furthermore, at the beginning of the field test, subjective stated

number of days per week with fitness exercises performed and the hours in sitting position were included in the multidimensional clustering, as these 2 variables were available for almost all (163/165, 98.8%) users. In total, 14 features were used for the calculations of the multidimensional clusters of 165 users.

As Jenks NB only works for 1D data, a different clustering algorithm needed to be used. We focused on a partitioning clustering method because it is easier to interpret and implement than hierarchical approaches [33].

The cluster group size was determined using the Elbow method, and the PAM algorithm (see the study by Kaufman and Rousseeuw [13] for the idea and details of PAM) was applied for cluster calculation as the PAM algorithm is less sensitive to outliers and the sequence of input data compared with k-means [34].

User Statistics

For the analysis, we included 77% (127/165) women and 23% (38/165) men (compiled from field tests 1 and 2) who used the *Fit at home* function on the tablet or on Orbbec Persee at least once between test weeks 2 and 13. The participants were located in Vienna (79/165, 47.9%) and Salzburg (86/165, 52.1%). They were born between 1946 and 1957 (mean 1952.6, SD 2.36; age ranged from 62-73 years in 2019) and used the *ILSE* app on the tablet, on Orbbec Persee, or on both devices.

Results

User Clusters

In the following section, the derived number of cluster groups and cluster thresholds for each approach are presented.

Semi-data-Driven Usage Frequency-Based Clustering Approach: Jenks NB

Table 2 lists the cluster thresholds of the 4 user groups based on the application of the Jenks NB algorithm. Applying the expert-based lower threshold for *low* users and the manually set number of 4 groups, 38.2% (63/165) of the participants used the *ILSE* once a week up to every second day. About 30% (49/165) visited the *ILSE* app between once a day and every second day (*moderate* use), and 4% (7/165) used *ILSE* ≥ 2 times per day (*high* use) on average over the 12 test weeks. Analyzing the descriptive statistics in **Table 2** showed that although almost all of the oldest group were *low* or *light* users, the younger users, aged between 62 and 65 years in 2019, generally fell into the *moderate* and *high* user types. In addition, although more than three-fourths (66/86, 77%) of the users from Salzburg were in the *light* or *moderate* group, more than three-fourths (62/79, 78%) of the users living in Vienna were part of the *low* and *light* group. Statistically significant associations were found between the *ILSE* app user-type group and gender ($\chi^2_3=9.9$; $P=.02$), region ($\chi^2_3=13.1$; $P=.004$), and age class ($\chi^2_6=23.7$; $P<.001$). In terms of household size and education, there was no

significant relationship between usage group and household size ($\chi^2_9=3.1$; $P=.96$), as well as education ($\chi^2_{33}=379$; $P=.26$).

Table 3 analyzes the app user types with regard to user experience and amount of daily movement. Although 40% (10/24) of the users who were rated as less fit (level 2) are in the *low* usage groups, 19% (7/37) of the very fit participants (level 4) are in the *low* usage group. Furthermore, more users rated as very fit (level 4) or fit (level 3) are in the *moderate* and *high* usage groups than those rated as less fit (level 2). Regarding the self-reported average duration of a training session, it can be shown that those who do <30 minutes of sports activities are in the *low* and *light* usage groups. In addition, at almost 60% (10/17), more people who said they never ride a bicycle are in the *moderate* or *high* usage group than those who said they ride a bicycle frequently (>3 times per week; 5/17, 29%). However, no significant associations between these variables and the app usage group were found (fitness level: $\chi^2_6=4.8$, $P=.56$; sports duration: $\chi^2_9=13.9$, $P=.13$; fitness exercises days per week: $H_3=2.1$, $P=.55$; sitting hours per week: $H_3=2.8$, $P=.42$; days riding a bicycle per week: $H_3=1.9$, $P=.60$).

Table 2. Demographics of the cluster groups of *ILSE* app users applying Jenks natural breaks in the semi-data-driven approach. Apart from the birth year, the age reached in 2019 is given in parenthesis (N=165).

Demographics	Low use	Light use	Moderate use	High use
Users, n (%)	46 (27.9)	63 (38.2)	49 (29.7)	7 (4.2)
App visit frequency range (per week)	≤ 1	1.1-3.6	3.65-7.42	7.49-14.56
Gender, n (%)				
Male	18 (47.4)	10 (26.3)	8 (21.1)	2 (5.2)
Female	28 (22)	53 (41.7)	41 (32.3)	5 (3.9)
Year of birth (age in years), n (%)				
1946-1949 (70-73)	15 (65.2)	7 (30.4)	0 (0)	1 (4.3)
1950-1953 (66-69)	18 (25.4)	29 (40.8)	22 (31)	2 (2.8)
1953-1957 (62-65)	13 (18.3)	27 (38)	27 (38)	4 (5.6)
Location, n (%)				
Vienna	30 (38)	32 (40.5)	14 (17.7)	3 (3.8)
Salzburg	16 (18.6)	31 (36)	35 (40.7)	4 (4.6)
Education, n (%)				
ISCED ^a 2	1 (16.7)	3 (50)	2 (33.3)	0 (0)
ISCED 3	14 (21.5)	22 (33.8)	27 (41.5)	2 (3.1)
ISCED 4	0 (0)	4 (100)	0 (0)	0 (0)
ISCED 5	17 (39.5)	13 (30.2)	10 (23.3)	3 (7)
ISCED 6-8	13 (31.7)	18 (43.9)	8 (19.5)	2 (4.9)
Type of household, n (%)				
Single	11 (26.8)	14 (34.1)	14 (34.1)	2 (4.9)
2 persons	29 (26.4)	44 (40)	32 (29.1)	5 (4.5)
3-4 person	6 (42.9)	5 (35.7)	3 (21.4)	0 (0)

^aISCED: International Standard Classification of Education.

Table 3. Initial training experience grouped to categories and fitness level of the cluster groups of ILSE app users before interventions applying Jenks natural breaks in the semi-data-driven approach (N=165).

	Low use, n (%)	Light use, n (%)	Moderate use, n (%)	High use, n (%)
Fitness level				
2	10 (40)	9 (36)	6 (24)	0 (0)
3	18 (26.9)	25 (37.3)	20 (29.9)	4 (6)
4	7 (18.9)	16 (43.2)	11 (29.7)	3 (8.1)
Number of fitness exercises (per week)				
0	13 (38.2)	10 (29.4)	9 (26.5)	2 (5.9)
1-2	19 (26)	29 (39.7)	23 (31.5)	2 (2.7)
3-5	12 (26.1)	19 (41.3)	12 (26.1)	3 (6.5)
6-7	2 (20)	4 (40)	4 (40)	0 (0)
Duration of sports (minutes)				
<30	5 (71.4)	2 (28.6)	0 (0)	0 (0)
30-60	6 (15.8)	16 (42.1)	14 (36.8)	2 (5.3)
60-120	12 (17.6)	32 (47.1)	21 (30.9)	3 (4.4)
>120	8 (32)	9 (36)	7 (28)	1 (4)
Duration of sitting (hours per week)				
<6	17 (26.6)	26 (40.6)	19 (29.7)	2 (3.1)
6-8	20 (27)	25 (33.7)	26 (35.1)	3 (4.1)
>8	9 (36)	11 (44)	3 (12)	2 (8)
Number of days of riding a bicycle (days per week)				
0	2 (11.7)	5 (29.4)	9 (52.9)	1 (5.9)
1-3	13 (29.5)	14 (31.8)	16 (36.4)	1 (2.2)
>3	4 (23.5)	8 (47.1)	5 (29.4)	0 (0)

Data-Driven Multidimensional Clustering Approach: PAM

After calculating a number of clusters of size 1 to 10, a total of 4 groups were also used for multidimensional clustering, analogous to the 1D clustering (Figure 3).

Applying the PAM algorithm to the 14 features resulted in 4 clusters of 60 (cluster A), 30 (cluster B), 42 (cluster C), and 33 (cluster D) users. Examination of the clusters showed that cluster B included those users who used the app the most, with a mean use of 50.5 (SD 13.6) total days compared with 8.2 days (SD 5.9) in cluster D (Figure 4).

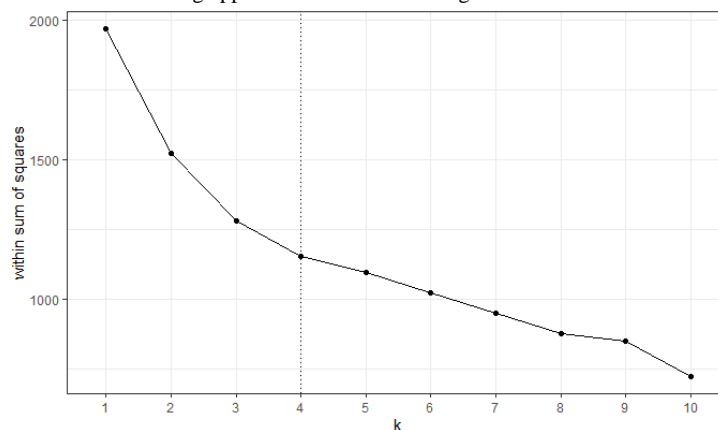
Figure 3. Elbow plot of the multidimensional clustering approach. PAM: Partitioning Around Medoids.

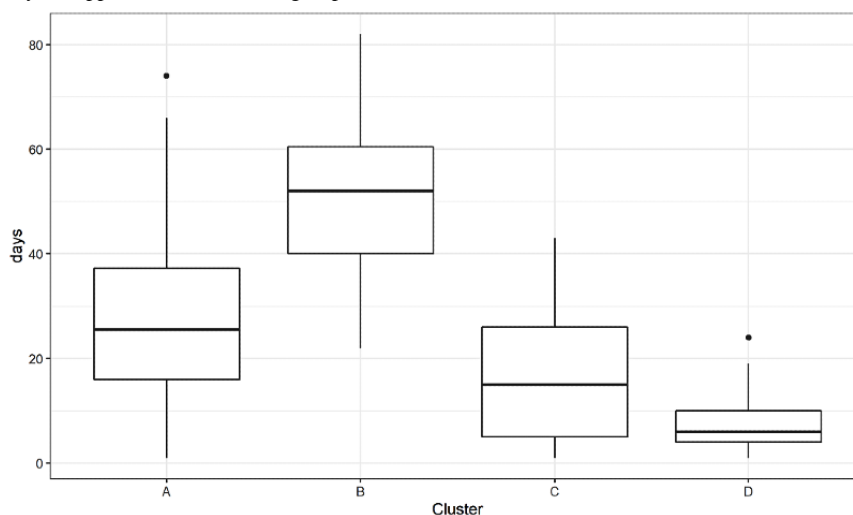
Figure 4. Number of total days of app use in the 4 cluster groups.

Table 4 shows the descriptive statistics of the clusters, and Table 5 lists the sports- and fitness-related variables. A detailed analysis of the 4 multidimensional cluster groups revealed the following characteristics.

- Cluster A was formed by users who mainly used the devices in the morning. A total of 80% (48/60) were women, and 55% (33/60) lived in Salzburg.
- Cluster B had the highest number of average app visits and consisted of 90% (27/30) of female users. Two-thirds (20/30, 66%) of users in this cluster lived in Salzburg. *ILSE* app users in this group also made greater use of other features of the *ILSE* app and were younger than those in the other clusters.
- Cluster C was formed by users who used the devices mainly in the evening. A total of 50% (21/42) lived in Vienna, and 50% (21/42) lived in Salzburg.
- Cluster D had the lowest number of average app visits and was formed by 63% (21/33) of users who lived in Vienna and by users who reported doing fitness exercises 4 days per week or less but not more than 4 days. In addition, this cluster was disproportionately formed by men.

Table 4. Demographics of the 4 cluster groups derived by the Partitioning Around Medoids algorithm (N=165).

	Cluster A (n=60)	Cluster B (n=30)	Cluster C (n=42)	Cluster D (n=33)
Days of use, mean (SD)	29.0 (16.1)	50.5 (13.6)	15.9 (12.5)	8.2 (5.9)
Gender, n (%)				
Male	12 (20)	3 (10)	10 (23.8)	13 (39.4)
Female	48 (80)	27 (90)	32 (76.2)	20 (60.6)
Year of birth (age in years), n (%)				
1946-1949 (70-73)	27 (45.5)	10 (33.3)	19 (45.2)	15 (45.5)
1950-1953 (66-69)	27 (45.5)	10 (33.3)	19 (45.2)	15 (45.5)
1953-1957 (62-65)	28 (24.2)	20 (66.7)	15 (35.7)	8 (24.2)
Location, n (%)				
Vienna	27 (45)	10 (33.3)	21 (50)	21 (63.6)
Salzburg	33 (55)	20 (66.7)	21 (50)	12 (36.4)
Education, n (%)				
ISCED ^a 2	2 (3.5)	1 (3.4)	3 (7.3)	0 (0)
ISCED 3	24 (42.1)	17 (58.6)	14 (34.1)	20 (31.3)
ISCED 4	2 (3.5)	0 (0)	1 (2.4)	1 (3.1)
ISCED 5	13 (22.8)	6 (20.7)	9 (22)	15 (46.9)
ISCED 6-8	16 (28.1)	5 (17.2)	14 (34.1)	6 (18.8)
Type of household, n (%)				
Single	17 (28.3)	9 (30)	8 (19)	7 (21.2)
2 persons	36 (60)	20 (66.7)	32 (76.2)	22 (66.7)
3-4 person	7 (26.7)	1 (3.3)	2 (23.8)	4 (3)

^aISCED: International Standard Classification of Education.

Table 5. Initial training experience grouped to categories and fitness level of the cluster groups of ILSE app users before interventions applying the Partitioning Around Medoids algorithm (N=165).

	Cluster A (n=60), n (%)	Cluster B (n=30), n (%)	Cluster C (n=42), n (%)	Cluster D (n=33), n (%)
Fitness level				
2	7 (14.3)	2 (8.7)	11 (32.4)	5 (21.7)
3	25 (51)	15 (65.2)	17 (50)	10 (43.5)
4	17 (34.7)	6 (26.1)	6 (17.6)	8 (34.8)
Number of fitness exercises (per week)				
0	10 (16.7)	4 (13.3)	9 (4.8)	11 (33.3)
1-2	26 (43.3)	16 (53.3)	18 (28.6)	13 (39.4)
3-5	16 (26.7)	9 (30)	12 (42.9)	9 (27.3)
6-7	7 (11.7)	1 (3.3)	2 (21.4)	0 (0)
Duration of sports (minutes)				
<30	1 (2)	0 (0)	3 (8.6)	3 (12.5)
30-60	16 (31.4)	2 (32.1)	9 (25.7)	4 (16.7)
60-120	26 (51)	17 (60.7)	14 (40)	11 (45.8)
>120	8 (15.7)	2 (7.1)	9 (25.7)	6 (25)
Duration of sitting (hours per week)				
<6	19 (32.2)	13 (43.3)	16 (39)	16 (48.5)
6-8	33 (55.9)	11 (36.7)	18 (43.9)	12 (36.4)
>8	7 (11.9)	6 (20)	7 (17.1)	5 (15.2)
Number of days of riding a bicycle (days per week)				
0	8 (27.6)	2 (11.8)	7 (41.2)	0 (0)
1-3	14 (48.3)	12 (70.6)	8 (47.1)	10 (66.7)
>3	7 (24.1)	3 (17.6)	2 (11.8)	5 (33.3)

Discussion

Principal Findings

This study aimed to define *ILSE* app user types and calculate thresholds in a data-driven manner to identify usage patterns. For this purpose, 2 approaches were applied to the usage data of *Fit-mit-ILSE*'s exercise module *Fit at home*. The calculated thresholds within this work were calculated for the specific case of *Fit-mit-ILSE*; therefore, the comparison of the resulting thresholds with other works is impractical. However, the cluster thresholds were compared with the WHO recommendations for functional balance and strength training for adults ≥ 65 years old (3 or more days per week at moderate or greater intensity) indicates that the *moderate* and *high* user types accomplished the WHO-recommended training frequency. From 1D clustering, 33.9% (56/165) of all users fell into these groups.

Applying the Jenks NB clustering algorithm to the mean app usage per day showed that most of the users of the *Fit-mit-ILSE* program were *light* users of the *ILSE Fit at Home* module, using the module between once a week and every other day with a manual definition of the lowest threshold. The proportion of men in the *low* user group was higher than that of women. In general, male users of the *Fit at home* module were mainly found in the *low* and *light* usage groups. This finding is in

contrast to the analysis of Lee [35], who studied 276 older adults from senior centers based on self-administered questionnaire data and found that, in this sample, men engaged in significantly higher amounts of leisure time physical activity than women. Thus, it could be that the *ILSE* app and its functions mainly addressed women, which could be because of several reasons. One assumption could be that the design of the system and the indoor training modules is more likely to motivate women than men, who may prefer to train with physical coaches or independently, without instructions from web-based coaches. As described in the user statistics, 77% (127/165) of the participants were women. This unbalanced sample could influence the analysis of app user groups, as women were more likely to use the app than men, on average. Therefore, future research should include a more gender-balanced sample by, for example, using needs assessments and questionnaires to address men's expectations related to fitness apps.

Analysis of app user groups in terms of age also showed that older users were disproportionately more likely to be assigned to the *low* and *light* usage groups than younger users, who were more often identified as *moderate* or *high* users. This could be because they are less technology-savvy than younger app users. In the work of Gitlow [36], lack of knowledge, fine motor difficulties, negative attitudes, and age-related physical changes, for example, hearing loss, were identified as barriers for older

adults in using technology. To increase older adults' app usage, additional support could be offered to older participants in the future, particularly concerning technical questions.

In addition, the analysis revealed regional differences in app use, and users living in Salzburg had higher average app use than users from Vienna, suggesting that there may be regional differences between the city of Vienna and the state of Salzburg. Users from these 2 different regions may need to be addressed and motivated differently, which could also be addressed through participatory approaches in the design and development phase of future projects. These results go well with the analysis of Cleland et al [37], who found in their study that adults in rural areas reported significantly more physical activity than adults in urban areas.

As part of the multidimensional clustering approach of *ILSE* app users, 4 different user groups were identified, which differed mainly by the total number of app visits, gender, region, and the time of app use during the day.

Limitations and Future Research

The analysis of *ILSE* app usage data is subject to some limitations that suggest ideas for future research. Although there was a support team to help with technical and *ILSE* app-orientated questions, some of the users experienced difficulties in using and setting up *ILSE*, especially at the beginning of the field test phases [38]. Therefore, a support team should be planned in future studies, focusing more on supporting older people, as the analysis showed that this group was less likely to use the app.

In addition, there were 3 system issues where the server was shut down for several hours and the *ILSE* app was unavailable during this time, during which use data may be lost. However, as app usage for several weeks was investigated, the shutdown of some hours did not affect the analysis.

Furthermore, as described in the Methods section, the 2 phases of the field test were combined for this analysis. It should be considered that the 2 field tests were conducted in different seasons and that the app was slightly modified (with adapted functions) in the second field test phase. Therefore, the use of the *ILSE* app may be influenced by seasonal effects or seasonal variations. However, as previously reported, there were no remarkable differences in app usage between the 2 phases.

App user types were clustered based on app usage frequency within the study period of 12 weeks. Therefore, changes in usage frequencies over time were not considered and could be interesting for further research.

Participants used *ILSE* in their homes and were instructed to use the app only by themselves. However, owing to the unsupervised setting, other people could theoretically have used the *ILSE* app, which would have increased the number of app visits.

This work focused on analyzing the overall use of the *ILSE* app and focused mainly on the number of visits to the app, as this metric is easy to interpret and comparable with, for example, the WHO recommendations. The correlation between the number of app visits and visit duration per user showed a significantly strong positive Pearson correlation ($r=0.87$). For further studies, however, other data, such as visit duration, should be investigated in detail.

Future research could also investigate the effect of and change in app use frequency on fitness status. A detailed analysis of participants' dropout reasons and dropouts could also provide relevant insights.

Finally, clustering involves some challenges, such as the definition of the clustering method [39,40]. Another disadvantage of clustering is that different algorithms often result in different partitions [39]. Moreover, determining the number of clusters using the Elbow method is not always clear if the graph has no unique elbow or more than one elbow [41]. Therefore, future work could investigate clustering algorithms other than the Jenks NB and PAM algorithms.

Conclusions

Applying the Jenks NB and PAM algorithms to the example of *ILSE* app usage data showed that data-driven calculations of user groups can replace expert-based definitions and provide objective thresholds for the analysis of app usage data.

For example, when evaluating a new fitness app, statistical methods and data-driven clustering techniques could help identify the impact of this newly developed app on subgroups of a particular population, describe usage patterns and users, and draw conclusions about which groups of people may not yet be addressed. Using these insights, groups that have not yet been targeted can be specifically addressed and supported.

The cluster analysis of the *Fit at home* module of the *ILSE* app revealed differences in app use by gender, age, region, and time of app use. On average, higher app use was observed among women, younger users, and app users living in Salzburg.

In general, from determining the number of cluster groups to identifying cluster thresholds and ranges, data science offers a variety of alternative methods and algorithms to identify patterns in data.

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Conflicts of Interest

None declared.

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Abbreviations

AAL: active and assisted living

Jenks NB: Jenks natural break

PAM: Partitioning Around Medoids

WHO: World Health Organization

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Original Paper

Diagnosis of Atrial Fibrillation Using Machine Learning With Wearable Devices After Cardiac Surgery: Algorithm Development Study

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Abstract

Background: Some attempts have been made to detect atrial fibrillation (AF) with a wearable device equipped with photoelectric volumetric pulse wave technology, and it is expected to be applied under real clinical conditions.

Objective: This study is the second part of a 2-phase study aimed at developing a method for immediate detection of paroxysmal AF, using a wearable device with built-in photoplethysmography (PPG). The objective of this study is to develop an algorithm to immediately diagnose AF by an Apple Watch equipped with a PPG sensor that is worn by patients undergoing cardiac surgery and to use machine learning on the pulse data output from the device.

Methods: A total of 80 patients who underwent cardiac surgery at a single institution between June 2020 and March 2021 were monitored for postoperative AF, using a telemetry-monitored electrocardiogram (ECG) and an Apple Watch. AF was diagnosed by qualified physicians from telemetry-monitored ECGs and 12-lead ECGs; a diagnostic algorithm was developed using machine learning on the pulse rate data output from the Apple Watch.

Results: One of the 80 patients was excluded from the analysis due to redness caused by wearing the Apple Watch. Of 79 patients, 27 (34.2%) developed AF, and 199 events of AF including brief AF were observed. Of them, 18 events of AF lasting longer than 1 hour were observed, and cross-correlation analysis showed that pulse rate measured by Apple Watch was strongly correlated (cross-correlation functions [CCF]: 0.6-0.8) with 8 events and very strongly correlated (CCF>0.8) with 3 events. The diagnostic accuracy by machine learning was 0.9416 (sensitivity 0.909 and specificity 0.838 at the point closest to the top left) for the area under the receiver operating characteristic curve.

Conclusions: We were able to safely monitor pulse rate in patients who wore an Apple Watch after cardiac surgery. Although the pulse rate measured by the PPG sensor does not follow the heart rate recorded by telemetry-monitored ECGs in some parts, which may reduce the accuracy of AF diagnosis by machine learning, we have shown the possibility of clinical application of using only the pulse rate collected by the PPG sensor for the early detection of AF.

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KEYWORDS

wearable device; atrial fibrillation; photoplethysmography; cardiology; heart; mHealth; mobile health; pulse; development; pilot study; Apple Watch; sensor; algorithm; detection; diagnose; cardiac surgery; machine learning

Introduction

Atrial fibrillation (AF) is the most common, persistent arrhythmia in adults, with a lifetime risk of 25%-33%, and it is associated with heart failure, stroke, dementia, and death [1,2]. However, approximately one-third of patients with paroxysmal AF are asymptomatic, making it difficult to diagnose an arrhythmia without symptoms unless an ECG monitoring is performed in a medical facility [1,3-5]. In fact, up to 50% of patients who have a stroke due to AF are diagnosed with AF after the stroke has occurred [6-9].

The European Society of Cardiology guidelines recommends opportunistic screening for AF using pulse checks or ECG rhythm strips in patients over 65 years of age [10]. With the recent advent of mobile devices and wearable sensors, it has become possible to continuously monitor health status in daily life. The number of connected wearable devices worldwide has more than doubled in 3 years, from 325 million in 2016 to 722 million in 2019; by 2022, the number of devices is expected to reach more than 1 billion. In addition, their sales are expected to grow from US \$14.93 billion in 2020 to US \$17.35 billion in 2021, at a compound annual growth rate of 16.2%, making wearable devices increasingly popular [11,12].

Recent smartwatches are equipped with photoplethysmography (PPG) that uses infrared light-emitting diode optical sensors to monitor changes in microvascular blood volume, making it possible to continuously monitor pulse rate in daily life. The clinical applicability of PPG has been addressed in several studies, one of the most famous is the Apple Heart Study [13]. Of the participants who received arrhythmia notifications from their Apple Watch, more than one-third had AF confirmed by a subsequently worn ECG patch monitoring, and of the arrhythmia notifiers who returned their ECG patches, 84% (72/86) had a positive ECG patch (ie, positive for AF). Positive notifications were consistent with AF 84% of the time (95% CI 76-92) [13].

We previously measured pulse rate in patients after cardiac surgery wearing 2 wearable devices and showed that heart rate in sinus rhythm correlated well with pulse rate measured by wearable devices; however, during AF, the accuracy was slightly lower, but the pulse rate tracking was accurate enough for clinical applications [14].

Further innovations in wearable devices have led to the technology of single-lead ECG collection. By touching the wearable device with the contralateral finger for about 30 seconds, a single-lead ECG can be taken, and the ECG data can be used to diagnose AF. Although this method is by a single lead, it has been shown to have a higher sensitivity and specificity due to the ECG information such as P waves and QRS waves [9,15-17].

However, many patients with AF are older people, and it is difficult to have them voluntarily perform the task of touching

the wearable device with the contralateral finger for 30 seconds to collect a single-lead ECG when they are notified of an arrhythmia.

There have been many attempts to detect arrhythmias using wearable devices, but most of these studies have been based on brief observations and data collection under ideal conditions in selected patients. In this study, we conducted long-term pulse rate monitoring during hospitalization of patients undergoing cardiac surgery to collect data under real clinical conditions.

This is the second part of a 2-phase study aimed at developing a method for the immediate detection and diagnosis of paroxysmal AF using a wearable device with a PPG sensor. We investigated the possibility of clinical application of heart rate monitoring by wearable devices in the special environment post cardiac surgery.

Methods**Ethics Approval**

In accordance with all applicable regulations, this study was approved by the Clinical Research Ethics Committee of Chiba University Hospital (Clinical Research Protocol jRCTs032200032) on October 23, 2020. We obtained written informed consent from all study participants to allow data monitoring as well as data registration and management to be performed by the Chiba University Hospital Clinical Trials Data Center. In addition, an independent Data Monitoring Committee has been established within the Department of Clinical Trials at Chiba University.

Participants

Between June 2020 and March 2021, 80 patients scheduled for cardiovascular surgery at a single institution were recruited for this study. The exclusion criteria were the following: a history of permanent pacemaker implantation, skin disorders at the wristband site, and past hypersensitivity to wristbands (or rubber products); in addition, patients with chronic AF who did not undergo arrhythmia surgery and patients who were unfit for the safe conduct of this study according to the principal investigator or subinvestigator were also excluded.

After written informed consent was obtained, 80 subjects were given an Apple Watch (series 4) and asked to wear it on one forearm. A spare, fully charged smartwatch was always available to measure their pulse for 24 hours continuously. The Apple Watch was removed on the day the patient underwent surgery; the Apple Watch was reapplied when the patient was discharged from the intensive care unit (ICU) to the general ward after cardiac surgery (ie, usually the day after the surgery); all Apple Watch wearing was done under the supervision of a physician. Apple Watch was worn continuously until discharge or for up to 14 days after discharge from the ICU unless the study was interrupted for clinical or personal reasons.

A publicly available HeartWatch mobile app (Tantsissa) was used to access data from a standard commercially available Apple Watch.

Apple Watch has 2 functional modes for measuring pulse rate: standby mode and workout mode. In standby mode, the pulse rate is measured once every few minutes, resulting in less data. Therefore, all participants' Apple Watches were set to workout mode during wear.

Central ECG monitoring using a telemetry system (VitalSignTelemater GZ-130P; Nihon Kohden) was continued in all patients until hospital discharge. If AF was suspected, a 12-lead ECG monitoring was performed, whenever possible, for confirmation.

AF was diagnosed based on the guided diagnostic criteria by 2 qualified physicians [10].

When an arrhythmia was identified, the telemetry data were checked, and the time of the onset and cessation of arrhythmia was recorded. These procedures were repeated each time an arrhythmia was suspected on the central monitor.

Heart Rate and Pulse Rate Measurements

Heart rate data were obtained from a telemetry electrocardiograph that calculates the heart rate every 3 seconds based on the previous RR interval.

Pulse rate data were obtained from an Apple Watch with built-in PPG; in Apple Watch workout mode, the pulse rate is calculated every 5-6 seconds. The time interval of each pulse rate calculation on the Apple Watch may vary depending on the conditions (eg, low perfusion conditions and dark skin color) because the Apple Watch has an automatic optimization function that increases the brightness of the light-emitting diodes and the sampling rate to compensate for low signal levels [18].

Cross-Correlation Analysis

Using the same technique as in part 1 of this study [14], we created time series pulse rate trends and heart rate trends and analyzed the similarity of the trend patterns.

Events in patients with brief AF or bouncing between AF and atrial flutter have negative impacts on correlation analysis; therefore, cross-correlation analysis was performed on AF events lasting longer than 60 minutes that transitioned from sinus rhythm to AF and from AF back to sinus rhythm, as measured by central ECG monitoring and the Apple Watch. The complete pulse rate data measured by the central ECG and Apple Watch were included in the analysis.

We then used the trend data to check the accuracy of PPG-based pulse rate measurement with reference to ECG-based heart rate measurement during AF.

Machine Learning Model for AF Diagnosis

We used a gradient boosting decision tree (GBDT) [19] to diagnose AF based on pulse rate data from the Apple Watch and patient background information summarized in Table S1 in [Multimedia Appendix 1](#). We computed features of the pulse rate data every minute and treated them as a single record for training and validation of the GBDT model. As pulse rate features, the mean and SD of pulse rate per minute within 10 minutes of the timing for the AF diagnosis were calculated. The median value of the mean and SD of heart rate up to the time of diagnosis was used as the baseline. GBDT is a kind of ensemble learning that can handle missing values without complementation and is known to provide high prediction accuracy by boosting technology. The Python package LightGBM (version 3.3.2; Python Software foundation) was used for the GBDT implementation, and hyperparameter was tuned by Bayesian optimization with cross-validation, using the Optuna framework [20]. The data of 79 patients were first split into a training cohort of 59 patients and a test cohort of 20 patients; only the training cohort was used for hyperparameter tuning, variable selection, and training of the machine learning model. The variable importance of the GBDT model was calculated for the training cohort by the "permutation importance" function implemented in the Python package eli5 (version 0.11.0; Python Software foundation). To evaluate the performance of the machine learning model for AF diagnosis, a receiver operating characteristic (ROC) analysis was performed. The ROC analysis plots the change in sensitivity and specificity, as the threshold for the probability of AF is varied. The ROC analysis was performed using the R package pROC (version 1.18.0; Xavier Robin).

Other Statistical Analysis

Summary of statistics are presented as frequency and percentage for categorical data, mean (SD) for continuous variables, and frequency and percentage for categorical variables.

All statistical analyses were performed using SAS (version 9.4 for Windows; SAS Institute Inc).

Results

Patient Background

Of the 80 patients, 1 had redness on the area the Apple Watch was worn, and we stopped the study before she underwent surgery. The demographics of the 79 patients are shown in [Table 1](#).

Table 1. Characteristics of study participants (N=79).

Demographics	Values
Age (years), mean (SD)	65.8 (13.4)
Sex (male), n (%)	57 (72.2)
Left ventricular ejection fraction, mean (SD)	58.9 (8.8)
Off-pump coronary artery bypass grafting, n (%)	18 (21.5)
Valve surgery, n (%) ^a	57 (72.2)
Other surgery, n (%) ^b	4 (5.1)
Minimally invasive cardiac surgery, n (%)	7 (8.9)
Monitoring period (days), mean (SD)	13.3 (2.5)
Use of antiarrhythmic drugs before the event, n (%) ^c	30 (38.0)

^aIncluded multiple surgeries.

^bIncluded 2 thoracic surgeries, 1 atrial septal defect closure, and 1 ventricular septal myectomy, and on-pump coronary-artery bypass grafting.

^cTypes of antiarrhythmic drugs included pilsicainide, flecainide, amiodarone, verapamil, digoxin cibenzoline, sotalol, bepridil, and β -blockers.

Arrhythmias

The mean number of days of smartwatch wear per patient was 13.3 (SD 2.5) days, and the median number of days of wear was 14 (IQR 11-15) days. Of 79 patients, 69 had a good postoperative course and were discharged within 14 days after transfer from ICUs to the general ward; 10 patients required

more time for treatment of complications or postoperative rehabilitation, so pulse rate measurement with the Apple Watch was ended 14 days after leaving the ICU as per protocol.

The total number of arrhythmia events diagnosed in the 79 patients included in the analysis was 429 in 31 patients. The total number of AF events was 199 in 27 patients (Table 2).

Table 2. Arrhythmia events in patients (N=79).

Event	Patients, n (%)	Events, n	Total time (h)
Atrial fibrillation	27 (34.2)	199	713.7
Atrial fibrillation and atrial flutter ^a	1 (1.3)	13	4.2
Atrial flutter	7 (8.9)	37	163.8
Atrial flutter and premature atrial contractions ^b	1 (1.3)	3	5.4
Atrial tachycardia	6 (7.6)	97	114.9
Paroxysmal supraventricular tachycardia	1 (1.3)	10	0.8
Ventricular tachycardia	1 (1.3)	67	0.6
Other ^c	1 (1.3)	3	61.7

^aAtrial fibrillation and atrial flutter are mixed.

^bAtrial flutter and premature atrial contractions are mixed.

^cIncluded sinus arrest and unidentified arrhythmias.

Cross-Correlation Analysis of Pulse Rate Accuracy Based on PPG Sensor During AF

Table 3 shows the results of the CCF analysis of the 1-minute moving average of the central monitor ECG heart rate and Apple Watch pulse rate in the 18 AF events lasting more than 1 hour used in the analysis.

Of the 18 events, 8 events had a strong correlation (CCF: 0.6-0.8), and 3 events had a very strong correlation (CCF>0.8) [21].

Figure 1 shows 2 time series curves (one for heart rate trend and the other for pulse rate trend) for one event that showed a very strong correlation (Event 12), and Figure 2 presents another event that showed a weak correlation (Event 11). In Figure 1, the Apple Watch pulse rate follows the central monitor ECG heart rate very well, but in Figure 2, the Apple Watch pulse rate does not follow the central monitor ECG heart rate after the heart rate exceeds about 120 per minute and is measured as a low value.

Table 3. Time series correlation of pulse change in paroxysmal atrial fibrillation.

Event number	Cross-correlation function ^a	P value
1	.69869	<.001
2	.06296	.33
3	.17394	.001
4	.35918	<.001
5	.81694	<.001
6	.76119	<.001
7	-.19029	.07
8	.64214	<.001
9	.77215	<.001
10	.76217	<.001
11	.02752	.64
12	.88082	<.001
13	.60062	<.001
14	.84744	<.001
15	.64360	<.001
16	.41605	<.001
17	.17998	.14
18	.75319	<.001

^aFor reference, the strength of correlation [20] can be classified in the literature as follows: <0.19 as very weak; 0.2-0.39 as weak; 0.4-0.59 as moderate; 0.6-0.79 as strong; and >0.8 as very strong.

Figure 1. Time series trend curves during atrial fibrillation (AF) (event 12). The figure compares the trend curve of the Apple Watch (red curve) with central monitor heart rate (blue curve). The green curve shows the time trend of AF diagnosis prediction rate by machine learning. The purple dotted line indicates the diagnostic threshold for AF (0.018). BPM: beats per minute.

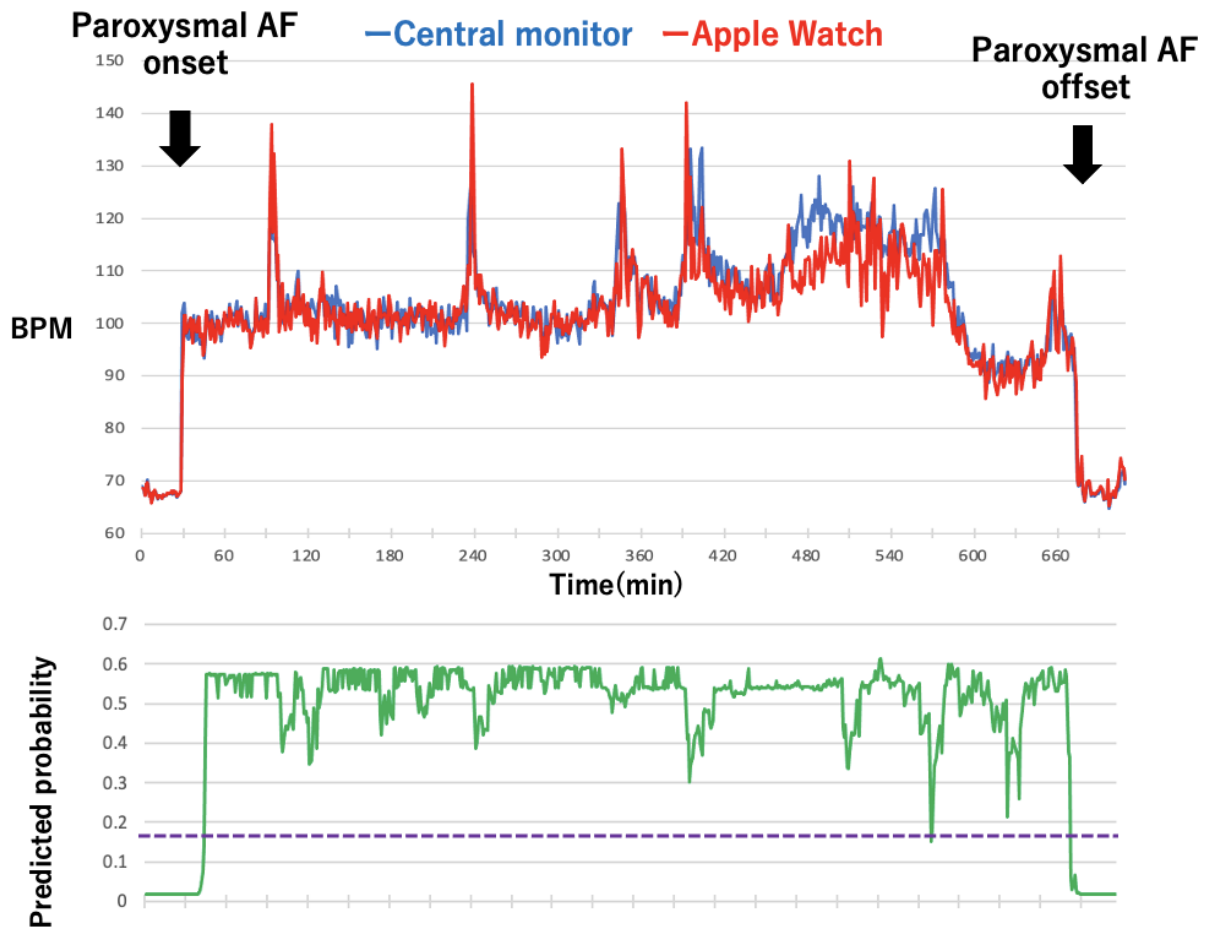
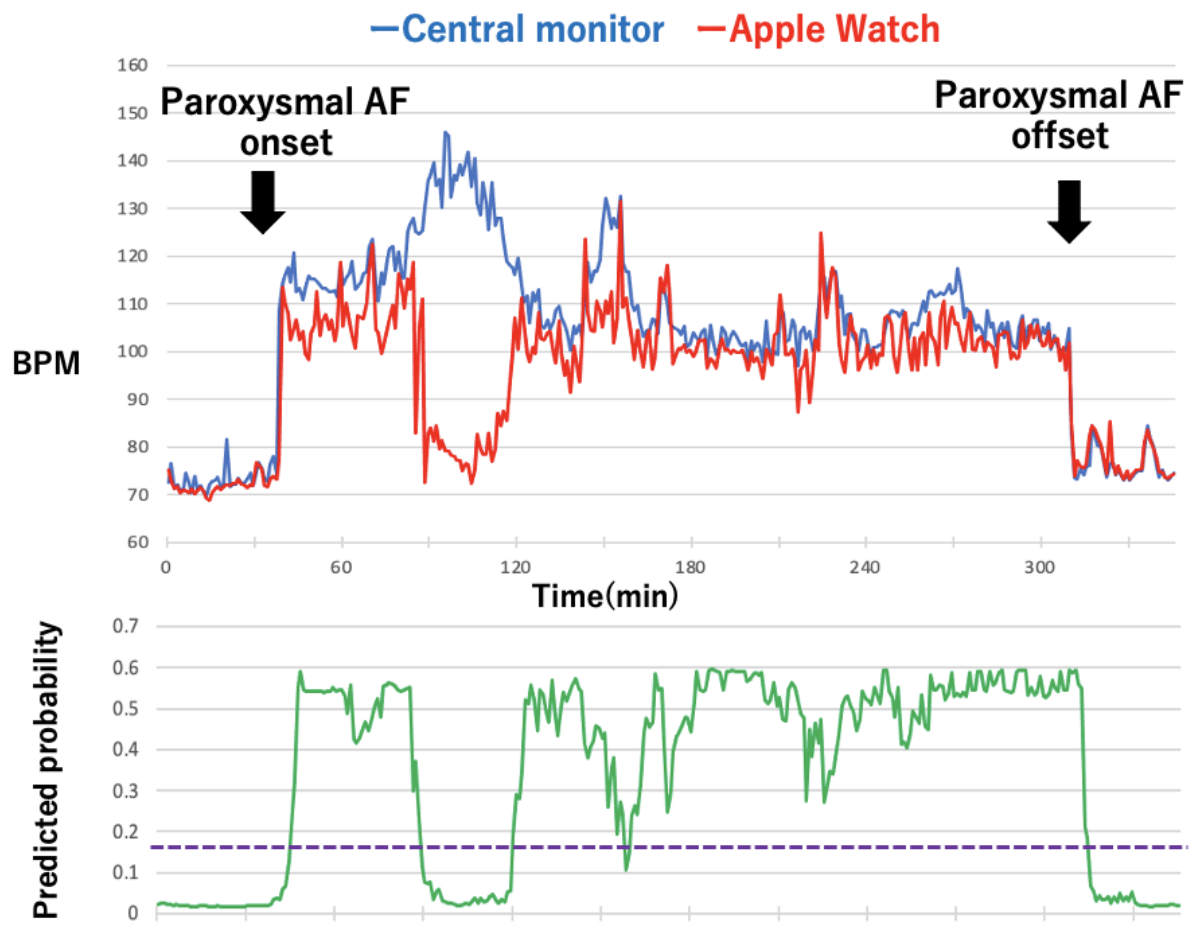


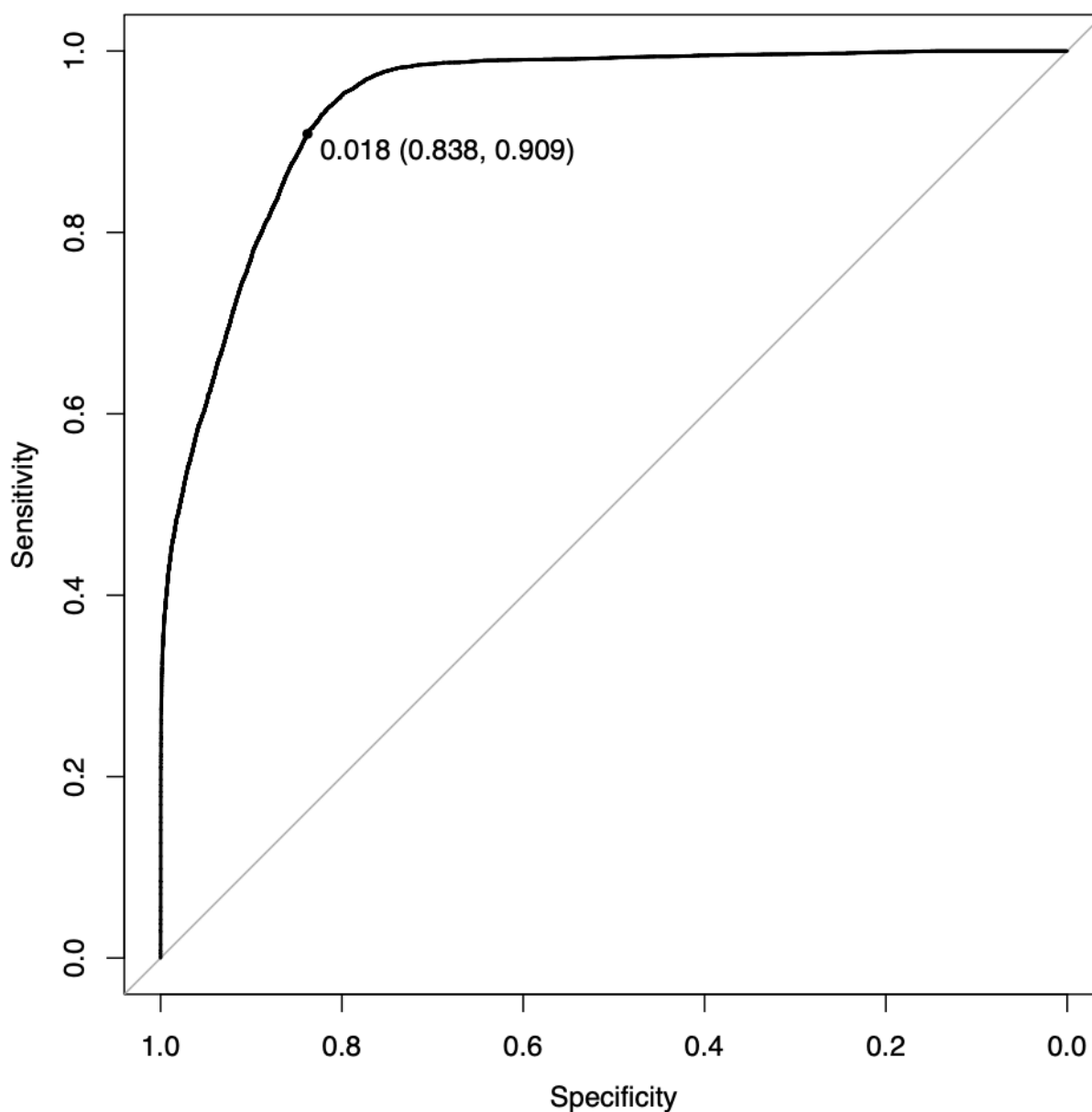
Figure 2. Time series trend curves during atrial fibrillation (AF) for event 11. The figure compares the trend curve of the Apple Watch (red curve) with central monitor heart rate (blue curve). The green curve shows the time trend of AF diagnosis prediction rate by machine learning. The purple dotted line indicates the diagnostic threshold for AF (0.018). BPM: beats per minute.



Diagnosis of AF by Machine Learning

In this study, the area under the ROC curve for the diagnosis of AF with the GBDT model was 0.9416, with a sensitivity of 0.909 and a specificity of 0.838 at the point closest to the top left (Figure 3; Table 4). The importance of the GBDT model is

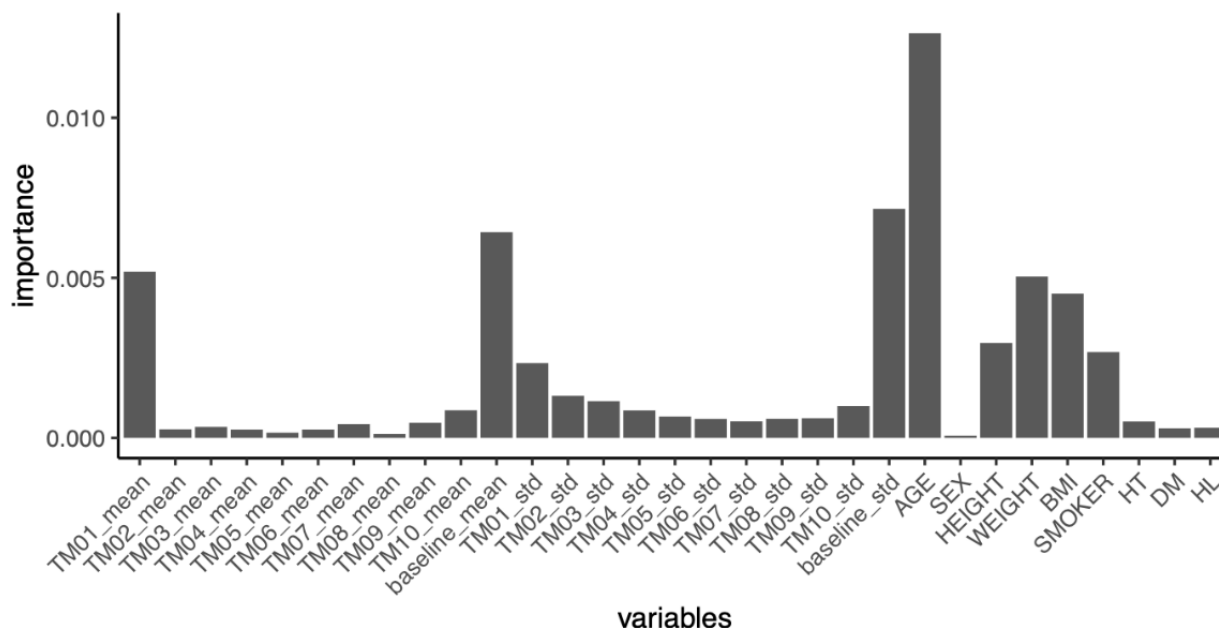
shown in Figure 4. The importance of age and baseline SD was high. In Figure 1 and Figure 2, the diagnostic predictive rate of AF is plotted as time series, and in Figure 2, where the Apple Watch pulse rate did not track the actual heart rate, the diagnostic rate dropped notably at that site.

Figure 3. Receiver operating characteristic curve of atrial fibrillation diagnosis rate.**Table 4.** The sensitivity and specificity of the gradient boosting decision tree (GBDT) atrial fibrillation (AF) prediction.

	Gold standard diagnosis		Total
	AF positive	AF negative	
GBDT AF prediction			
AF positive	8113	25,622	33,735
AF negative	816	132,515	133,331
Total	8929	158,137	167,066
Sensitivity (%)	90.9	— ^a	—
Specificity (%)	83.8	—	—

^aNot applicable.

Figure 4. Factors contributing to the diagnosis of atrial fibrillation. DM: diabetes mellitus; HL: hyperlipidemia; HT: hypertension; TM01_mean: mean heart rate 1 minute before the timing; TM02_mean: mean heart rate 2 minutes before the timing; TM03_mean: mean heart rate 3 minutes before the timing; TM10_mean: mean heart rate 10 minutes before the timing; baseline_mean: mean heart rate at the timing; TM01_std: SD 1 minute before the timing; TM02_std: SD 2 minutes before the timing; TM03_std: SD 3 minutes before the timing; TM10_std: SD 10 minutes before the timing.



Discussion

Principal Findings

In this study, we measured the pulse rate of 79 patients undergoing cardiac surgery by a wearable device on their forearm for 24 hours during hospitalization and continuously until discharge (for a maximum of 14 days after discharge from the ICU). The pulse rate data obtained were used in a machine learning model to create a diagnostic algorithm for AF. The diagnostic accuracy of this algorithm was 0.9416 (sensitivity 0.909 and specificity 0.838 at the point closest to the top left) for the area under the ROC curve. Some authors have reported that the diagnostic accuracy of AF by wearable devices is high with an area under the ROC curve of 0.9 or higher [22-24]. However, these are based on data sampling in a limited ideal environment (eg, at rest, or when data collection time is only a few hours) and with a preselected group of patients with a history of AF. For patients after cardiac surgery who are prone to various arrhythmias other than AF, these studies have a large proof-of-concept aspect, and it is desirable to conduct research and development for practical use in the real world of patients with cardiac diseases.

In this study, we measured pulse rates under real clinical conditions and were able to diagnose AF with high accuracy, using only time series pulse rate data and patient background information. The Apple Watch with a silicon band was worn by patients, and although 1 patient complained of an itchy sensation with redness at the site of wearing, no other adverse events caused by the Apple Watch occurred. Some patients, after coronary artery bypass surgery, had radial artery grafts and forearm wounds extending to the wrist, which limited the use of the watch in some cases; however, the watch could be worn and monitored for a long time in clinical practice. In the perioperative period, various arrhythmias other than AF occur,

as well as circulatory conditions such as water overflow and dehydration. To the best of our knowledge, no study has attempted continuous and prolonged monitoring and machine learning for AF diagnosis using a wearable device in such an environment.

In this study, the cross-correlation coefficient between the heart rate obtained from central ECG monitoring and the pulse rate data obtained from the Apple Watch for AF lasting more than 1 hour showed a strong correlation in 11 out of 18 events. As shown in Figure 2, there were cases where the Apple Watch pulse rate did not follow the timing of the faster heart rate. Al-Kaisey et al [25] also reported that pulse rate during AF is underestimated compared to sinus rhythm. Since the PPG sensor is a pulse pressure waveform that originates from heart contraction and propagates through the cardiovascular system, as shown in our previous study [14], depending on pathophysiological conditions such as intravascular volume, heart rate, and heart condition, sufficient pulse pressure may not be generated [14,26-28]. For the above reasons, pulse rate data obtained from PPG sensors may not accurately represent the heart rate, especially in patients with cardiac disease or after cardiac surgery, making it difficult to diagnose AF. In this study, as shown in Figure 2, the diagnostic accuracy dropped where the Apple Watch pulse rate did not track the actual heart rate.

The main factors contributing to the AF diagnosis with GBDT were age and baseline SD. There have been many attempts to use machine learning to diagnose AF; however, to our knowledge, there have not been studies that have identified the factors contributing to its diagnosis. Although the machine learning in this study was not able to achieve a high diagnostic accuracy that could be immediately applied in actual clinical practices, it suggests the possibility that a wearable device can be used to monitor pulse rate for a long period of time and diagnose AF in the special environment after cardiac surgery.

Limitations

There are several limitations to this study, one of which is the small sample size. We believe that we sampled a relatively large number of patients in a study of long-term monitoring under real clinical conditions, but the sample size is still too small for machine learning. Second, the Apple Watch wearing process was done entirely by a physician, and when the patient removed the watch by himself, the heart rate measurement stopped, and some data were missing. The data collected from the Apple Watch were synchronized each time the Apple Watch was charged and were stored in the iPhone, but there were times when data were not transferred to the iPhone for some unknown reason, resulting in missing data.

Clinical Outlook

In this study, we developed an algorithm to immediately diagnose AF, using machine learning on the collected data; however, there are reports indicating that analysis using deep learning as an artificial intelligence technology can diagnose AF with higher accuracy [29].

We are planning to create a classifier with higher accuracy and diagnostic performance by using a new diagnostic algorithm

based on deep learning. Once a classifier with enough accuracy to withstand clinical use is completed, patients will be able to know their own arrhythmia in real time, and heart rhythms can be monitored safely with a very simple wristwatch device. It is said that potential AF is involved in the development of cerebral infarction and stroke, but there is little evidence on the threshold for developing cerebral infarction, which remains controversial [30]. If it becomes possible to accurately record AF at all stages, this is expected to become an extremely useful tool to determine the threshold for stroke onset and may lead to the introduction of anticoagulation therapy in appropriate patient groups to prevent stroke.

Conclusions

In the second phase of the 2-phase study, the Apple Watch was safely worn for a long period of time even in the special environment post heart surgery. Furthermore, the findings of this study showed that the Apple Watch could potentially detect AF with a machine learning classifier during the recovery period after heart surgery. The next step will be to improve the accuracy of immediate diagnosis of AF by deep learning.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Patients' background information.

[DOCX File, 19 KB - [formative_v6i8e35396_app1.docx](#)]

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Abbreviations

AF: atrial fibrillation
CCF: cross-correlation function
ECG: electrocardiogram
GBDT: gradient boosting decision tree
ICU: intensive care unit
PPG: photoplethysmography
ROC: receiver operating characteristic

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Original Paper

Using the Transformative Storytelling Technique to Generate Empowering Narratives for Informal Caregivers: Semistructured Interviews, Thematic Analysis, and Method Demonstration

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Abstract

Background: The transformative storytelling technique is an innovative top-down approach to narrative therapy that aims to provide building blocks for creating flourishing narratives for target groups or populations. This approach acts as a facilitator for implementing the human-centered design in developing digital self-help tools for larger samples or target groups.

Objective: This study applied the transformative storytelling technique, as a new approach in mental health, to develop empowering audio narratives for informal caregivers.

Methods: A narrative inquiry was conducted with 17 informal caregivers (16 women and 1 man) who completed a semistructured interview, “Caregiver Life Story,” acquiring information about the beginning of the role, rising action, and critical point of the role. The participants’ ages ranged from 41 to 84 years, with all participants providing care for at least a 6-month period. This inquiry was guided by the transformative storytelling technique, and aimed to collect data relevant to creating fictional stories based on real-life themes.

Results: Twenty-five overall themes were distinguished across three a priori-set categories, providing narrative building blocks for the informal caregiver life stories. The final empowering caregiver life story was created as an example for this study, demonstrating the application of the transformative storytelling technique in an informal care context.

Conclusions: The creation of empowering stories for populations or target groups in mental health care requires a unified and guided approach that will follow clear guidelines and storytelling principles. The transformative storytelling technique is a first of its kind in the mental health context, representing an initial step in enabling and supporting the creation of meaningful stories and the development of relatable, but productive, narratives. Such narratives have the potential to serve across media and digital platforms for supporting and improving well-being, and potentially triggering self-change in the target group or population.

KEYWORDS

informal care; story; storytelling; stories; patient narrative; digital narrative; informal caregiver; caregiver; caregiving; transformative storytelling technique; audio stories; audio story; digital health; eHealth; empower; fiction; life narrative; audio narrative; self-help; user-centered design; human-centered design; innovation in mental health; mental health; therapy

Introduction

The narrative approach in therapy is a technique grounded in feminist, anthropological, and multicultural theories, offering a collaborative narrative journey and honoring the life experiences of the client [1]. Following this approach, a narrative therapist assists a client to reauthor the problematic experience into a more constructive personal story by relying on the notion of “multiple truths” within the story rather than the client’s subjective stance.

The therapist works with the “problem-saturated” story the client holds about his/her life or some aspect of life, and collaboratively engages in the process of “unpacking” and “reauthoring” the story. This bottom-up approach aims to mutually arrive at the preferred narrative of the story, deconstructing the experience to emphasize the disregarded but helpful aspects and to reconstruct it into a more positive self-story.

Some of the common applications of the narrative approach can be seen in counseling for depression; recovery from abuse; addiction; posttraumatic reactions; and in therapeutic work with couples, adults, and children [2-4]. However, a significant limitation of the highly personal nature of narrative therapy is the challenge to implement it for a target group or population. More concretely, a target group or population is here defined as a large group of people sharing a common issue (eg, alcohol abuse), difficulty, or mental health problem (eg, posttraumatic stress disorder).

Guided by the idea of expanding narrative therapy principles to the individuals belonging to wider groups and populations, we developed the transformative storytelling technique (TST) [5] as a top-down approach to traditional narrative therapy.

Unlike the bottom-up approach where the clients work on creating a productive self-narrative following various narrative techniques (eg, narration, journaling, mapping the influence of the problem, outcome questions, counterviewing questions), the top-down approach starts from a ready story to be delivered to a specific group (eg, informal caregivers).

In this manner, the ready TST narrative acts as a template and a pathway for assisting with self-story restructure for the individual, with no additional knowledge of narrative techniques needed. Concretely, the TST-structured fictional stories act in a 2D manner. The primary dimension is to assist end users (eg, informal caregivers) to create a more productive self-story within the context (eg, caregiving) by using the fictional TST story as a template. The second dimension facilitates and enables users to anticipate and intercept the potential role-related issues and prepare appropriate coping strategies.

However, outside of the mental health context, the fundamental of storytelling is both art and craft. While art is an instinct-driven process, the crafting part of storytelling requires a technique in the form of a guided approach that builds the story. Some traditional storytelling techniques include Monomyth, also known as the Hero’s Journey; Rags to Riches; The Mountain, or the Freytag pyramid; Nested Loops; Sparklines; In Medias Res; False Start; and Converging Ideas [6]. These techniques provide a cohesive structure for the narrative in literature and allow a writer to set a proper stage for telling the story. For example, the Monomyth, like Joseph Campbell’s Hero Journey, sets the storytelling in a circular plot where the protagonist leaves the known and sets out on a journey [6]. Throughout this journey, the protagonists experience difficulties, despair, and lessons, or encounter teachers that help them move on and return to the starting point as a better and improved version of the self (ie, Hero).

Conversely, the Nested Loops approach enables the core message to be communicated through several narratives delivered within one story. Similarly, the Mountain, which is also known as the Freytag pyramid, allows the storytelling formation in a rising line that marks the dramatic points and resolution of the difficulties [6]. In fact, the Freytag pyramid is one of the oldest and most classic techniques, which is easily utilized and simply structured, allowing even amateur writers to set their story appropriately. Therefore, we adopted this approach in developing our TST.

Unlike the traditional approaches serving the literature structure, the TST provides clear guidelines in creating and structuring empowering digital stories. This technique relies on the narrative approach to therapy and storytelling principles in the narrative, allowing the implementation of narrative therapy principles (eg, narration, storytelling; nonlinear, linear, or chronological narrative formation) to larger groups or members of a target population simultaneously through audio or video stories.

Specifically, with the TST, we aim to address the narrative identity needs (ie, understanding the self in the story) of a group or target population. The TST provides clearly structured digital narratives that act as a cue for triggering self-restructuring within the narrative identity of “the self.” In such a manner, with the TST, we strive to empower end users by giving them a tool that will facilitate the adaptation of adverse or unexpected life circumstances (eg, caregiving) into the productive story of “the self.”

The TST facilitates the process of human-centered design in the creation of digital therapeutic narration for larger groups and populations, and is currently the only existing technique that provides clear guidelines in creating digital stories for mental health. In line with this concept, the TST differs from the traditional storytelling techniques mentioned above because

it focuses on structuring the experiences of target groups to produce building blocks for the creation of productive template stories that trigger self-restructure. Moreover, unlike the real-life accounts of individuals, the TST allows integration of multiple experiences within a given context, resulting in richer and more representative storytelling content.

In this study, we focus on informal caregivers as a target population for developing a healing story guided by the TST. Informal caregivers are considered a backbone of the health care systems across Europe, and we define this population as long-term unpaid primary care providers who assist a family member or a close other in need (eg, spouse, parent, cousin, in-law, close neighbor) with daily life activities over a course of an illness or chronic condition.

Informal caregivers of older adults and individuals living with dementia have been reported to experience depressive symptoms, anxiety, and increased levels of stress throughout their role when compared to noncaregivers [7]. Moreover, numerous adverse health outcomes for informal caregivers have been noted across the literature [8-10]. Reflecting on the Italian caregiving context, long-term care provision in Italy as well as other Mediterranean countries has been labeled as “familialist” or family-run [11]. This type of care regime puts the responsibility of providing long-term care for a loved one in need on the family members, who often reach out for additional support mostly from migrant care workers and less frequently from the social and health systems [11].

A closer look at the existing mental health support and interventions for informal caregivers indicates respite care, psychosocial interventions, and information and communication technology support as the most common therapeutic options used by mental health experts [12]. Although numerous studies recognize the existing narrative-identity issues within the caregiving role [13-16], there is no study available that explored the potential of applying or adapting the narrative approach to accommodate shifts in self-identity of informal caregivers. Informal caregivers often place caregiving activities into primary

focus within their lives, while personal life and needs become secondary [17]. In this manner, caregivers take the responsibility of providing care for a loved one in need while negotiating newly formed and unfamiliar roles within the relationship and neglecting other aspects of life [17].

In fact, this all-consuming nature of caregiving inevitably interferes with social and relational roles, resulting in identity disruptions [18]. These disruptions mostly occur when personal experiences do not align with the preconceived “self,” ultimately causing distress and loss of meaning in life [18].

Interestingly, informal caregivers report a loss of self as an outcome of the caregiving role, and as the caregiving role becomes more prominent, informal caregivers require meaning-making in the context of their caregiving identity [17,19]. In line with this situation, the ability to reconcile the discrepancy between self-identity and caregiving identity is detrimental in productive adoption of the caregiving role into the narrative identity of self [20].

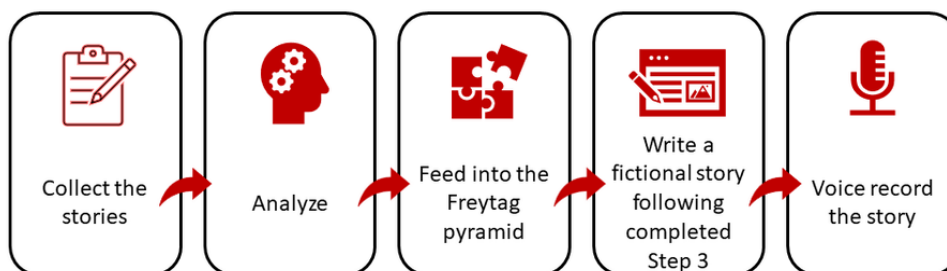
Accordingly, the aim of this study was to provide a step-by-step demonstration of application of the TST for creating a productive and empowering story in the informal care context. Such a story can then be used as a cue for triggering self-restructuring within the narrative identity of an informal caregiver, and serve as a guide to facilitate familiarization and understanding of the caregiving experience for the caregivers early in the role.

Methods

Overview of the TST

The TST is a top-down approach to traditional narrative therapy that we developed to create ready stories with flourishing narratives for larger groups or target populations. In this study, we used the TST for the creation of audio stories, built through a series of five consecutive steps (see Figure 1), acting as a concrete guideline that we follow in developing the empowering digital story for an informal caregiver sample.

Figure 1. Steps of the transformative storytelling technique.



The therapeutic aspect of the TST is based on narrative principles in therapy and draws from the theory of narrative identity [21], which poses the identity of “the self” as a construct based on an internalized and evolving story required for the meaning-making about the self and others. The storytelling aspect of the TST is based on the Freytag pyramid, which was introduced in 1894 for developing engaging and dramatic story plots in literature [22]. This pyramid is a mountain type of storytelling technique, commonly used in narratives owing to

its simplicity, which allows use by individuals who are not experienced writers.

By applying the TST, we (1) collected the stories of the target population (ie, informal caregivers) through structured interviews; (2) thematically analyzed the stories in search for themes; (3) fed the obtained themes into the Freytag pyramid structure, which enabled visualization of the key elements for (4) writing the fictional story that will be (5) audio-recorded with voice actors, and used as a blueprint of a flourishing

narrative and a cue for triggering self-restructuring within the narrative identity of the target population. The fictional story is freely constructed, while strictly following the building blocks retrieved in step 3. Therefore, the obtained story is just a sample of numerous potential fictional stories that can be created following the step-3 building blocks. This paper complies with Standards for Reporting Qualitative Research, as recommended by O'Brien and colleagues [23].

Ethical Statement

The study was approved by the Commissione Etica della Ricerca in Psicologia (CERPS) Ethical Committee of Università Cattolica del Sacro Cuore (UCSC) under protocol number 20-21, and was conducted in compliance with the latest version of the Declaration of Helsinki. Informed consent, provided to the participants in a written version, included a page containing an information sheet about the study and a page addressing the General Data Protection Regulation, as well as the participant's right to withdraw from the study at any point with no penalties. The informed consent followed the template provided by the CERPS of UCSC and was additionally adapted to include the specific information about the study.

Participants and Procedure

The participants were long-term primary caregivers (eg, spouse, daughter, daughter-in-law) of an elderly family member or close other who requires care due to a chronic condition, advanced age, or age-related illness (N=17; 16 women, 1 man). They were recruited on a voluntary basis through a nonprofit caregiver association in Italy. The participants had to be providing primary care at the point of recruitment for at least a 6-month period regardless of the living conditions (living with the care recipient or living outside of the care recipient's home). Several recruitment strategies were employed, including posting an information sheet about the study on the information corner in the association, telephone calls to the members of the association who indicated they would like to take part in future studies, and through announcements by the self-help group facilitators who disseminated the study and referred interested caregivers to the information corner where the information sheet was available.

Participants received a link for the online interview through email or during their visit to the caregiving association by the group facilitator or researcher (SB), depending on their presence within the association. The structured interview was available via the Type Form platform, with an average completion time of 10 minutes. Some of the participants who expressed the desire to participate in the study but did not feel comfortable due to the ongoing pandemic or were not sure of how to use the Type Form website were assisted by the researcher in charge of data collection (SB). Furthermore, due to COVID-19 restrictions at the time of data collection, most caregivers chose to be contacted via telephone to prevent potential contagion of virus transmission to the care recipient. The researcher performed the interview and filled in the data in Type Form on behalf of the

participant. The telephone interviews were audio-recorded (at the researcher's request and upon participants approval) and then transcribed into Type Form by the researcher. All participants agreed to be recorded. The duration of the structured interview varied (10-30 minutes) depending on the amount of information shared by the participants, and each participant was interviewed only once.

Interviews

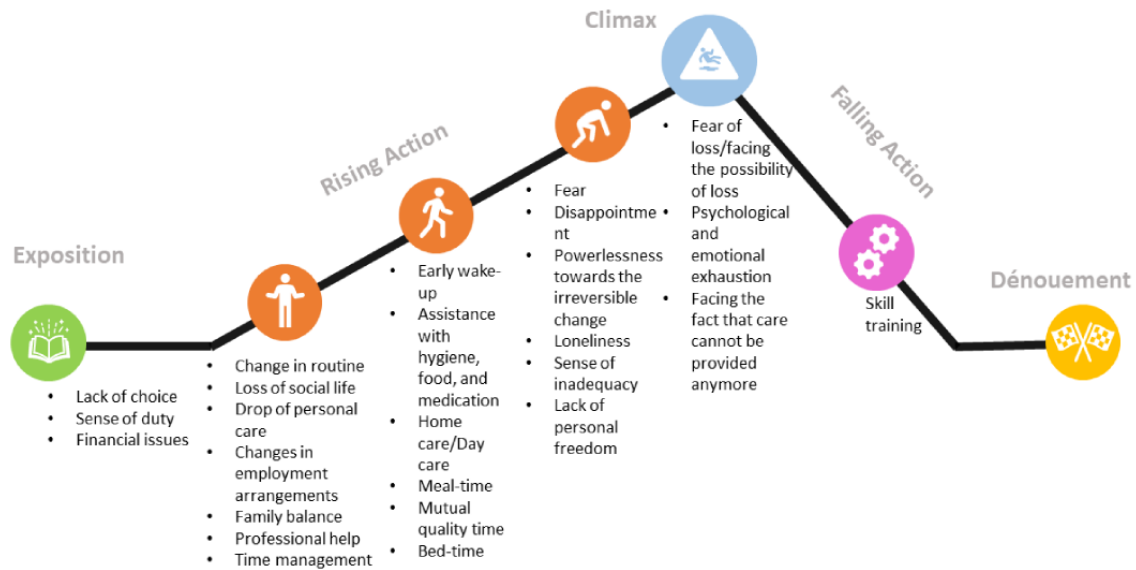
A structured interview, named "Caregiver Life Story," was created for the purpose of this research. Following the general form suggested by the TST, the interview questions inquired about (1) the beginning of the caregiving role/issue/event, (2) changes that took place, (3) the new routine/outcome, (4) psychological and emotional challenges of the caregiving role/issue/event, and a (5) a critical/climax point of the issue/role/event.

In addition, the interview assessed demographic (ie, age, gender) and care recipient illness-related (ie, age and health condition of the care recipient, relationship with the care recipient) information.

Analysis

Thematic analysis was performed following an inductive approach and the six-phase guidelines proposed by Braun and Clarke [24]. The phases included (1) familiarization with the text, (2) initial coding, (3) search for themes, (4) revision of themes, (5) definition of themes, and (6) final output (see [Multimedia Appendix 1](#)). Within the TST, each question acts as an a priori category derived from the Freytag pyramid. In essence, each category collects the data for a specific part of the story plot (deductive) of the Freytag pyramid (see [Figure 2](#)). To ensure the extraction of relevant data, we performed the initial coding, which was then refined with more specific and narrowed codes that allowed for an easier search for themes and definition of themes. The data were analyzed by two researchers independently. Namely, a large amount of interview data contained particularly emotional responses and confessions from the everyday life of informal caregivers that could potentially influence the interpretation. To mitigate the potential effects that highly personal and emotional recollections shared by the participants could have on the objectivity of the analysis, independent analyses were performed by two researchers (MP and ML) and the findings were then jointly compared and discussed until potential disagreements were resolved. The final codes and themes were established by noting and sorting the overlapping codes from the researchers' analysis. The third researcher (GA) supervised this process of distinguishing the themes independently and establishing the final themes jointly. In instances where the researchers disagreed, the points of disagreement within data were marked and blindly validated by the third researcher (GA) without prior knowledge on the specifics of the disagreement.

Figure 2. Themes inserted into the Freytag pyramid serving as building blocks for a story.



Results

Participants

The sample consisted of 16 female informal caregivers and one male informal caregiver (see Table 1). This number generally reflects the unequal gender distribution in informal care, pointing to women as the usual primary caregivers [25]. The most common illness among care recipients was Alzheimer disease,

often associated with other chronic conditions. Interestingly, the gender distribution among care recipients was quite homogenous in contrast to the caregivers being predominantly women. Participants provided care mostly for a parent or both parents at once, while there were also some participants providing care for a mother-in-law.

The following results are presented in line with the steps of the TST (see Figure 1 and Multimedia Appendix 1 for the detailed coding procedure).

Table 1. Characteristics of the study population.^a

Participant ID	Gender	Age (years)	Gender of the care recipient	Age of the care recipient (years)	Relationship to the care recipient
P1	Female	41	Male	70	Father
P2	Female	62	Male	67	Husband
P3	Female	46	Female	82	Husband's aunt
P4	Female	55	Female	77	Mother-in-law
P5	Female	57	Female	80	Mother-in-law
P6	Female	61	Female	NA ^b	Mother
P7	Female	78	Male	79	Husband
P8	Female	55	Male	81	Father
P9	Female	63	Male	68	Husband
P10	Female	73	Male	78	Husband
P11	Female	47	Male and female	80 and 80	Parents
P12	Female	64	Female	85	Mother
P13	Male	84	Female	NA	Wife
P14	Female	65	Male and female	91 and NA	Parents
P15	Female	74	Male	80	Husband
P16	Female	57	Female	84	Mother
P17	Female	59	Female	82	Mother

^aIllness-related data are removed to respect the privacy of the participants.

^bNA: not available; information not shared or recipient recently deceased.

Step 2: Analysis of the Stories

Overview of Themes

The thematic analysis resulted in 25 overall themes. A full list of initial coding, refined coding, and theme formation within each category is available in [Multimedia Appendix 1](#). The 25 final themes were sorted into a priori categories of the TST. Each interview question collected data for a specific category: (1) the beginning, belonging to the category of *exposition/the beginning*; (2) life changes, daily life, and psychological and emotional challenges, belonging to the category *rising action*; and (3) critical point, belonging to the category *climax/critical point*.

Exposition/The Beginning Category

The themes retrieved in the first category reflect the role onset/exposition, which include *the lack of choice, sense of duty, and financial issues*. The role onset has been marked with a *lack of choice* in accepting the caregiving duty either due to the living condition (eg, spouse), or the lack of another caregiver available or willing to provide care (eg, other siblings denied caregiving, children living across the country), often imposing the caregiving role upon the only available family member.

The *sense of duty* in providing care was the second noted theme. The sense of duty appeared due to a personal understanding of the relationship, family ties, marital responsibility, or being the only child that is willing to assume care, hence feeling as the last resort available, which is in essence closely related to the first theme of a lack of choice. The caregivers described the sense of duty with statements such as “I have to, she is my mother”; “I am the wife”; or “I am the daughter it’s my duty.”

The third theme of the first category, *financial issues*, appeared at the beginning of the role. In line with the theme lack of choice, caregivers also reported that the financial aspect has been an important factor in their decision to become a caregiver. There was a noted lack of financial resources for care homes as well as in-home formal caregiver support, which also seemed to further add to the prolonged care even when the caregiver was not willing to continue the care provision.

Rising Action Category

Main Category

This category explores the rising action through reported daily changes that occur in individuals’ lives due to the caregiving role, average daily life after the changes occurred, and finally psychological and emotional challenges of the role. The category *rising action* constitutes the following three subcategories.

Daily Changes Subcategory

Seven themes were noted within the daily changes subcategory. Caregivers reported that a *change in routine* took place after the role was assumed, which forced them into giving up numerous habits and adjust to the new way of living. The caregivers expressed this through statements such as “I lost my routine,” “the day was organized in the service of her,” “I gave up my personal time,” and “had to be more present for my parents.”

The following theme within the subcategory daily changes was the *loss of social life*. Caregivers noted this as a relevant aspect of the daily changes that took place through shared statements such as “loss of friends”; “lack of social life”; “gave up my social life”; “all activities we had together stopped, hence our friends drifted apart”; and “my social life doesn’t exist anymore.”

The third theme, the *drop of personal care*, was evident through the lack of sleep or sleep disruption, limited sleeping hours, strict waking-up hours, loss of freedom for personal time and activities with family and friends, as well as lack of time to visit the doctor for personal health reasons. This theme was reflected in statements such as “I cannot take care of my own health issue, nor make the time to visit the doctor”; “I have to monitor her during the night because she already fell once”; and “my mother remains my priority.”

The fourth theme of the daily changes subcategory was *changes in employment arrangements*, which appeared in all cases where employment existed prior to the caregiving role. Some of the statements supporting this theme included “full-time to part-time work,” “I had to quit my job,” “I was waking up at 4:30 AM going to work and returning home at 8:30 AM.”

The fifth theme in the subcategory daily changes was *family balance* disruptions, which reflects internal family problems that informal caregivers experienced in different contexts due to their role. Disrupted family time or activities were reported among spouses, parents and children, and siblings. The disruptions involved changes in the usual weekend-routine patterns of a family, the amount of time spent together, vacation routine, free time among parents and children, and free time for spouses. Moreover, the family balance was also affected among spousal caregivers reporting that what used to be regular mutual activities have now ended. Additionally, the family balance has also been affected over a course of caregiving due to lack of involvement of other family members who were considered obliged to caretake (eg, brothers not assisting with caregiving to sister, daughters not assisting with caregiving activities to mother), resulting in the deterioration of the overall family relationship.

The sixth theme, *professional help*, was noted when caregivers addressed the professional help either in the form of day care or professional/semiprofessional caregivers who were hired for in-home assistance. The caregivers who had the financial resources to cover the in-home professional/semiprofessional care expenses hired help regardless of the living arrangements or their full-time presence in the home. Some of the statements the caregivers made regarding professional help included “I paid the woman to help me,” “I had to send him to day care against his will so that I can work,” and “I had 24-hour home assistance.”

The seventh theme of *time management* within the rising action subcategory of daily changes included all the relevant issues regarding the daily organization of time and changes that took place within the personal schedule. For instance, caregivers reported “all day revolved around the care recipient,” “the day was organized in the service of the care recipient,” and “I had to give up my personal time.”

Average Day Subcategory

The average day subcategory explores a day in the life of an informal caregiver, including all of the relevant activities concerning care after the initial routine has been shifted and caregiving became a part of life. We noted six emerging themes within this subcategory pointing to *early waking hours*; *assistance with hygiene, food, and medication*; *daycare center/home*; *meal time*; *mutual quality time*; and *bed time*.

Informal caregivers reported *early waking hours* as the beginning of each day, followed by *assistance with hygiene, food, and medication*. These two themes were reported by all caregivers regardless of the living arrangements (eg, living together or separately). The caregivers reported that the first activity in the morning involved assistance with showering, cleaning, dressing, breakfast, medications, and therapy. This assistance was provided alone or, in a few cases, together with the professional/semiprofessional in-home caregiver. Caregivers also noted that the assistance with personal hygiene was the most uncomfortable aspect of the caregiving role and the aspect that was also seen as repulsive in the beginning of the caregiving role.

The third theme was *home care/day care*. Care recipients either visited the daycare center for a couple of hours, or home care continued with the existing daily routine such as brief walks, grocery shopping, and reading newspapers. Caregivers who had the opportunity to spend some time away from the care recipient noted that they felt good about these hours even though they were still occupied with the caring obligations.

The *meal time* theme followed the home care/day care theme. The care recipient would usually return from the daycare center or the late-afternoon home care would continue with early dinner. The *mutual quality time* theme was noted as a small period existing after dinner where the care recipient and caregiver spent quality time together, such as listening to music, talking, reading, or watching TV. These moments were also marked with the occasional efforts of informal caregivers to reminiscence with the care recipient about the past and good moments lived together.

Bed time was the final theme within the average daily life subcategory, in which caregivers prepared the care recipient for sleep, distributed the medication, assisted with other care needs, and helped the care recipient go to bed. The caregivers mostly reported going to bed sometime later, after small house chores were complete.

Psychological and Emotional Challenges Subcategory

Psychological and emotional challenges of the role were identified through six emerging themes, including *fear*, *disappointment*, *powerlessness*, *loneliness*, *sense of inadequacy*, and *lack of personal freedom*.

The theme *fear* was noted as an important aspect of the subcategory emotional and psychological challenges. Fear experienced by caregivers was related to the care recipients' health and possible deteriorations of their health. In instances where the care recipient was ill, or the condition suddenly worsened, the caregivers reported fearing the possible outcomes and/or that they will not be able to appropriately assess the

seriousness of the condition, which might have severe or lethal consequences on the care recipient.

Following the theme of fear, the *disappointment* theme emerged in the subcategory of emotional and psychological challenges as caregivers described daily events that affected them the most. It was noted that caregivers were disappointed with the disease progression and the outcomes, stating that related events are particularly difficult since they are taking place right in front of the caregivers. Some of the statements portraying these themes include "seeing your mother not recognizing you and not knowing anymore," "becoming a mother of my parents," and "I have always seen my parents as pillars and instead I discovered all their weaknesses."

The *powerlessness* theme appeared as an outcome of the irreversible change in the disease progression, when, despite the care provided, the condition was still deteriorating/not improving. Caregivers reported "the inability to do something against the disease/the sense of powerlessness caused by the disease weighted the most," "maintain a normal relationship when you are overwhelmed by the suffering that involves seeing the decline due to the disease," and "I feel so angry and I feel lonely."

Loneliness was noted as a fourth theme of the psychological and emotional challenges subcategory, overlapping with the loss of social life theme noted in the subcategory of daily changes. Loneliness was identified by statements such as "I feel lonely," "I find it hard to be the only one who has to follow him," and "she is refusing other caregivers' presence."

Sense of inadequacy was the fifth theme noted when the care recipient condition worsened or difficult symptoms occurred. Caregivers reported feeling as if they were not sufficiently or adequately prepared to manage caregiving duties, or being in need of time to adapt to new circumstances/worsening of the condition. The examples were noted through a variety of statements such as "the moments of aggression that he had"; "feeling inadequately equipped to provide assistance"; "my movement had to be exactly the same as hers and this cannot happen overnight, you have to adapt"; "she once grabbed my neck"; and "she was waking up at night and ran."

Finally, *lack of personal freedom* was the sixth theme caregivers repeatedly noted in the subcategory of psychological and emotional challenges. This theme was reflected in planning out private time, going out alone, socializing, organizing weekends with family, or simply managing to spend time with people other than the care recipient. Furthermore, caregivers reported a lack of personal freedom in statements such as "lack of freedom is what oppresses me," "inability to spend time with children," and "sense of guilt for not having the time for everyone."

Climax/Critical Point Category

The climax point in the TST is the peak moment where the story begins to unravel since it reached the moment of the greatest tension. The climax/critical point category reflects the peak point for informal caregivers, where the provision of care has reached its peak in terms of difficulty, burden, and negative experiences, and hence must change or terminate. This category

explores the themes emerging from the experiences of the most critical moments in the role of caregiving.

The initial theme recognized within the critical point category was the *fear of loss/facing the possibility of loss*. Caregivers reported that the critical points occurred when they were confronted with the further/serious health deterioration of the care recipient that implied the possibility of a lethal outcome. This theme appeared in the later phases of caregiving and could be potentially related to the following theme of *psychological and emotional exhaustion*. Concretely, when the caregiver had the resilience and strength to carry the role-related burden, the fear was less present/obvious. Some of the caregivers' statements shedding light on the theme of fear of loss/facing the possibility of loss include "when he gets ill/does not feel well I am scared because I believe it is serious"; "while my father was still having a driving license, since he was a danger to himself and others"; "when he is ill I do not know what the outcome will be"; and "the most critical moment is the last days when you know that nothing else could be done." This fear appeared to surface after the first encounter with the critical situation where the life of a care recipient was jeopardized.

The theme *psychological and emotional exhaustion* was reflected through numerous examples of negative emotions experienced, tiredness within the role, and the concern about the continuation of the caregiving activity. Furthermore, a few caregivers reported that due to psychological and physical fatigue—which could, in turn, be the consequence of psychological exhaustion—they were concerned if caregiving could last any longer. Caregivers expressed this through statements such as "I have experienced all the feelings of this world, anger, frustration, resentment, loneliness"; "I feel alone and criticized by my siblings while they are not truly aware of the situation"; "yes, there are mornings when I'm more tired and hearing the same things over and over again is heavy"; and "physical fatigue that prevented me from seeing the situation clearly/the worst moment was when I realized I cannot bear the caregiving for much longer."

The final theme noted within the category of climax/critical points was *facing the fact that care cannot be provided anymore*. It seems that such confrontation with the reality of the situation comes after first experiencing physical, psychological, and emotional exhaustion. Such a conclusion could also be related to the previous argument about the themes of fear, disappointment, and powerlessness, argued as early indicators that imply the caregiver is reaching a critical point within the role.

Step 3: Arranging Themes Into the Freytag Pyramid

The obtained themes were used as building blocks for development of a fictional story guided by the real-life experiences common to the target population (ie, informal caregivers). The real-life experiences are reflected in the obtained themes, while the TST is used for incorporating these real-life experiences into a flourishing narrative. Following the third step of the TST, the obtained building blocks/themes were fed into the Freytag pyramid (Figure 2) and used for the creation of numerous stories and different narratives for informal caregivers.

Step 4: Creation of the Final Story

The fourth step of the TST consists of writing a fictional story using the obtained figure from step 3 (see Figure 2). The created fictional story provides the viewer/listener an identification with the protagonist who experiences similar challenges throughout the role (ie, identification is supported by the building blocks/themes) but also an emotional distance that allows taking an objective stance toward the caregiving experience through a third-person perspective (ie, the narrator telling the story to the caregiver, or the protagonist). A sample of a fictional story created as step 4 of the TST is included in Textbox 1 (see Multimedia Appendix 2 for the full story).

Once the final step of the TST is completed and the written story is audio-recorded using a voice actor, the audio will be available on the Voice Me Out platform we designed for the informal caregivers (the platform is not yet publicly available).

Textbox 1. Final fictional caregiver stories created. Words in italics are the retrieved themes incorporated into the fictional story.

- Excerpt from the category “The beginning”

I think I can describe it simply; I *did not have a choice*, but to take her with me that night. “*It is my duty*”—I said to myself—because she is my family. Besides, I *cannot afford anyone* to take care of her. As the days were going by, I had to change so many things in my life, one after another. I had never expected all of it to happen that way. I had to reorganize the space in my house and empty a room for her.

- Excerpt from the category “Rising action”

My entire morning routine had to adapt to her from day one. I had to *change my working hours* and shift to *part-time work* because I couldn’t get to work by 9 any longer and stay there until 5. It is difficult sometimes to follow my own schedule.

My spouse often complains, and I do understand him, but I don’t see what else I can do. I can’t put her into a nursing home. My children didn’t seem bothered at the beginning. In fact, they were excited to have Grandma home, but there comes a time when they try to make plans for us to go to the park on the weekend, as we used to, but I can’t promise anything because I do not know if she will be in her good mood that weekend and able to leave the house. My *family balance* is completely disturbed.

- Excerpt from the category “Climax/critical point”

Fear, this is how I can describe such moments. I did not know what to do. I was scared for her, for my children. It was fear that didn’t let me think for a moment. I felt *powerless* because she wasn’t getting any better; she was either the same or getting worse. I couldn’t make her get better and I think I was making her worse by not knowing what to do exactly. I was *completely alone*. No one could truly understand what I was going through. I didn’t know what to do and I had no one to call. Everyone I knew had already advised me many times to consider a nursing home. I couldn’t just take a break to have a *moment for myself* to think. It had been like that for months. I had lost my *personal freedom*. I felt trapped.

I took the phone and called an ambulance.

Discussion

Principal Findings

This study implemented the TST [5] for developing empowering narratives in an informal care context. We demonstrated how to use the TST to obtain and categorize building blocks of a universal informal caregiver life story to develop an empowering fictional story. The final 25 themes have been distinguished across three a priori categories (ie, the beginning/exposition, rising action, critical point), covering a wide range of experiential, practical, and emotional changes, along with experiences throughout the role.

Numerous obtained themes (eg, within the beginning, and psychological and emotional challenges categories/subcategories) are in line with the past literature and reflect the important aspects of the informal care experience. Although some of the themes such as those within the subcategory of daily life constitute a major part of informal caregiver life and activities, they have been rather neglected in the literature to date (see Figure 2). It can be suggested that some of these themes also have an important role in the caregiver burden.

Interestingly, following the TST, we obtained qualitative data that have already been reported in the literature, but never gathered in one study. Namely, the TST enabled an all-encompassing approach to collecting, structuring, and grouping these findings chronologically. In other words, the TST enabled and facilitated gaining a magnified overview of the detailed caregiving experience.

Findings in the beginning/exposition category, which reflects on the early experiences in the role, indicate that informal care is often taken because of personal beliefs about family duties and obligations. This theme is also in line with prior research noting that informal caregivers consistently report this sense of

duty across different cultures [26-28]. Additionally, when several children were available to provide care for a parent, other siblings commonly expected the female child or the oldest child to assume the caregiving role.

Therefore, the sense of duty is arguably not equally present in all potential caregivers, but rather formed by certain expectations for the specific family member to assume care (eg, the female sibling or the oldest sibling). It could be suggested that the sense of duty or the internal perception of duty is one of the distinctions between those that will assume care in the future and those that will refuse it. However, no current data are available comparing the sense of duty among siblings when more than one child is available to assume the role. Furthermore, it can be added that the existing perception of the feminine nurturing role additionally disadvantages female family members when the caregiving arrangements are being determined [29].

The financial aspect/lack of resources for formal or institutional care appeared as an important theme in the role assumption. Informal caregivers that had resources to support formal care or financially cover the placement into the nursing home/daycare center reported such actions early in the role. Moreover, caregivers who were able to afford assistance of any kind reported fewer caregiving tasks, ultimately allowing more personal freedom and time for other activities.

In line with this argument, findings from a recent study across 12 European countries assessing existing care policies and health of informal caregivers point to a significantly lower health status of informal caregivers who provide home-based care [30]. Similarly, our results indicate that in instances where informal caregivers were not able to afford any type of help, the emotional experiences in the subcategory of psychological and emotional challenge within the rising action category were described to a greater extent, with vivid examples and recollections of numerous difficult situations. Another

interesting finding is that caregivers who provide only home care reported more severe emotional responses toward the care recipient and frustration toward the caring situation, which was reflected in the rising action category exploring the psychological and emotional challenges concretely. This insight can also be related to the past literature pointing to psychologically and physically abusive behaviors occurring in the informal caregiving context [31-33], suggesting that the type of care (in-home only vs shared care with respite/or a day center) could be related to more severe reactions.

Informal caregivers noted the loss of social life and personal time early in the role, describing these experiences as part of the changes that took place due to the role. A similar theme reemerged as loneliness in the category of psychological and emotional challenges, described mostly as “lack of friends,” “lack of support group,” and “lack of people that can serve as a reference point or companion during the difficulties.” Interestingly, these findings are consistent with a previous study noting the presence of similar experiences of social isolation and lack of support [34].

The relevance of the theme *drop of personal care* can also be aligned with the existing literature pointing to the gradual decrease in the physical health of informal caregivers who provide care for a longer period [35]. Arguably, the drop of personal care can be attributed to the maladaptation to two other themes, *loss of social life* and *changes in the routine*, ultimately occurring as an unconscious process in the caregiver. Moreover, a drop in personal care may act as a potential mediating factor in the decrease of physical health noted in the literature. The past literature exploring personal self-care in informal caregivers underlines the strong association between self-care and emotional well-being, pain, perceived stress, and general health [36].

Changes in employment arrangements is another theme in line with numerous studies, pointing either to the lack of social policy that will provide flexible working hours for informal caregivers or inadequate long-term financial support for the hours missed from work (see [30,37,38]).

Caregiver fear, discovered as another theme, has also been noted in the literature in the context of specific illnesses such as pulmonary fibrosis, amyotrophic lateral sclerosis, and heart failure (see [39-41]), where caregivers did not know how to manage specific illness-related aspects of care. However, the role of an overall fear in informal caregivers about assuming and providing caregiving has been rather neglected.

Another interesting theme discovered in this study is the sense of powerlessness. This theme emerged right before the critical/climax point category. In fact, the themes of fear, disappointment, and powerlessness toward irreversible change could be argued as early indicators that the caregiver is reaching a critical point in adverse experiences within the role, where the care provision either needs to be terminated, restructured, or shared to avoid critical situations.

Sense of loneliness and social abandonment/isolation are present from the early stages of taking up the role and seemed to be most strongly expressed in the emotional and psychological

challenges subcategory. These themes are also consistent with the literature, pointing to the reported sense of isolation and abandonment in caregivers (see [42-44]).

The aforementioned themes within the psychological and emotional challenges subcategory could be argued as a set of early indicators leading to the confrontation with the fact that care can no longer be provided, as a part of the critical point category. Following such a perspective, if the early indicators are not appropriately addressed, the critical point follows or can be avoided by perpetual therapeutic work on fear, disappointment, and powerlessness within the role.

Following the categorization of the building blocks (Figure 2) and the creation of the empowering informal caregiver fictional story, these findings demonstrate how the TST can act on two levels. First, the categorization of building blocks with the TST can serve as an informative pathway for further research and interventions. Concretely, building blocks provide a path of the informal caregiver life experience from the beginning of the role until the critical point, and as such, proper steps can be developed to prevent, intercept, or manage problematic experiences in practice.

Second, the value of the created story and the potential effects of this story on informal caregiver well-being need to be assessed in a pilot trial, ensuring that informal caregivers benefit from such stories. The stories serve as a sample of a productive caregiving narrative to be used as a template in self-restructuring of the personal caregiving life stories. If TST stories show positive outcomes for informal caregivers in the currently ongoing pilot testing, we can further explore the development of flourishing gender-adapted narratives through digital health tools. This approach would further facilitate human-centered design in eHealth tools for informal caregivers, and provide a new method of exploring adverse experiences while offering a path for creating flourishing and empowering digital narratives.

Limitations

Unlike the traditional storytelling approaches, the TST allows for the collection of universal building blocks for target groups or populations rather than individuals. In this sense, the technique enables in-depth exploration of the dominant/repetitive themes in the concrete categories of experience, acting as building blocks of an individual narrative within the target population.

Such collection and representation of the building blocks provide (1) an informative template for research and practice, (2) a pathway in the design and development of tools and interventions, (3) an overview of the narrative of the experience, (4) a blueprint for self-restructuring within the personal story of “the self,” and (5) a top-down approach to narrative therapy (ie, providing ready empowering narratives linked to personal experience).

Several limitations of this study must be considered. Further work on gathering and comparing themes in informal care following the TST is required to verify the universality of the retrieved themes in acting as building blocks for informal care narratives. Therefore, although our focus was on distinguishing universal caregiving experiences through the TST, we cannot

assume the generalizability of our findings until the ongoing pilot trial data are retrieved and until the retrieved themes are reproduced by using the TST in further studies. The majority of our sample was predominantly female informal caregivers, leading to possible perspective bias. The male experiences need to be collected and compared against the obtained themes to ensure the generalization of themes as building blocks for informal care narratives. In this sense, minimizing bias in future studies would strengthen the scientific rigor for obtaining universal themes of the informal care experience. Another consideration regarding the scientific rigor that must be acknowledged is that all the participants had already taken part in self-help group meetings of the association, which might have prepared them and facilitated their capacity for self-reflection but likely also contributed to preconception of the emotional difficulties. In this sense, some experiences shared with our researcher (SB) might have already been predefined and conceived in self-help groups rather than reflected on for the purpose of our interview. This might ultimately affect the validity of the reported experiences, since they might have been reassessed and adapted in a self-help meeting to better resonate with the support group members rather than resonating with the general informal care experience.

Moreover, it must be noted that this study did not define an upper age limit for informal caregivers, allowing even elderly

caregivers to take part in the study. The age difference among informal caregivers raises a question about the universality of the experiences across generations.

Finally, our sample consisted of informal caregivers who provided care for family members with concrete illnesses such as Alzheimer disease, Parkinson disease, or dementia. Therefore, the obtained experiences in this study could be potentially biased or formed by the specific illness presented in the care recipient. A larger sample of informal caregivers including other chronic conditions would be desirable in better exploring and creating universal themes of the informal caregiving experience.

Conclusions

The rapid expansion of storytelling applications in mental health calls for structured and tested techniques that will provide consistent narrative structures with clearly defined purpose and goals. The TST is the result of our effort to create a technique for developing structured, meaningful, and empowering narratives for larger groups or populations that can be easily adapted and applied to a digital format. The translation of personal narratives into empowering digital stories is one of our next goals in implementing the human-centered design in digital health development for informal caregivers, where the value of every individual is recognized in the overall process of the group experience.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Phases of theme development.

[\[DOCX File, 20 KB - formative_v6i8e36405_app1.docx\]](#)

Multimedia Appendix 2

Final story (translated to English).

[\[DOCX File, 19 KB - formative_v6i8e36405_app2.docx\]](#)

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Abbreviations

CERPS: Commissione Etica della Ricerca in Psicologia

TST: transformative storytelling technique

UCSC: Università Cattolica del Sacro Cuore

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Original Paper

A Personalized Ontology-Based Decision Support System for Complex Chronic Patients: Retrospective Observational Study

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Abstract

Background: Due to an increase in life expectancy, the prevalence of chronic diseases is also on the rise. Clinical practice guidelines (CPGs) provide recommendations for suitable interventions regarding different chronic diseases, but a deficiency in the implementation of these CPGs has been identified. The PITeS-TiSS (Telemedicine and eHealth Innovation Platform: Information Communications Technology for Research and Information Challenges in Health Services) tool, a personalized ontology-based clinical decision support system (CDSS), aims to reduce variability, prevent errors, and consider interactions between different CPG recommendations, among other benefits.

Objective: The aim of this study is to design, develop, and validate an ontology-based CDSS that provides personalized recommendations related to drug prescription. The target population is older adult patients with chronic diseases and polypharmacy, and the goal is to reduce complications related to these types of conditions while offering integrated care.

Methods: A study scenario about atrial fibrillation and treatment with anticoagulants was selected to validate the tool. After this, a series of knowledge sources were identified, including CPGs, PROFUND index, LESS/CHRON criteria, and STOPP/START criteria, to extract the information. Modeling was carried out using an ontology, and mapping was done with Health Level 7 Fast Healthcare Interoperability Resources (HL7 FHIR) and Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT; International Health Terminology Standards Development Organisation). Once the CDSS was developed, validation was carried out by using a retrospective case study.

Results: This project was funded in January 2015 and approved by the Virgen del Rocío University Hospital ethics committee on November 24, 2015. Two different tasks were carried out to test the functioning of the tool. First, retrospective data from a real patient who met the inclusion criteria were used. Second, the analysis of an adoption model was performed through the study of the requirements and characteristics that a CDSS must meet in order to be well accepted and used by health professionals. The results are favorable and allow the proposed research to continue to the next phase.

Conclusions: An ontology-based CDSS was successfully designed, developed, and validated. However, in future work, validation in a real environment should be performed to ensure the tool is usable and reliable.

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KEYWORDS

adherence; ontology; clinical decision support system; CDSS; complex chronic patients; functional validation; multimorbidity; polypharmacy; atrial fibrillation; anticoagulants

Introduction

Chronic Diseases and Multimorbidity

Due to an increase in life expectancy, the prevalence of chronic diseases is also rising [1]. According to the World Health Organization (WHO), chronic diseases are health problems requiring treatment over years or decades [2]. The diagnosis of 2 or more chronic conditions in a patient at the same time is called multimorbidity [3]. Patients with multimorbidity, called complex chronic patients (CCPs), are characterized by being fragile, with polypharmacy, of older age, in emergency departments frequently, and having a higher rate of hospital readmissions [4]. CCPs also constitute a challenge for the health system, particularly for health professionals, as there are few specific guidelines for providing integrated health care [5].

Polypharmacy

The increase in the number of CCPs is linked to a higher incidence of polypharmacy [6], defined as a patient taking 5 or more drugs [7]. The drugs offer clinical benefits and risks, but the complexity of CCPs makes this group more susceptible to errors [8].

Polypharmacy is associated with increased adverse reactions, reduced adherence to treatment, and increased demand for health care resources [9]. Currently, clinical practice guidelines (CPGs) recommend drugs for disease management based on clinical trials for specific diseases. However, CPGs do not consider the complications that can arise in a CCP due to interactions between different drugs for different diseases [10].

All this highlights the need for personalization of care and prescriptions due to each patient's specific situation [11].

Clinical Guidelines

CPGs are defined as “systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances” [12]. Some CPGs provide recommendations for good interventions regarding different chronic diseases. However, there is lack of implementation of these CPGs in clinical practice due to different factors, such as subjective interpretation by health care professionals, the lack of time for health care professionals to read these CPGs [13], and clinical inertia [14], among others. In addition, a study carried out by the National Institute of Health and Care Excellence (NICE) compared 12 CPGs and detected numerous dangerous interactions between the different recommendations given by each CPG [15].

Today, health care systems face the challenge of providing a new care model integrating all the CPGs [10] that do the

following: take into account the individual situation of each patient; identify possible interactions between drugs prescribed to the same patient to avoid complications; consider the patients' life expectancy as, in some situations, prescribing the drug will not provide significant benefit to the patient; and if life expectancy is low, recommend beneficial and effective but less aggressive treatments.

Clinical Decision Support Systems

Clinical decision support systems (CDSSs) are handy tools in the health framework and have 3 requirements [16]: (1) computable biomedical knowledge, (2) information about the specific situation of each patient, and (3) reasoning mechanisms to be able to provide personalized recommendations to each patient.

However, even with years of research in this field, health care professionals' acceptance of CDSSs is not satisfactory. This is one of the reasons why 95% of CDSSs are discarded [17]. Different studies have been conducted to determine what needs to be fulfilled during the development of the CDSS to be well accepted in the health care environment and especially by health care professionals. Shortlife et al [18] reported that biomedical informaticians had identified the following characteristics necessary to achieve good acceptance of a CDSS: users, in this case, health care professionals, must understand the basis and reasoning behind the CDSS recommendations; the CDSS developed in the health care environment should be intuitive and easy to use; the CDSS should support the health care professional by providing advice but always respecting their experience and knowledge; and the recommendations provided by the CDSS should be evidence-based and offer resources (scientific papers, CPGs, studies, etc) to review the validity of those recommendations.

Trinkley, Blakeslee, et al [19] explored the beneficial features of a CDSS for primary care from the health professional's perspective. They concluded that the design of the CDSS should be user-centered and take into account the user's needs in terms of content, presentation, and functionality and that the CDSS should be personalized to the health professional's needs, providing relevant information and optimizing the workflows.

Trinkley, Kahn, et al [17] highlighted the importance of reducing alerts to a minimum to minimize health professional fatigue, including all health care team members in the workflow, and encouraging health professionals to follow the recommendations. The latter point focuses on time savings during health care, such as ordering a test directly from the CDSS or updating the medical record with the data entered in the CDSS automatically.

Ontology-Based Systems

Studies such as that by Van de Velde et al [20] demonstrate that integrating the knowledge contained in CPGs and other knowledge sources into a CDSS improves clinical practice. To carry out this integration, it is necessary to make an intermediate step that models this information's content [21]. One way to perform this intermediate step and, in this way, to infer the specific clinical knowledge, is by designing an ontology.

An ontology is an excellent way to organize existing knowledge in CPGs [22]. These kinds of resources define a common vocabulary that allows researchers to share information about the same field [23]. Borst [24] defines ontology as “an explicit and formal specification of a shared conceptualization.” According to Lekhchine [25], each element of the definition of ontology provided by Borst should be understood as follows: explicit specification—each ontology concept and associated features are defined in a declarative form; formal—this allows ontologies to be interpretable by a machine; shared—here, the knowledge that is shared in the ontology is consensual; and conceptualization—this involves linking to the abstraction of a phenomenon by identifying concepts related to that phenomenon.

Konaté et al [22] identified the most critical needs for the decision to develop an ontology to be the following: a shared understanding between different software developers; reuse of knowledge in a particular domain; helping the different actors in a domain to understand each other better and increase their knowledge; distinguishing 2 types of knowledge, operational knowledge and domain-focused knowledge; and analyzing existing knowledge about a domain.

With consideration to all the characteristics analyzed in this section and to provide personalized and integrated care to CCPs, the PITeS-TIiSS (Telemedicine and eHealth Innovation Platform: Information Communications Technology for Research and Information Challenges in Health Services) tool has been designed, developed, and validated.

The main objective of the PITeS-TIiSS project is to improve evidence-based decision-making capacity and reduce variability in clinical practice in the domain of integrated care of CCPs through the use of advanced semantic interoperability and clinical decision support methods and tools.

Methods

Ethics Approval

This study obtained authorization from Virgen del Rocío University Hospital (VRUH) review board chaired by Victor Margalet on November 24, 2015 (number PI15/01213).

Selecting the Study Scenario

For the development and clinical validation of the PITeS-TIiSS tool, a specific study scenario was defined.

To design this study scenario, the prevalence of chronic diseases was taken into account in the health area where this clinical validation was carried out. This ensured the recruitment of

patients for the study and the high availability of information recorded in the electronic health record (EHR).

The ultimately chosen scenario focused on treatment with anticoagulant drugs in patients with atrial fibrillation. This pathology has a high prevalence, and an early treatment protocol needs to be established due to the complications it can cause [26].

The study was conducted in the Andalusian Health Service in Andalusia, a Spanish region with more than 8 million inhabitants. Specifically, the study area was located at the VRUH in Seville and the Primary Care Center in Camas (Seville).

Study, Analysis, and Selection of Knowledge Bases

Selection Criteria

Once the study setting was defined, the clinical researchers analyzed the evidence-based knowledge bases most commonly used in clinical practice concerning atrial fibrillation, care of CCPs, and oral anticoagulant therapy. More than 20 clinical documents with relevant information were identified. Several criteria were also considered in the selection of clinical records to be used for knowledge extraction: the frequency of application in clinical practice of the information included in the document; the level of updating of the clinical data; the level of consensus of the clinical data; and the clinical documents included in the clinical action protocols of the VRUH and its affiliated centers, where the PITeS-TIiSS tool was to be validated.

After the analysis of the identified clinical documents, it was decided to select the following sources of knowledge.

STOPP/START Criteria

These criteria were first published in Ireland in 2008 and were updated in 2014 [27]. This knowledge base focuses on describing the most common errors in drug prescription. One of their most important features is that these criteria can be integrated into computer systems [28]. This knowledge base is used at the European level to analyze drugs prescribed to older adult patients. These criteria aim to control the polypharmacy to which this type of patient is usually subjected in order to optimize the drugs prescribed and prevent side effects that cause major complications. This document makes it possible to study each patient's individual and specific situations and obtain personalized recommendations for these situations. Moreover, it provides 2 types of recommendations: (1) prescription of drugs necessary for each patient according to the patient's condition; and (2) deprescription of drugs whose effect, due to the particular situation of each patient, may be more harmful than beneficial. These criteria have been demonstrated to detect potentially dangerous and inappropriate prescriptions and improve the quality of prescriptions.

LESS-CHRON Criteria

These criteria guide the optimization of drug prescription in patients with chronic diseases and have been developed using the Delphi method. This document analyzes different pharmacological characteristics, including the indications for which the drug is prescribed, conditions that recommend

deprescribing the drug, health variables to monitor the behavior of the drug, and the time that should elapse between different follow-ups. Based on these characteristics, a list of 27 criteria has been compiled [29].

PROFUND Index

The PROFUND Index is a scale designed by Spanish physicians and is widely used in Spain. It is a prognostic index for CCPs. It includes different types of variables: demographic, clinical, laboratory, functional, socio-familial, and care [30].

Clinical Practice Guidelines

CPGs are systematically developed guidelines to assist health professionals in developing care to provide personalized care for individual patients in specific clinical circumstances [13]. Clinical researchers recommended using a CPG on the diagnosis and treatment of atrial fibrillation [31].

Knowledge Extraction and Decision Rule Design

After selecting the knowledge bases, 2 researchers (ERV and CAV) specializing in medical informatics extracted the relevant information for the defined study scenario. Due to the length of some of the documents, information was searched using keywords related to anticoagulant and antiplatelet drugs, such as “oral anticoagulants,” “anticoagulation,” “anticoagulants,” “vitamin K antagonists,” “antiaggregants,” “antiaggregation,” “acetylsalicylic acid,” and “clopidogrel.”

The information extracted from the selected documents was collected in a tabulated record in the form of rules. The clinical researchers (BBF, MJGL, and LMG) validated these before continuing with the procedure.

The extracted rules have a specific structure. Clinical concepts are the variables that are associated with the values (numeric, Boolean, and others), for example, age, atrial fibrillation, antiaggregants, etc. Premises are the values and features that are associated with clinical concepts, for example, greater than or less than, true or false, and number.

Clinical statements include the text that makes the recommendation to be shown to the health professional, for example “Deprescribe in any case.”

Likewise, 2 types of rules have been defined: mini-rules are rules that relate to a single clinical concept and a single premise

associated with a clinical statement, for example “IF Treatment with Ticlopidine THEN Deprescribe in any case”; super-rules are those that relate to several clinical concepts and their premises to a clinical statement. for example “IF Atrial Fibrillation AND (Mitral Stenosis OR Mechanical Heart Valve) THEN Do Not Prescribe New Oral Anticoagulants (Apixaban, Dabigatran, Edoxaban, and Rivaroxaban).”

A total of 59 clinical recommendations related to the prescription and deprescription of drugs were extracted in the clinical setting of patients with atrial fibrillation. The clinical recommendations were displayed in a personalized way in the CDSS developed based on the information collected for each patient.

Information Modeling and Mapping

With all the necessary information collected in the tabulated document, the ontology was defined. To implement the clinical concepts, the premises, clinical statements, and the relationships between them, Protégé software was used.

Initially, the clinical concepts were added and mapped through annotations with the Health Level 7 Fast Healthcare Interoperability Resources (HL7 FHIR) standard [32] to facilitate syntactic interoperability and with Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT) [33] to facilitate semantic interoperability (Figure 1).

Specifically, Figure 1 is about the drug acetylsalicylic acid. Overall, 100% of the ontology concepts were mapped with FHIR, and 52% of the concepts were mapped with SNOMED CT. It was not possible to map all the concepts with SNOMED CT, as some of these concepts do not exist within that terminology.

Once the clinical concepts were introduced, the premises and clinical statements were implemented. The ontology's internal logic was established through the use of object properties, data properties, and the relationships between the concepts.

The establishment of the relationships between the clinical concepts and the premises to design the mini-rules was carried out through a propositional logic system (true or false, less than or greater than, etc). For the super-rules' design (Figure 2), the logical relationships between the different clinical concepts and premises (and/or) was also established.

Figure 1. Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT) and Health Level 7 Fast Healthcare Interoperability Resources (HL7 FHIR) mappings.

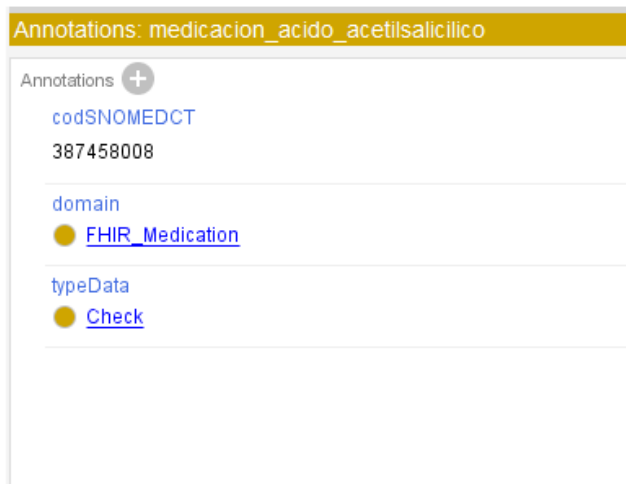


Figure 2. Super-rule example. HAS: Hypertension, Abnormal Renal/Liver Function, Stroke; HAS-BLED: Hypertension, Abnormal Renal/Liver Function, Stroke, Bleeding History or Predisposition, Labile INR, Elderly, Drugs/Alcohol Concomitantly.

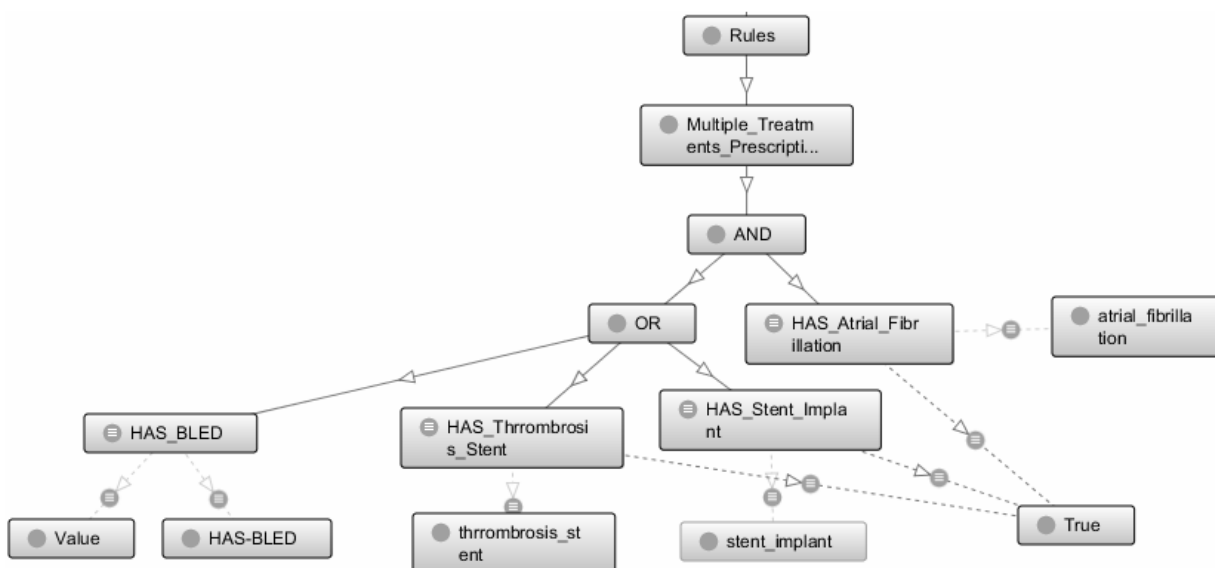


Figure 2 shows an example of the super-rule related to the National Institute of Health Stroke Scale (NIHSS). In this case, for the rule to be fulfilled, the patient must necessarily have multiple prescribed treatments and atrial fibrillation and additionally have 1 or more of the following characteristics: a certain value on the HAS-BLED (Hypertension, Abnormal Renal/Liver Function, Stroke, Bleeding History or Predisposition, Labile INR, Elderly, Drugs/Alcohol Concomitantly) score on bleeding risk, an implanted stent, or a thrombosis in a stent.

Design and Development of the CDSS

For the design and development of the CDSS, including the user interface, the ITCBio (Infrastructure for Translational and Clinical Research based on Standardization, Integration, Advanced Analytics) infrastructure [34] was used. This is a computer tool based on free software that has been developed to provide support for research in Andalusia (Spain).

First, the technical developer technicians (JMC, JARG, and GAER), together with the researchers specializing in medical

informatics (ERV and CAR), completed the user interface design. Based on the tabulated document, the questions that are shown to the health professionals to collect information on each patient were formulated. In order to make the tool usable and speed up the collection of information, the questions are distributed in different sections related to the patient's anamnesis, exploration, complementary tests, and treatment (Figure 3). Based on each premise, a question is formulated and presented to the health professionals through the tool's interface. Thus, depending on the answers selected by the health professionals, the premises may or may not be fulfilled, and the recommendations whose premises are fulfilled are then executed.

Second, for the integration of the ontology containing the ITCBio infrastructure rules, the free software integration engine Mirth Connect was used, whose function is focused on the integration of tools in the health care field. One of this integration engine's most important functions is that it natively provides the following HL7 messaging standards. This

integration engine allows interoperating with the clinical information of the recruited patients present in the EHR through the development of specific channels.

Once the health professional enters the information into the CDSS, ontology queries are made, rules are executed, and recommendations related to the pharmacological prescription are generated all through the Mirth Connect integration engine.

Figure 4 shows an example of the information used by the Mirth Connect integration engine after querying the ontology. In this case, it is a mini-rule in which the clinical concept corresponds to the attribute “name_bd” and is “Ticlopidine treatment.” The Premise corresponds to the attribute “values” and, in this case, has the value “TRUE.” The Clinical Statement corresponds to the attribute “recommendation,” and its value in this example is “Deprescribe in any case.”

Figure 3. Tool interface.

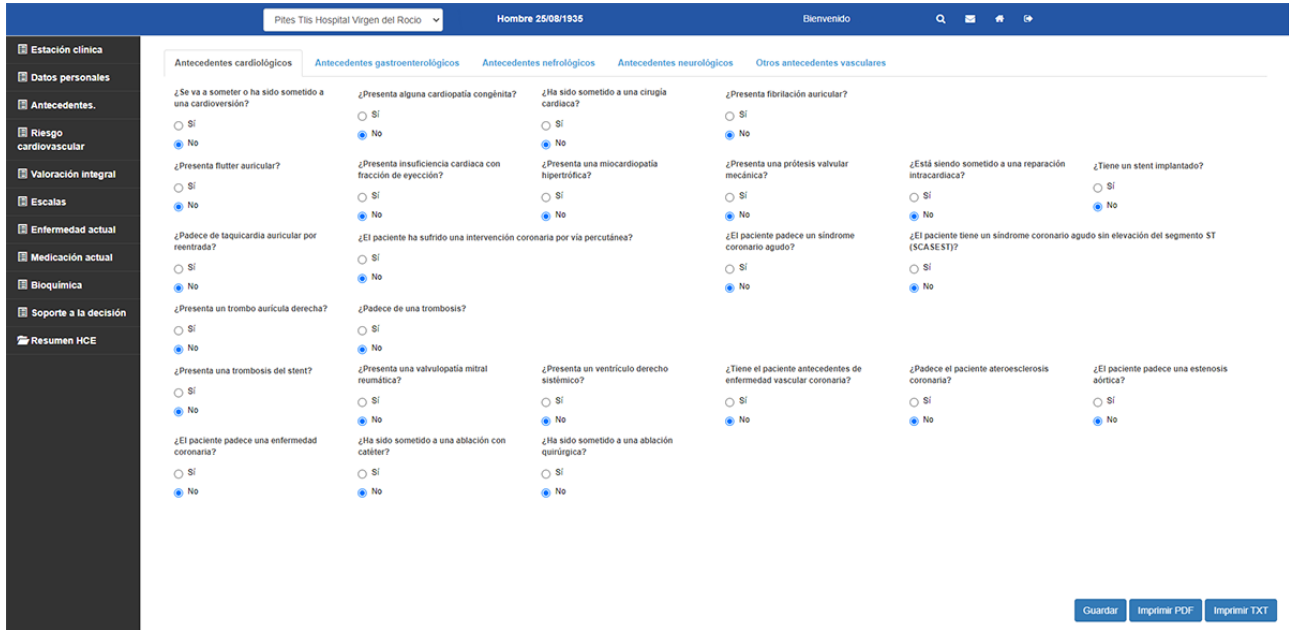


Figure 4. Mini-rule.

```

"rule-0": {
  id: "rule-0",
  logicalType: "AND",
  type: "rule",
  children: {
    "condition-0": {
      id: "cond-0",
      type: "condition",
      logicalType: "AND",
      operator: "equal",
      itemToEvaluate: {
        item_id: "6142",
        nombre_bd: "Tratamiento con Ticlopidina",
        nombre_formulario: "¿Se está medicando con Ticlopidina?",
        values: [
          { text: "Sí", value: "True" },
          { text: "No", value: "False" },
        ],
      },
      conditionalValue: { text: "Sí", value: "True" },
    },
  },
  recommendation: "Deprescribir en cualquier caso",
};
    
```

Figure 5 shows an example of the information used by Mirth Connect concerning a super-rule. In this case, 3 clinical concepts can be observed. One of them must have the value “TRUE,” and the other 2 are nested, and only 1 of them must have the value “TRUE” for the recommendation to be presented.

In this way, 3 types of information are shown to health professionals: (1) recommendations on prescribing, (2) recommendations on deprescription, and (3) recommendations that have not been implemented due to a lack of information.

To check that the rules have been executed correctly, each recommendation contains a drop-down list showing the assumptions that have been taken into account to execute the rule. Additionally, health professionals are shown information on the clinical concepts and premises that have been fulfilled to execute the rule and display the recommendation, the CPG from which the recommendation has been extracted, the page

and section of the CPG where the recommendation appears, and the level of evidence of the recommendation.

Moreover, for those rules that are not executed due to a lack of information, the CDSS simulates the result that would be generated if that value had been completed, fulfilling the premise and not fulfilling it. In this way, the tool analyzes whether the result would be affected by fulfilling these 2 hypotheses, and the rule would be executed.

Figure 5. Super-rule.

```

"rule-0": {
  id: "rule-0",
  logicalType: "AND",
  type: "rule",
  children: {
    "condition-0": {
      id: "cond-0",
      type: "condition",
      logicalType: "AND",
      operator: "equal",
      itemToEvaluate: {
        item_id: "6142",
        nombre_bd: "Tratamiento_con_Ticlopinga",
        nombre_formulario: "¿Se está medicando con Ticlopinga?",
        values: [
          { text: "Sí", value: "True" },
          { text: "No", value: "False" },
        ],
      },
      conditionalValue: { text: "Sí", value: "True" },
    },
    "group-2": {
      id: "group-2",
      type: "group",
      logicalType: "AND",
      children: {
        "group-2-condition-0": {
          id: "group-2-cond-0",
          type: "condition",
          logicalType: "OR",
          operator: "equal",
          itemToEvaluate: {
            item_id: "7845",
            nombre_bd: "estenosis_mitral",
            nombre_formulario: "¿Presenta estenosis mitral?",
            values: [
              { text: "Sí", value: "True" },
              { text: "No", value: "False" },
            ],
          },
          conditionalValue: { text: "Sí", value: "True" },
        },
        "group-2condition-1": {
          id: "group-2-cond-1",
          type: "condition",
          logicalType: "OR",
          operator: "equal",
          itemToEvaluate: {
            item_id: "5936",
            nombre_bd: "valvula_cardiaca_mecanica",
            nombre_formulario: "¿Tiene implantada válvula Cardíaca Mecánica?",
            values: [
              { text: "Sí", value: "True" },
              { text: "No", value: "False" },
            ],
          },
          conditionalValue: { text: "Sí", value: "True" },
        },
      ],
    },
  },
  recommendation:
    `No prescribir Nuevos Anticoagulantes Orales
    (Apixabán, Dabigatrán, Edoxabán y Rivaroxabán).`,
},

```


Clinical Validation

For patient recruitment and subsequent clinical validation, a number of inclusion criteria were defined: 65 years old or older, polypharmacy (5 or more drugs daily [7]), multimorbidity (with at least 2 chronic diseases or comorbidities in the multimorbidity classification [4]), with atrial fibrillation, and undergoing oral anticoagulants treatment. Meanwhile, the exclusion criterion was as follows: patients at the end of life with a short-term prognosis of less than six 6 months.

Results

Once the PITeS-TiSS tool was designed and developed, 2 different tasks were carried out to test the functioning of the tool. First, retrospective data from a real patient who met the inclusion criteria were used. Second, the analysis of an adoption model was performed through the study of the requirements and characteristics that a CDSS must meet in order to be well accepted and used by health professionals.

Functional Validation

For the functional validation, a patient was identified from the Camas Health Center in Seville, Spain, who met the inclusion criteria.

After this, the process of extracting knowledge from the EHR and generating personalized recommendations was carried out. This process of extracting clinical information consisted of 3 phases: (1) In the first stage, patient's identification data were included in the ITCBio platform; once the patient was included, the ITCBio platform extracted the information on hospitalizations, prescriptions, and other patient data useful for the study. (2) In the second stage, the tool had not been tested in a real environment, and retrospective data were used for functional validation; these data were extracted from the EHR of the patient chosen by a clinical researcher (ERV) and entered

into the PITeS-TiSS tool; this was obtained from the date on which the patient was diagnosed with atrial fibrillation and prescribed medication. (3) In the third phase, based on the data entered into the PITeS-TiSS tool, the rules whose assumptions were met were executed, and personalized recommendations on the prescription of medicines were generated.

As seen in [Textbox 1](#), patient 0 meets the first, third, and fourth inclusion criteria, as he is over 65 years old, has multimorbidity, and has been diagnosed with atrial fibrillation.

He also met the inclusion criteria related to polypharmacy and prescription anticoagulants ([Textbox 2](#)).

Once this patient's information was entered into the PITeS-TiSS tool, including the results of the Pfeiffer Questionnaire, PROFUND Index, and CHA₂DS₂-VASc (congestive heart failure, hypertension, age ≥ 75 years, diabetes, stroke, vascular disease, age 65 to 74 years, and sex category), 9 personalized recommendations were displayed ([Textbox 3](#)).

For each recommendation shown for this clinical case ([Textbox 3](#)), the following assumptions have been met: recommendation 1, the patient has atrial fibrillation and is prescribed a vitamin k antagonist; recommendation 2, the patient has atrial fibrillation and is prescribed antiaggregants and oral anticoagulants; recommendation 3, the patient has atrial fibrillation; recommendation 4, the patient has atrial fibrillation and arterial hypertension and is prescribed oral anticoagulants; recommendation 5, the patient has atrial fibrillation and is prescribed oral anticoagulants; recommendation 6, the patient has atrial fibrillation and is prescribed oral anticoagulants; recommendation 7, the patient has atrial fibrillation and is prescribed oral anticoagulants; recommendation 8, the patient is prescribed a vitamin k antagonist; recommendation 9: the patient has atrial fibrillation and is prescribed antiaggregants and oral anticoagulants.

Textbox 1. Patient 0.

<p>Patient 0</p> <p>Gender: Male</p> <p>Age: 70 years</p> <p>Pathologies:</p> <ul style="list-style-type: none"> • Dyslipidemia • Obesity • Arterial hypertension • Diabetes Mellitus 2 • Atrial fibrillation • Asthma • Chronic obstructive pulmonary disease • Mild nonproliferative retinopathy • Prostatic adenocarcinoma.
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Textbox 2. Prescribed drugs.**Prescribed drugs**

- Treatment for type 2 diabetes mellitus: rapid and mixed insulin and metformin
- Treatment for arterial hypertension: irbesartan, hydrochlorothiazide and amlodipine
- Analgesic treatment with paracetamol
- Treatment for prostate cancer with decapeptyl, tamsulosin hydrochloride, and bicalutamide
- Antiaggregant treatment with acetylsalicylic acid
- Anticoagulant treatment with aldocumar
- Lipid-lowering treatment with atorvastatin
- Omeprazole stomach protector

Textbox 3. Personalized recommendations for patient 0.**Personalized recommendations displayed by the PITeS-TIiSS tool**

1. “It is recommended to keep the therapeutic range time (TRT) as high as possible.”
2. “It is recommended to avoid the combination of antiaggregants and anticoagulants if there is no other indication for platelet inhibition.”
3. “Antiplatelet therapy in monotherapy is not recommended for the prevention of stroke in patients with atrial fibrillation.”
4. “Blood pressure should be monitored closely in this patient.”
5. “Moderate alcohol consumption is recommended, as there is a risk of bleeding.”
6. “It is recommended that renal function be evaluated once a year.”
7. “It is recommended to thoroughly review the prescription, eliminating drugs that may cause bleeding and shortening prescription times.”
8. “It is recommended to reduce the dose of vitamin K antagonists if the patient is taking amiodarone.”
9. “It is recommended to deprescribe ASA [acetylsalicylic acid] as it is of no benefit.”

Following the retrospective validation of the tool, a health professional from a primary care center performed a thorough analysis of the results.

First, the health professional reviewed the EHR of the selected patient and checked that the data entered in the PITeS-TIiSS tool were correct.

Subsequently, the recommendations displayed for this patient were reviewed. As indicated in the section on the development methodology of the tool, the assumptions that execute each rule and show each recommendation can be checked by reviewing a drop-down that shows them.

After reviewing the assumptions, the health professional reviewed the displayed recommendations and the additional information in the CPGs that support each recommendation.

The health professional concluded that she would comply with all the recommendations provided.

Adoption Model

Taking into account the analysis of the needs that a CDSS must meet to be well accepted that was carried out in the Introduction section, an adoption model was designed, consisting of an analysis of the 8 requirements that the PITeS-TIiSS tool must meet and how it can do so:

1. Health professionals need to understand the basis and reasons why the CDSS makes the relevant recommendations: the tool

provides below each recommendation the premises fulfilled for that recommendation to be displayed. Thus, the health professional can quickly recognize which items are related to each recommendation and why it is displayed.

2. CDSS should be intuitive and easy to use (usability). For the design and development of the PITeS-TIiSS tool, the ISO 13407:1999 standard has been followed. Human-centered design processes are required for interactive systems, as this complies with the 4 following principles of user-centered design contemplated in this standard: (1) active involvement of users as specified in point 5; (2) appropriate assignment of roles to the PITeS-TIiSS tool and the user—different roles have been established to access other tool modules, such as the developer role and health professional role; (3) iterative design solutions—during the tool's design and development stage, meetings were held between the development team and the health professionals to achieve a tool adapted to their needs, and the rules were also revalidated by presenting different clinical cases in these meetings; (4) multidisciplinary design—the PITeS-TIiSS tool has been designed and developed by technical developers and clinical informatics researchers (JMC, JARG, GAER, ERV, and CAR) who have provides their clinical and informatics vision.

3. The CDSS should support the health professional and offer advice while respecting his or her experience and knowledge: the PITeS-TIiSS tool's recommendations are not presented as mandatory. In the interface where the recommendations are

displayed, the health professional can indicate which rules will be followed and which rules are considered not to be followed. In turn, the health professional can justify why he or she has decided not to follow a specific recommendation. The latter allows the CPGs to be compared with actual clinical practice and to include changes in the CPGs that can improve clinical practice.

4. Recommendations should be evidence-based and provide resources to review the validity of these recommendations: in this case, the PITEs-TIiS tool offers the option of displaying in a PDF format the reasons why the recommendation has been shown. It shows the clinical concepts, the premises that have been met, the CPG from which this information has been extracted, the text in which the recommendation is found, the page and section where the recommendation is located, and the level of evidence of the recommendation.

5. The CDSS should be user-centered, taking into account the user's needs. Numerous meetings were held with the team of hospital and primary care health professionals throughout the design and development process. In these meetings, in addition to validating the content of the rules and recommendations, the health professionals' needs in terms of the development of the tool's interface were taken into account.

6. Fatigue-inducing alerts should be minimized. The PITEs-TIiSS tool does not display alerts or pop-up windows. Once the workflow has been completed and all the necessary patient information has been entered, the tool displays the personalized and justified recommendations.

7. All team members and workflow should be included in the tool's use. In this case, the PITEs-TIiSS tool focuses on health professionals—mainly internists, primary care physicians, and nurses.

8. Health professionals should be encouraged to use the tool. This feature is mainly about facilitating health professionals' work. It focuses on the need for a CDSS to connect to the EHR and primarily share information. The PITEs-TIiSS tool does not have a connection to the EHR. However, in the new Smart-PITEs project grant (#PI18/00700; Learning Health System for the Integrated Care and Adherence Management of Complex Chronic Patients), which is a continuation of the PITEs-TIiSS project, it is intended to connect with the EHR.

Discussion

Principal Findings

A personalized ontology-based CDSS called PITEs-TIiSS tool was designed and developed. A first functional validation was carried out to test and evaluate the proper functioning of this tool. A basic model for adopting the technology was designed by analyzing the needs of a CDSS to encourage its successful adoption in the health care field. These needs were extracted from different scientific publications that deal with this subject in-depth and have been added as references in this paper in the Introduction section.

The PITEs-TIiSS project is the third phase of a network of collaborative research projects whose overall objective is to

provide a secure, open, and interoperable digital ecosystem to facilitate the design, development, validation, and implementation of telehealth service innovations. Specifically, this third phase aims to incorporate advanced semantic interoperability and clinical decision support tools into clinical practice to provide integrated and personalized care to CCPs.

Concerning functional validation, the results have been favorable and allow the research proposed for the fourth phase of this network of research collaboratives projects, called Smart-PITEs, to continue.

Moreover, a new front is emerging concerning different CPGs. This is because there may be inconsistencies between each CPG's recommendations, and, thanks to the information provided by health professionals on the reasons why they choose not to follow a specific recommendation, changes in the CPGs based on health care can be considered.

Limitations

Although the research results are favorable, we intend to address several limitations during the completion of the Smart-PITEs project. Regarding the knowledge bases, those used to design the decision rules are those most commonly used in the VRUH health care area. It may happen that, in any other health care area, other CPGs are used. However, the established methodology can be applied to the design of new decision rules.

Due to many existing drugs and pathologies, to facilitate development and clinical validation, it was decided to study a specific scenario. In this case, it was CCPs with atrial fibrillation and prescribed oral anticoagulants. However, it is necessary to broaden the study of pathologies and drugs to provide real integrated care. In addition, the validation was carried out with a single clinical case, which does not conclusively ensure that the tool works correctly. Moreover, the validation of the PITEs-TIiSS tool was carried out with retrospective data. However, this potential limitation to prospective validation is expected to be addressed by the Smart-PITEs project currently underway and continuing this research approach. Finally, a lack of integration with the EHR has been identified, which means that one of the needs for the successful adoption of the health care field tool is not being met. One of the objectives of the Smart-PITEs project is to remedy this limitation.

Comparison With Prior Work

CDSS are useful tools for clinical practice. This is why there is a wide variety of proposals for such tools.

In Velickovski et al's [35] work in the field of CDSS for CCPs, they propose a CDSS focused on diagnosis and prevention in patients with chronic obstructive pulmonary disease. However, in this research, they did not use ontology as information modeling. Furthermore, they focused on a single pathology. Böttiger et al [36] also did not use ontology for the development of their CDSS. Instead, they focused on preventing and avoiding drug-drug interactions and adverse effects. Zhang et al [37] did use ontology as the main element of development. Their proposal focused on the diagnosis, assessment, and treatment of patients with type 2 diabetes mellitus. The difference between this proposal and the PITEs-TIiSS tool is that the first focuses

on a single chronic disease, while the proposed tool aims to address numerous chronic pathologies. Beyond this, PITeS-TiSS reports the assumptions that have been met for the personalized recommendations to be displayed. Konaté et al [22] proposed the development of a decision support system using an ontology. However, the field of development was not health care. The CDSSs proposed by Chen et al [38] and Madhusanka et al [39] were also based on an ontology. However, they again focused on a single pathology, such as type 2 diabetes mellitus 2. Bouaud et al [40] also proposed a CDSS and relied on an ontology for development. In this case, the researchers focused only on primary breast cancer patients. Finally, Miñarro-Giménez et al [41] developed an ontology-based CDSS focused on decision support for health professionals by providing pharmacological data to both

professionals and patients. This tool is specifically focused on patients with genetic disorders to prevent adverse reactions or drug interactions in these patients. They concluded that this tool could be useful for personalized medicine.

Conclusions

An ontology-based CDSS was successfully designed, developed, and validated. However, it has only been validated with retrospective information from 1 case study, so a more robust validation would be necessary to ensure that the tool is usable and reliable.

The next phase, the Smart-PITeS project, aims to overcome the limitations found in this project and also to ensure that the tool performs automatic learning and predictive models in relation to care and adherence to treatment of CCPs.

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Conflicts of Interest

None declared.

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Abbreviations

CCP: complex chronic patient

CDSS: clinical decision support system

CHA2DS2-VASc: congestive heart failure, hypertension, age ≥ 75 years, diabetes, stroke, vascular disease, age 65 to 74 years, and sex category

CPG: clinical practice guideline

EHR: electronic health record

ERDF: European Regional Development Fund

HAS-BLED: Hypertension, Abnormal Renal/Liver Function, Stroke, Bleeding History or Predisposition, Labile INR, Elderly, Drugs/Alcohol Concomitantly

HL7 FHIR: Health Level 7 Fast Healthcare Interoperability Resources

ITCBio: Infrastructure for Translational and Clinical Research Based on Standardization, Integration, Advanced Analytics

ITEMAS: Innovation in Medical Technologies and Health

NICE: National Institute of Health and Care Excellence

NIHSS: National Institute of Health Stroke Scale

PITeS-TiSS: Telemedicine and eHealth Innovation Platform: Information Communications Technology for Research and Information Challenges in Health Services

SNOMED CT: Systematized Nomenclature of Medicine Clinical Terms

VRUH: Virgen del Rocío University Hospital

WHO: World Health Organization

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Original Paper

Feasibility of Text Messages for Enhancing Therapeutic Engagement Among Youth and Caregivers Initiating Outpatient Mental Health Treatment: Mixed Methods Study

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Abstract

Background: Pathways to mental health services for youth are generally complex and often involve numerous contact points and lengthy delays. When starting treatment, there are a host of barriers that contribute to low rates of therapeutic engagement. Automated text messages offer a convenient, low-cost option for information sharing and skill building, and they can potentially activate positive behaviors in youth and caregivers prior to beginning formal therapy. To date, there is little evidence for the feasibility of initiating transdiagnostic text messages during the early stages of youth and caregiver contact with community outpatient mental health services.

Objective: To develop and test the feasibility of implementing 2 novel text messaging campaigns aimed at youth clients and their caregivers during the early stages of engaging with outpatient mental health services.

Methods: A multidisciplinary panel of experts developed two 12-message interventions with youth and caregivers prior to deployment. Each message included a link to an external interactive or multimedia resource to extend skill development. Enrollment of youth aged 13 to 18 years, their caregivers, or both occurred at 2 early treatment timepoints. At both time points, text messages were delivered automatically 2 times a week for 6 weeks. Analytics and survey data were collected in 2 phases, between January and March 2020 and between January and May 2021. Enrollment, willingness to persist in using the intervention, engagement, satisfaction, perceived value, and impact were measured. Descriptive statistics were used to summarize youth and caregiver outcomes.

Results: A total of 41 caregivers and 36 youth consented to participate. Follow-up survey response rates were 54% (22/41) and 44%, (16/36) respectively. Over 1500 text messages were sent throughout the study. More than three-quarters (14/16, 88%) of youth reported that they learned something new and noticed a change in themselves due to receiving the texts; the same proportion (14/16, 88%) of youth said they would recommend the text messages to others. Youth ranked the first text message, related to coping with difficult emotions, as the most helpful of the series. Caregivers reported acting differently due to receiving the texts. Over two-thirds of caregivers were satisfied with the texts (16/22, 73%) and would recommend them to others (16/22, 73%). Caregivers perceived diverse levels of value in the text topics, with 9 of the 12 caregiver texts rated by at least one caregiver as the most helpful.

Conclusions: Results are preliminary but show that brief, core skill-focused text messages for youth clients and caregivers in community outpatient mental health services are feasible. Both youth and caregivers reported promising knowledge and behavior change with exposure to only 12 messages over 6 weeks. A larger study with statistical power to detect changes in both perceived helpfulness and engagement is required to confirm the effectiveness of this type of transdiagnostic intervention.

KEYWORDS

text messaging; youth; mental health; waiting list; informatics; health behavior; self-care; mental health literacy; caregivers; transdiagnostic

Introduction

Successfully addressing the mental health concerns of youth depends not only on timely help-seeking behavior, but also on a rapid and appropriate response by the mental health system [1,2]. Pathways to mental health services for youth are generally complex and often involve numerous contact points and delays [3]. Initial assessment does not guarantee referral to treatment, and many of those referred do not attend their first scheduled appointment [4]. It is increasingly clear that planned early interventions across initial system contact points, including preclinical contact, can help avoid downstream negative impacts (ie, worsening symptoms, lower treatment satisfaction, and no-shows) and build momentum for sustained engagement [5-7]. Even a single early destigmatizing experience may be sufficient to promote future help-seeking behavior in youth and even delay illness progression [8].

Transforming reluctance into investment in treatment requires establishing mutual understanding among clinicians, youth, and their caregivers about the purpose, goals, and actions needed by all involved for positive change in the client's life [9]. With a growing body of literature showing that the constituent "practice elements" of evidence-based interventions can be relevant to a wide variety of child and youth mental health conditions (ie, they are not restricted to treatments for a specific type of problem or disorder) [10-13], there is an opportunity to automate universal low-intensity supports and make them part of routine service initiation pathways. Socializing youth and caregivers to help them learn transdiagnostic skills that target core-skill mechanisms (eg, strategies for emotional regulation, skills for dealing with positive and negative valence systems, problem solving, sleep regulation, self-identity, and communication skills) [14] could have significant positive individual and system level outcomes [15].

A recent scoping review of youth and family engagement research found that facilitating early access to complementary and digital mental health services is particularly desirable when wait times cannot be avoided, or when community conditions and geographic constraints prohibit routine engagement with outpatient services [16]. Short messaging service (SMS) or text messages offer a convenient, low-cost communication channel with which to establish connections with youth and their caregivers and activate transdiagnostic mental wellness strategies and skills. A scoping review by our team [17] showed that text messaging interventions are now used in many areas of child and youth mental health, including mild to moderate anxiety [18], bipolar disorder [19], appointment reminders [20], medication adherence [21], and mood disorders [22].

The literature shows high rates of acceptability among youth [23,24], with only a small percentage of users unsubscribing from therapeutic text messages [25] when given the opportunity.

Thematic analysis of interviews with youth who presented to the emergency department for mental health treatment indicated that cognitive behavioral therapy-based messages resonated with them, as did emotional regulation messages [26]. In some instances, text message interventions have led to significant behavior change [27] and a decrease in symptoms [28]. Exploring the feasibility of using text messages to deliver transdiagnostic supportive messages to both caregivers and youth during early interactions with outpatient services is a novel contribution to this evolving field.

The intention of this study was to develop and assess a text messaging campaign to engage youth clients and their caregivers while initiating outpatient service pathways. Through sharing tips, self-care ideas, and skill-building strategies and promoting new behaviors, the text messages were viewed as an opportunity to empower youth and caregivers to activate self-management skills prior to initiation of formal therapy.

The specific questions guiding the study were: (1) How many youth clients and caregivers want to receive text messages to support their general wellness when initially offered? (2) Once signed up to receive the text messages, do youth or caregiver clients choose to stop receiving text messages? (3) Which topics or types of resources being communicated through text messages are youth and caregivers most interested in? (4) In what ways do youth and caregivers feel that the text messages are or are not helpful in supporting behavioral change and in preparing them for their next appointment?

Methods

Study Design

A multimethod, descriptive research design was used for formative feasibility testing. Web analytics and survey data were collected in 2 phases between January 2020 and May 2021.

Text Message Development

The text message intervention was informed by an earlier cross-sector knowledge mobilization project involving several of the authors. That project sought to address local gaps in youth mental health supports using technologies such as text messaging [29]. In particular, the intervention aimed to focus on patient activation, which was defined as creating a common language for patients to share their concerns with health care providers; to learn about their condition to enable informed future decisions about treatment; to set expectations that they would take an active role in their own care; and to learn basic coping skills to manage symptoms [30]. Development and deployment of the text message intervention for youth and caregivers occurred in 5 steps, described in the following sections.

Step 1

Prioritization of content for the text messages was identified through the results of the team's scoping review [17] and a team activity completed by community mental health and addictions team clinicians at IWK Health. Clinicians were asked to come up with a list of the most important core skills in working with local clients and families. To the degree that a given skill or activity (eg, relaxation techniques, facing fears, and sleep hygiene) targeted multiple disorders (eg, anxiety, depression, and conduct problems) the text messages were viewed as potentially transdiagnostic.

Step 2

A panel was created with 5 members who had a broad range of expertise, including clinical psychology, psychotherapeutic competencies, behavior change, digital health, and implementation science. The panel achieved early consensus on several key aspects of the text message interventions to be created: (1) include a web link to an outside resource for each text message topic, (2) minimize the burden on users by presenting a brief and engaging topical prompt for each text message, and (3) establish a time-limited messaging period with no more than twice-weekly messages being sent.

Step 3

Taking the list of important core skills identified in step 1, the panel engaged in a collaborative process to draft prototype versions of the text message intervention for youth and

caregivers. The panel aimed to create messages appropriate for a broad spectrum of individual youth and caregiver experiences and needs. Each text message contained a short topical statement and a link to a further resource to deepen understanding, build skills, or reinforce concepts through interactive multimedia. The linked resources were all publicly available online and were vetted by the panel for clinical and developmental appropriateness and to ensure a variety of modalities (ie, not all videos or not all PDFs). Many of the links were resources familiar to clinicians on the team and already in use as informational resources that youth and caregivers might be directed to as part of treatment sessions.

Step 4

Drafts of the text messages and links were checked for face validity with 6 youth and 5 caregivers. The testers suggested rewording, deleting some proposed content areas, noted links that they did not like, and suggested resources and links. Each tester also ranked a series of text message topics to determine which 12 topics were the most salient to them. Feedback was incorporated, and the final list of messages was completed (Table 1). Examples of the text messages included: (1) (for teens) "Sometimes it feels good to let your feelings out. But don't let yourself get overwhelmed by the ones you don't want, like fear and rejection. Learning to control feelings can help a lot. Here's some ideas on how to do that" and (2) (for caregivers) "Is your teen's fear controlling your family? When worry starts to take control you need to coach your teen to face it: one step at a time."

Table 1. Youth and caregiver message themes and description of resources.

Message number	Topic	Linked resources for youth	Linked resources for caregivers
1	Difficult emotions	Animated YouTube video about anxiety	Animated YouTube video about empathy
2	Facing fears	Handout on building a plan to face your fears	Activity on how to build a fear ladder
3	Calming anger	Handout with tips on reducing anger	Web article on emotional coaching
4	Sleep habits	Website with frequently asked questions on how to deal with sleep challenges	Web article with tips for talking to youth about sleep
5	Self-care strategies	Interactive website with searchable self-care activity library	Guidebook for caregivers including tips for caregiver self-care
6	Relaxation skills	Animated video on breathing exercises	Web article on how to dial back conflict at home
7	Problem-solving	Structured problem-solving worksheet	Structured problem-solving worksheet
8	Negative thinking	Visual comparing negative versus realistic thinking	Web article on responding to youth's negative self-talk
9	Behavioral activation	Catalogue of 365 fun activity ideas	Catalogue of 365 fun activity ideas
10	Mindfulness	Animated, guided mindfulness exercise	Website with >40 downloadable podcasts
11	Values	Animated YouTube video on finding your own happiness	Animated YouTube video on finding your own happiness
12	Social media	Infographic on how to hold a "digital detox"	Blog post on being a digital mentor to your teen

Step 5

The text messages were set up for automated delivery using an SMS platform (SimplyCast) [31]. The platform provided a user-friendly interface to build text message campaigns, embed study surveys, and track user engagement. SimplyCast utilizes

firewalls, cryptography, and access-control procedures to protect information from unauthorized access. SimplyCast is ISO 27001, 27017, and 27018 certified. All information within the SimplyCast platform is stored on servers located in Canada. Text messages were set up to be automatically sent out at 6:00 PM, 2 times per week (3 days apart), for 6 weeks. This time of

delivery was chosen because youth and caregivers were more likely to be out of school or work at that time, thus increasing the probability that they could engage with the linked resource. Participants could text “STOP” at any time to opt out of receiving the text messages. After the participant received their 12th therapeutic text message, a final message provided an embedded direct link to a brief web-based follow-up survey.

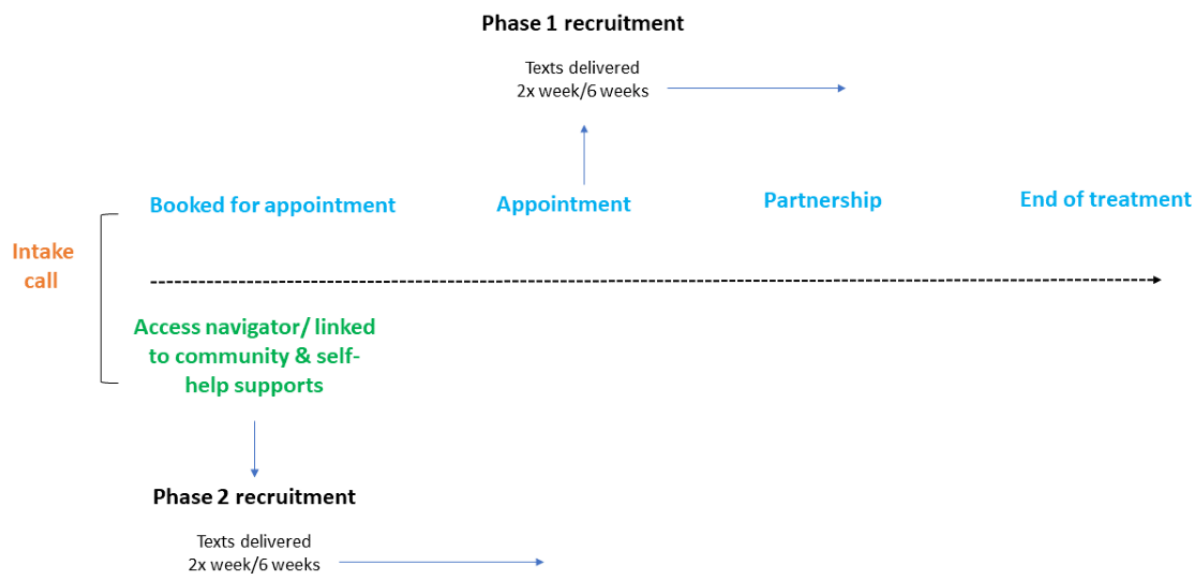
Setting

The IWK community mental health and addictions teams use the choice and partnership approach (CAPA) to outpatient child and youth mental health and addictions treatment. CAPA is a service transformation model that includes active collaboration with clients and families, lean thinking concepts, and therapeutic engagement tasks [32]. After an initial intake call, the family is either booked for a choice appointment with a clinician or receives support from an access navigator to connect directly with community resources appropriate to meet their mental wellness needs (Figure 1). The choice appointment is a time for collaboratively developing a plan with the youth, family, and clinician for next steps that could be helpful to meet their mental health goals, regardless of whether returning for clinical

treatment sessions is part of that plan. Based on the identified goals, options for next steps may include self-help information or helping the youth and family to access relevant supports within or external to the outpatient community mental health services. A fundamental stance of the CAPA way of working is to value the expertise of the youth and family and engage them in actively participating in goal setting and decision-making. Administrative data from 2019 show that approximately 1987 youth were referred for a choice appointment after their intake call that year. Youth who have mental health treatment needs are offered an opportunity to book for treatment (partnership) after the choice appointment.

The 2-phase recruitment plan for this study was partially driven by real-time data monitoring. Initially, in 2019, the wait time between the choice appointment and the partnership ranged from 15 to 76 days (Figure 1); this presented an important window, where contact via text message could help bridge the lapse in contact with outpatient clinicians. In the second phase, during the early months of 2021 (January to March) we anticipated a potential influx of referrals due to the pandemic; data showed that the wait for choice appointments ranged from 36 to 39 days.

Figure 1. Process flow diagram for text message delivery within the treatment pathway.



Population

Census data related to the IWK catchment area show that the community from which the study participants were recruited could be characterized as urban, predominantly English speaking, and White; 17% of the population are in households considered to have low incomes [33]. Participants were youth, aged 13 to 18 years, and their caregivers, who had inquired about services from the IWK community mental health and addictions program. Participants did not have to sign up as a youth-caregiver dyad, to ensure access to anyone who was interested. In this way, youth could still participate even if a caregiver did not attend the appointment. Youth clients and caregivers were eligible if they spoke English, had a cell phone, could read text messages, and were willing to receive up to 12 messages over a 6-week period.

Recruitment and Informed Consent

Recruitment occurred in 2 phases. In phase 1 (January to March 2020), clinicians described the study to families while they were facilitating a choice appointment and helped those interested to sign up while in the office, before going home. If youth came to appointments without a caregiver, only the youth was offered the service. Clients and caregivers signed up by texting a short code (ie, IWKTEEN or IWKCAREGIVER) to a specific number. Following the short code, an automated welcome text message with an embedded web-based consent form was sent. In phase 2 (January 2021 to May 2021), access navigators on the intake team described the study to the youth or caregivers at the end of their intake phone call and offered to assist those interested in signing up during the call. A welcome text message with an embedded web-based consent form was sent, as in phase 1. No remuneration was offered to those participating.

Measures

By reviewing the existing literature on outcomes associated with text messaging interventions for youth mental health [17], discussing what outcomes were of interest to local decision-makers, and aligning the outcome measures to the purpose of a pilot study (ie, to identify potential effects and associations to explore in a larger study) we selected a range of exploratory engagement, impact, and satisfaction measures.

Uptake

In phase 1 only, clinicians in 3 outpatient clinics tracked the number of youth and caregivers who were offered and subsequently enrolled in the text messaging service. We calculated the percentage of those who accepted as a preliminary measure of uptake.

Willingness to Use the Service

In addition to the data tracked about participant recruitment and enrollment, we tracked instances when participants did not desire to continue using the service. Dropouts (ie, those who texted “STOP”) were recorded.

Engagement

To measure engagement with the text messages, we calculated the total overall number of times each link within a message was clicked or relicked.

Satisfaction

A 10-item follow-up survey was used that included 2 satisfaction questions. A global measure was ascertained by asking users to rate their level of satisfaction with the text messages on a 5-point Likert scale: “very dissatisfied,” “slightly dissatisfied,” “neutral,” “slightly satisfied,” and “very satisfied” (item # 1). A second question asked about satisfaction with the text message frequency (item #2).

Value

Four survey questions assessed perceived value. A global measure was assessed by asking users to rate the text message intervention on a 5-point Likert scale of helpfulness: “not helpful at all,” “somewhat helpful,” “neutral,” “helpful,” and “very helpful” (item #3). In addition, participants were asked to identify which 1 of the 12 text messages was the most helpful (item #4) and which was the least helpful (item #5). One additional question asked respondents if they would recommend the text messages to someone they knew (item #7).

Impact

Four questions on the survey measured impact. One asked about changes in knowledge; in other words, if the user learned anything from receiving the text messages (item # 8). Another asked if the user found themselves acting differently or changing their behavior after receiving the text messages (item #9) or noticed any changes in themselves as a result of receiving the text messages (item #6). Lastly, during phase 1, we asked the users if the text messages helped ready them for their next step

in the therapeutic pathway (ie, attending their partnership appointment) (item #10).

Analysis

As the underlying parameters of the interventions were the same across recruitment phases (same messages, delivery schedule, and links), data from both phases of recruitment were pooled. Descriptive statistics appropriate for the level of measurement were conducted using Jeffrey’s Amazing Statistics Program (JASP) [34]. Frequency counts and percentages were used to summarize the results. Graphs were used to examine engagement over time.

Ethics Approval

Institutional review board approval was obtained from the IWK Health Research Ethics Board (1024462) and all participants provided informed consent.

Results

Across both phases of recruitment, a total of 41 caregivers and 36 youth consented to participate. Of the 77 users enrolled, 54% (22/41) of caregivers and 44% (16/36) of youth completed the post-study survey. Over 1500 text messages were sent in total during the study.

Uptake and Willingness

Enrollment data during phase 1 showed that 63% (33/52) of youth approached about the study in the clinics agreed to participate. Reported reasons for declining included not being interested (7/19, 37%), not having a data plan or a cell phone (5/19, 26%), and caregivers not providing consent for participation (1/19, 5%). Reasons were not provided by 32% (6/19) of youth who declined. Among caregivers approached, 78% (29/37) agreed to participate in the study. Only 2 caregivers gave reasons for declining: one was not interested, and one did not have a data plan. Willingness to use the text service was 97% (75/77), with only 2 participants texting “STOP” before the end of the 6-week intervention period.

Engagement and Satisfaction

Overall, youth and caregivers opened links to resources and supports 551 times. Figure 2 shows the text message links clicked the most by youth, which were related to coping with difficult emotions (49 clicks; text message #1) and facing fears (34 clicks; text message #2). The linked resources clicked the most overall by caregivers were related to coping with difficult emotions (34 clicks; text message #1) and facing fears (26 clicks; text message #2). Overall, satisfaction with the text messages was positive, with 75% (12/16) of youth and 73% (16/22) of caregivers reporting they were “very satisfied” or “slightly satisfied” (Table 2). Message frequency was highly satisfactory for both groups, with 81% (13/16) of youth and 86% (19/22) of caregivers saying that 2 messages a week worked well. Of the 16 youth, 2 (13%) thought it would have been better to receive more than 2 text messages a week.

Figure 2. Total number of text message clicks by youth and caregivers across topics.

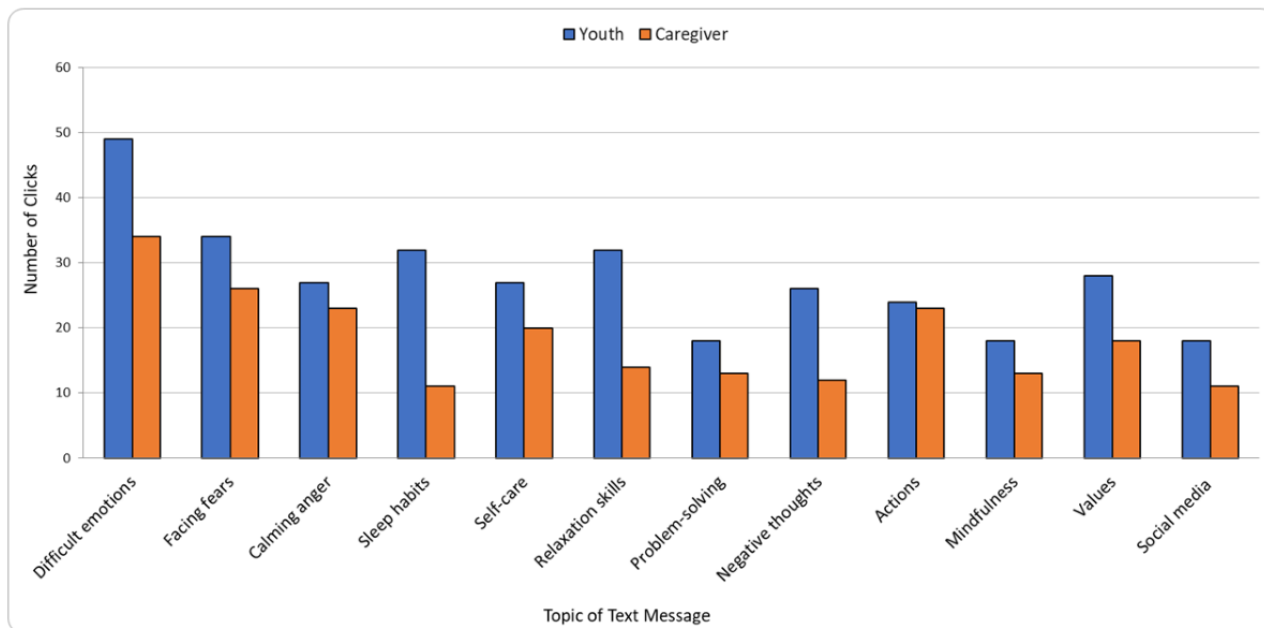


Table 2. Comparison of youth and caregiver experiences with text messages.

Survey item	Number of responses by youth (N=16), n (%)	Number of responses by caregivers (N=22), n (%)
Satisfaction		
Very satisfied	6 (38)	11 (50)
Slightly satisfied	6 (38)	5 (23)
Neutral	2 (13)	5 (23)
Slightly dissatisfied	2 (13)	1 (4)
Very dissatisfied	0 (0)	0 (0)
Frequency		
Timing worked for me	13 (81)	19 (86)
Should have been less often	1 (6)	3 (14)
Should have been more often	2 (13)	0 (0)
Helpfulness		
Very helpful	0 (0)	0 (0)
Helpful	7 (44)	13 (59)
Neutral	7 (44)	5 (23)
Somewhat helpful	2 (12)	4 (18)
Not at all helpful	0 (0)	0 (0)
Noticed personal change		
A lot of change	0 (0)	0 (0)
A fair amount of change	3 (19)	4 (18)
A bit of change	12 (75)	10 (45)
No change	1 (6)	8 (36)
Would recommend		
Yes	14 (88)	16 (73)
Maybe	1 (6)	6 (27)
No	1 (6)	0 (0)
Learned new information		
Yes	14 (88)	14 (63)
Maybe	1 (6)	4 (18)
No	1 (6)	4 (18)
Acted differently		
Yes	2 (12)	10 (45)
Maybe	8 (50)	6 (27)
No	6 (38)	6 (27)
Readied for next step		
Yes	7 (44)	5 (23)
Maybe	7 (44)	7 (32)
No	2 (12)	10 (45)

Value and Impact

Among youth completing the follow-up survey, 50% (8/16) indicated that the most helpful text message was the one related to coping with difficult emotions (text message #1). Three text messages were identified as the least helpful: healthy use of

social media (4/16, 25%; text message #12), facing fears (4/16, 25%; text message #2), and personal values (4/16, 25%; text message #11). Fifty-six percent (9/16) of youth said the messages were “helpful” or “slightly helpful,” with an additional 44% (7/16) reporting a neutral response on helpfulness (Table 2). At the same time, 94% (15/16) of youth noticed at least some

degree of change since receiving the text messages; 88% (14/16) indicated they had learned something new from the text messages, and 88% (14/16) would recommend it to someone they knew. Only one youth (1/16) provided an example when prompted to describe what they found themselves doing differently. The youth wrote “I was being more aware of myself and others. The timing of the text messages and my current life lined up exactly.”

Among caregivers completing the follow-up survey, there was less consensus as to the most helpful message. Nine of the 12 caregiver text messages were rated by at least one caregiver as the most helpful. The message focused on coping with difficult emotions (text message #1) was rated as the most helpful by 18% (4/22) of caregivers. The least helpful text messages, according to caregivers, were the ones about healthy social media use (6/22; 27%; text message #12) and sleep hygiene (4/22; 18%, text message #4). Among caregivers, 45% (10/22) reported acting differently since receiving the text messages, 63% (14/22) noticed at least some degree of change in themselves, and 63% (14/22) indicated they had learned something new from the text messages. When prompted to provide examples of the observed changes since receiving the text messages, caregivers pointed to a range of impacts. For example, “having more engaging conversations” with their teen, “keeping even tones when having difficult discussions,” “processing negative thoughts differently,” “managing anger,” and learning to “take a break from the conflict.” Seventy-three percent of caregivers (16/22) indicated they would recommend the text messages to people they knew. No youth or caregiver reported that the text messages were “very helpful,” but conversely, no youth or caregiver reported that the messages were “not helpful at all.”

When asked if the text messages had helped them feel ready for the next step in their treatment journey, 44% (7/16) of youth answered “yes,” and an additional 44% (7/16) answered “maybe.” Twenty-three percent of caregivers (5/22) said the text messages had helped them feel ready for their youth’s next step in the treatment journey, and 32% (7/22) answered “maybe.”

Discussion

Principal Findings

The intention of this pilot study was to develop and assess the feasibility of delivering a novel text-message campaign to engage youth clients and their caregivers during early stages of the mental health treatment pathway. As pilot testing is an almost essential prerequisite for a full-scale controlled study, this study helped test methods, learn more about the sample population, investigate recruitment strategies, and identify potential effects and associations that should be explored in a larger study [35].

Unlike other text-message interventions that have targeted a single clinical subpopulation (eg, those experiencing early psychosis) or desired behavior (eg, medication adherence), this study focused on transdiagnostic mental wellness and patient activation strategies for both youth and their caregivers. Our

results suggest that for youth and caregivers new to outpatient mental health care and who are interested in gaining insights into mental wellness skills and strategies, a brief, time-limited text message intervention may be viable. These results bolster ongoing efforts to distill and integrate core mental wellness strategies that may be helpful across a variety of clinical conditions [36]. Theorizing about why certain text messages or linked resources were engaged with more than others was outside the scope of this pilot study but will be an important direction for future research to optimize and tailor the intervention to the needs and interests of the population. In the future, other avenues (eg, social media) for promoting and introducing transdiagnostic strategies, skills, and techniques could be explored.

The major finding of this study was that most youth and caregivers reported experiencing positive knowledge and personal change because of the intervention and found the text messages satisfactory. Enrollment rates and willingness to use the intervention were consistent with other text-messaging studies [37,38]. More than two-thirds of the youth (14/16, 88%) answered “yes” to questions asking if they learned something new from receiving the text messages, noticed a change due to receiving the text messages, and would recommend the text messages to others. Almost half (10/22, 45%) of the caregivers reported acting differently due to receiving the text messages. More than two-thirds (14/22, 63%) said they learned something new and would recommend the text messages to others. For a low-intensity intervention, these are not inconsequential real-life impacts. However, considerable work remains in the field of text-message interventions in general to refine and validate outcome measures that are sufficiently sensitive to changes (long-term and short-term) resulting from microinterventions like the brief series of text messages used here. Considering the minimal human resources required to deliver the automated services and the range of real-world changes participants reported (eg, managing anger better and having more engaging conversations between youth and caregivers), there is a significant opportunity to refine the intervention, refine the outcomes of interest, and leverage this modality in routine outpatient pathways in the future. Future research could examine whether early text-message support helps socialize youth and caregivers moving on to formal psychotherapy to the fact that therapeutic treatment requires active practice and application of skills, as opposed to something they passively receive. Text messages could even be trialed with individuals looking at e-mental health options online who choose not to enter the mental health system at that time.

Our findings may serve as a caution to future developers to avoid oversaturating youth and caregivers with too-frequent text messages. Two text messages a week over 6 weeks, a relatively brief campaign, was described as “timing worked for me” by 81% (13/16) of youth and 86% (19/22) of caregivers. The considerable variation in text messages identified as most and least useful suggests that technological capabilities would be useful to allow greater tailoring based on end-user preferences and concerns. While this study leveraged preexisting free online content, there could be advantages to cocreating locally relevant content that aligns with and reflects the preferences of the local

community. Additionally, as we observed some downward trends in engagement over time, future studies could compare the order of the messages and the timing of delivery as features that could be optimized to promote ongoing engagement.

An unexpected finding, to be interpreted with caution given the small sample size, was that 45% of caregivers felt the text messages were not helpful for getting them ready for the next step of treatment. This may be because caregivers do not always perceive themselves to be part of the treatment and instead focus on their youth as the primary client. Caregivers may not have viewed their role in a mental health treatment journey as vital or something they needed to prepare for. It is also important to note that we did not measure which youth or caregivers would be coming back for further treatment (partnership appointments) and which had collaboratively decided that no further treatment was needed after the choice appointment. Future work could explore caregivers' expectations of treatment pathways and how text messages could support transitions or further socialize caregivers to their vital role in the treatment success of youth. Collecting and analyzing data in caregiver-youth dyads could also help uncover important effects, interactions, and associations unique to particular family dynamics.

The study recruitment occurred in 2 time-limited phases during complex service and social changes due to COVID-19. It is unclear how that complexity may have impacted uptake, sense of helpfulness, views on which text messages were most valuable, or the ability of youth and caregivers to act on suggestions offered in the text messages (ie, suggested self-care strategies may have been impacted by physical distancing requirements or closures). In addition, phase 1 recruitment required clinicians to remember to introduce and enroll consenting youth and caregivers during a session. Future research may help illuminate the barriers to and enablers of clinician versus self-referral pathways and potential impacts on clinical workflow (eg, time and administration support needs).

It is also important for future research to explore the possible mediating effects of clients' personal clinicians introducing or promoting a text message intervention (phase 1) as opposed to individuals receiving a generic offer to enroll (phase 2).

Limitations

Several limitations should be mentioned. First, although our follow-up survey response rate was consistent with the mean response rate of other youth mental health studies [39,40] a larger study, with statistical power to detect changes in both helpfulness and engagement, is required to confirm the effectiveness of the intervention. The small sample size, nonexperimental design, and short follow-up period prevent conclusions about any sustained behavior changes or the detection of significant differences between youth and caregivers' usage and experiences. Second, to reduce the data entry burden on youth and caregivers, no baseline demographic data (eg, gender, symptom severity, or mental health literacy level) were collected, which limits our understanding of possible covariates. Third, youth and caregivers were sampled from an urban, community outpatient service and therefore may not represent broader youth and caregiver experiences. Finally, most outcome data were self-reported and subject to possible bias.

Conclusions

Transdiagnostic mental wellness text messages for youth clients and caregiver engagement in community outpatient treatment are feasible. Although the sample size was small, the participants who followed through with the intervention had favorable impressions and reported promising changes in knowledge and behavior. Brief, skill-focused text messages may support youth and caregivers in experimenting with new ideas that could be helpful in making changes related to their mental health as a possible first step in community outpatient mental health services.

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Conflicts of Interest

None declared.

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Abbreviations

CAPA: choice and partnership approach

SMS: short messaging service

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Original Paper

Remote Moderator and Observer Experiences and Decision-making During Usability Testing of a Web-Based Empathy Training Portal: Content Analysis

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Abstract

Background: COVID-19 restrictions severely curtailed empirical endeavors that involved in-person interaction, such as usability testing sessions for technology development. Researchers and developers found themselves using web-based moderation for usability testing. Skilled remote moderators and observers are fundamental in this approach. However, to date, more empirical work is needed that captures the perceptions and support needs of moderators and observers in testing situations.

Objective: The aim of this paper was to identify remote moderator and observer participant experiences and their use of certain tools to capture feedback of users as they interact with the web browser application.

Methods: This research is part of a broader study on an educational web browser application for nursing students to learn perspective taking and enhance their perceptual understanding of a dialogue partner's thoughts and feelings. The broader study used a quantitative and think-aloud qualitative problem-discovery usability study design. This case study explored written accounts of the remote moderator and observer participants regarding their roles, experiences, and reactions to the testing protocol and their suggestions for improved techniques and strategies for conducting remote usability testing. Content analysis was used to analyze participants' experiences in the usability testing sessions.

Results: We collected data from 1 remote moderator and 2 remote observers. Five themes were identified: dealing with personal stressors, dealing with user anxiety, maintaining social presence, ethical response to the study protocol, and communication during sessions. The participants offered recommendations for the design of future remote testing activities as well as evidence-informed training materials for usability project personnel.

Conclusions: This study's findings contribute to a growing body of endeavors to understand human-computer interaction and its impact on remote moderator and observer roles. As technology rapidly advances, more remote usability testing will occur where the knowledge gleaned in this study can have an impact. Recommendations based on moderator and observer participant perspectives identify the need for more evidence-informed training materials for their roles that focus on web-based interpersonal communication skills, execution of user testing protocols, troubleshooting technology and test user issues, proficiency in web conferencing platforms, behavior analysis and feedback technologies, and time management.

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KEYWORDS

web browser; user-centered design; qualitative research; internet; empathy

Introduction

Background

Moving Toward Remote Usability Testing

Usability testing is a fundamental step for evaluating and developing quality technologies, products, or services [1]. Usability testing involves the systematic evaluation of how effective, efficient, and satisfactory a product or service is when a user interacts with it [2]. This testing helps developers identify and refine the product or service before full-scale uptake by potential future users or implementation in the marketplace. Since the COVID-19 pandemic, in-person testing sessions for technology development have been curtailed. Remote usability testing has become the default approach to maintain advancements in technology evaluation or research [3]. Many system developers, usability personnel, and researchers have resorted to web-based moderation for remote usability testing, which is the focal context of this paper.

Remote usability testing was introduced 20 years ago as a means of conducting usability assessments of participants or users who were in separate locations or separated by time from the researchers or practitioners [4,5]. Since that time, a range of web conferencing platforms have emerged, and an array of features and functions are now available that can advance remote usability testing (eg, Microsoft Teams, Zoom, Skype, and Cisco Webex). Hill et al [5] provided an overview of the different types of remote usability testing methods and a summary of key findings about their use with users. Across these different methods, skilled remote moderators and observers are essential.

The literature on remote usability testing is evolving in an emerging field [5]. Gaps in knowledge still exist regarding the method. Wozney et al [6] were among the first authors to highlight the empirical gap in the influence of moderators and observers on remote web-based usability testing. The empirical literature has instead tended to focus on the feasibility, logistics, and pros and cons of the method. The rapid review of studies by Hill et al [5] found benefits to remote usability testing, such as facility attendance not being required and being more convenient and affordable for research personnel and participant users, the ability to more easily recruit a broad and diverse participant sample, and the opportunity to use technology more realistically in the participant user's own environment. The disadvantages were the loss of contextual information, challenges in detecting nonverbal cues, and dealing with technology network issues [5]. Other factors that can influence the efficiency, validity, and reliability of remote usability testing and are difficult to control include user characteristics, internet speed, devices used, pace of the testing session, technical skills of participant users, and unforeseeable disruptions or interruptions [5].

Of note, Molich et al [7] explained that best practices or guidelines for remote moderation and observation are often derived from experiential evidence that is published in books

and websites. However, *human factors* associated with the moderator and observer role are receiving increasing attention as salient influences on the “quality” of usability testing results. Such factors can include the moderator's cognitive load, communication challenges, and handling of multiple technical issues that affect their role and social presence and, thus, participant users' performance outcomes [6]. Wozney et al [6] identified these as “sociotechnical human factors,” including the attentional divide between auditory, textual, and visual stimuli. In testing sessions, these factors are dynamic and put cognitive demands on remote moderators and observers. In an earlier article, the impact of social context on performance outcomes was reviewed by Trivedi and Khanum [8]. These authors identified the social context or social environment as comprising people (eg, participant users, research personnel such as evaluators, and other people) whose presence during testing can have a substantial role in usability evaluations. However, to date, social context and human factors linked to the moderator and observer roles have not received the same attention as the physical context (ie, laboratory and field settings) as potential moderators or mediators of usability testing outcomes [6,8].

The Remote Moderator Role

The remote moderator is pivotal in usability testing. This role requires skilled, simultaneous execution of the following tasks: knowledge and use of technology and its features or functions; observation skills in watching the user interact with the product; careful documentation of usability issues; good communication skills that include ad hoc questioning, probing for clarity, and verbal and nonverbal communication; careful listening to the user's spoken-out-loud thoughts and feedback; and knowing when to take the lead in asking the participant to perform tasks and when to stay quiet as the user engages in the tasks. The goal is to build trust with the user and obtain honest feedback about the product or service and the user's experiences as well as foster user motivation to complete the assigned tasks. Wozney et al [6] explained that these skills are similar to those used by qualitative researchers. Others have stated that these skills affect the quality of the usability testing findings and user feedback [7].

The Remote Observer Role

Most of the time, the literature tends to focus on the moderator role [7]. However, considering the multitude of simultaneous tasks required of the moderator, it makes sense to include a “silent” observer or note-taker in the testing sessions. The observer or note-taker can serve as a vital second pair of eyes and ears in witnessing how the user interacts with the technology, product, or service. Tullis and Albert [9] described how the observer or note-taker has better “behind the scenes” opportunities than the moderator does to observe participants directly (eg, what they are doing, where they struggle, and how they succeed) and quickly record the user's performance (eg, recording the time to complete tasks). The early stages of the design and development process often involve small sample

sizes (eg, 5 to 6 participants) to identify issues with the design and administer fixes to those issues. Regardless of sample size, it is plausible that involving both an observer and a moderator could help lessen the odds of missing major usability issues in comparison with when the busy moderator needs to observe alone.

In summary, while conducting a review of the remote usability testing literature for the broader project, we discovered studies that reported on “how to” support the moderator and observer roles [7,10,11]. Other authors [5,6] made a call to action to better comprehend complex linkages among human factors (eg, social context or environment or “who” is present at testing), human-computer interaction, and web-based technology and tools to advance the remote usability testing approach. More peer-reviewed research needs to focus on moderator and observer subjective viewpoints regarding their influence and related factors for successful usability testing efforts (eg, motivating users to engage with tasks, obtaining quality feedback from users, and efficient decision-making about priority design refinements).

Study Aim and Research Question

Our broader project involved usability testing of an educational web browser application (called In Your Shoes) for nursing students to learn perspective taking and enhance their perceptual understanding of a dialogue partner’s thoughts and feelings. The aim of this study was to present an adjunct component of this broader project, where the experiences of 1 moderator and 2 silent observer participants during remote usability testing sessions were uncovered. The qualitative research question was “What are the perceived experiences of the lead remote moderator and 2 silent remote observers using web conferencing and various tools to capture user feedback on the empathy application during remote usability testing?”

Methods

Research Design and Usability Testing Context

A single-case methodology was used as an adjunct to a broader study that used a quantitative and think-aloud qualitative

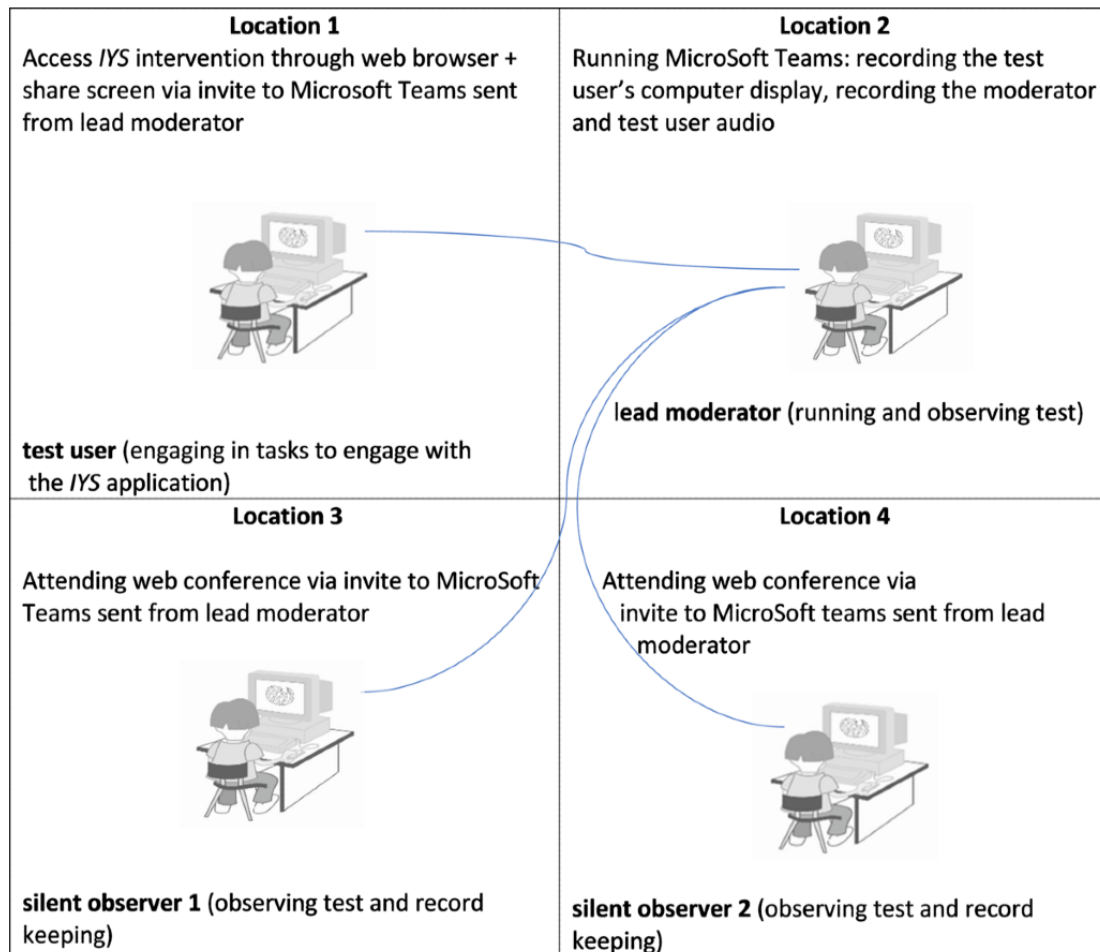
problem-discovery usability study design. A report on the quantitative and qualitative user feedback will be provided elsewhere. In this paper, we report only the experiences of the remote moderator and remote observers. The case method approach allowed us to closely explore the experiences of the lead remote moderator and 2 silent remote observers using a web conferencing platform during their remote testing of the empathy web training portal with nursing student users [12]. The “case” was the lived experience of “how” the remote moderator and remote observers executed the study protocol and “why” they had responses to certain “live” events. The “context” of the lived experiences was the protocol-driven usability testing sessions [13]. We collected and content-analyzed their written responses to a list of questions about their experiences in their roles and reactions to the usability testing protocol.

Ethics Approval

This study was conducted remotely with participant users in a midprairie province city in Canada. This study received ethics approval HS24965 (R1-2021-082) from the University of Manitoba Research Ethics Board and access approval from the College of Nursing. The remote moderator obtained informed consent from users before commencing the study protocols with them.

The broader study consisted of 3 consecutive phases. Each phase was interspersed with elements of data analysis and iterative design refinements for application prototype redevelopment [9,14]. A summary of the usability testing setup is provided in [Multimedia Appendix 1](#). [Figure 1](#) depicts the usability testing session scenarios for phases 1 and 2 and the roles. Phases 1 and 2 entailed a 1-hour video recording as moderated by the remote moderator. The remote moderator guided users to engage in tasks followed by immediate content analysis by the principal investigator (ML), the remote moderator, and the remote observers of the transcriptions of the users’ speak-aloud responses and video-recorded “performance” of tasks. Before starting our usability testing protocol, ethics approval was obtained from our institutional research ethics board, and access approval was obtained from the College of Nursing.

Figure 1. Web conferencing test environment set up for phases 1 and 2.



Characteristics of the User Sample

Undergraduate Nursing Students

We aimed to recruit 12 undergraduate nursing students from 1 university. The sample size was based on sampling and recruitment for usability studies to maximize the expected level of problem discovery [9,14]. Owing to the small number of student volunteers (n=8) with constrained schedules to participate freely, random assignment to each phase was not feasible. Instead, the remote moderator selected a combination of second- to fourth-year male and female students from the undergraduate baccalaureate program in nursing who owned or had access to a PC desktop computer, an Apple desktop computer, or a tablet device for 3 cohorts of a total of 8 students (phase 1: n=3, 38% of students; phase 2: n=3, 38% of students; and phase 3: n=2, 25% of students).

Recruitment

All second- to fourth-year students received an initial email invitation from our unit's research office on behalf of ML that was followed by 2 email reminder invitations. Interested students contacted the remote moderator, who emailed them an information package about the usability testing sessions. At a convenient time, the remote moderator conducted a video or phone call with potential users to further explain the study and expectations during the testing sessions. The remote moderator's script was as follows: "We are testing the application to get user

feedback, so we will have a video call where I will be joined by 2 other research assistants. They will be silent observers, so they will have their cameras and microphones off. During the call, I will get you to share your screen and see how you interact with the application; I will prompt you to answer questions and ask you to do tasks on occasion. We really want to get insight into the user experience, so we want honest feedback about the thoughts and feelings of the users. The video call will be about an hour long, give or take 15 minutes."

Setting, Access, and Preparation for the Usability Testing Sessions

Overview

An undergraduate research assistant from the computer sciences served as the lead remote moderator from her isolated setting with no distractions. The remote moderator facilitated the testing sessions using a functioning microphone and the institutionally adopted Microsoft Teams screen- and audio-sharing tool that allowed student users to share their screens. Remote observation via screen sharing, aided by Microsoft Teams and video files viewable in Microsoft Teams, helped the team capture and review behaviors and narrations as the users performed the tasks. In total, 2 undergraduate research assistants in computer sciences and computer engineering served as silent remote observers who watched and recorded user behaviors during tasks from their respective isolated settings. The remote

observers also performed application refinements based on user input.

A member of our investigative team (Yumiko Sakamoto) was an expert in human-computer interaction who trained the remote moderator and remote observers on how to conduct a 1:1 session with users. The training included how to observe and keep records in Microsoft Excel, prompt users to speak aloud to explain the actions they were taking, and conduct user exit interviews. The users were not provided with the task list to review before the scheduled session. Instead, at scheduled sessions, the remote moderator provided users with realistic task scenarios to interact with the application interface and perform tasks in the sequence of steps that they would need to carry out if they were using the application in a real-life setting (ie, set up an account, open training documents, upload an mp4 video, engage in video tagging, and obtain their perceptual understanding score) [15].

Pilot Test

The first step was to conduct pilot-testing sessions using Microsoft Teams that were remotely moderated with 2 nursing student users at the end of June 2021 and the beginning of July 2021. The pilot sessions helped the remote moderator and remote observers become acquainted with each other, determine the best approach to conduct the testing sessions collaboratively, and identify issues related to moderating sessions (eg, avoiding asking leading questions and the need to send participants a video to upload in advance of the testing session). The remote observers also identified that the performance metrics tool required reformatting based on the anticipated order of the user tasks to be performed. On the basis of pilot test user feedback, the remote observers made application refinements (eg, provided clearer explanations of key features directly on the application pages, inserted colored text to delineate application “taggers,” and fixed glitches with log-in and sign-out functions). Commencing in mid-July 2021 until the end of August 2021, 3 phases of user testing sessions were successfully executed at the College of Nursing.

Description of the Web Browser Application

We developed and tested the first prototype of an empathy-related video feedback intervention (*In Your Shoes*) to improve perspective-taking skills and perceptual understanding by clinicians of their clients (or accurate understanding of another person’s thoughts and feelings) that requires attendance in a laboratory setting plus a desktop, a stationary camera, and a commercial video analysis software program [16,17]. Our *In Your Shoes* intervention was adapted from the award-winning research in social psychology on empathic accuracy (or the extent to which an individual’s inferences of the content of another person’s thoughts and feelings are accurate) by Dr William Ickes et al [18,19]. The work by Ickes provided us with a practical, reliable, and objective method for measuring an individual’s ability to accurately infer another person’s thoughts and feelings during a video-recorded interaction.

To enhance accessibility and ease of use, our investigative team and the Red River College Polytechnic ACE Project Space

students transformed the existing in-laboratory desktop approach into a unique web browser application version to learn perspective taking on any computer or tablet device. The development process consisted of the front end, server, database, and cloud storage system as the 4 key interconnected system components required to deploy the *In Your Shoes* web application. The front end retains the user’s interface (ie, everything that the user sees is rendered here) and was developed using the React framework (Meta). The data displayed on the front end are stored mainly in MongoDB (MongoDB Inc), which houses data including user information, tags, and video data. The videos are stored on Amazon Web Services using an S3 bucket, whereas links to the videos are stored in MongoDB. For the front end to use and display the data from the database and cloud storage system, the Django Representational State Transfer framework (Django Software Foundation) is used on the server to structure the data in a way that is easily accessible from the front end. Essentially, the data are taken from storage, structured on the server, and rendered on the front end so that the user can interact with them (see [Multimedia Appendix 2](#) for the system components). The application was developed to replicate the existing in-laboratory process with no special requirements for hardware. The only hardware needed is a computer, laptop, or mobile device with a functioning browser and internet access. To secure evidence on prospective users’ experiences with the *In Your Shoes* application features and functions and to obtain feedback for further application refinements, we conducted a usability testing project with the remote moderator and silent observers who were the focus of this case study.

Study Procedure

Remote Moderator Role, Responsibilities, and Recommendations for the Broader Study

The remote moderator was responsible for facilitating the remote testing sessions, answering user questions during testing sessions, managing the virtual video recording and transcription platform, and editing the transcripts, as well as for data collection, data analysis, and data management via the Qualtrics (Qualtrics International Inc) and Microsoft Teams platforms. After the study’s expectations were explained, the remote moderator sent users the Qualtrics link to the informed consent and demographic data form for phases 1 and 2. Users in phase 3 were sent the Qualtrics link to the consent form and demographic data form plus the usability tool. A total of 24 hours before the scheduled session, the remote moderator sent instructions to download the Microsoft Teams application and an mp4 video to upload during the testing session. Once the consent and demographic forms were signed, the remote moderator sent a Microsoft Teams calendar invitation to the user and remote observers for the testing session. Approximately 5 minutes before the video call, users were sent the link to the *In Your Shoes* application. There was 1 participant who did not attend the initial or rescheduled sessions. In addition, 2 other students signed their consent forms but never responded to the remote moderator’s email requests to schedule a testing session. A recommendation is for future users to send out several

reminders (ie, 48 and 24 hours in advance of the scheduled testing session).

Once the user was logged into the session, the remote moderator immediately thanked them for participating. A repeated explanation of the study expectations was provided. The remote moderator encouraged users to be honest with their feedback. Despite having sent students a reminder to download the Microsoft Teams application in advance of the session, most students used the browser application instead. Regarding users' computer technology skill level and experience with Microsoft Teams, some had used it before, but most had not. This lack of experience resulted in the remote moderator needing to explain to them how to share their screens. During the testing session, the remote moderator learned that the desktop and browser versions of the Microsoft Teams functions and features were different. This became an issue when the remote moderator would explain how a user could share their screen and the user was using the browser instead of the desktop version. In that case, the remote moderator was challenged to help them as the user did not have access to the same buttons as the remote moderator, who used the desktop version. For the few users who had a very slow internet connection, the video quality of the call was fine, but it would take a while to upload a video to the application for the video-tagging exercise. While they were uploading the video, the remote moderator would either perform another task with the users or just wait for the video to be uploaded. Otherwise, the remote moderator and remote observers found Microsoft Teams intuitive to use. The recording and transcription facilities were extremely helpful in capturing session data, which allowed them to quickly rewatch the sessions to ensure the accuracy of the data that they had collected.

During phase 1 and phase 2 sessions, the remote moderator encouraged the user to engage with the application as if they were alone with it. Allowing the user to figure things out on their own was the most useful approach. The most information about user interaction with the application came from observing the user and asking them questions about their actions instead of telling them how to perform the task. The strategy used was to wait for the user to interact with the web application and remind them to speak out loud while they were doing an activity. Asking the user to speak aloud was helpful when editing the transcripts wherever users were unclear and when adding context to the testing session. It was easier to determine what was happening when the user described the webpage they were interacting with during the session.

For phase 3, users engaged with the application in their own environments for 1 week, and they were not observed. The remote moderator sent them detailed instructions about the purpose of the study and specific tasks for them to complete. The users emailed the remote moderator to express their confusion about uploading a video that they were asked to create based on a conversation they were asked to have with a family member or friend. Owing to pandemic restrictions, both users explained that they could not locate a family member or friend that they felt comfortable with to do a video-recorded dialogue and then upload and analyze this video recording in the application. Testing the independent use of these tasks (ie, the main functions of the application) was not possible.

Once the users had engaged with the application for 1 week, a scheduled 60-minute video-recorded and scripted interview was led by the remote moderator, who administered the usability tool to capture user "satisfaction" with the *In Your Shoes* application [20]. A total of 3 questions were added to capture language understandability, visual-interactive appeal, and whether use expectations were met. A think-aloud process was used where the remote moderator asked users to speak aloud their thoughts as they completed each statement on the usability tool [21]. The remote moderator used probes such as "I would like to hear what you were thinking when you answered this question." Users also provided information on the type, brand, and operating system of the device used; the number of times they accessed the application; and the amount of time they spent on the application each time they accessed it over the previous week.

Remote Observer Roles, Responsibilities, and Recommendations for the Broader Study

Silent remote observation was an important aspect of phases 1 and 2. In total, 2 remote observers monitored how each of the participants traversed through the application and maintained a record of (1) the user's test environment, (2) paths that users navigated to perform a task, and (3) temporal and cognitive resources each user spent when performing a task. Once the remote observers had reviewed the data collected in the usability testing session, they performed refinements to the application to make the user experience better for the subsequent phase.

For phases 1 and 2, the remote observers developed a predefined protocol, as guided by Tullis and Albert [9] and Nielsen [14], to capture performance metrics on predefined tasks that the users had to perform. The performance metrics were recorded by the remote observers as they monitored an ongoing testing session. The remote observers used 2 electronic forms with Google Forms that supported a wide range of inputs ([Multimedia Appendix 3](#)). The think-aloud method used by the remote moderator with the users helped the remote observers identify technical issues and required refinements to the application [22]. One remote observer recorded the success of the user in completing predefined tasks and some remarks regarding how well they completed the tasks. The other remote observer recorded the number of mouse clicks required for the user to complete each task. This proved to be challenging at times depending on the device used by the user. Some users had mouse devices that were inaudible, which made it difficult for the remote observer to see and hear the clicks to capture them in the performance metrics. In addition, there were occasional issues with choppy video depending on the user's internet connection. Hotjar (Hotjar Ltd) with heat maps was also used as a behavior analytics and feedback data tool (see [Figure 2](#) for scrolling activity and [Figure 3](#) for clicking activity). This tool helped the project team understand what the users were doing on the website pages (eg, where they clicked or scrolled and what they looked at or ignored) and then identify priority application refinements. The performance metrics spreadsheets were stored on Google Drive, which made it easy for the team to manage access and collaborate in evaluating the results. Overall, there was great benefit to having the remote observers directly monitor and record the impact of their implemented

changes when different users interacted with the application across the phases.

The remote observers were also the “application fixers” who were able to quickly and accurately identify required application refinements by directly communicating with the users at the end of the usability testing sessions. This dialogue summarized how well the remote observers felt the user did during the session and allowed the remote observers to ask the user about further suggestions for application refinements. The remote observers participated in testing sessions at their physically distanced work stations in remote settings where external disturbances were limited; this fostered their focused observation and accurate data collection. Unforeseen disruptions did arise

occasionally during remote testing sessions in the form of network disruptions or user and researcher computer malfunctions. When such situations arose, the team prioritized the user’s comfort by reassuring the user and worked through solutions. This approach by the remote observers was essential to prevent users from being influenced by negative experiences that could bias their reactions toward the application.

At weekly meetings, the remote moderator and remote observers reported on user feedback to ML. Priority application refinements that would influence the design iteration before advancing to the next phase were identified for attention within 1 week.

Figure 2. Hotjar (Hotjar Ltd)—scrolling activity (on the application’s Training Portal for a sample of 282 scrolling activities; red indicates that all or almost all users have seen this part of the page).

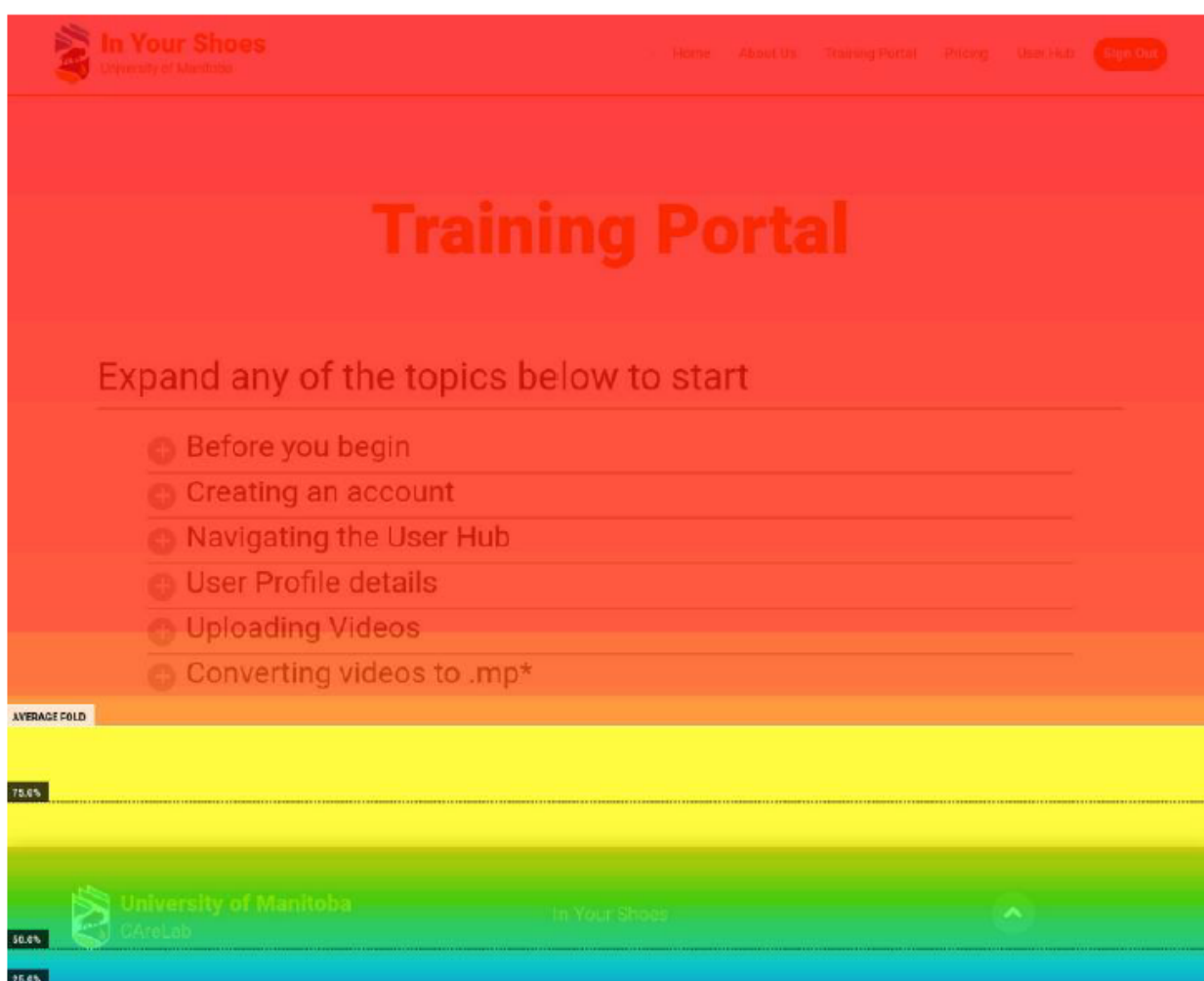
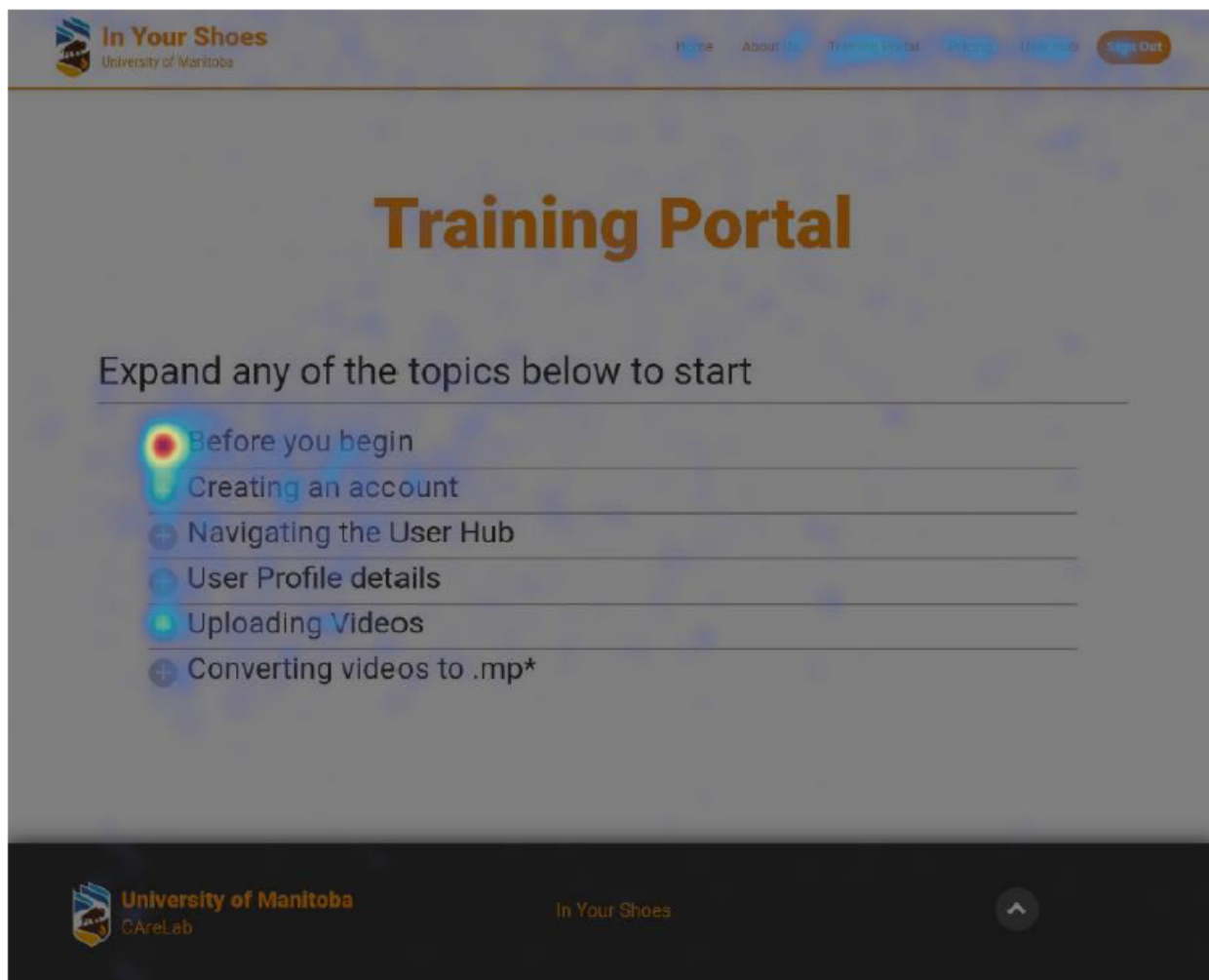


Figure 3. Hotjar (Hotjar Ltd)—clicking activity (on the application’s Training Portal for a sample of 175 clicks).



Data Management by the Remote Moderator and Silent Observers in the Broader Study

Once the testing session was done, the remote moderator immediately edited the Microsoft Teams transcripts and replaced the user’s name with a code number. Although the video quality for the recordings in Microsoft Teams was very good, the automatic transcription was challenging to work with in terms of occasionally getting wrong the order of who spoke, at times breaking up sentences in a way that was nonsensical, not always accurately capturing what the user was saying, and adding words not said or inserting odd words; for example, every time the user said “tag,” the transcription would show they said “take.” The remote moderator relied heavily on listening to the video-recorded session to decipher what the user was saying or referring to during the session. For example, if a user said, “I will click this button” in the transcript, the remote moderator was able to look back on the video and put an annotation in the transcript as to the exact button they clicked. The edited transcripts from the testing sessions were downloaded as a docx file and saved in the Microsoft Teams folder.

Some time was required by the remote moderator to become familiar with how to use the Qualtrics platform to capture project data. Creating the forms in Qualtrics was easy, as was editing them. However, linking separate forms proved to be challenging

with the loss of consent forms and demographic data forms in phase 3. Both users in phase 3 had to complete the 2 forms again. The demographic data form and the usability tool were exported to respective csv files with the names and email addresses of the users removed. These csv files and consent forms (downloaded from Qualtrics) were uploaded for secure storage on ML’s system drive folder.

After each session, similar to the remote moderator, the remote observers relied on Microsoft Teams video recordings and transcripts to confirm their recorded values (eg, number of mouse clicks) on the performance metrics tool. The performance metrics tool was stored on Google Forms, and the videos were accessed by the remote observers from Microsoft Teams. Upon completion of the analysis, the performance metrics tool was uploaded and securely stored in ML’s system drive folder. Video recordings of the Microsoft Teams meetings were deleted after the transcripts had been edited, and the remote observers cross-checked their record keeping against the video-recorded sessions.

Data Collection for This Case Study

ML circulated a written list of questions about the personal accounts and experiences of the lead remote moderator and 2 remote observers while executing their roles and responsibilities during the usability testing sessions ([Multimedia Appendix 4](#)

[6]). The list of questions was adapted from the questions by Wozney et al [6] used with moderators in their remotely moderated study. The remote moderator and remote observers submitted their written accounts to ML in response to each of the questions posed on the list.

Results

Overview

In response to the research question, the following is a narrative account of the respective role experiences of the remote moderator and the remote observers during the usability testing sessions. Their personal accounts are accompanied by reflections on their assigned tasks plus recommendations for the design of future usability testing sessions. ML collated and analyzed their written accounts. Content analysis was conducted, and the coded data that emerged were organized, synthesized, and interpreted as themes by ML [13]. ML's analysis of the data was shared with the remote moderator and remote observers, who read the interpretation and contributed correct information or additional perspectives about their experiences.

The following are emerging themes from the analyses of the written accounts of the remote moderator and the remote observers: (1) dealing with personal stressors, (2) dealing with user anxiety, (3) maintaining social presence, (4) ethical response to the study protocol, and (5) communication during sessions.

Themes

Dealing With Personal Stressors

The remote moderator experienced anxiety during the first few sessions that was greatly reduced in subsequent sessions. The initial anxiety was mainly due to having not yet established a comfortable flow of tasks; for example, it seemed that the initial users took too much time to read the training documents, which caused a sense of urgency in the remote moderator. However, the anxiety dissipated when the remote moderator grew to appreciate that, realistically, engaging with the educational training application and documents could take between 1 and 1.5 hours. She also found that working with Qualtrics was anxiety-provoking because of her limited experience and learning curve with the program. One mishap involved the loss of 2 signed consent forms because of the way the remote moderator set up the consent form in Qualtrics.

Cognitive overload for the remote moderator also occurred most often in the first few sessions. The remote moderator struggled to pay attention not only to what the users were doing but also to how to guide them when they became reliant on her for direction while also concentrating on their think-aloud responses. Future remote moderators should be well rested to better focus on conducting the interviews. It is also good to follow a script of user tasks with possible responses to anticipated user questions.

Dealing With User Anxiety

The remote moderator would start most sessions by chatting with and asking the user how their day was going, talking about a topic other than the testing session, or laughing at a shared

joke. The occasional sidebar conversation occurred, which helped the users feel more comfortable during the testing session. During the course of the testing sessions, if the remote moderator detected that the user was feeling anxious, she would usually ask them about how they were feeling in that moment, and common user responses were "I am confused," "I want to do good on this," or "This is a lot of reading and I am a bit overwhelmed." In addition to providing reassurance, the remote moderator made it clear that the users were not being tested but rather being asked to provide honest feedback about the application.

The early testing sessions involved users who would pause during the task without explanation. The remote moderator assumed that they were just resting and did not ask if they were confused. After the first 2 interviews, the remote moderator took a different, more validating approach that entailed instructing the user to explain what was on their mind or asking a specific question to clarify the user's thoughts. The remote moderator would interject if the user was clearly not understanding how to complete a task (eg, when they tried to complete the tag multiple times, read the error message, and still did not understand how to tag instances in the timeline). Prompts by the remote moderator would be "What on this page do you want to click on?," "Is there anything you are confused about on this page?," or "What do you think you should do next?" Other times, it seemed that the user wanted direction from the remote moderator when they would say things such as "How do I do..." before engaging with the application on their own. In these situations, the remote moderator would try to remain impartial and respond with "What would you do if you were on your own right now and you had to figure that out?" Additional usual responses by the remote moderator were "What page on this website have you been to that might have that?" or "Maybe go read the documents again" instead of just directly telling them how to do it. However, if the user was struggling hard to figure something out, the moderator would tell them how to do it. This happened most frequently when users did not understand how to annotate ("tag") the video when attempting to capture their inference of the dialogue partner's thoughts or feelings.

Maintaining Social Presence

The remote moderator and remote observers found no ill effects in not being able to draw on in-person visual cues (eg, full body language) to provide expressive guidance to the user or for the remote moderator to gauge users' responses to the application. Other visual cues were noticeable with screen sharing, especially the user's facial reactions such as confusion with certain aspects of the application. Getting the user to think aloud was very helpful as they would narrate what action they were performing and the reasons behind it. The remote moderator consciously used her hands and facial expressions as visual cues for the user. By contrast, being in person could have made it easier for the remote moderator to explain where to locate something (eg, physically pointing and saying, "It is in the top left corner under the other button...no up a bit more"). Overall, there was no evidence of a negative impact of being physically distanced on the performance of the user.

The remote observers had limited social interaction with the users. However, toward the end of the testing sessions, the remote moderator would invite the remote observers to make some remarks to the user (eg, thank them for participating and share their appreciation for helpful feedback). This was important for rapport building, helped the user see how well they did during the session, and provided a last chance to offer added suggestions for application refinements to the remote observers. Otherwise, the remote moderator asked the remote observers to interject amid the testing session only if needed (eg, assistance with a task). A remote observer described that being remote allowed him to focus on record keeping without being distracted by the presence or actions of another person. This remote observer felt that, if user testing sessions were done in person, his own reactions or behaviors could potentially pose an undue influence on the user's responses to interacting with the application.

Ethical Response to the Study Protocol

The remote moderator described how her virtual interaction with the users was likely different than it would have been if she had engaged in person with the users. The remote moderator felt obligated to work hard at making the user feel comfortable by consciously using verbal cues versus having a wide range of bodily cues to better express herself at her disposal. Users also required a lot of reassurance as they were conscious of their appearance and other visual cues (eg, facial expressions and body movement) while being video recorded. This might have made them more reticent to share their thoughts and feelings about the application. To foster user trust in the remote moderator and testing process, the remote moderator explained to the users before the scheduled session that 2 remote observers would be present who would have their cameras and microphones turned off while they took notes throughout the session. The remote observers would be invited to interact with the users before the end of the testing session.

Communication During Sessions

During the sessions, the remote moderator and remote observers used the private chat function in Microsoft Teams for impromptu requests such as requesting the remote moderator to ask the user to add questions or give feedback to one another without distracting the user. The remote observers would send the remote moderator a message if she forgot to do something, such as not starting the recording or forgetting to tell the user to do something. The chat function also helped the remote observers engage with the remote moderator in troubleshooting issues that arose during the testing sessions. At first, the remote moderator found the communication features in Microsoft Teams folders to be confusing. Sometimes, she would receive a notification from one of the remote observers and she would not know if it came from the chat box or a different communication channel in Microsoft Teams. Overall, the remote moderator and remote observers found that Microsoft Teams was a comprehensive platform with built-in features that fostered discrete and timely communication with each other during the testing sessions. After each testing session, Microsoft Teams made transcriptions readily accessible for the team to quickly

analyze and then communicate in a timely manner to make joint decisions about priority application refinements.

Tangled conversations were common when the remote moderator and the user would speak over or interrupt each other. Other users would mumble or speak to themselves when using the application or reading the training documents. This caused issues for the remote moderator, particularly when she attempted to accurately discern their user experiences while editing the transcriptions. The users were simply asked to repeat themselves in live sessions whenever tangled or interrupted speech occurred. Overall, the remote moderator and remote observers felt that these issues were unique to remotely moderated testing sessions and required careful attention to promote clarity in user communication for quality audio capture and transcription.

Discussion

Principal Findings and Research Implications

Wozney et al [6] described that real-time usability testing involves human impact factors—often unpredictable—that can influence the quality of the testing session results. Extant literature provides only a rare glimpse into the influence of test environments on moderator and test user performances, which warrants further attention. Therefore, our aim was to contribute to the literature by providing further qualitative information for consideration in the design of future remote usability testing sessions. In this section, we discuss the main experiences encountered by the remote moderator and remote observers related to triangulating methods of data collection and using unfamiliar technology and software as well as managing personal stressors and user anxiety, maintaining social presence, and ensuring good lines of team communication during testing sessions. The recommendations identified in this section describe how the remote moderator and remote observers felt that emerging issues could be better addressed during testing sessions.

The usability methods used in this study were comparable with those used in related studies. In their recent scoping review, Maramba et al [23] found that 6 different usability methods were often used: quantitative methods using questionnaires and task completion and qualitative methods using think-aloud, interviews, focus groups, and heuristic methods. Our broader study saw that the remote moderator and remote observers used 4 of the 6 methods: a questionnaire, task completion, think-aloud, and interviews. The efforts of the remote moderator and remote observers corroborate those described by Maramba et al [23], where the use of the think-aloud protocol by developers led to further iterative application development (in comparison with the use of questionnaires, task completion, interviews, and focus groups). In total, 3 iterations of the application were informed by user feedback obtained in our pilot tests and from each phase of usability testing. In their review, Maramba et al [23] found that only 31.3% of the included papers reported having done at least one further iteration of the application. Although the think-aloud method might slow the process, it does not have a negative impact on the flow of user thoughts [22]. Tiriticco [24] described this method as simple, flexible, and affordable as well as not needing

“special skills” or equipment. As in this and related studies, evidence suggests that the think-aloud process is an optimal method to garner user feedback for application refinement and ought to be the focus of training for remote moderators and observers.

When they described positive experiences, the remote moderator and remote observers said that they were primarily enabled by the functionality and features of the Microsoft Teams web conferencing technology and software with screen-sharing, video recording, and transcription features. Despite the initial lack of familiarity with the Microsoft Teams platform, the team quickly learned the technology because of their respective backgrounds in computer science and technology. Wozney et al [6] described that having to learn new web conferencing software can create a “cognitively demanding environment.” The team could have benefited from viewing demonstration videos or web-based tutorials about Microsoft Teams features (eg, chat and channel communication and the use of desktop and browser versions of the software) [7]. This would be in addition to running pilot sessions intended to clarify protocol steps and enable the coordination of team members in preparation for “real” testing sessions.

Technology also eased the cross-checking of the accuracy of record keeping as performed by the remote observers, who accessed the video-recorded sessions and transcriptions provided by Microsoft Teams. Furthermore, the use of Hotjar aided the remote observers in making more objective observations of how the user engaged with the application’s webpages (eg, user clicks, taps, scrolling behavior, and mouse movements) and identifying usability issues more easily. The triangulation of methods to capture user experiences (ie, video recordings, written transcriptions, and visualization of how the user maneuvered on the webpages) strengthened the reliability of the remote observers’ interpretation of user behavior [1]. This, in turn, led to their optimal decision-making regarding priority application refinements and rapid resolution of how to make application refinements before advancing to the next phase.

Regarding cognitive challenges, the remote moderator especially described her experience as stress-evoking. She needed to “take in” textual stimuli as well as auditory and visual stimuli while relying on her memory and interpretation skills as part of encouraging users to provide useful feedback for the remote observers and their application refinements [6]. Remote observers were less affected by cognitive overload and felt more efficient in their tasks. The lead remote moderator role was expected to not only learn the features and proficiently manage the functionality of Microsoft Teams in a short period (ie, during brief testing sessions) but also respond to anxious users’ questions, needs, and behaviors and to private chat room communication with remote observers during sessions. These expectations existed for the remote user who also needed to create a warm, inviting environment for users to provide honest responses to their experiences with the application. A recommendation to reduce the cognitive load for the lead moderator is to conduct pilot sessions with sufficient time for personnel to become familiar with testing demands and jointly strategize how to reduce anticipated cognitive challenges [22]. This would entail practice time to (1) learn advanced features

in Microsoft Teams, such as the private chat function, to communicate with other team members; and (2) engage in rapport building with other team members (eg, silent observers) who will serve as a reassuring pair of added eyes and ears to address emerging issues during testing sessions. The other option is to hire experienced moderators and silent observers with advanced skills and knowledge of remote usability testing to efficiently deal with cognitive demands during sessions.

There were differences in opinion between the remote moderator and the remote observers regarding the benefits of in-person versus remote or virtual testing sessions in promoting social presence. Although the remote moderator had a larger role in interacting with the user, it is understandable that she felt constrained in not being able to provide more expressive instructions to the users—especially to users who were anxious when performing tasks. The remote observers did not feel hindered doing remote sessions. Rather, they felt that their use of screen sharing was sufficient for them to conduct silent observation and record keeping and not bias the user’s responses to the application. To overcome constrained communication with users, the remote moderator used the camera and audio features to maintain social presence (eg, with eye contact and body language) without feeling a need to talk more than necessary with the user. As described by Wozney et al [6], establishing and maintaining a social presence entails a combination of technical and interpersonal communication skills in the lead moderator. Practice exercises in virtual communication using technology and obtaining feedback from dialogue partners would be helpful in training research personnel in social presence.

Communication was an essential element that the team was keen to focus on to attain successful testing outcomes as fostered by technology. For instance, the private chat function in Microsoft Teams allowed for timely in-session communication and impromptu problem solving between the remote moderator and the 2 remote observers as required during the sessions. Being sensitive to the potential ill effects of physical distancing saw the team engage in careful efforts to create a friendly and accommodating environment for users [22]. For example, the remote observers were sensitive to their method of secretly communicating with the remote moderator during testing sessions and making themselves known to the user at the end of the session. The remote observers appreciated the opportunity to debrief with the user, express their gratitude, compliment the user for their efforts, and invite further user feedback. It is believed that these actions promoted trustworthiness in the testing experience and in the research personnel. Drawing on emerging evidence on establishing good web-based communication [22] would also be helpful in training remote moderators and silent observers.

Limitations

A limitation related to “how” and “when” we captured the remote moderator’s and remote observers’ perceived experiences. First, the remote moderator’s and remote observers’ responses were based on their experiences with a small sample of nursing student participants from 1 setting, which poses a caveat to generalizing these findings to a wider student

population. Second, their feedback was not solicited until after all usability testing sessions were completed and during a time when their student commitments were heavy. Furthermore, their narrative accounts may have been negatively affected by memory biases. A more reliable approach to capturing trustworthy accounts would have been to record a debriefing session individually with the remote moderator and remote observers immediately after each testing session. A focus group approach involving the remote moderator and remote observers could have also stimulated rich and more in-depth responses to their joint experiences in the testing sessions. The remote moderator and remote observers would need to feel comfortable enough with each other to honestly share how their collaborative efforts unfolded and were affected by each other's behaviors.

This study's main findings revealed a wealth of learning experiences by the remote moderator and remote observers in their respective roles when executing the usability testing protocol. Their use of web conferencing and survey technologies enabled adequate remote communication with users, good collaboration among research team members, the capture of user feedback, automatic transcription with immediate access for quick analysis, and easy remote administration of questionnaires. See [Multimedia Appendix 5](#) for the remote moderator's and remote observers' recommendations relating to future usability testing sessions and a training protocol for research personnel.

Conclusions

With the growing availability of web conferencing platforms, application developers are no longer restricted to in-person

testing sessions. We anticipate a rising use of remote usability testing sessions as applications, services, technology, and software platforms continue to evolve and grow [23]. Usability testing is a relatively young science. This work contributes to the scarce literature on remote usability testing with web browser applications developed in academia, especially in health sciences [23]. "Best practice standards" are emerging where developers are required to publish evidence of user involvement and user satisfaction when seeking uptake of their application in the real world (eg, in clinical practice [25]).

Our results suggest that remotely moderated usability testing can serve as a valid substitute for traditional in-person usability testing. However, there remains a great need for more rigorous research to better comprehend the influence of remote moderator and silent remote observer characteristics, their previous experiences, and team collaboration on user responses. We also need more research that contributes evidence as a foundation for training remote moderators and remote observers in web-based interpersonal communication skills, the execution of usability testing protocols in virtual environments, team decision-making (eg, joint troubleshooting of emerging technical and user issues in "live" testing sessions), and technology and web conferencing technology skill proficiency. Finally, ongoing development and testing of reliable and valid methods to capture data remotely and record-keeping tools are warranted to ensure that rigorous studies are performed and outcomes are being captured to advance the science in usability testing. With such evidence in hand, videoconferencing software and technology developers can continue to create sound tools and methods for uptake by usability testing personnel.

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Authors' Contributions

ML conceived the study; acquired funding; and participated in design, coordination, and supervision of research personnel. She was the lead author of the manuscript. PRB, AA, and AL participated in revising the study protocol, data collection, data analysis, and made significant contributions to the manuscript. All authors have read and approved the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Usability project setup.

[\[DOCX File, 14 KB - formative_v6i8e35319_app1.docx\]](#)

Multimedia Appendix 2

Application development process.

[\[DOCX File, 13 KB - formative_v6i8e35319_app2.docx\]](#)

Multimedia Appendix 3

Performance metrics tool.

[\[DOCX File, 24 KB - formative_v6i8e35319_app3.docx\]](#)

Multimedia Appendix 4

Remote moderator and remote observer interview questions.

[\[DOCX File, 26 KB - formative_v6i8e35319_app4.docx\]](#)

Multimedia Appendix 5

Recommendations for conducting future usability testing sessions and developing a training module.

[\[DOCX File, 26 KB - formative_v6i8e35319_app5.docx\]](#)

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Original Paper

Posttraining Outcomes, Acceptability, and Technology-Based Delivery of the STAC Bystander Bullying Intervention Teacher Module: Mixed Methods Study

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Abstract

Background: Bullying is a significant problem for youth associated with wide-ranging negative consequences. Providing students who witness bullying with intervention strategies to act as *defenders* can reduce bullying and negative associated outcomes for both targets and bystanders. Educating teachers about bullying and training them to support students to intervene as *defenders* may increase the efficacy of bystander programs as teachers' attitudes and responses to bullying relate to bystander behavior. This is particularly important in middle school, when bullying peaks and rates of reporting bullying to teachers begin to decline. Reducing implementation barriers, including limited time and resources, must also be considered, particularly for schools in low-income and rural areas. Technology-based programs can increase access and scalability but require participant buy-in for adoption.

Objective: We used a mixed methods design to inform the development of the STAC teacher module, a companion training to a brief bullying bystander intervention. STAC stands for the four bystander intervention strategies: *Stealing the Show*, *Turning it Over*, *Accompanying Others*, and *Coaching Compassion*. Objectives included examining the effectiveness of the STAC teacher module and informing the translation of the training into a technology-based format that can be used as a companion to the technology-based STAC.

Methods: A sample of 17 teachers recruited from 1 middle school in a rural, low-income community completed pre- and posttraining surveys assessing immediate outcomes (ie, knowledge, confidence, comfort, and self-efficacy), intention to use program strategies, and program acceptability and relevance, followed by a qualitative focus group obtaining feedback regarding program appropriateness, feasibility, content, perception of need, and desire for web-based training. Descriptive statistics, 2-tailed independent-sample *t* tests, and thematic analyses were used to analyze the data.

Results: Assessment of pre- and posttraining surveys indicated that teachers reported an increase in knowledge and confidence to support *defenders*, confidence and comfort in managing bullying, and bullying self-efficacy. Furthermore, most participants reported that they were likely or very likely to use STAC strategies to support students who intervene in bullying. Quantitative and qualitative data revealed that participants found the training easy to use, useful, relevant, and appropriate. Qualitative data provided feedback on ways of improving the program, including revising role-plays and guidance on understanding student behavior. Participants shared positive perceptions regarding program feasibility and need for bullying-specific prevention, the most significant barriers being cost and parent buy-in, suggesting the importance of including parents in the prevention process. Finally, participants shared the strengths of a web-based program, including ease of implementation and time efficiency, while indicating the importance of participant engagement and administration buy-in.

Conclusions: This study demonstrates the effectiveness of the STAC teacher module in increasing knowledge and bullying self-efficacy and provides support for developing the module, including key information regarding considerations for web-based translation.

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KEYWORDS

teacher bullying interventions; technology-based bullying intervention; STAC; middle school

Introduction

Background

Bullying is a significant problem for youth, which is associated with a wide range of socioemotional consequences in childhood and adolescence [1] that extend into adulthood [2]. Bullying peaks in middle school, with 28% and 33% of students in the United States reporting being bullied at school and cyberbullied, respectively [3]. Among middle school students, being a target of bullying is associated with poor academic performance [4,5], absenteeism [5,6], somatic symptoms [7], anxiety [1,7], depression [1,7,8], suicidal ideation, and suicide attempts [1]. A growing body of literature demonstrates that students who witness school bullying as bystanders also report negative outcomes, including an increased risk of depression, anxiety [9-11], and somatic symptoms [12]. Similar trends are also emerging for middle school students who witness cyberbullying [13-15].

Bystanders as Defenders

Most students (ie, up to 80%) report witnessing school bullying as bystanders [11], and approximately 50% report witnessing cyberbullying [16]. However, only 20% to 30% of students report intervening in school bullying [17], and as few as 10% report intervening in cyberbullying [18]. When bystanders interrupt a bullying situation by telling the bully to stop or by reporting bullying to an adult, bullying decreases [19] and bystanders report improved emotional adjustment [20]. However, often, bystanders do not intervene as they lack the knowledge or skills to act as *defenders* [21,22]. Therefore, equipping bystanders with strategies that they can use when they witness bullying can reduce both bullying and the negative associated consequences for both targets and students who witness bullying.

The STAC Intervention

Researchers developed the STAC intervention [23] to train middle school students to act as *defenders* on behalf of targets of bullying using the following four intervention strategies: (1) *Stealing the Show* (using humor or distraction to interrupt a bullying situation and remove the attention from the target), (2) *Turning it Over* (identifying a trusted adult at school, reporting, and asking for help during a bullying incident), (3) *Accompanying Others* (befriending or providing support to a peer who was a target of bullying), and (4) *Coaching Compassion* (gently confronting the perpetrator and increasing empathy for the target). STAC is a brief bystander intervention comprising a 75-minute training that includes didactic and experiential components. In the didactic portion, students learn about the definition of bullying, types of bullying, negative

associated consequences, bystander roles, and the 4 STAC strategies. The experiential component comprises role-plays during which students practice using the STAC strategies and receive feedback from the trainers. After the training, students participate in two 15-minute booster sessions to reinforce learning and skills. Boosters include check-in, support, and brainstorming of how to use the STAC strategies more effectively.

Research conducted with middle school students has shown that students report posttraining increases in knowledge of bullying and the STAC strategies, as well as the confidence to intervene on behalf of targets [23-26]. The findings also indicate that the STAC intervention is effective in reducing bullying victimization [24,27] and perpetration [24], as well as improving bystander mental health, including reducing anxiety [24,28], depression [24,29], and suicidal ideation [29], and increasing self-esteem [30].

Use of STAC Strategies to Act as a Defender

Although $\geq 90\%$ of middle school students report using at least one of the four STAC strategies to intervene in bullying situations after training [24,26,31], middle school students report using *Turning it Over* less frequently than elementary school students. Specifically, the prevalence rates of using “Turning it Over” declined from 78% in elementary school [31] to 69.1% in middle school [26]. Interestingly, this is not the case for the other 3 strategies, with prevalence rates increasing from 50.9% to 69.1% for *Stealing the Show*, from 76.4% to 90% for *Accompanying Others*, and from 44.4% to 69.1% for *Coaching Compassion* among elementary school students [31] and middle school students [26], respectively. A possible explanation for the lower rates of using “Turning it Over” in middle school is that middle school students may believe that teachers do not care enough about bullying to take action and perceive bullying as a less significant problem than students do [25]. Therefore, providing education to teachers about bullying and training them on how to support students when they report bullying or ask for help may be important additions to the STAC intervention at the middle school level.

Equipping Teachers to Support Student Defenders

Middle school students indicate that school bullying occurs most often in the classroom, accounting for 42.3% of all school bullying incidences [32]. However, national data indicate that only approximately half (51.7%) of middle school students report bullying to an adult at school, with report prevalence declining from sixth grade (57.2%) to eighth grade (47%) [32]. Although students report bullying to teachers more often than to any other adult at school [33], reporting behavior is influenced by a student’s perception of teachers’ responses to bullying.

Students are more likely to report when they believe teachers will intervene [34], effectively handle the situation [35], and reward students' efforts when they report or intervene in bullying [36]. In addition, students' future reporting behavior is influenced by how teachers respond to students' initial reporting [37]. Students are less likely to report bullying [33] and rates of bullying are higher in the classroom [38] when students perceive that teachers have low self-efficacy in handling bullying situations. As such, it is important for teachers to demonstrate comfort with and confidence in handling bullying situations. Training teachers to effectively respond to bullying and to encourage and support students who report and intervene in bullying are important components of bullying programs aimed at increasing student bystander intervention.

Reducing Barriers to Access and Implementation

Successful implementation of bullying prevention programs requires key stakeholder buy-in that can be enhanced by reducing barriers through the reduction of time and cost while increasing training flexibility [39]. We are in the process of translating the in-person STAC intervention into a technology-based format (STAC-T) [40,41] to increase accessibility, particularly for schools in low-income and rural communities. Developing a technology-based teacher module has the potential to enhance program efficacy, reduce implementation barriers [42], and increase program scalability [43]. Although web-based training outcomes (eg, increased knowledge, self-efficacy, and behavioral intentions) are equivalent to in-person training outcomes [42], perceived usefulness [44] and participant buy-in [39] are both important factors that contribute to program acceptability. Therefore, it is important to understand the perspectives of teachers regarding the strengths and barriers related to a technology-based format.

Initial Development of the STAC Teacher Module

The purpose of the development of the STAC teacher module was to enhance intervention outcomes by equipping teachers with knowledge and skills to appropriately address bullying and support students who witness bullying to intervene as "defenders." The content of the STAC teacher module was originally developed through focus groups conducted with high school teachers [45] and then adapted for the middle school level through focus groups conducted with middle school personnel, including teachers, an administrator, and a school counselor [46]. Preliminary research with high school teachers indicates that the training was effective in increasing teachers' knowledge; confidence in supporting student bystanders to intervene as *defenders*; and comfort, confidence, and self-efficacy in intervening in bullying situations [45]. Qualitative data from focus groups conducted with middle school personnel suggest that the content of the STAC teacher module is useful, relevant to, and appropriate for middle school settings [46]. In addition, middle school personnel indicated a need for the program and identified barriers to implementation, including cost, time, and teacher buy-in. Participants also provided feedback on delivering the program in a technology-based format, appreciating the flexibility of a technology-based program while expressing concerns regarding participant engagement.

Study Objectives

The purpose of this study was to build on our prior research on developing the STAC teacher module, examining the effectiveness of the training, as well as providing data to inform the translation of the training into a technology-based format that can be used as a companion module to the STAC-T program. To date, we have collected posttraining data from high school teachers and qualitative data from middle school teachers and other school personnel. This study represents the next step in the development of the STAC teacher module for middle schools. Specifically, we aimed to evaluate immediate posttraining outcomes (eg, changes in knowledge, confidence, self-efficacy, and teachers' intention to use the STAC strategies) among middle school teachers and obtain additional feedback from a new group of middle school teachers recruited from a different school district regarding program content, acceptability, need, and delivery via a technology-based format. To achieve these aims, we used a mixed methods research design to answer the following research questions: (1) Do the trained teachers report increases in knowledge and confidence to support students who act as *defenders* and increases in confidence, comfort, and self-efficacy in managing and handling bullying? (2) Do teachers indicate behavioral intentions to use the STAC strategies after training? (3) Is the STAC teacher module acceptable and relevant to middle schools? (4) What was the teachers' feedback regarding program appropriateness, feasibility, content, perception of need, and desire for web-based training?

Methods

Participants

Participants were teachers (N=18) recruited from 1 public middle school in a rural, low-income community in the northwestern United States. We selected the school based on a prior and ongoing research partnership. The school was a Title I school located in a rural community, with 89.1% (304/341) of the student population qualifying for reduced or free lunch. The race or ethnicity of the student body included 64.5% (220/341) Hispanic, 34.3% (117/341) White, and 1.2% (4/341) other. Of the 18 participants who completed the pretest survey, 17 (94%) completed the immediate posttest survey. The final sample comprised 76% (13/17) women and 24% (4/17) men. Among the participants, ages ranged from 25 to 62 (mean 44.76, SD 12.16) years, and years of experience as a middle school teacher ranged from 1 to 26 (mean 10.24, SD 7.82) years. Most of the teachers in the sample were female (13/17, 76%) and identified as White (16/17, 94%). Of the 17 teachers who completed the immediate posttest survey, 6 (35%) signed up and participated in the focus group. The sample comprised 35% (6/17) women who identified as White. A series of chi-square analyses and 2-tailed independent-sample *t* tests revealed no statistically significant demographic differences between those who participated in the focus group and those who did not participate.

STAC Teacher Module for Middle School

Overview

The STAC teacher module is a 50-minute module that includes (1) normative feedback regarding the prevalence of bullying to engage teachers; (2) didactic information about bullying, including the definition and types of bullying and the associated negative consequences; (3) a review of the student STAC strategies and corresponding strategies that teachers can use to support students who act as “defenders,” followed by role-plays to reinforce skill acquisition; and (4) information about “perceptions vs. facts” about bullying that can influence how teachers shift the school climate and demonstrations of how teachers can apply research-based strategies to positively influence and shift the school climate.

Normative Feedback

The normative feedback module begins with teachers estimating the local and national prevalence rates related to bullying among middle school students. Example questions include the following: (1) What percentage of middle school students say that they have been bullied in the past year? (2) What percentage of middle school students say that they have been cyberbullied in the past year? (3) Rank the order of the location middle school students are most frequently bullied (ie, hall/stairwell, classroom, cafeteria, outside of school grounds, and bathrooms/locker rooms), and (4) Among middle school students, what percentage of students report bullying to an adult?

After the teachers indicate their estimates, trainers provide actual prevalence data in comparison with their responses and facilitate a brief discussion regarding discrepancies.

Bullying Education

Teachers are presented with the definition of bullying, including examples of behaviors that would not be considered bullying (eg, what is not bullying). Trainers also discuss different types of bullying (ie, physical, verbal, relationship, and cyberbullying), negative associated consequences for students who are targets or bystanders, and positive outcomes for students who are trained and intervene as “defenders.” This information is presented in a manner that parallels the STAC training for students.

STAC Strategies and Role-plays

Overview

Trainers present the 4 STAC strategies (ie, *Stealing the Show*, *Turning it Over*, *Accompanying Others*, and *Coaching Compassion*) that students are taught to use to intervene as *defenders* when they witness bullying at school. Next, trainers discuss the skills that teachers can use to support students using each of the 4 STAC strategies. After each strategy is presented, trainers ask for teacher volunteers to engage in a role-play to practice the skills the teachers can use to support students acting as “defenders.” The 4 STAC strategies with the corresponding teacher strategies are outlined in the following sections.

Stealing the Show

Students are taught to use humor or distraction to interrupt a bullying situation. Teachers can support students using this

strategy by approaching the situation, joining in the conversation, or laughing at a joke that appropriately interrupts the bullying situation. Teachers are encouraged to disperse the peer group so that the perpetrator or perpetrators do not have access to a peer audience. Teachers are also encouraged to reinforce the *defender* with positive feedback, check in on the target, and report the situation to the administration when appropriate.

Turning It Over

Students are taught to use *Turning it Over* or reporting the bullying situation to an adult at school, and they are encouraged to always use this strategy if they witness physical or cyberbullying. Teachers can support students who report bullying by assuring them that they did the right thing. Trainers encourage teachers to reinforce to students that bullying is not acceptable and that it requires maturity and strength to report bullying and ask for help. As students generally believe that their peers will perceive them as a “Snitch” if they report bullying to adults [47], teachers are also encouraged to share with *defenders* that research shows that students are generally supportive of their peers who report bullying. In addition, trainers instruct teachers to share with students that it often requires continued documentation for adults to be able to take significant action and that a process may be occurring outside of a student’s awareness because of issues related to confidentiality. As such, teachers should encourage *defenders* to continue reporting and, in the case of cyberbullying, documenting by taking immediate screenshots or pictures. Teachers should also follow up and report bullying to their administration when appropriate.

Accompanying Others

Students are taught to use *Accompanying Others* to befriend or support peers whom they witness being a target of bullying. Student *defenders* can use this strategy without calling attention to the situation by inviting students who were targeted to sit with them at lunch or walk with them to class. Depending on the nature of their relationship, *defenders* can share with the target that they witnessed what happened, state that the perpetrator’s behavior was unacceptable, and ask whether they would like to talk about it. Teachers are encouraged to let students who use this strategy know that they are being a good friend and positively affecting their peer’s experience at school. Trainers also encourage teachers to reinforce to *defenders* that by befriending targets, they are communicating to their peers that they care about them and that they are not alone at school. Furthermore, teachers are instructed to encourage *defenders* to check back in with their peers who were targeted the day following the incident to build an acquaintanceship or friendship, as well as to follow up with the targets themselves or report the bullying incident if appropriate.

Coaching Compassion

Students are taught to use *Coaching Compassion* to gently confront students who perpetrate bullying behaviors during or after a bullying incident. Only students who are older, have a higher social status, or are good friends with the perpetrators are encouraged to use this strategy. The goal is to raise the awareness of students who bully that bullying is unacceptable

while fostering empathy toward the target. Trainers instruct teachers to support students using this strategy by paying close attention to the situation and becoming involved if necessary to ensure safety. In addition, teachers are encouraged to reinforce to *defenders* that they did the right thing in intervening and that bullying is unacceptable and share that research indicates that for students who bully infrequently, increasing awareness and empathy often decreases bullying [48].

Perceptions Versus Facts About Bullying and Teachers' Role in Shaping the School Climate

Trainers present statements related to bullying and school climate, and teachers are asked whether these statements are true or false. Trainers then discuss the correct answers and supporting research. For example, teachers are asked (1) whether most students have negative attitudes toward peers who report bullying to teachers; (2) whether students perceive that teachers think bullying is developmentally appropriate and that teachers do not care enough about bullying; and (3) in schools where teachers appear to be less judgmental of bullying, whether students are bullied more often. The training concludes with a demonstration of a teacher intervening in a classroom bullying situation reinforcing strategies that research supports are effective in positively shifting the school climate.

Procedures

Participant recruitment and data collection occurred during the spring of 2022. The inclusion criterion was being a middle school teacher at the participating school. The exclusion criterion was being a staff member other than a teacher. The team worked with the school principal to recruit all teachers from 1 middle school to be trained on the STAC teacher module. The first author (AM) and a Master's student conducted study recruitment, data collection, and the STAC teacher module training in person at the school during a professional development day. The researchers conducted the informed consent process immediately before collecting the baseline data, which was then followed by the STAC teacher module and postintervention data collection. The pre- and postintervention data collection took 15 to 20 minutes to complete, and the training lasted 50 minutes. After postintervention data collection, the researchers invited all study participants to sign up for a follow-up focus group that occurred within a week of the training and was conducted on the web. A doctoral student and a master's student conducted the focus group, which lasted approximately 45 minutes and was recorded for verbatim transcription. Participants received a US \$50 Amazon gift card as an incentive to participate in the STAC teacher module and complete pre- and posttraining surveys. Participants also received a US \$50 Amazon gift card as an incentive to participate in the follow-up focus group.

Ethics Approval

We used active informed consent for this study. The researchers provided the participants with an informed consent form that contained information about the study, including purpose and background, procedures, risks or discomforts, extent of confidentiality, benefits, payment, and how to contact the primary investigator and the institutional review board of the

university. All study procedures were approved by the institutional review board of the university (101-SB21-051) and by the school district. Although the principal recruited teachers to participate in the training, the research team members conducted study recruitment. Teachers were informed that their participation in the study procedures (ie, completing surveys or participating in a focus group) was voluntary and that they could choose not to participate or withdraw from the study at any time without penalty. We believe that this procedure minimized any pressure teachers may have felt to participate in the research because of the principal's role in recruiting teachers to participate in the training.

Measures

Demographic Survey

The teachers completed a brief demographic questionnaire that included questions about age, gender, race or ethnicity, and years of experience teaching.

Knowledge and Confidence to Support Defenders

The Teacher-Advocates Pre and Post Scale [45] was used to measure knowledge and confidence in supporting "defenders." The questionnaire comprises 11 items that measure knowledge of bullying behaviors, knowledge of how to support students using the STAC strategies, and confidence in supporting students who intervene in bullying situations. Examples of items include "I know what verbal bullying looks like," "I know how to support students who reach out to students who are targets of bullying," and "I feel confident in my ability to do something helpful to support students who report bullying to me." Items are rated on a 4-point Likert scale ranging from 1 (*totally disagree*) to 4 (*totally agree*). All the items are summed to compute the total scale score. Possible scores range from 11 to 44. Higher scores reflect higher levels of knowledge and confidence. The Teacher-Advocates Pre and Post Scale has established internal consistency, with Cronbach α ranging from .72 to .95 [45]. The Cronbach α was .71 for this study.

Confidence in Managing Bullying

The Teacher's Attitudes about Bullying Questionnaire [49] is a 22-item questionnaire that contains 5 subscales. We used the 3-item Confidence in Managing Bullying Subscale, which includes the items "I am confident that I will know what bullying is when I see it," "I am confident that I will know how to respond if one of my students is being victimized by a peer," and "I am confident that I will put my knowledge into practice and actively respond in bullying situations." Items are rated on a 5-point Likert scale ranging from 1 (*strongly disagree*) to 5 (*strongly agree*). All the items are summed to compute the total scale score. Possible scores range from 3 to 15. Higher scores reflect higher levels of confidence in managing bullying. The Cronbach α was .67 for this study.

Comfort With Managing Bullying

The teachers' comfort with managing bullying was measured using items from the National Education Association Bullying Survey [50]. The teachers were asked the question "How comfortable would you feel intervening when you see the following bullying behaviors?" followed by four types of

bullying and their definitions: (1) physical (hitting, pushing, or kicking), (2) verbal (general teasing or name calling), (3) relational (rumor spreading or excluding someone from a group), and (4) cyberbullying (sending or posting harmful material or engaging in other forms of social aggression using the internet or other digital devices, such as mobile phones). Items are rated on a 4-point Likert scale ranging from 1 (*very uncomfortable*) to 4 (*very comfortable*). All the items are summed to compute the total scale score. Possible scores range from 4 to 16. Higher scores reflect higher levels of comfort with managing bullying. Items were summed to create the scale. The Cronbach α was .71 for this study.

Bullying Self-efficacy

The teachers' self-efficacy in handling bullying situations was measured using 2 items from the National Education Association Bullying Survey [50]. The items "I have effective strategies for handling bullying" and "I have effective strategies for supporting students to intervene in a bullying situation" are rated on a 4-point Likert scale ranging from 1 (*strongly disagree*) to 4 (*strongly agree*). All the items are summed to create the scale. Possible scores range from 2 to 8. Higher scores reflect higher levels of self-efficacy. The Cronbach α was .81 for this study.

Intention to Use Teacher STAC Strategies

The intention to use teacher STAC strategies was measured using an adapted version of the Use of STAC Strategies [28] for students. The items were adapted from the student version to be appropriate for teachers. The 4-item measure asks teachers the following: "How likely are you to support students using these strategies to intervene in bullying in the future?: a) Stealing the Show—support students using humor or distraction to get the attention away from the bullying situation, b) Turning it Over—support a student who reported bullying to you or supporting students to report to a principal or SRO, c) Accompanying Others—support students who reach out to the student who was the target of bullying, or d) Coaching Compassion—support students who help the student who bullied develop empathy for the target." Items are rated on a 5-point Likert scale ranging from 1 (*very unlikely*) to 5 (*very likely*), with higher scores reflecting higher levels of intention to use the strategies.

Acceptability and Relevance of the Teacher STAC Training

Acceptability (ie, ease of use or utility) and relevance of the STAC training were assessed using a social validity survey comprising 8 items. Items were ranked on a 4-point scale from 1 (*strongly disagree*) to 4 (*strongly agree*), with higher scores reflecting higher levels of acceptability and relevance. The survey was based on social validity surveys used to assess the appropriateness of interventions adapted for a new population with demonstrated reliability and validity [51,52]. The Cronbach α was .97 for this study.

Interview Questions

Within a week of being trained and completing the posttraining survey, a subset of teachers (6/17, 35%) participated in a focus group. Participants were asked semi-open-ended questions about the relevance and appropriateness of the training.

Participants were asked (1) what they liked and did not like about the training; (2) what information was missing from the training to equip teachers to support students to act as *defenders* in a bullying situation; (3) how useful they perceived the training was to prepare teachers to address the problem of bullying at school; (4) whether the content of the program was relevant to and appropriate for their students and community; (5) what was the practicality and workability of the training for their school setting; (6) what types of similar training they had received, including training specifically about bullying; (7) whether they thought there was a need and whether they would use this training at their school; (8) what barriers may prevent their school from adopting or implementing a bullying intervention program; (9) what were the strengths or barriers to implementing this program as a web-based program; and (10) what was the usefulness of web-based training.

Data Analysis

Quantitative

Quantitative data from the questionnaires were analyzed using SPSS (version 28.0; IBM Corp). Before conducting the statistical analyses, the data were examined for outliers and normality, and all variables were within the normal range for skewness and kurtosis. We computed descriptive statistics for all variables at pre- and posttest measurements. We conducted a series of paired-sample *t* tests to evaluate changes from pre- to posttest measurements. All analyses were considered significant at $P < .05$. The Cohen *d* was used to measure effect size, with the magnitude of effects interpreted as follows: small ($d = 0.20$), medium ($d = 0.50$), and large ($d = 0.80$) [53].

Qualitative

One team member, who facilitated the focus group, transcribed the data verbatim. The data analysis team comprised 2 faculty members with expertise in qualitative data analysis and a doctoral student. The lead analyst developed an analysis plan. First, analysts wrote an individual precoding memo reflecting on potential biases and assumptions about the research questions. Subsequently, they participated in a preanalysis meeting where they discussed initial memos and coordination for the analysis process. Team members used thematic analysis, which is a phenomenological approach focusing on participants' experiences, and an inductive approach to coding the transcript and interpreting the data [54,55]. Analysts coded the focus group transcript individually, wrote a postcoding memo, and met twice to achieve a consensus on themes and finalize the results. The team used the participants' quotes to resolve disagreements. An external auditor reviewed the results and provided the team with feedback through email correspondence. No identifying information was included in the interview transcripts.

Results

Quantitative Analysis

Posttraining Outcomes

Means, SDs, and statistical contrasts for pre- to posttest training outcomes are presented in Table 1. The teachers reported an increase in knowledge and confidence to support *defenders*

($P<.001$), confidence in intervening in bullying situations ($P<.001$), comfort with intervening in bullying situations ($P<.001$), and bullying self-efficacy ($P<.001$). All the effect sizes were large. The results support the effectiveness of the

teacher training in increasing knowledge and confidence in both working with student bystanders and intervening directly in bullying situations from before the training to after the training.

Table 1. Means, SDs, and statistical contrasts for paired-sample t tests.

Item	Pretest time point, mean (SD)		Posttest time point, mean (SD)		
	Values, mean (SD)	Values, mean (SD)	t test (df)	P value	Cohen d
Knowledge and confidence in supporting <i>defenders</i>	30.71 (2.95)	37.34 (3.90)	8.31 (16)	<.001	2.02
Confidence in intervening in bullying	10.47 (1.70)	13.12 (1.54)	7.09 (16)	<.001	1.72
Comfort with intervening in bullying	11.42 (1.62)	13.06 (1.95)	4.20 (16)	<.001	1.02
Bullying self-efficacy	4.65 (0.86)	6.82 (1.01)	9.44 (16)	<.001	2.29

Intention to Use Teacher STAC Strategies

The teachers' ratings of their intention to use teacher STAC strategies are reported in Table 2. As seen in Table 2, most teachers indicated that they were likely or very likely to use the STAC strategies to support students who intervene in bullying in the future. For specific strategies, >90% (16/17, 94%) reported that they would be likely or very likely to support

students using *Stealing the Show*, >90% (16/17, 94%) reported that they would be likely or very likely to support students using *Turning it Over*, 100% (17/17) reported that they would be likely or very likely to support students using *Accompanying Others*, and >85% (15/17, 88%) reported that they would be likely or very likely to support students using *Coaching Compassion*.

Table 2. Intention to support students using STAC strategies in the future (N=17).

Strategy	Agreement, n (%)				
	Very likely	Likely	Not sure	Unlikely	Very unlikely
Stealing the Show	7 (41)	9 (53)	1 (6)	0 (0)	0 (0)
Turning it Over	8 (47)	8 (47)	1 (6)	0 (0)	0 (0)
Accompanying Others	6 (35)	11 (65)	0 (0)	0 (0)	0 (0)
Coaching Compassion	5 (31)	9 (56)	2 (13)	0 (0)	0 (0)

Acceptability and Relevance of the Teacher STAC Training

The percentage of agreement for the social validity survey items is reported in Table 3. Overall, the scores suggest a very high level of program acceptability and relevance. Most teachers

found the STAC teacher module to be easy to understand (16/17, 94%), useful (16/17, 94%), interesting (15/17, 88%), and relevant (16/17, 94%) to middle school teachers. Most teachers also indicated that they had learned something from the program (16/17, 94%) and would recommend it to other teachers at their school (16/17, 94%).

Table 3. Participants reporting agreement with social validity items (N=17).

Item	Agreement, n (%)			
	Strongly agree	Agree	Disagree	Strongly disagree
The STAC teacher training was easy to understand.	11 (65)	5 (29)	0 (0)	1 (6)
The STAC teacher training was useful.	11 (65)	5 (29)	0 (0)	1 (6)
The STAC teacher training was interesting.	9 (53)	6 (35)	0 (0)	2 (12)
The STAC teacher training information was relevant to middle school teachers.	14 (82)	1 (6)	1 (6)	1 (6)
The STAC teacher training examples of bullying were relevant to middle school teachers.	11 (65)	5 (29)	0 (0)	1 (6)
The STAC teacher training strategy role-plays were relevant to middle school teachers.	11 (65)	5 (29)	0 (0)	1 (6)
I learned something from the STAC teacher training.	12 (71)	4 (24)	0 (0)	1 (6)
I would recommend the STAC teacher training to other teachers at my school.	13 (77)	3 (18)	0 (0)	1 (6)

Qualitative Analysis

Overview

Qualitative feedback for the STAC teacher module supported the quantitative findings and was positive overall, with participants sharing the perception that the STAC teacher module was useful, relevant, and appropriate, as well as sharing ways of improving the program. In addition, teachers shared positive thoughts about program feasibility, the need for bullying-specific training for teachers, and strengths of and implementation barriers to a web-based program. The results are presented in the following sections, organized according to the following themes: (1) positive program attributes; (2) relevance and appropriateness; (3) program feedback; (4) feasibility, need, and current program offerings; (5) potential barriers; and (6) web-based offering.

Positive Program Attributes

Participants spoke positively about the STAC teacher module, including liking the teacher strategies to support students who report bullying, finding the strategies easy to implement, and finding the role-plays useful. Participants also liked that the STAC program provides students with the knowledge and skills to intervene in bullying situations. A participant shared the following:

You know there are so many things to be concerned about in a classroom and a lot of bullying, I think, is pretty under the radar. So, having the tools to know what to look for and maybe how to interpret some of the things we see. I think it's really beneficial.

When talking about the strategies they had learned, a teacher added the following:

These are just simple easy things, it is not something that is super difficult or a lot of steps you have to remember to be able to implement some of those strategies so that is really helpful.

Another participant indicated the following:

...the role-playing did help. It just lets you know, yeah, it's okay to say this and you know gives you something to fall back on.

When discussing the value of empowering students, a participant stated the following:

You know just to be able to have those tools, so they [students] can be empowered to help other kids or to help themselves.

Relevance and Appropriateness

When asked whether the STAC teacher module was relevant to and appropriate for their school and community, all participants expressed agreement. A teacher stated the following:

I guess if we see it in our schools it's happening in our community too. If we can deal with it here hopefully that will bleed out into the community and have an effect, there too.

Another teacher indicated the following:

I think there is a need [for the STAC Teacher Module] and I think, you know, there is some staff that are attuned to it. So, I think there would be definitely some teachers that would use it more than others, which is probably good because we need lots of personalities to connect with different student personalities. My guess is that it is really hard to say we are all going to do this and have it really be effective, but I think given the training and the tools there would be more teachers that would implement it.

Program Feedback

When participants were asked for feedback regarding areas that were missing from the training, a few participants indicated the need for role-plays with more realistic scenarios; additional guidance to discern whether students were genuinely acting as defenders or being disingenuous, especially when using humor; and concern about the impact of labeling a student as a bully. A participant indicated the following:

Maybe some scenarios of things that actually might occur, so we have a better idea of what to look for because sometimes they look like they are playing and maybe that is okay. But, then other times, they really are not playing, you know, and so what are some, you know, different scenarios that would help us to identify or see some of the things that really affect middle schoolers that we could kind of tune in on.

Another participant added the following:

Yeah, characteristics to look for because it is hard to know what is genuine and what's not especially when they are in middle school because everything is a joke. Which I like, I use humor as a tool all of the time, but everything is a joke and sometimes a kid will interpret someone's humor as bullying.

In terms of concerns about labeling students, a teacher stated the following:

The issue that I struggle with is labeling somebody as a bully because once us, as teachers, identify that behavior as bullying, then all of the sudden other students look at that student differently. When it could be that they just needed to learn. I don't know I struggle with that as well because once you label them as a bully then it is kind of stuck with them and other students look at them differently. And then all of the sudden the bullying actually shifts and they start to look at that kid negatively.

However, another participant responded as follows:

On the other hand sometimes we don't acknowledge when somebody is a bully. And we just keep justifying their behavior and it makes the kids that are being bullied like victimized more and so I think it is important that we get that conversation going...

Feasibility, Need, and Current Offerings

Participants indicated agreement on the program being practical and workable. Participants also spoke about the need for training

and support in addition to the current offerings on social-emotional learning and identifying a need for bullying-specific training for teachers. When asked if the program seemed practical and workable, a participant indicated the following: “Yeah, I think that would be great.” Another participant added that “I think it would be a feasible thing to do...” In terms of current offerings, a participant stated the following:

As a district we also have a 21st Century program that serves our elementary school and our middle school kids and they have a huge focus on the social emotional learning.

When asked about training that teachers received specifically about bullying, a participant indicated the following: “Uh, no not enough... We have a little, you know.”

Potential Barriers

Participants spoke about concerns regarding cost, potential pushback from parents, and maintaining an open mind. For example, a teacher stated that “Cost, if there is a cost to it—there is going to be one [barrier] there.” Another teacher shared the following:

Yeah, and I think even some kind of pushback from parents, you know, because we’ve seen that kids that you would think are perfect kids, they are the actual ones that are bullying, and their parents can’t believe it.

Finally, a teacher shared the following:

It’s hard to redefine people that you think you know. So, if you think of them as a perfect student and then you hear that they’re a bully as well, well is that really true or is it you know so having that open-mindedness to just say oh I guess what I thought was wrong.

Web-Based Programs

When addressing completing the STAC teacher module as a web-based program, participants talked about strengths such as ease of implementation and time efficiency, as well as challenges, including less engagement and missing the in-person connection. Participants also spoke about inherent issues related to technology and the importance of administration buy-in. For example, when speaking about strengths, participants indicated the following:

...you can go back and review it. So, if I’m thinking, okay, what did we say about that, or whatever or the kids need a refresher or those kinds of things. Technology does give us access to that as well as consistency.

Another participant added the following:

Technology would make it really easy to do a follow up with this kind of course...a refresher using technology and a quick setting.

A third participant added the following:

One thing is nice with web-based because you don’t have to have a sub and you don’t have to miss class

and that’s really valuable because we spend a lot of time doing sub plans and different things.

However, this participant went on to say the following:

But it’s just not as engaging [to complete the program online]

Another participant added the following:

When you’re trying to implement bullying strategies, how to deal and handle and cope, there is something to be said with the interpersonal relationship having someone in person teaching it versus online...

Another teacher stated the following:

...sometimes that removed, that technology piece, you don’t engage the same way as if you’re in person...

Participants also mentioned technology issues as barriers; for example, a teacher stated that “Access to technology, yep.” Finally, a participant shared the following about the importance of buy-in:

Yeah, I think there is buy-in and if there is buy-in from our administration then it’s a go. You know, and I think you kind of need a little bit of our administration to push it out and teachers that really see a need for it to buy-it and to push it out to the other teachers. I think a lot of us do different things as situations arise, we talk about it in our classrooms, that’s—we don’t have anything like whole school [programming]

Discussion

Principal Findings

The purpose of this study was to build on our prior research on developing the STAC teacher module, examining the effectiveness and acceptability of the training, as well as providing data to inform the translation of the training into a technology-based format that can be used as a companion model to the STAC-T student bystander bullying intervention. Quantitative findings indicated that teachers reported increases in knowledge and confidence to support students who intervene as *defenders* and to directly intervene in bullying situations from before training to after training. The teachers also reported behavioral intentions to use the STAC teacher strategies. Furthermore, the participants’ responses demonstrated high levels of program acceptability and relevance to middle school teachers. Qualitative findings were consistent with the quantitative results and revealed the following themes: (1) positive program attributes; (2) relevance and appropriateness; (3) program feedback; (4) feasibility, need, and current program offerings; (5) potential barriers; and (6) web-based offering.

Comparison With Prior Work

Consistent with prior research conducted with high school teachers trained in the STAC teacher module [45], quantitative data demonstrated increases in knowledge and confidence to support *defenders* as well as increases in confidence, comfort, and self-efficacy in managing and handling bullying from before training to after training. In addition, the teachers reported that they would use all 4 strategies to support students who act as

defenders on behalf of targets. Qualitative data supported these findings, indicating that the teachers liked the strategies and found them easy to implement. These findings are important as increases in teacher knowledge and bullying self-efficacy have been associated with directly intervening in bullying [33], which, in turn, could lead to students being more likely to report bullying behavior [34]. By rewarding students' efforts when they report or intervene in bullying [36], teachers are also likely to reinforce and increase bystander intervention, which has been shown to decrease bullying behaviors [48].

In terms of program acceptability and relevance, quantitative data indicated that most participants (16/17, 94%) reported that the STAC teacher module was easy to understand, useful, and relevant to middle school teachers. Furthermore, most participants (16/17, 94%) indicated that they learned something from the training and would recommend it to others. Consistent with our prior research with middle school personnel [46], the teachers reported that the training was useful, relevant to, and appropriate for middle school settings. Qualitative data supported these findings, with all teachers indicating agreement about the training being relevant. As program adoption and implementation are associated with acceptability and relevance [56], these findings are particularly promising.

The teachers also provided feedback on program feasibility and perception of program need. Although they confirmed the need for bullying programs that equip teachers to intervene and to support students who act as "defenders," the teachers also spoke about barriers, including cost, as well as the importance of considering parents in bullying programs. These findings are consistent with our previous studies concerning the implementation of both the STAC teacher module [46] and the student STAC-T program [40,41], suggesting that there is a need for a cost-effective STAC teacher module that incorporates parental participation.

Regarding program content, the teachers provided feedback indicating that the role-plays corresponding to the 4 STAC teacher strategies were helpful; however, a few participants expressed a desire for more realistic scenarios to further improve the training. In addition, although a few teachers stated concern about the impact of labeling a student as a bully, they also acknowledged the importance of recognizing bullying behavior. This reluctance to acknowledge bullying is similar to findings from previous studies in which teachers indicated a desire to remain neutral [45]. However, it is important for teachers to be willing to communicate that bullying behaviors are unacceptable, reinforce students who intervene as *defenders* [36], and discipline students who perpetrate bullying [37] to establish a school climate that does not condone or promote bullying.

Finally, when asked about their perspectives on web-based programs, the teachers pointed out strengths, such as ease of implementation and time efficiency, as well as challenges, including less engagement and missing the in-person connection. Participants also suggested that these barriers could be mitigated by administrative buy-in. These findings are similar to prior research conducted with school personnel emphasizing the importance of flexibility while expressing concerns about

participant engagement [46]. As training acceptability is related to stakeholder buy-in [39], it may be important to emphasize that web-based training decreases program costs and allows for training schedule flexibility [42]. Designing the training to include web-based assessment and personalized feedback components to individualize the user experience [57] can be integrated to maintain engagement.

Limitations

Although this study contributes to the literature, certain limitations must be considered. First, we only collected data from teachers in 1 rural, low-income middle school in the northwestern United States. We chose to use only 1 school as this study represents one of a series of studies conducted as formative research on the development of the STAC teacher module. Our prior research included teachers from 2 middle schools. This sample represents teachers from a third middle school.

Furthermore, because of the small sample size and lack of a control group for the quantitative portion of the study, we cannot make causal attributions or generalize our findings to the larger middle school teacher population. Therefore, it would be helpful for future studies to include middle schools from different regions in the country with greater racial or ethnic diversity and to conduct a randomized trial to assess training efficacy. In addition, as most of the sample was female, the interpretation of the results for men should be made cautiously. Formative research conducted during the development of the prototype application of the STAC teacher module should use purposeful sampling to ensure that men are included. Finally, our findings were based on self-reported data. It is possible that the teachers' responses to the survey questions and the focus group interview were influenced by their desire to please the researchers. They may have been particularly influenced as team members who trained the teachers were present during both quantitative and qualitative data collection. Future research in which team members who act as trainers are different from those who conduct data collection would be helpful in reducing participants' potential desirability effects.

Implications

This study has important implications for the development of the STAC teacher module and the translation of the training into a technology-based format that can be used as a companion module to the STAC-T program. First, the teachers reported increased immediate posttraining outcomes (ie, knowledge, confidence, comfort, and self-efficacy) in managing and handling bullying and supporting student bystanders to intervene in bullying situations. Furthermore, the teachers indicated behavioral intentions to use the STAC strategies after the training and reported that the training was feasible as long as the program was cost-effective. In addition, although the response to the training was very positive, a few teachers indicated a desire for more realistic scenarios for role-plays; as such, it may be beneficial for researchers to conduct additional focus groups with both teachers and students to further investigate student reporting behavior and teachers' responses. Furthermore, participants identified potential parent pushback as a barrier. Therefore, the development of a parent training

intervention to educate parents about the STAC program by providing information that parallels the STAC teacher module may be an important next step in program development.

The findings of this study also support the initial prototype development and testing of a technology-based version of the STAC teacher module. The teachers pointed out that the benefits associated with web-based training included ease of implementation and time efficiency. However, the teachers cautioned that maintaining engagement in web-based training is important. The teachers talked about the importance of administrator buy-in for successful adoption and implementation. Thus, when designing an internet-based program to maximize teacher engagement, integrating feedback from both teachers and administrators will be an essential element in developing a technology-based version of the STAC teacher module.

Conclusions

Bullying is a significant problem for youth in the United States, reaching its peak in middle school. Although training students in the STAC program to act as *defenders* is a promising approach to bullying interventions, equipping teachers to support students who intervene may increase the effectiveness of the program. Findings from this study demonstrate immediate posttraining outcomes, including increased knowledge, confidence, comfort, and self-efficacy, as well as teachers' behavioral intentions to use the STAC strategies. Furthermore, this study demonstrates program acceptability, relevance, feasibility, and the need for a teacher training intervention, as well as interest in a web-based translation. This study provides support for the effectiveness of the STAC teacher module and provides data to inform the translation of the training into a technology-based format that can be used as a companion model to the STAC-T bystander bullying intervention.

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Conflicts of Interest

None declared.

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Original Paper

Evaluation of a Digital Self-management Platform for Patients With Chronic Illness in Primary Care: Qualitative Study of Stakeholders' Perspectives

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Abstract

Background: Population aging and multimorbidity has led to increasing chronic care needs associated with new challenges in managing growing costs, rising health care professional workloads, and the adoption of rigorous guidelines. These issues could all benefit from greater digitalization and a more patient-centered approach to chronic care, a situation brought to the fore by the COVID-19 pandemic. Little is known about real-life use in primary care.

Objective: This study aimed to explore the views, thoughts, usability, and experiences concerning a recently introduced digital self-care platform for chronic conditions in 3 Dutch primary care practices.

Methods: We conducted an explorative study combining questionnaires and interviews among patients and general practitioners from 3 general practices that used the digital platform. Questionnaires were sent to patients in each practice to seek the views and experiences of both patient nonusers (n=20) and patient users (n=58) of the platform, together with standardized questionnaires about illness perception and quality of life. In addition, patients (n=15) and general practitioners (n=4) who used the platform took part in semistructured interviews. We transcribed interviews verbatim and performed qualitative content analysis using a deductive approach. The results of the questionnaires were analyzed with descriptive analysis.

Results: Among patients who had not actively used the platform but had received an explanation, only 35% (7/20) would recommend its use due to concerns over communication and handling. However, this percentage increased to 76.3% (45/59) among the people who actively used the platform. Interviews with patients and general practitioners who used the platform uncovered several key benefits, including reduced time requirements, reduced workload, improved care quality, and improved accessibility due to the greater patient-centeredness and use of different communication tools. In addition, the self-management tool led to greater patient autonomy and empowerment. Although users considered the platform feasible, usable, and easy to use, some technical issues remained and some patients expressed concerns about the reduction in human contact and feedback.

Conclusions: The overall experience and usability of the platform was good. Support for the online self-management platform for chronic care increased when patients actively used the tool and could experience or identify important advantages. However, patients still noted several areas for improvement that need to be tackled in future iterations. To ensure benefit in the wider population, we must also evaluate this platform in cohorts with lower digital and health literacy.

KEYWORDS

primary care; chronic disease; telemonitoring; digital health; self-management; patient-centered care; chronic care; chronic care management; illness; healthcare; healthcare professional; user; patient; platform; tool; communication; empowerment; online

Introduction

Western health care systems are facing challenges due to population aging and the rising number of chronic diseases [1,2]. Crucially, these chronic diseases are costly for individuals and the health care system, representing an important limiter of life quality [3,4], and are responsible for increased workloads experienced by general practitioners (GPs) [5]. Traditional clinical pathways offer standardized care that can be seen as rigid when physicians make decisions for their patients based on strict guidelines, and this can result in poor adherence and ownership by patients [5-7]. However, this approach contradicts modern views that patients should be responsible for their health and lifestyle [7]. Health care systems require a shift toward patient-centered care, with prevention and health lead by patients themselves [8].

Patient-centered care considers the individual preferences, needs, and values necessary to guide all clinical decisions [9] to improve quality of life for patients [10]. To achieve patient-centered care, patients must also engage in self-management and shared decision-making. Self-management requires that patients with chronic disease manage their own symptoms, treatment, lifestyle changes, and any consequences [6]. This can empower patients by increasing their autonomy [11], and it benefits by offering direct feedback via the required self-monitoring of vital signs [12]. Shared decision-making is a process through which health care providers make important decisions with patients regarding disease management or a lifestyle change [13].

Digital health can facilitate the change to patient-centered care by offering web-based information programs, remote monitoring, teleconsultations, and home care supported by mobile devices [14]. Health outcomes when comparing these services with in-person consults to date have either been similar [9,15] or have shown improvement [16]. Digital health can also improve health care effectiveness, efficiency, and accessibility in the context of population aging and greater disease chronicity [12], helping to manage increased GP workloads [17] while still offering patient-centered care [18]. The COVID-19 pandemic led to a marked increase in digital health implementations [19], consistent with models that predict health behavior and acceptance of technology, such as the health belief model [20] and the unified theory of acceptance and use of technology (UTUAT) model [21], respectively.

We implemented an online self-management platform for patients living with chronic illness in 3 Dutch primary care facilities. In this study, we aim to describe this innovative approach and evaluate (1) views on care digitalization and intention to use the new platform among patients who did not use the platform questionnaires, (2) experiences with the platform and thoughts about illness and quality of life among

patients who used the platform questionnaires, and (3) experiences of GPs and patients who used the platform.

Methods

Online Platform

Three Dutch primary care practices (Westerdokters, Veendokters, and Wouwe Markt), all members of the Flexdokters Cooperative, introduced a digitally supported self-care platform in April 2020. Designed by GPs from Flexdokters as a tailor-made service for patients with chronic illness, it used the online Viduet platform (Medicine Men), an independent tool to monitor chronic diseases that is partly integrated with the electronic health information system of the GP. It does not contain all medical information of the patient, only data that are relevant for chronic diseases like, for example, blood pressure and glucose levels. The costs are mainly covered by health insurance and offered for free to participating patients. GPs can recommend the platform to eligible patients and offer an initial explanation via video call or in-person contact. Shared decision-making is then used to select appropriate measuring devices, symptom questionnaires, contact options, and measurement frequency. If they agree, patients receive the necessary devices and user manuals at their home address and a link by email to create a platform account. Patients can then use validated questionnaires to monitor asthma, chronic obstructive pulmonary disease, cardiovascular risk, diabetes, depression, or other chronic diseases. Available devices include blood pressure monitors, glucose meters, oxygen saturation meters, smartwatches, fitness trackers, thermometers, and weighing scales, which are sent if needed.

Data are input manually or automatically (via Bluetooth). The platform offers access to a technical help desk for health care professionals and patients that refers any medical questions from patients to the health care provider. The GP retains control over a given patient's participation, but that patient has full autonomy over their care. Patients must grant permission for GPs to access their data via a viewer in the electronic patient record, which can also give alerts if measurements are above or below certain predetermined thresholds or if data collection stops.

Study Design

This explorative study comprised 3 elements (see Table 1). All patients with known chronic care needs, irrespective of platform use, received an email invitation from their GP asking if they would participate in the study, and if agreeable, to return an included questionnaire and informed consent form. Thereafter, nonusers received a combined questionnaire covering their disease status and thoughts about the platform, while users received a Dutch revised version of the Illness Perception Questionnaire-Short (IPQ-K) [22,23], the 12-Item Short Form

Survey (SF-12) [24] for quality of life, and the System Usability Scale (SUS) [25].

We used convenience sampling to include participants based on time and availability to respond during a 2-month period. Participants also needed to be able to speak Dutch or English and could have no disability that might limit their ability to

answer questions. The research team included 2 GPs, one epidemiologist/psychologist, 2 information technology (IT) experts, and 3 research assistants. Two master's in business administration in health students (research assistants) at the University of Groningen received training in qualitative research and performed the interviews.

Table 1. Study design.

Element	Sample, n	Participants and methods	Aim
1	20	Patients in the practice who do not use the platform questionnaire	Evaluation of views on digitalization of care and intention to use the new platform
2	61 partly 58 fully	Patients who use the platform questionnaires (IPQ-K ^a for illness perception, SF-12 ^b for quality of life, and SUS ^c for usability)	Evaluation of their experiences with the platform and their thoughts toward illness and quality of life
3	19	Semistructured interviews with patients (n=15) and general practitioners (n=4) who used the platform	Evaluation of their experiences with the platform

^aIPQ-K: Illness Perception Questionnaire–Short.

^bSF-12: Short Form Survey–12 Item.

^cSUS: System Usability Scale.

Ethics Approval

The University of Groningen approved this research (20200060047). Each participant completed an informed consent form that included their rights and what to expect prior to inclusion. Participation was voluntary and data were anonymized during collection. Identifiable information were kept to a minimum, stored on a safe drive at the university, and only used for this study.

Data Collection

Questionnaires

Questionnaires were sent by GPs via the Qualtrics system for online questionnaires from December 2020 to January 2021, and participants could complete and upload them online.

To understand how relative outsiders viewed the platform, patients who had not used it were asked about their digital activity in daily life and their opinion of the platform after receiving information about its aims and content ([Multimedia Appendix 1](#)). We used multiple choice and 7-point Likert scales and recorded their age, sex, and chronic disease to enable comparison with users.

To clarify the practical aspects of the platform, users were asked to provide an evaluation by completing the SUS. In addition, the IPQ-K and SF-12 standardized questionnaires were completed, and we obtained data on age, sex, chronic disease, and health-related quality of life.

Interviews

Patients and GPs who used the platform were interviewed by phone until saturation (15 patients) or until no additional participants were available (4 GPs). The interviews included general questions about IT and digital health, personal experiences with the platform, effort expectancy, user intentions, barriers, and facilitators. Factors were chosen based on the health

belief model and the UTUAT model. Quotes from interviews are used to illustrate the study findings.

Data Analysis

Questionnaire data were analyzed descriptively using proportions and numbers. All interviews were recorded and transcribed verbatim. Thematic and axial coding were used to analyze the qualitative data, starting with the main interview themes, before performing deductive coding to look for patterns in the transcripts. ATLAS.ti (ATLAS.ti Scientific Software Development GmbH) was used for coding.

Results

Element 1: Questionnaire Responses of Platform Nonusers

In total, 20 patients (55% female, average age 69 [SD 9] years) completed the questionnaire. The main chronic diseases were hypertension/cardiovascular disease, chronic respiratory disease, and a few individual cases of thyroid disease and prostate hypertrophy. Age, sex, and chronic disease characteristics were comparable with users.

All respondents had access to the internet at home, with 85% (17/20) using laptops or smartphones, 60% (12/20) using tablets, and 50% (10/20) using desktop computers at least weekly. When asked about their digital skills, one considered computer use and two considered smartphone use a bit difficult, while the remaining 85% (17/20) considered themselves digitally skilled. Two respondents considered technology a bad development for health care because they wanted “to be treated as individual and not as robot” or “to have a GP in front of me to spar together.” Those who thought it was a good development liked the speed and efficiency of the process for patients and GPs, stating “it can be practical and reduce time to have digital consultations.”

According to 35% (7/20) of respondents, they expected that communication with the health care professional would change

when using the platform. One did not expect that the information provided would be treated confidentially, while 40% (8/20) wanted to share their data in the platform with other health care professionals. The following free-text comment was made regarding data exchange:

I have reservations. Not so much about the app itself, but...about the handling, data processing, and follow-up. Treatment and cure is more than collecting data. [Patient]

Overall, however, slightly more than a third (35%) would recommend the platform after they received an explanation of its functions.

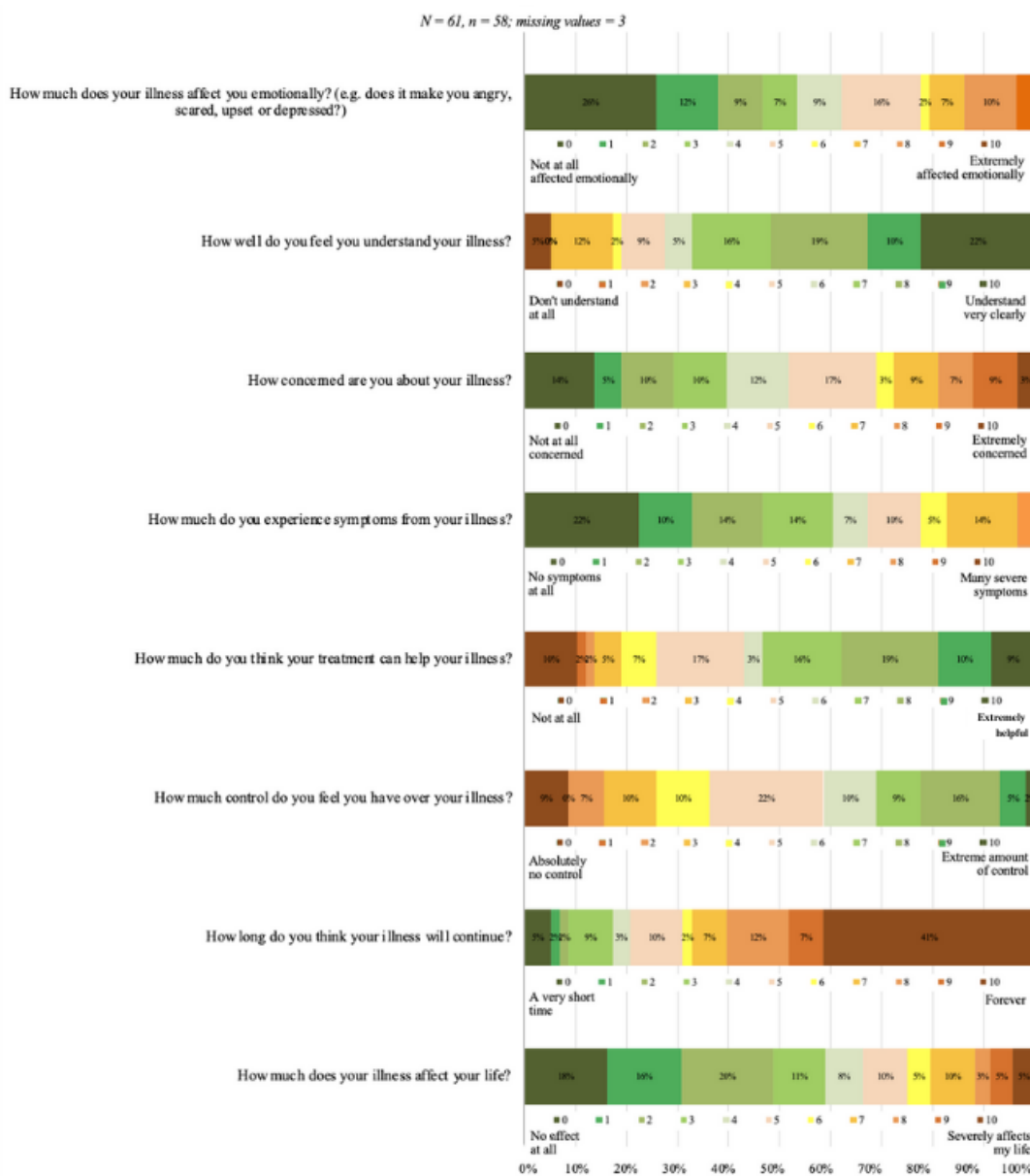
Element 2: Questionnaire Responses of Platform Users

Among the patients who used the platform, 61 partially completed and 58 fully completed the 3 questionnaires (33/61, 54.1% female, average age 62 [SD 8] years).

IPQ-K Instrument

Users more often reported that they are largely unaffected by symptoms, will have them for life, have some control over them, know that treatment helps, and that they cause only moderate worry (Figure 1). They typically reported having a good understanding of their complaints and that these did not severely influence their mood. In general, the complaints had a relatively minor impact on patients. The 3 most frequently mentioned causes of their complaints were stress, heredity/genes, and lifestyle habits (eg, overeating, alcohol, and lack of exercise), while events (eg, COVID-19 or an accident) or mental/physical conditions were mentioned less often.

Figure 1. Results of Illness Perception Questionnaire–Short.

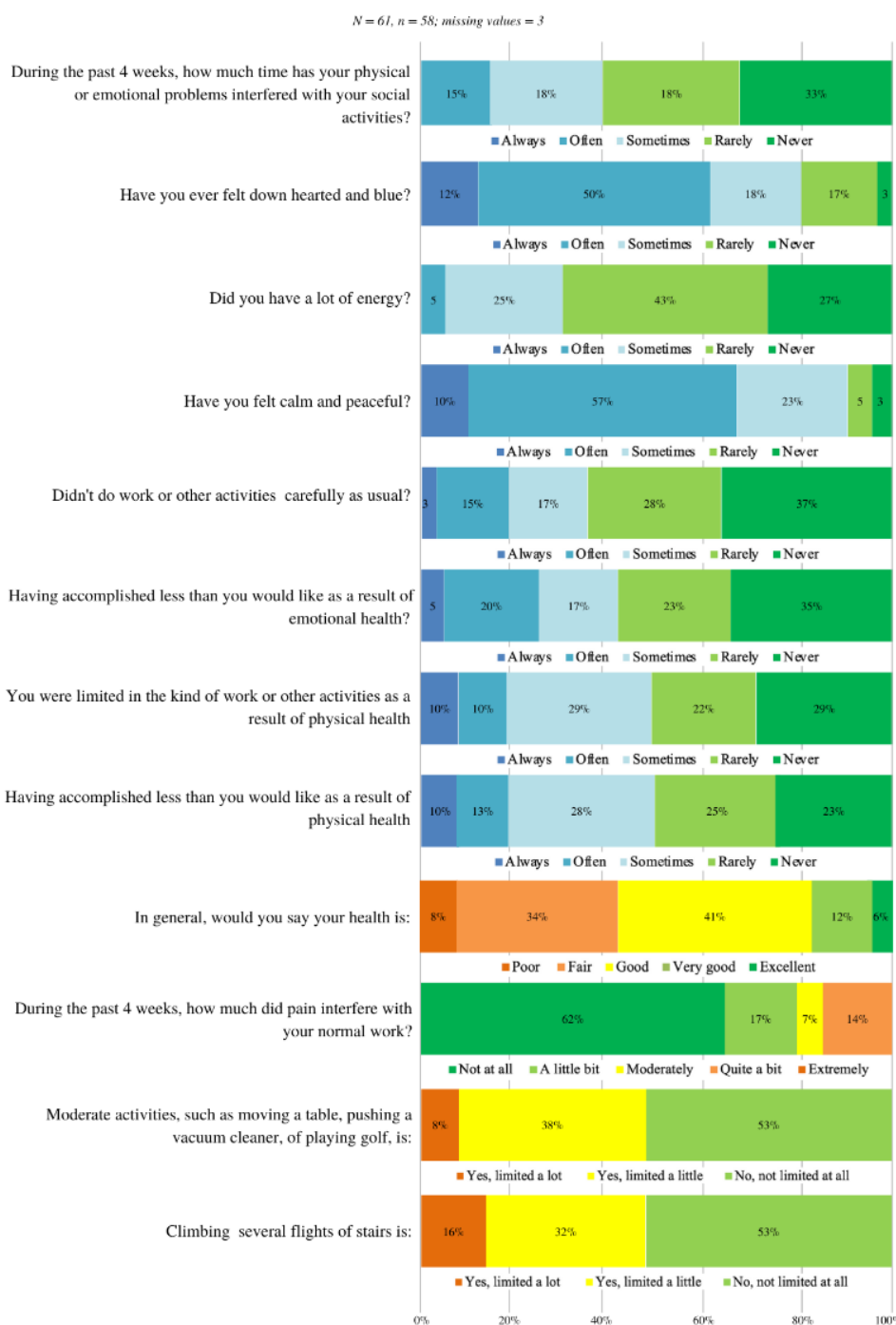


SF-12 Instrument

Figure 2 summarizes the questions and responses concerning health-related quality of life among platform users. Patients who used the platform rated their health from poor to excellent, with most considering it fair or good. Over half (30/59, 50.8%) indicated that they were not limited at all when engaging in moderate levels of exertion, with most users considering themselves somewhat or not limited by their symptoms.

Regarding how health affected work and other daily activities, the distribution varied from sometimes to never being affected. Moreover, users were typically never or rarely bothered by their mental health, while most were not hindered at all and none were hindered very much by pain. In the 4 weeks preceding the questionnaire, users typically reported that they felt calm and content, had a lot of energy, did not feel gloomy or dejected, and were rarely or never hindered by their physical or emotional health during social activities.

Figure 2. Short Form Survey–12 Item: summary of responses for health-related quality of life among platform users.



SUS Instrument

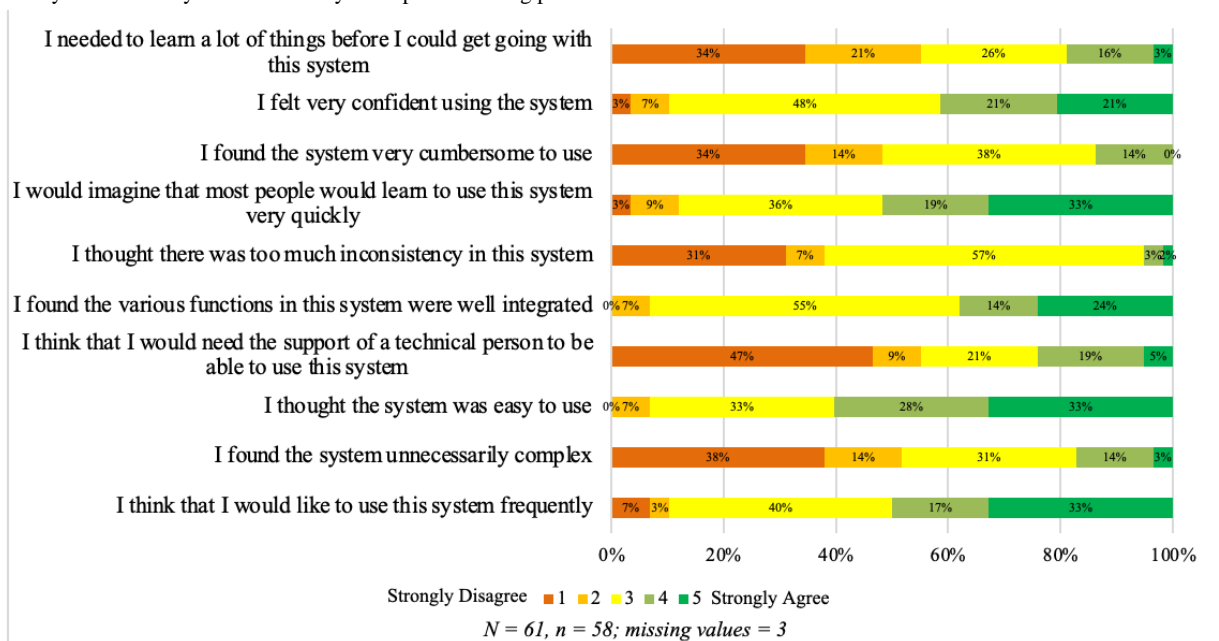
Users indicated the extent to which they agreed or disagreed with each of 10 statements (Figure 3). Only 10.1% (6/59) of

users stated that they will not use the platform regularly, with 6.8% (4/59) answering that it was not easy to use. Almost a quarter (14/59, 23.7%) of users mentioned that they would like to receive external support while using the platform. Users were

neutral on the statements regarding how well functions were integrated (33/60, 55.0%), the presence of inconsistencies (34/60, 56.7%), whether most people will learn to use the platform quickly (21/59, 35.6%), whether the platform is too cumbersome (23/60, 38.3%), and whether they felt confident using the platform (29/60, 48.3%). However, users typically disagreed completely with the statements that the platform was

unnecessarily complicated (23/60, 38.3%), that they needed technical support (28/59, 47.4%), or that they had to learn a lot before they could use the platform (21/66, 35.0%). The total SUS value was 66.55 (on a scale of 0-100), which is below the threshold of 68 for acceptability [26]. However, most of the users (45/59, 76.3%) positively recommended the platform with various degrees of enthusiasm.

Figure 3. System Usability Scale: summary of responses among platform users.



Element 3: Interviews With Users (GPs and Patients)

Participants

All participating GPs from the 3 practices that use the platform took part in the interviews (n=4; average age 46 years; 3 females; average interview duration 53 minutes) together with

their patients who use the platform (n=15; average age 63 years; 9 females; average interview duration 32 minutes). The chronic conditions of users were similar to those of nonusers, with most suffering from cardiovascular and pulmonary chronic conditions. Some had more than one chronic disease. Interview results are described by topic and summarized in Table 2.

Table 2. Overview of topics and themes concerning the platform, as identified by questionnaire and interview.

Interview topics and themes	Examples
Overall opinions	
Factors that may influence use	Viewpoint of GP ^a
Recommendation to other patients	Not hypochondriac and must be digitally literate
Recommendations for the platform	Personal health environment and need to expand before it is efficient
User experience and needs	
Use of other features	Interest in other features (eg, scale, Fitbit, and glucose meter)
Learning process for using the platform	Learning how to use the platform
User friendliness	Easy interface
Satisfaction measuring tool	Three easy-to-use measurements
Continued use of the platform	Intent to continue using the platform
Advantages	
Time and task efficient	Workload reductions
Increased quality	More insight and involvement
Increased accessibility	Lower threshold for consultation
Self-management	More autonomy and empowerment
Limitations	
Fixed time	Felt rigid and strict
Technical questions	Difficulty using Bluetooth
Lack of communication	Sometimes a bit impersonal
Lack of feedback	Difficult to be motivated without a reaction

^aGP: general practitioner.

Time and Workload for Patients and GPs

A GP indicated that patient-centered care led to more efficient care and could be supported by digital health. This can improve quality and accessibility, moving patients from a passive role to active self-management. All participating GPs indicated that the traditional model was no longer feasible due to high workloads, with one stating that the platform increased efficiency.

I think it is also quite easy for the doctor because all is arranged. ...they automatically receive a message about how the week went, and [if needed] they can call the patients or intervene. [GP]

One reason for the decreased workload was that improved self-management by patients can save time for GPs.

...it takes less time, so you can do more. Yes, you can do it with fewer people. How many exactly? Yes, that needs to be determined by experience. Time will tell that, but this does relieve the workload; that is obvious. [GP]

Of course, it saves a lot of time. You know the great thing about this way of working? You let the patient do a lot themselves and you lose the 'noise' from having to perform routine checks...which if it is done well...actually takes 5 minutes. [GP]

Although digital health saves on travel time and expenses for GPs and patients, its implementation requires an initial time investment to become familiar with the system. However, patients did state that GPs responded faster and could be contacted more easily.

I much prefer that I can reach my doctor with an e-consultation, or [that] when I call, I can schedule a call-back time. This is better than when I am on hold for half an hour. [Patient]

When I have finished a weekly measurement, it goes right to the GP...[and they]...see it...immediately. So, it is a lot faster. You need fewer steps to get to the goal. So, I think that's a very big advantage. [Patient]

Despite these positive experiences, some GPs warned that the system can increase workload. The contact options for patients can generate reminders and administrative actions. For example, one explained that she was unable to answer all the messages generated by patients. Some patients also used the platform more than needed, which GPs thought could increase workloads.

People check very often, so we may have to do something with that...because of course...you don't have to measure your blood pressure every day. [GP]

Personalized Care

Where time was saved by GPs using the platform, it could be used to improve patient-centered health care by allowing GPs to afford patients additional support.

Performing a hypertension check is of course not interesting...for the patient [or] the doctor. So that does not contribute much to your...relationship. But if you have a difficult period in your life, for whatever reason, and you just had several conversations and contacts with your doctor during that period, then you build a bond. [Patient]

Although most patients and GPs experienced the advantages of personalized care through the platform, there were also a few who experienced the tool and digital health in general as more impersonal than traditional care.

The human dimension is becoming less and less important in health care. People must justify everything. A person is a person...not a machine. So yes, the interaction is also lessening...deteriorating. [Patient]

Quality of Care

Opinions regarding care quality varied, with both positive and negative effects mentioned. Repeated monitoring by patients can help them feel seen by their GP, creating a sense of safety when GPs intervene because values indicate poor disease control. Patients with chronic illness who require support but never visit the practice can also be reached more easily because the platform is more accessible. Measurements are also more accurate because they are taken frequently, over a longer period, and at home, minimizing the potential stress and inconvenience of testing in a clinical setting. Prevention is another advantage of digital health. GP visits can become more efficient because evaluation has already started.

My doctor can monitor me without me noticing. You can have a precautionary look with each other, based on numbers, before having an appointment. I think that's a big advantage. [Patient]

Accessibility of Health Care

Patients and GPs were generally positive about the digital platform, viewing it as the future of health care. Having the support of GPs was crucial to implementing change because all patients initially started to use the platform based on a GP's recommendation. When patients were actively involved with their GP, they tended to be enthusiastic about the platform. Patients felt the platform improved accessibility.

Because it's just a lot easier. It's fast, simple, and works well. [Patient]

I can start using those questionnaires...I find it useful that it can be done remotely, even in a non-Corona era; I think it is just practical. [Patient]

The digital skills of patients also affected accessibility, but patients typically had no problems.

Once you have it installed on your phone...it is not that difficult. [Patient]

Physicians added that frail patients may not be able to take full control, but that monitoring should be possible in all cases. Technical problems could also affect accessibility to digital health services. For example, patients had difficulty using Bluetooth and synchronizing with the blood pressure monitor. They indicated that it sometimes worked and sometimes did not.

When I switch on my iPad, it synchronizes to the blood pressure monitor. Then it indicates that synchronization was successful and includes the result in a graph. [The last few times]...something has gone wrong in that process. [Patient]

Most agreed that the platform was very user-friendly, with an interface that was clear and easy to use.

What I have used was quite simple, I must say. [Patient]

I think it is very good. I can quickly look up patient data. [GP]

However, patients wanted better instruction and communication about services, with some not knowing why a device was being used or who to approach with queries.

Self-management by Patients With Chronic Illness

It was noted that the platform requires that patients take an active role in managing their disease, which can represent an important change.

The patient starts to work on his own health, hopefully. That's the idea. I really hope that it will give patients more insight into their disease and perhaps improve control. [GP]

It is demanding for the patient [who] must understand what it is about and that it is best if he is also in charge of it himself. It is no longer what you [the GP] are going to do about it, but what [he] can do about it [him]self? [GP]

GPs believed that patients could take this role but that some do not want to and will not benefit from the platform. Therefore, patients must show enthusiasm to be deemed eligible. Care must also be taken to exclude patients considered vulnerable, known to be illiterate, or with intellectual/cognitive limitations who lack the skills needed for self-management, specifically through a digital platform.

Patients generally agreed on the importance of self-management and empowerment.

You do get a picture of how you are doing. Especially if your blood contains too much sugar...it is very good to be able to check that yourself. Yes, I think that is important...it is very good if you can control that yourself. I always say you are responsible for your own health. [Patient]

Discussion

Principal Findings

There was general agreement that the digital platform offered benefit from reducing time commitments and workloads for

patients and GPs when used with appropriately selected patients. The quality and accessibility of care improved through greater patient-centeredness and a lower threshold for contact through different channels, respectively. Importantly, the self-management required by the tool increased patient autonomy and empowerment, and users considered the platform to be feasible, being both usable and easy to learn to use. However, they reported some minor technical issues (eg, Bluetooth connectivity) and wondered if people with fewer digital skills could manage.

It was notable that patients who had not used the platform but who had received the explanation were least positive about this new approach to chronic care management. Although they were relatively experienced and skilled with digital media, only a minority of the nonusers would recommend the platform due to concerns over data security and handling. This might be explained by there being less trust in digital health interventions when they have not experienced the tool themselves [27]. Among platform users, the percentage who would recommend the platform increased to approximately 76%, although the SUS score of 66.55 was just below the score of 68 required to claim success [28]. Active patient involvement in new health initiatives can decrease hesitation toward innovations and contribute to higher acceptance and support of a digital tool that may offer new insights and introduce new elements [29].

From the results of the IPQ-K, it can be interpreted that the study participants typically had a good understanding of their complaints with the impression that treatment could affect their health although it would probably stay with them for the rest of their lives. Compared to other populations with chronic diseases, they score relatively high but this is probably related to the fact the study population has relatively limited levels of multimorbidity as they are still supervised in the primary care setting [30]. However, the results from the SF-12 show that around half of the population is prevented from accomplishing the work and activities they would like to due to their physical and emotional health. This also reflects that the majority expresses impact on their energy levels and mood, which is often a risk in populations with chronic diseases [31,32]. Most respondents reported being digitally literate, which is not surprising because this first version of the platform was considered unsuitable for highly vulnerable patients. As with most digital innovations, we first introduced it among people who are both digitally and health literate [33]. Although users did not know all the available functions, they did tend to find the platform easy to use. Further analysis of what these users require, possibly with better education about what is already included, could improve utility among IT literate populations with less severe chronic illness. This endeavor will hopefully lead to greater awareness of the needs of less digitally or health literate patients with chronic illness who are so often forgotten [34].

An important element to take into account is that the platform started in April 2020 when Covid stressed the relevance of distance monitoring of patients and worked as a catalyzer for health care organizations to implement digital health, and more specifically telemonitoring, among vulnerable and chronically

ill populations [35]. This definitely has positively influenced the uptake of the platform.

Opinions were divided regarding platform expansion. While GPs indicated that communication with other parties and improved data linkage to the GP information system was possible, patients were either neutral or had mixed opinions. Some patients wanted a personal patient environment, but others thought that the system was complicated enough. One GP agreed with this, elaborating to state that the platform should be simplified to have fewer functions and include less information, in line with the need for simplicity in use and scalability for digital health interventions in different settings [36]. This might also be further elaborated on when using the tool in populations with a lower digital literacy.

Patients saw that the digital platform brought many benefits, including improved efficiency, time savings, better care, and greater personal control over their illness. By contrast, GP opinions were more divided about whether the platform leads to preoccupation with illness and even restlessness, with some expressing concern that self-management changes the doctor-patient dynamic. This has been seen in similar interventions in neighboring countries [37]. It would be worthwhile to explore further what specific groups of patients with chronic illness are least and most suited for this type of platform.

Potential obstacles included the fixed time at which measurements were required, lack of communication and feedback, impersonal nature, and technical problems. Feedback was considered particularly necessary to ensure that patients know they are not measuring for nothing. Indeed, feedback is essential to achieve behavior change or ensure that patients take their medications and measurements [38]. Moreover, users were positive about the platform during this development phase, but they were neutral about whether they will use it regularly. This will depend not only on whether the platform is part of their treatment but also on the support and enthusiasm of the GP and their practice. While there is a responsibility for patients to use the platform, there is an equal responsibility for practitioners to keep the platform relevant. The role of the GP in these innovations should not be underestimated [39]. They also play an important role in influencing patients on the levels of perceived benefits and expected improvements in outcomes in the health belief model and UTUAT, which is also shown in other studies to be beneficial for adopting digital innovations [40].

GPs considered digital health to be the future, offering a good solution for organizing care more efficiently and positively influencing the doctor-patient relationship, as suggested elsewhere [41]. However, some patients considered the platform impersonal and were neutral about its impact on their relationship with the doctor. GPs thought that patients who avoid in-person care may have a lower threshold for using the platform than seeking in-person consultations and that any measurements will be more accurate. Although monitoring was considered possible for every disease group, it was mentioned that patients must be enthusiastic and have the necessary digital skills.

GPs were also concerned about the initial time investment and possible increased workload. This is an important consideration given that they need to be motivated. Similar studies have found that enthusiastic GPs can realize the extra impact on their work [42], but as in this study, they anticipate that benefits will come later. An important consideration in this is the tipping point at which an innovation used by a large group starts to become more efficient [43]. Current nonusers indicated that they would like to be notified when results are good, which could be a problem when a larger number of patients use the platform and are monitored. Handing control to patients could lead to the valid concern of actionable items increasing for GPs [42], with uncertainties about where to draw the line for blood pressure results and how to identify patients who are not completing the questionnaires correctly (or who do so too often). Another important element for motivation and reduction of perceived workload is that the integration of these kind of platforms with existing electronic health records should be very smooth [44].

Recommendations to Remove Barriers and Facilitate Implementation

Some barriers and potential facilitators related to implementation are detailed in Table 3. Patients need to understand how a given digital platform works. Information videos or clear and simple instructions could offer value, especially for patients who cannot see the potential benefits of the platform. Patients require a clear explanation of when they must measure, when they must stop, why it is necessary, when they have to contact the GP again, and whether the GP has access to their data. GPs and patients may be more likely to use the digital platform if they can add or remove features as needed. For example, a GP may wish to remove some features, while a patient may want to use different measuring instruments (eg, a Fitbit). Here, flexibility may be key.

Table 3. Recommendations to facilitate implementation and remove barriers.

Recommendation	Example
Ensure that there is sufficient information about the digital platform, its use, and the goals.	A manual or introductory video can help.
Be clear about what information the health care provider can view and when contact will occur.	Create standardized messages and discuss uncertainties before starting.
Avoid fixed measurement times.	This could be resolved by giving patients control over when to take measurements.
Make the platform adaptable to the users.	Certain functions could be added or removed from the user's personalized online environment.
Ensure balance between digital and in-person consultations to ensure that the platform is not experienced as impersonal.	Try to provide consultations at regular levels, either in person, by phone, or via the app, depending on the patient.
Start using the platform with patients who are less digitally and health literate to ensure that the whole population can benefit from the tool.	The population currently using the tool is clearly interested and equipped to work with such tools, but we must ensure applicability to all groups with additional research.

GPs indicated that it was useful to meet with a patient first to explain the process, but they also expressed concern that this can be time consuming. Both GPs and patients wanted medical questions to be resolved by the GP and technical questions to be resolved by the platform developer, requiring clarification on how the developer can be reached. Clear communication between the patient and GP also appears necessary, possibly with quarterly or yearly check-ups or a method to communicate when measurements are above or below that expected. Similarly, offering a standardized message when readings are within reference limits could prove beneficial, as has also been shown in the literature [44]. Functions must be adaptable to the patient, making it possible to take measurements on their own schedule to remove this obstacle and increase autonomy. Of course, measurement timings will still need to be specified (eg, 12 hours apart, every morning) based on clinical need and relevance, like measuring 1 week quarterly instead of daily the whole year round [45]. Given that patients in this study thought that digital health could appear impersonal, a balance will need to be struck with in-person consultations.

Strengths and Limitations

The major strength of this study is that various groups gave feedback on our digital platform for chronic care, with patient users and nonusers and GPs being involved in the implementation. This gives an interesting insight into how the attractiveness and interest for the digital health platform differs among the 3 groups. Another strength is that we used triangulation by evaluating experiences on the platform through questionnaires and interviews. However, there were some important limitations. First, there was the potential for bias in the questionnaires received from patients within the health care practice. It could be that both the patients and the participating GPs had greater motivation than their peers in the general population, an issue that could affect the generalizability of our findings. Second, the interviews took place early in the implementation, so they may need to be repeated to see if there have been any developments. This will also be needed because the intervention will be adjusted based on this feedback to improve not only the platform and its implementation but also the outcomes and experiences of all participants.

Conclusion

This study highlights the benefits of a digital platform for chronic illness in primary care along with the barriers and facilitators experienced by users. Both GPs and patients see this as an innovative tool that represents a good development improving care by offering time savings, greater efficiency, and greater patient-centeredness through improved autonomy and

empowerment. Users considered the fixed measurement schedules, impersonal nature, time investment in learning and use, and poor communication and feedback to be the main barriers. Based on these findings, several recommendations have been developed that might improve the implementation of this or similar platforms in the future. Research must now focus on how to ensure that all patients gain benefit.

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Conflicts of Interest

OvD is founder and CEO of MedicineMen, and JC is technical assistant at MedicineMen. All other authors declare that they have no conflicts of interest.

Multimedia Appendix 1

Original questionnaire in Dutch.

[[PDF File \(Adobe PDF File\), 150 KB - formative_v6i8e38424_app1.pdf](#)]

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Abbreviations

GP: general practitioner

IPQ-K: Illness Perception Questionnaire–Short

IT: information technology

SF-12: Short Form Survey–12 Item

SUS: System Usability Scale

UTUAT: unified theory of acceptance and use of technology

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Original Paper

Comparing Web-Based Venues to Recruit Gay, Bisexual, and Other Cisgender Men Who Have Sex With Men to a Large HIV Prevention Service in Brazil: Evaluation Study

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Abstract

Background: Internet and mobile phones, widely available in Brazil, could be used to disseminate information about HIV prevention and to recruit gay, bisexual, and other cisgender men who have sex with men (MSM) to HIV prevention services. Data evaluating the characteristics of MSM recruited through different web-based strategies and estimating their cost and yield in the country are not available.

Objective: We aimed to describe a web-based recruitment cascade, compare the characteristics of MSM recruited to a large HIV prevention service in Rio de Janeiro according to web-based venues, and estimate the cost per participant for each strategy.

Methods: We promoted advertisements on geosocial networking (GSN) apps (Hornet and Grindr) and social media (Facebook and Instagram) from March 2018 to October 2019. The advertisements invited viewers to contact a peer educator to schedule a visit at the HIV prevention service. Performance of web-based recruitment cascade was based on how many MSM (1) were reached by the advertisement, (2) contacted the peer educator, and (3) attended the service. We used chi-square tests to compare MSM recruited through GSN apps and social media. The estimated advertisement cost to recruit a participant was calculated by dividing total advertisement costs by number of participants who attended the service or initiated preexposure prophylaxis (PrEP).

Results: Advertisement reached 1,477,344 individuals; 1270 MSM contacted the peer educator (86 contacts per 100,000 views)—564 (44.4%), 401 (31.6%) and 305 (24.0%)—through social media, Grindr, and Hornet. Among the 1270 individuals who contacted the peer educator, 36.3% (n=461) attended the service with similar proportion for each web-based strategy (social media: 203/564, 36.0%; Grindr: 152/401, 37.9%; and Hornet: 107/305, 35.1%). MSM recruited through GSN apps were older (mean age 30 years vs 26 years; $P<.001$), more frequently self-reported as White (111/247, 44.9% vs 62/191, 32.5%; $P=.03$), and had higher schooling level (postsecondary: 157/254, 61.8% vs 94/194, 48.5%; $P=.007$) than MSM recruited through social media. GSN apps recruited MSM with higher HIV risk as measured by PrEP eligibility (207/239, 86.6% vs 133/185, 71.9%; $P<.001$) compared with social media, but there was no difference in PrEP uptake between the two strategies ($P=.22$). The estimated advertisement costs per participant attending the HIV prevention service were US \$28.36 for GSN apps and US \$12.17 for social media. The estimated advertisement costs per participant engaging on PrEP were US \$58.77 for GSN apps and US \$27.75 for social media.

Conclusions: Social media and GSN app advertisements were useful to disseminate information on HIV prevention strategies and to recruit MSM to a large HIV prevention service in Brazil. Compared to GSN apps, social media advertisements were less expensive and reached more vulnerable and younger MSM. Digital marketing campaigns should use different and complementary web-based venues to reach a plurality of MSM.

KEYWORDS

social media; web-based recruitment strategies; men who have sex with men; pre-exposure prophylaxis; PrEP; HIV prevention; Brazil; Latin America; HIV

Introduction

Gay, bisexual, and other cisgender men who have sex with men (MSM) are disproportionately affected by HIV infection in Brazil [1], with HIV prevalence estimated at 18.4% [2]. Recent data point to increased prevalence of HIV among young MSM aged 18-24 years [3]. Since 2017, Brazil has been offering oral preexposure prophylaxis (PrEP) at no cost to individuals eligible for PrEP, including MSM [4]. However, increasing awareness of PrEP and other HIV prevention strategies among most vulnerable MSM, including young and those with lower income, remains a challenge [5].

Rio de Janeiro metropolitan area has more than 13 million inhabitants, the 16th largest urban area in the world [6]. Rio de Janeiro has a disproportionately large number of vulnerable individuals who live on the outskirts of the city. These social inequalities have great consequences for health access [7], including inadequate HIV care and prevention [8], which were intensified after the onset of the COVID-19 pandemic [9]. Among MSM from Rio de Janeiro, HIV prevalence was estimated at 15.3% in 2016 [2] and increased among those aged 18-24 years from 4.4% to 13.3% between 2009 and 2016 [3].

Internet and mobile phones are widely available in Brazil and could be used to disseminate information about HIV prevention services. Despite large inequalities, Brazil has a large number of internet users in all social strata: 74% of individuals receiving a minimum monthly wage (US \$220.00) have access to the internet [10]. In Southeast Brazil, where Rio de Janeiro is located, 91% of the population have a mobile phone [11], and 99% have access to internet or apps via mobile phones [12].

Social media and geosocial networking (GSN) apps for sexual encounters (eg, Grindr, Hornet, and Scruff) are popular among MSM in Brazil [5,9,13,14]. A meta-analysis including 25 studies conducted in Australia, China, India, Thailand, and the United States showed that app users may have a higher prevalence of sexually transmitted infections (STIs) than nonusers [15]. In a web-based survey enrolling 11,367 Brazilian MSM, 93% reported using apps to seek sex partners, 54% of them with daily use. Willingness to use PrEP was similar among different sources of web-based recruitment, including GSN apps (Grindr and Hornet) and social media (Facebook and Instagram) [13].

Although different web-based venues have been used to recruit MSM, there are no Brazilian data evaluating the characteristics of MSM recruited through these strategies and estimating their cost and yield in the country. In this paper, we aimed to (1) describe the web-based MSM recruitment cascade, (2) compare the characteristics of MSM recruited to a large HIV prevention service according to different web-based venues, and (3) estimate the cost per individual of each strategy.

Methods

Study Design

We performed a digital marketing campaign targeting MSM from March 2018 to October 2019 using advertisements on GSN apps (Hornet and Grindr) and social media (Facebook and Instagram) to increase HIV knowledge, HIV testing, and PrEP awareness. The Instituto Nacional de Infectologia Evandro Chagas, Fundação Oswaldo Cruz (INI-Fiocruz) study team designed and implemented the campaign [16]. INI-Fiocruz has the largest HIV prevention service for adults (18 years or older) in Rio de Janeiro city and its metropolitan area in Brazil. The service is part of the Brazilian Public Health System (*Sistema Único de Saúde* [SUS]) at no cost to the user.

Recruitment Strategies

Hornet and Grindr are popular among MSM in Brazil, and recruitment using these GSN apps has been used in previous cross-sectional studies conducted in the country [5,9,13,14,17,18]. We used direct inbox messages and banners to advertise on Hornet and Grindr, respectively. In addition, we created posts on social media (Facebook and Instagram), which were boosted and appeared at user's feeds. We targeted social media users interested in subjects related to LGBTQIA+ people (people of diverse genders and sexualities, inclusive of and not limited to lesbian, gay, bisexual, transgender, queer, intersex, asexual, questioning, and pansexual) communities. Advertisement messages were built during meetings with key members of MSM communities from different socioeconomic status and race. These advertisements had information about HIV prevention and invited viewers to contact a peer educator (via phone number, email, and WhatsApp) to schedule a visit at the HIV prevention service for HIV risk assessment, HIV testing and referral to PrEP or postexposure prophylaxis (PEP).

Variables

All MSM referred by the peer educator who attended the HIV prevention service answered semistructured interviews conducted by trained counselors. Covariables were age at the time of the visit (categorized in 18-24, 25-35, and >35 years); race (Black, Pardo or mixed, and White); schooling (elementary [≤ 9 years], secondary [10-12 years] and postsecondary [>12 years]) and Municipal Human Development Index, a 3-level dimension measure of human development (life expectancy, education, and income), dichotomized into very high (≥ 0.800) or other (< 0.800) [19].

HIV testing was offered to all individuals who attended the HIV prevention service. HIV status was dichotomized into negative and positive according to HIV rapid test results, following Brazilian recommendations [20]. Counselors evaluated all HIV-negative MSM for PEP and PrEP eligibility based on Brazilian National Guidelines. Individuals reporting condomless

sex in the previous 72 hours were referred for PEP [21]. MSM with at least one of the following criteria in the last 6 months were eligible for PrEP: (1) condomless receptive anal sex, (2) sex with partner living with HIV, (3) transactional sex (in exchange for money, goods, and benefits, among others), and (4) history of STI [22]. PrEP uptake was defined as the number of participants who initiated PrEP divided by the number of participants eligible for PrEP [23].

Data Analyses

We evaluated the web-based recruitment cascade for Hornet, Grindr, and social media based on the number of MSM who (1) viewed the advertisement; (2) contacted the peer educator; and (3) attended the HIV prevention service. Conversion rate was calculated dividing the number of MSM who contacted the peer educator by those reached by advertisements. We used chi-square test to compare the characteristics of MSM recruited through dating apps (Hornet and Grindr) with those of MSM recruited by social media (Facebook and Instagram). We estimated the advertisement costs (in US dollars) to recruit one participant to HIV prevention service by dividing total advertisement costs by the number of individuals who attended the service (GSN apps or social media). Lastly, we used the same rationale to estimate the cost per individuals engaging on PrEP. All analyses were conducted in R Studio, using R version 4.0.3 (R Foundation for Statistical Computing).

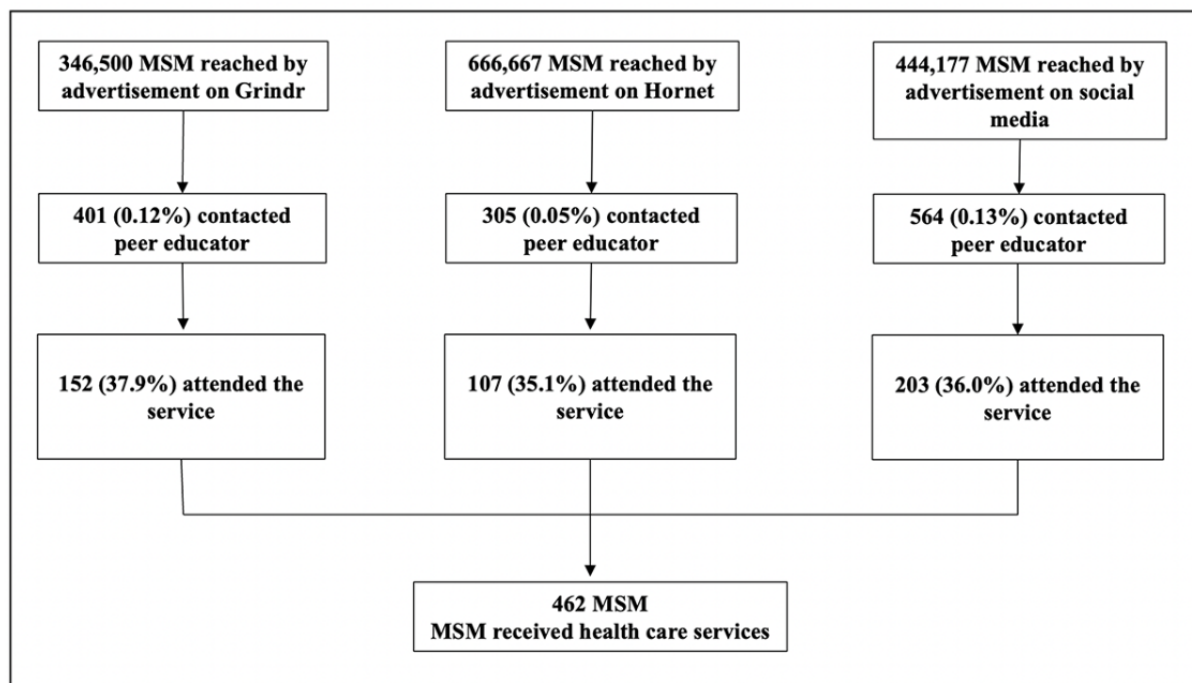
Ethical Considerations

This study was reviewed and approved by the INI-Fiocruz institutional review board (#CAAE 26095519.1.0000.5262). The board waived the informed consent as data were collected retrospectively from participants' charts and exams collected at INI-Fiocruz during HIV testing or prevention routine. Most participants attended the service only once, and personal information such as telephone number or address were nonexistent or outdated, avoiding collection of informed consent a posteriori.

Results

Our marketing campaign (all strategies combined) reached 1,477,344 individuals—346,500 (23.8%) from Grindr, 666,667 (45.7%) from Hornet, and 444,177 (30.5%) from social media (Figure 1). Overall, 1270 MSM contacted the peer educator (86.0 contacts per 100,000 views), with a higher conversion rate on social media (564/444,177, 0.13%) compared to Grindr (401/346,500, 0.12%) and Hornet (305/666,667, 0.05%). Among the 1270 MSM contacting the peer educator, 564 (44.4%), 401 (31.6%), and 305 (24.0%) were recruited on social media, Grindr, and Hornet, respectively. Of all 1270 MSM who contacted the peer educator, 36.3% (n=462) attended the HIV prevention service, with similar proportions for each web-based strategy (Grindr: 152/401, 37.9%; Hornet: 107/305, 35.1%; and social media: 203/564, 36.0%).

Figure 1. Web-based cascade to recruit gay, bisexual, and other cisgender men who have sex with men (MSM) for a large HIV prevention service at Rio de Janeiro, Brazil.



MSM attending the HIV prevention service (N=462) had a median age of 28 years (IQR 23-34), mostly self-identified as Black or Pardo (265/438, 60.5%), completed postsecondary schooling (251/448, 56.0%), and lived in very high Municipal Human Development Index neighborhood (301/461, 65.3%). A total of 38 (8.2%) MSM tested positive for HIV. Among the 424 HIV-negative MSM, 340 (80.2%) were eligible for PrEP;

PrEP uptake was 62.9% (214/340). Only 22 (5.2%) MSM were eligible for and initiated PEP.

MSM recruited by GSN apps were older (mean age 30 years vs 26 years; $P<.001$) and reported White race (111/247, 44.9% vs 62/191, 32.5%; $P=.03$) and higher schooling level (postsecondary: 157/254, 61.8% vs 94/194, 48.5%; $P=.007$)

than MSM from social media (Table 1). MSM from GSN apps reported higher HIV risk as measured by PrEP eligibility (207/239, 86.6% vs 133/185, 71.9%; $P < .001$) than MSM from social media, but there was no difference on PrEP uptake ($P = .22$).

The estimated advertisement cost per participant attending the HIV prevention service was US \$28.36 for GSN apps and US \$12.17 for social media. The estimated advertisement cost per participant engaging in PrEP was US \$58.77 for GSN apps and US \$27.75 for social media.

Table 1. Characteristics of gay, bisexual, and other cisgender men who have sex with men (MSM) recruited to HIV prevention service according to web-based strategies.

Characteristics	Total (N=462)	GSN ^a apps (n=259)	Social media (n=203)	P value
Age (years), median (IQR)	28 (23-34)	30 (24-37)	26 (23-31)	<.001
Age range (years), mean (SD)				
18-24	146 (31.7)	66 (25.5)	80 (39.8)	<.001
25-35	210 (45.7)	116 (44.8)	94 (46.8)	
>35	104 (22.6)	77 (29.7)	27 (13.4)	
Race, n (%)				.03
White	173 (39.5)	111 (44.9)	62 (32.5)	
Black	87 (19.9)	43 (17.4)	44 (23.0)	
Pardo or Mixed	178 (40.6)	93 (37.7)	85 (44.5)	
Schooling, n (%)				.007
Elementary	10 (2.2)	7 (2.8)	3 (1.5)	
Secondary	187 (41.7)	90 (35.4)	97 (50)	
Postsecondary	251 (56.0)	157 (61.8)	94 (48.5)	
MHDI^b, n (%)				.57
Very high	301 (65.3)	172 (66.4)	129 (63.9)	
Other	160 (34.7)	87 (33.6)	73 (36.1)	
HIV status, n (%)				.66
Negative	424 (91.8)	239 (92.3)	185 (91.1)	
Positive	38 (8.2)	20 (7.7)	18 (8.9)	
PEP^c initiation (n=424), n (%)				
Yes	22 (5.2)	11 (4.6)	11 (5.9)	.54
No	402 (94.8)	228 (95.4)	174 (94.1)	
PrEP^d eligibility (n=424), n (%)				<.001
Yes	340 (80.2)	207 (86.6)	133 (71.9)	
No	84 (19.8)	32 (13.4)	52 (28.1)	
PrEP uptake (n=340), n (%)				.22
Yes	214 (62.9)	125 (60.4)	89 (66.9)	
No	126 (37.1)	82 (39.6)	44 (33.1)	

^aGSN: geosocial networking.

^bMHDI: Municipal Human Development Index.

^cPEP: postexposure prophylaxis.

^dPrEP: preexposure prophylaxis.

Discussion

Principal Results

Our digital marketing campaign on different web-based venues was effective in recruiting MSM to a large HIV prevention

service in Brazil. We successfully reached and engaged diverse MSM of different ages and races and high PrEP eligibility. Nevertheless, MSM with lower education was the least accessed group, indicating that complementary recruitment strategies such as those on LGBTQIA+ venues or respondent-driven

sampling [24] may still be necessary to reach MSM at higher social vulnerability.

Social media recruited a larger proportion of young MSM, with lower income and schooling compared to those recruited via GSN apps. This underscores the importance of using social media to recruit MSM for HIV prevention services and to promote prevention campaigns targeting young MSM at HIV risk in Rio de Janeiro, Brazil. In addition, social media were more cost-effective to recruit individuals to attend the HIV prevention service and to use PrEP. Facebook was the most cost-effective web-based venue to recruit MSM to a qualitative study in Seattle [25] and was effective to recruit Latino gay couples in a study conducted in New York [26]. These findings confirm that social media platforms such as Facebook and Instagram could be used as an alternative option to reach and engage MSM in other HIV prevention services in resource-constrained settings such as Brazil.

By contrast, a study conducted in Philadelphia identified Grindr as the most effective strategy to recruit people for an HIV vaccine trial [27]. Although PrEP uptake did not differ between individuals recruited by different strategies, GSN apps were more effective in recruiting high-risk MSM, according to PrEP eligibility, compared to social media. As such, different web-based venues may be useful to recruit diverse MSM to HIV prevention services, especially young MSM, as shown in previous studies conducted in the United States [27,28].

Strengths

In addition to recruitment to the HIV prevention service, our campaign aimed to increase PrEP awareness, although the latter could not be measured in this study. Data from web-based surveys showed an increase in PrEP awareness in Rio de Janeiro, Brazil, from 2016 to 2018 [29], and 2020 national data indicated that 87% of sexual and gender minorities recruited on Hornet were aware of PrEP [9]. Moreover, HIV knowledge was associated with PrEP use among MSM eligible for PrEP in Brazil [17]. Digital campaigns are of utmost importance to promote information on HIV prevention, including PrEP and

other prevention technologies, among MSM. These results are particularly useful to develop public strategies and may contribute to designing campaigns to increase PrEP uptake in Brazil. Lastly, our study was conducted before the COVID-19 pandemic, and due to the increased use of digital recruitment for scientific studies [30], a more heterogeneous population would be expected to be reached nowadays.

Limitations

This study considered only MSM reached by a digital marketing campaign who contacted the peer educator. The advertisements may have reached other MSM who attended the HIV prevention service without contacting the peer educator or who attended other services in Rio de Janeiro, Brazil. Responses of web-based recruitment and PrEP or PEP eligibility were self-reported, thus introducing the possibility of recall, response, or social desirability bias. Participants reported sexual behavior during risk assessment for PrEP or PEP evaluation. However, data on sexual behavior practices have not been systematically collected, preventing further associations between web-based recruitment and sexual practices (eg, condomless receptive sex or transactional sex). This study helped to identify this issue, leading to modifications aiming to collect more detailed data on sexual behavior and other variables, such as substance use and previous STIs. Lastly, venue-based recruitment and peer referral may perform better than web-based recruitment for most vulnerable MSM (young, Black or Pardo, low-income, and low-educated individuals) [16], highlighting the importance of community networks.

Conclusions

Advertisements on social media and GSN apps were useful to disseminate information on HIV prevention strategies and to recruit MSM to an HIV prevention service in Brazil. Compared to GSN apps, social media advertisements were less expensive and reached more vulnerable and younger MSM. Our findings indicate that digital marketing campaigns should use different and complementary digital venues to reach diverse MSM.

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Conflicts of Interest

None declared.

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Abbreviations

GSN: geosocial networking

HDI: human development index

INI-Fiocruz: Instituto Nacional de Infectologia Evandro Chagas, Fundação Oswaldo Cruz

LGBTQIA+: people of diverse genders and sexualities, inclusive of and not limited to lesbian, gay, bisexual, transgender, queer, intersex, asexual, questioning, and pansexual

MSM: gay, bisexual, and other cisgender men who have sex with men

PEP: postexposure prophylaxis

PrEP: preexposure prophylaxis

STI: sexually transmitted infection

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Original Paper

Optimization of a Quality Improvement Tool for Cancer Diagnosis in Primary Care: Qualitative Study

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Abstract

Background: The most common route to a diagnosis of cancer is through primary care. Delays in diagnosing cancer occur when an opportunity to make a timely diagnosis is missed and is evidenced by patients visiting the general practitioner (GP) on multiple occasions before referral to a specialist. Tools that minimize prolonged diagnostic intervals and reduce missed opportunities to investigate patients for cancer are therefore a priority.

Objective: This study aims to explore the usefulness and feasibility of a novel quality improvement (QI) tool in which algorithms flag abnormal test results that may be indicative of undiagnosed cancer. This study allows for the optimization of the cancer recommendations before testing the efficacy in a randomized controlled trial.

Methods: GPs, practice nurses, practice managers, and consumers were recruited to participate in individual interviews or focus groups. Participants were purposively sampled as part of a pilot and feasibility study, in which primary care practices were receiving recommendations relating to the follow-up of abnormal test results for prostate-specific antigen, thrombocytosis, and iron-deficiency anemia. The Clinical Performance Feedback Intervention Theory (CP-FIT) was applied to the analysis using a thematic approach.

Results: A total of 17 interviews and 3 focus groups (n=18) were completed. Participant themes were mapped to CP-FIT across the constructs of context, recipient, and feedback variables. The key facilitators to use were alignment with workflow, recognized need, the perceived importance of the clinical topic, and the GPs' perception that the recommendations were within their control. Barriers to use included competing priorities, usability and complexity of the recommendations, and knowledge of the clinical topic. There was consistency between consumer and practitioner perspectives, reporting language concerns associated with the word *cancer*, the need for more patient-facing resources, and time constraints of the consultation to address patients' worries.

Conclusions: There was a recognized need for the QI tool to support the diagnosis of cancer in primary care, but barriers were identified that hindered the usability and actionability of the recommendations in practice. In response, the tool has been refined and is currently being evaluated as part of a randomized controlled trial. Successful and effective implementation of this QI tool could support the detection of patients at risk of undiagnosed cancer in primary care and assist in preventing unnecessary delays.

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KEYWORDS

cancer; primary health care; diagnosis; quality improvement; clinical decision support tool; general practice; pilot; feasibility; Clinical Performance Feedback Intervention Theory

Introduction

The diagnosis of cancer in primary care is complex, owing to the nonspecific nature of many presenting symptoms [1-3]. In particular, symptoms of cancer are often consistent with more common diagnoses [4-6]. This complexity can lead to delays in diagnosis and multiple visits to the general practitioner (GP) before cancer is considered [5], and significantly prolong the primary care interval (from a patient's first presentation to the GP up to specialist referral) [7,8].

While the factors that influence delays in diagnosis are multifaceted, a timely response to abnormal test results that may herald an underlying cancer can improve patient outcomes and reduce time to diagnosis [9-12]. In primary care, delays can be due to missed opportunities to consider a cancer diagnosis and arrange further investigations [13-15]. For example, over one-third of patients with iron-deficiency anemia are not investigated [16,17], and missed opportunities to investigate for gastrointestinal cancers in the presence of so-called *red flag* symptoms leads to delays [18]. While there is no population screening program for prostate cancer in Australia, rates of testing are high (close to 1.5 million prostate-specific antigen [PSA] tests were ordered in 2017) [19,20]. Controversy and confusion about PSA testing and changing guidelines, including altered thresholds for what is abnormal, all contribute to variable rates of follow-up in men with raised PSA levels [21-23]. Missed opportunities are also relevant in areas of new evidence [24]. Thrombocytosis has recently been identified as an important predictor in primary care for several cancers, including lung and colorectal, but many GPs may be unaware of this new evidence [25-27].

A previous systematic review of computerized decision support systems (CDSSs) to assist with the identification of patients at risk of an undiagnosed cancer found that they have the potential to minimize prolonged diagnostic intervals and reduce missed opportunities to diagnose cancer [28]. Quality improvement (QI) platforms involve a combination of interventions, which can include a CDSS with audit and feedback [29]. The evolution in technology allows for the use of the electronic medical record (EMR) to develop quality measures and to facilitate QI-based audit and feedback [30]. Practice population audit tools are complementary to CDSSs, in which algorithms are linked to a clinical knowledge base and produce patient-specific guideline-based recommendations or prompts for consideration at the point of care (PoC) [24,31].

While the development of QI tools is promising, challenges persist around implementation, especially when designed to identify patients who may be at risk of an undiagnosed cancer [28]. QI tools that are designed with continuous involvement and input from the end users are more likely to be effectively embedded in everyday practice [32]. This study explores the usefulness and feasibility of a novel QI tool using algorithms to identify inadequate follow-up of abnormal test results that could be indicative of an undiagnosed cancer and prompt further investigation.

Methods

Ethical Considerations

Ethical approval was granted by the University of Melbourne Human Research Ethics Committee and registered with the Medicine and Dentistry Human Ethics Sub-Committee (Ethics ID 1953614). Participation in the interviews and focus groups were voluntary, and informed consent was obtained from all study participants. Participants who completed an interview received gift vouchers (AU \$100) as a reimbursement for their time.

Participants and Study Design

The development of the QI tool Future Health Today (FHT) has been described elsewhere [33]. In summary, FHT consists of two primary components. The first, a PoC prompt, is a CDSS that provides guideline-based recommendations and is visible upon opening the patient's medical record ([Multimedia Appendix 1](#)). The second component is a web-based portal that contains an audit and recall tool, allowing practice staff to review the FHT recommendations at the practice population level and take steps for recall ([Multimedia Appendix 2](#)). Although FHT is designed to manage many different conditions, this study focused on the cancer recommendations. FHT uses EMR data to identify patients who may be at risk of an undiagnosed cancer using the results of abnormal tests (iron-deficiency anemia, raised PSA, and raised platelet counts) and patient information (age, sex, and previous cancer diagnoses). If no appropriate follow-up actions for these markers are identified, guideline-specific recommendations will prompt the GP to review relevant patient symptoms and guide further investigation.

FHT was implemented in 12 primary care practices in Melbourne, Australia as part of an optimization study prior to a cluster randomized controlled trial (RCT) [34]. GPs, general practice nurses (GPNs), and practice managers (PMs) were purposively sampled from 9 of the FHT pilot sites (3 sites did not receive the complete set of cancer algorithms due to limitations associated with pathology data in one EMR system). The PSA and platelet recommendations were released in December 2020, and the anemia recommendations were released in March 2021. Participants had been using FHT with recommendations for chronic kidney disease (CKD) for up to 3 months before the cancer algorithms were introduced. Interviews were conducted from February to May 2021; if the user had not seen the cancer recommendations via the PoC prompt during a consultation, the recommendations were shown using a demo of the tool over Zoom (Zoom Video Communications).

Data Collection

Semistructured interviews were carried out with GPs, GPNs, and PMs to explore their perspectives on the cancer module and recommendations for improving the tool. In addition, three focus groups were conducted, one with GPs and GPNs, and two with consumers. The general practice focus group explored the audit tool and barriers to use. Consumer focus groups explored

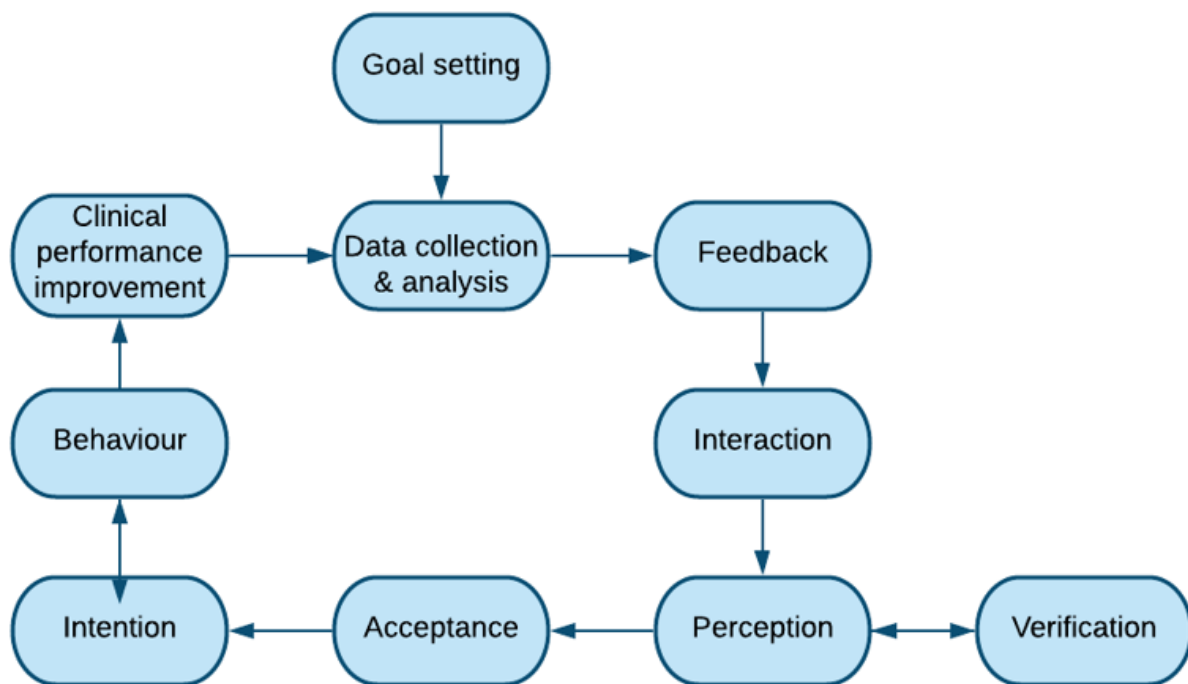
their perception of the cancer recommendations, barriers to uptake, and current priorities.

Data Analysis

We analyzed all interviews and focus groups using NVivo (version 12; QSR International). The transcripts were independently coded by two reviewers (SC and BH) using an inductive approach to identify themes in the data [35]. Discrepancies in the interpreted data were discussed by the two coders until a consensus was met. For the general practice data, we applied a deductive approach using the Clinical Performance Feedback Intervention Theory (CP-FIT) [36]. A number of frameworks were considered for this analysis. CP-FIT was chosen as it incorporates and builds upon 30 pre-existing theories and, unlike other frameworks, was developed specifically for health care to explain factors that influence feedback success. The theory posits that the feedback cycle

(Figure 1) is affected by feedback variables (eg, display and delivery), recipient variables (eg, knowledge of the clinical topic), and context variables (eg, the implementation process) [36]. It describes mechanisms such as compatibility and complexity, which explain how the variables influence the feedback cycle, and resulting clinical performance. In the context of FHT, guideline-based recommendations are communicated to GPs and GPNs. CP-FIT outlines the steps that the user moves through: algorithms are applied to the EMR (data collection and analysis); recommendations are delivered to GPs and GPNs (feedback); and the recommendation is received (interaction), interpreted (perception), and interrogated (verification). If there is acceptance of the recommendation, the user responds to the recommendation (intention and behavior), and ultimately, this leads to changes in patient care (clinical performance improvement) [36].

Figure 1. The Clinical Performance Feedback Intervention Theory feedback cycle.



Results

We conducted 14 interviews with participants from 6 general practice clinics. As not all participants had experienced the cancer recommendations in practice, follow-up interviews were

scheduled with 3 GPs (for a total of 17 interviews). Interviews ranged from 18 to 40 minutes. A total of 8 participants took part in the general practice focus group, of whom 4 had participated in individual interviews. There were 10 participants in the consumer focus groups. Participant characteristics are presented in Table 1.

Table 1. Characteristics of the participants and method of data collection

	Interview participants, n (%)	Focus group participants, n (%)
Role		
General practitioner	9 (64)	6 (33)
Practice nurse	4 (29)	2 (11)
Practice manager	1 (7)	0 (0)
Consumer	0 (0)	10 (56)
Gender		
Female	11 (79)	9 (50)
Male	3 (21)	9 (50)
Rurality of practice^a		
Metro	7 (50)	6 (75)
Regional/rural/remote	7 (50)	2 (35)

^aGeneral practice interviews and focus groups only.

CP-FIT

We mapped practice staff perspectives to CP-FIT. The resulting themes could be mapped across the three constructs: context, feedback, and recipient variables.

Context Variables

Organization and Team Characteristics: Workflow and Competing Priorities

Most participants reported using the CDSS either before or after the consultation; only 1 GP reported using it exclusively during the consultation. Opening the patient's file prior to the consultation aligned with the use of FHT, where participants could read, verify, or address the recommendation and, if needed, prepare and print off patient resources or investigation request forms.

In some ways I organise routine care for a consultation before I see the patient, because I won't remember once they've come in and told me all the medicines they need and those kinds of things. [GP2]

All practice staff reported competing priorities and an already busy schedule as a barrier to use for all components of the FHT tool.

I haven't had a lot of time to actually play around with the cohort and implement bringing people in. [PM1]

That was coupled with the priorities of the patient as a barrier to being able to address the recommendations during the consultation.

If time allows, I'll deal with it. It won't be the first thing because when the patient comes in, they're coming in because they want to come in. [GP8]

While most GPs felt that the recommendations were feasible, some discussed their limited ability to control the consultation and guide the patient to the issues raised by FHT because the patient comes in with their own agenda. This was also discussed in the context of being able to manage the prompts in a single

consultation because some recommendations may require long time-intensive conversations to address the patient's questions and potential worries.

But cancer's a huge thing - it was much easier to say, by the way, the kidney - this is bad therefore we should do this. Whereas the cancer one is much more nebulous and much more challenging and scary. [GP1]

For GPs who had seen the cancer recommendations in practice, half considered delegating some responsibility to either GPNs or medical students. This was driven by their ability to conduct longer consultations and focus on one specific issue raised by FHT.

Their [GPN] ability to engage patients at a level and to quickly put them at ease, I think is quite extraordinary [GP8]

Patient Population: Clinical Appropriateness and Choice Alignment

Participants were able to determine when the recommendation was not clinically appropriate for their patient. However, the balance of perceived risk (eg, patient distress or risks associated with further investigation) when deciding to investigate for cancer based on the platelet recommendation was raised by two GPs. This may be indicative of a knowledge gap on the association between raised platelets and undiagnosed cancer (see Recipient Variables section).

If you're going to do a CT of somebody's chest, you're clearly exposing them to radiation, what's the positive likelihood that you're going to find something if you're using platelets as a cancer marker? [GP2]

Participants frequently framed their reflections on FHT through the lens of their patient population. Some participants saw barriers to actioning the recommendations associated with the patient's health literacy, language skills, health complexity, and common anxieties associated with the word *cancer*. Others felt that their cohort of patients were well-prepared and responsive to recommendations from the GP.

Our patients are highly health literate. They're very interested in their health. They really are prepared to do something about it. We're very lucky. [GP6]

Implementation Process: Cost, Training, and Support

While the interviews focused primarily on the cancer module, there were themes around the implementation of the QI tool more broadly, which affected the uptake of the cancer recommendations. For all users, the perceived cost of the CDSS in relation to time was low. Overall, it was reported to be subtle and nondisruptive to the consultation, while the time and resource cost associated with using the audit tool was high and often described as a barrier to use.

I think really useful. It's all sitting behind in there if you want. It gives you options of having a quick look. It gives you options of re-skilling and it gives you the option of educating the patient as well. [GP3]

More than half of the participants reported perceived technical issues, which highlighted areas where more training was needed. For example, to access the audit tool, users needed training on the registration process and errors they may encounter from this process not being completed properly.

I haven't managed to get my head around exactly how it works [audit tool], so I'm only using the front [CDSS] which pops up on the patient. [GP2]

Feedback Variables

Goal: Importance, Controllability, and Relevance

The themes of importance, relevance, and perceived controllability were present in all participant interviews. The benefits of the intervention were visible to most recipients, and there was a recognized need for the recommendations, which included helpful reminders, reassurance, keeping up with changing guidelines, and ensuring timely action. There was also a recognized need for decision support tools in general.

So, I would be using these tools for re-educating me and ensuring I'm doing best practice because I'm getting older now and things change. [GP3]

However, exposure to the recommendations in practice highlighted a shift in priorities. Despite the recognized need for the recommendations, addressing the recommendation became less important and less relevant, as the GPs did not have enough information (see next section) or because of competing priorities.

Feedback Display: Usability and Framing

Significant barriers were identified relating to usability. This was due in part to the clarity, length, and language used in the recommendations, which required too much time to process in the time available. The way the recommendations were presented impacted the GP's ability or desire to engage with the recommendations and indicated a need to modify how we presented the information. Participants reported that the recommendations could be made more concise or were missing essential information (eg, appropriate next steps). Further, it was indicated that the wording of the platelet recommendation was too prescriptive, and therefore, the function of the

recommendation did not allow for the GP to exercise their clinical judgement.

In terms of the increased platelets, that's helpful. What it is though, it's a bit diffuse in terms of why. Most people are saying, what's the relationship with thrombocytosis. What cancers does that show, for instance? [GP8]

Feedback Delivery: Active Delivery, Frequency, and Function

The importance of active delivery was demonstrated in GPs primarily using the CDSS and not using the audit tool (ie, prompts are sent to the users as part of the CDSS, but the audit tool required participants to take steps to obtain the information).

It's not as if it's just not even there and you're never going to see it. When it comes up like that, you know, it might be worthwhile having a look at this and see what's there. It will be a good thing. [PN2]

Participants spoke of prompt fatigue in relation to other (non-FHT) prompts or reminders. Participants contrasted these systems with FHT, reporting that they did not find FHT to be an obstruction or an irritant, rather that it had a good balance of appearing when needed, drawing attention but not demanding it, and allowing for action or inaction as the clinician decides.

I do like just it's a subtle - it's not in your face that's coming up all the time as a reminder, because we've got so many flashes. [GP3]

The GP's perception of the function of the recommendations was to support them in providing quality care. Most talked about the recommendations as being helpful and beneficial given how much they need to be thinking about, and often framed it as a *suggestion* or *reminder*, indicating that they see it as a supportive rather than a correction or judgement.

I think just to be reminded that a raised platelet count is associated with cancer is a very good thing and I think a lot of GPs wouldn't be aware of it. [GP6]

Recipient Variables

Health Professional Characteristics: The Role and the Knowledge and Skills in the Clinical Topic

There was a difference in uptake of the CDSS and the audit tool by clinical role. Most GPs reported using the CDSS regularly, but only 1 GP reported accessing the audit tool. In comparison, all GPNs had used the audit tool in some capacity where they felt it aligned with their role in the facilitation of patients for recall. However, they did not consider it part of their role to address the cancer recommendations in the PoC. For GPNs, there was a lack of ownership around the content of the recommendations; most stated that the responsibility of doing something about an abnormal test result that a GP had ordered fell solely on the GP. This was an interesting finding, considering the suggestions by some GPs that they would delegate the responsibility of some recommendations to GPNs or medical students (see Context Variables section).

I might do the recalls, I might call people in but in the end, GPs need to be accountable for their work and not me. [PN1]

In general, the attitude toward the cancer recommendations was positive both before and after use. Most GPs felt confident acting on the iron-deficiency anemia and PSA recommendations. However, they identified the need for more education to act on the platelet recommendation given that it comes from relatively new evidence. Some GPs felt they did not have adequate knowledge and skills on the clinical topic, which influenced the credibility of these recommendations and the user’s trust in the tool.

I gather from Future Health Today I should be actively looking for occult cancers in this group. But I need – I need a bit more education about it. [GP1]

Consumer Perspectives

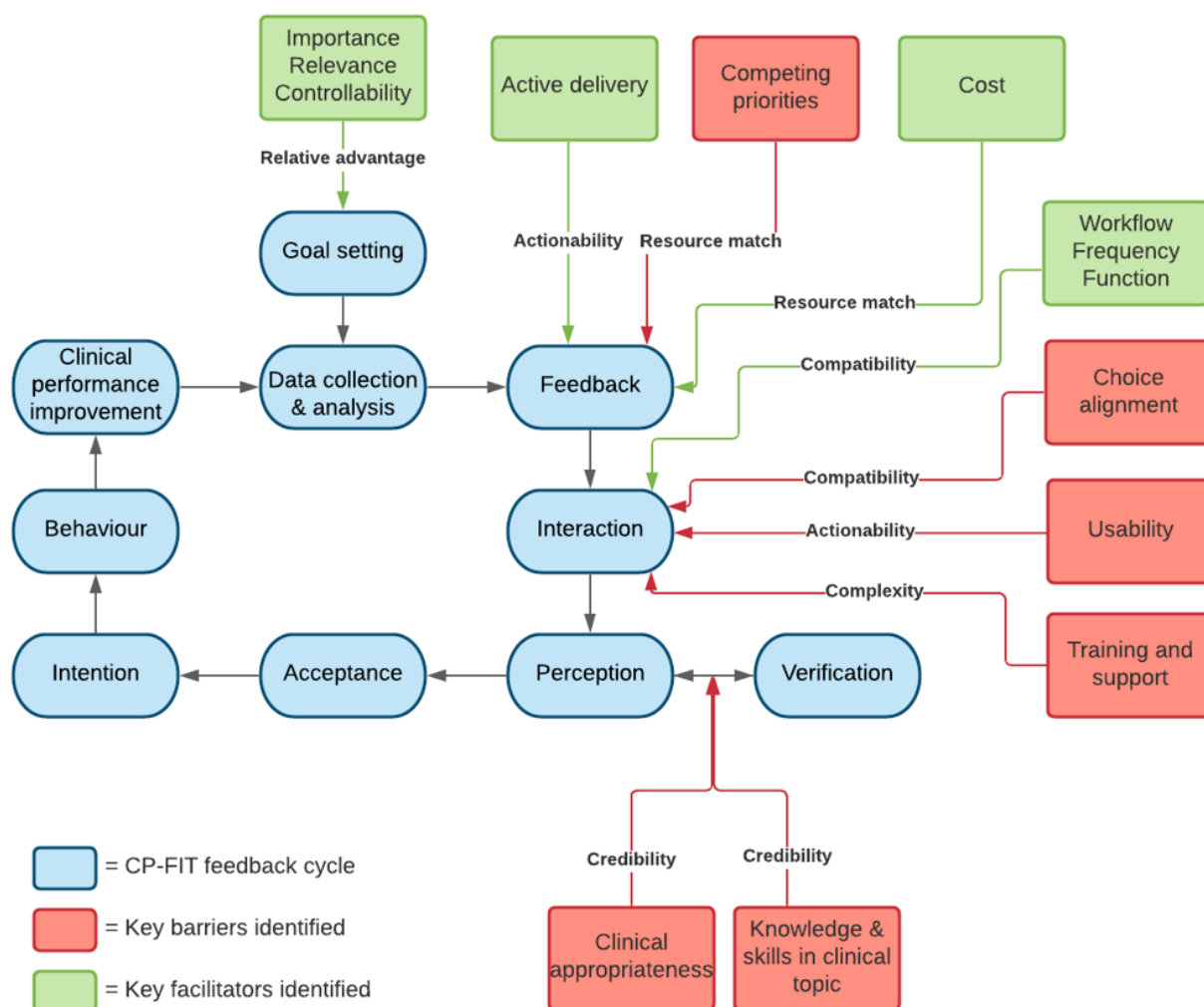
The consumer focus groups elicited key themes around language and innate concerns associated with the words *cancer* and *abnormal*. These themes aligned with those identified in the

general practice interviews and focus group. Consumers expressed concerns about the short time frame of most consultations coupled with their need to discuss and understand the issues raised by the GP or GPN. There was a consensus around the need for tailored patient resources to aid communication in the consultation and to give patients the ability to digest and review the information in their own time.

The Feedback Cycle: Which Variables Influence Implementation and How?

The themes identified as part of this qualitative study can be mapped onto the CP-FIT feedback cycle [36]. Further, the framework analysis allows for the identification of the underlying mechanisms, which provides information as to why and how the platform does, or does not, work as an effective feedback loop. As illustrated in Figure 2, the key components of the feedback cycle where participants were getting *stuck* is the interaction and verification stages. These findings provide an explanation for how FHT for cancer diagnosis in primary care can be improved and guides appropriate action in refining the tool.

Figure 2. How CP-FIT explains the effectiveness of the Future Health Today intervention. CP-FIT: Clinical Performance Feedback Intervention Theory.



Discussion

Principal Findings

In this optimization study, participants reported that FHT was easy to use and nondisruptive to the consultation. The cancer recommendations were seen to meet a need that participants recognized and, for most, did not require a change to their consultation style and workflow. However, with repeated exposure to FHT, participants highlighted the complexity that stemmed from the way the cancer recommendations were communicated to users. There was a need to improve the usability and clarity of the recommendations as well as to provide ways for the GP to verify the recommendations. Further, there were barriers when applying the recommendations in practice relating to patient worry, patient communication, and the patient group that the GP saw most often.

We also found that many of the concerns raised by the GP mirrored those raised by consumers. One of the most important although not surprising findings is the importance of language and communication. Both consumers and the GP expressed a need for tailored patient resources to explain why they had recommended further tests and concerns about the time constraints of consultations to address the patient's worry. The utility of the QI tool for cancer diagnosis relies in the ability to communicate all necessary information accurately, effectively, and concisely in a format that ensures brevity but comprehensiveness at the PoC [37].

By applying CP-FIT as a framework, we were able to illustrate the differences when comparing those who were shown the cancer recommendations at the time of interviewing (ie, a researcher-led simulation) to those who had experience with the recommendations in practice, including those who were reinterviewed after extended exposure. Although the sample size was small, it highlighted in the initial conceptual interviews (when asked to provide immediate feedback on the recommendations) the most prevalent and recurrent themes sat within the *goal* feedback variable at the start of the CP-FIT feedback cycle (ie, importance, relevance, and controllability). Because these variables were met, the response was overwhelmingly positive (there was both acceptance and intention, and the mechanisms indicated actionability and a relative advantage to the way they currently approached these processes). However, once the users had repeated exposure to the recommendations and the users began to move through the feedback cycle (ie, from goal setting to interaction), new barriers were identified (experiential feedback). Although all participants reported competing priorities, this was partially alleviated by ensuring the required time cost was low and the recommendations were actively delivered. However, barriers such as the user's knowledge of the clinical topic, the usability and clarity of the recommendations, and the need for training and support led to many participants getting stuck at this point in the feedback cycle.

Limitations

Given the complexities associated with the implementation of QI tools, this study provided an opportunity to evaluate and refine the QI tool for cancer diagnosis with end users. A novel

framework was chosen to support the analysis [36]. Participants were recruited from a range of practices, in both rural and metropolitan areas, to ensure a wide range of perspectives. There were, however, significantly more women than men in our sample. While this study targeted GPs and GPNs to explore the clinical appropriateness of the tool and to refine the cancer recommendations, we aim to capture a broader range of perspectives from the primary care workforce in the RCT.

Due to the low frequency with which GPs were exposed to the recommendations, some participants had not seen any cancer recommendations at the time of interviewing and were therefore providing feedback on their expectations of using FHT in practice rather than their actual experience, limiting the generalizability to the usual workflow in the consultation. To address this, we reinterviewed half of the GPs who had not initially seen the recommendations, and this allowed for comparisons of participants' perception of the recommendations before and after use. The iron-deficiency anemia recommendation was released 3 months after the other recommendations, potentially limiting the amount of feedback on this prompt.

The timing and environment in which this study was conducted is also important. This pilot and feasibility study was conducted during the COVID-19 pandemic, which caused a large disruption to the usual workflow of most primary care professionals. The effects of the pandemic seen in primary care are numerous, with an increase in telehealth appointments, a shift in health perceptions and priorities, and the resulting staff turnover in primary care [38]. We aim to explore how these ongoing changes to usual practice have impacted the use of FHT in the RCT.

Comparison With Prior Work

While QI tools for cancer diagnosis in primary care are posited to improve the quality of care for patients, reduce practitioner errors, and allow for efficiency in everyday practice, previous studies have reported a range of barriers to implementation and low acceptance in practice. Issues with CDSSs for cancer include tools that are underused [39], too complex [40], incompatible with the workflow [41], incompatible with GP software [42], or do not align with practitioner practice [43]. The results of this study align with the findings of a previous systematic review [28]. The ability to verify the recommendations by understanding the research underpinning the recommendation was not being met as part of FHT [28]. For the diagnosis of cancer, embedding tools in the workflow is often a key barrier [39]; however, the limited disruption caused by the tool and the timing of the prompt meant that FHT aligned with most participants workflow.

The use of a researcher-led simulation in the earlier interviews aligns with previous research that shows that simulations are not able to replicate the stress, workflow, and competing priorities of a usual busy general practice [44]. Nevertheless, they showed a recognized and potentially unmet need around the follow-up of abnormal test results that could be due to an underlying cancer. The later interviews indicated that the perceived usefulness did not translate to optimal usability, and refinements were necessary to address these barriers before

testing the efficacy in a large RCT [45]. In particular, changes were made to the language, phrasing, length, and clarity of the recommendations; tailored resources were created to address knowledge gaps; and custom resources were created to address patient communication barriers.

There are implications for further development of this tool. FHT has been developed for use across multiple disease types. The cancer module was implemented in practices after participants had used FHT for CKD. While the tool and its functionality remained constant, the recommendations for CKD showed progression through the feedback cycle (this may be due, in part, to familiarity with CKD guidelines). However, this indicates that the technology has the potential for effective

behavior change and improvement in clinical care but highlights that there is no *one size fits all* in the development and messaging of recommendations across disease types. Further work on how to develop, modify, embed, and prioritize these recommendations for use in primary care is needed, especially as the number of conditions within FHT is expanded.

Conclusions

QI interventions are difficult to implement. This study highlights the benefit of optimization and refinement before testing the efficacy and clinical utility in a large cluster RCT. Successful implementation of this QI tool could be used as a support system to detect patients at risk of an undiagnosed cancer in primary care and assist in reducing diagnostic delays.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

An example of the decision support tool, with a recommendation for a patient with raised platelets.

[PNG File, 3 KB - [formative_v6i8e39277_app1.png](#)]

Multimedia Appendix 2

An example of the audit tool, with recommendations for patients with iron-deficiency anemia.

[PNG File, 159 KB - [formative_v6i8e39277_app2.png](#)]

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Abbreviations

- CDSS:** computerized decision support system
- CKD:** chronic kidney disease
- CP-FIT:** Clinical Performance Feedback Intervention Theory
- EMR:** electronic medical record
- FHT:** Future Health Today
- GP:** general practitioner
- GPN:** general practice nurse
- PM:** practice manager
- PoC:** point of care
- PSA:** prostate-specific antigen

QI: quality improvement

RCT: randomized controlled trial

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Original Paper

Understanding Preconception Women's Needs and Preferences for Digital Health Resources: Qualitative Study

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Abstract

Background: Improving preconception health can benefit all women, their children, and their families regardless of their individual pregnancy intentions. Rapidly increasing access to information technology and online engagement have created opportunities to use digital health resources to engage with preconception women regarding lifestyle behaviors.

Objective: This study explores how preconception women engage with digital health resources and online platforms to inform the design and development of a digital health resource to support women to make positive behavior change for their preconception health.

Methods: This codesign research followed the Double Diamond process, which focuses on contextualization and explorative processes in phase 1 and ideation and development processes in phase 2. Phase 1 is reported on in this study and was undertaken via a series of 1-on-1 in-depth interviews with female participants (N=12) aged 18-45 years over 3 months. Interviews were designed to explore participants' lived experiences in relation to their health and desired supports for healthy lifestyle behaviors. The first interview focused on participants' perceptions of health and health behaviors, the second interview focused on social connections for health, and the third interview focused on digital health information and supports. Conversations from the first interview informed the development of the second interview, and conversations from the second interview informed the development of the third interview. Community advisors (N=8) met to provide feedback and advice to the researchers throughout the interview process. Qualitative analyses of transcripts from interviews were undertaken by 2 researchers before a deductive process identified themes mapped to the capability, opportunity, motivation, and behavior (COM-B) framework.

Results: In total, 9 themes and 8 subthemes were identified from 124 codes. In relation to digital health resources, specifically, participants were already engaging with a range of digital health resources and had high expectations of these. Digital health resources needed to be easy to access, make women's busy lives easier, be evidence based, and be reputable. Social connectedness was also highly important to our participants, with information and advice from peers with similar experiences being preferred over yet more online health information. Online communities facilitated these social interactions. Participants were open to the idea of chatbots and virtual assistants but acknowledged that they would not replace authentic social interactions.

Conclusions: Codesigned digital health resources should be evidence based, reputable, and easy to access. Social connections were considered highly important to women, and designers of digital health resources should consider how they can increase opportunities for women to connect and learn from each other to promote health behaviors.

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KEYWORDS

digital health; preconception; health promotion; behavior change; women's health; maternal health; digital health resource; healthy life style; qualitative analysis; online health information

Introduction

Optimal preconception health has benefits beyond fertility and pregnancy for mothers, children, and women who do not have children [1-3]. A public health view of the preconception period encompasses the months and even years prior to a potential pregnancy, when health behaviors may impact maternal health status at the critical weeks around conception [2,4]. Taking this broad view is useful when considering that the event of pregnancy is never certain, that a relatively large proportion of pregnancies are unplanned [5], and that some women remain nulliparous. Health behaviors in relation to nutrition, physical activity, and weight management can improve preconception health, prevent chronic disease across the life span [6-8], and assist with managing existing health conditions [9]. Positive health behaviors are often observed by others and can have a positive influence on children, families, and those in the broader community [10].

Women's awareness of the importance of their health behaviors during the preconception period is low [11]. This issue is exacerbated by social, economic, and physical environments that tend to promote or enable suboptimal health behaviors [12]. Globally, the most rapid increase in rates of overweight and obesity is in reproductive aged women [13,14], and approximately 40% of women conceive with a BMI that is considered unhealthy [15]. Preconception behavior change interventions tend to target women of a reproductive age who are planning a pregnancy [16]. These women have been labeled pregnancy "intenders" [17]. Intenders are identified by their goal to conceive and motivation to have a healthy pregnancy [17,18]. Women of a reproductive age who are not planning a pregnancy in the foreseeable future have been labeled "nonintenders" [17]. Their health behaviors are equally important as intenders' as they may eventually impact a future pregnancy, planned or unplanned, and the health of the women themselves [2,4]. Nonintenders are generally not motivated by the event or chance of a pregnancy, possibly far off in the future, to change health behaviors [17]. In fact, they tend not to resonate with the term "preconception" at all, considering it to be something that applies to those planning a pregnancy [19]. These women may have a range of other nonpregnancy-related motivators for behavior change [17]. Regardless of women's pregnancy intentions, optimizing health behaviors in the preconception period can improve every woman's health and, in the event of pregnancy, can improve the health of future generations.

Digital health is defined by the World Health Organization as knowledge and practice associated with the development and use of digital technologies to improve health [20]. Digital health is facilitated by a range of existing technologies, such as mobile and online platforms and devices, as well as emerging data science, artificial intelligence, and robotics technologies [20,21]. A range of commercial online digital health resources have engaged women from the general population to make health

behavior change, at least in the short term (eg, Michelle Bridges 12 Week Body Transformation [22], 28 by Sam Wood [23], Weight Watchers Digital [24]). However, cost is likely to be a barrier to access for some women. Online and social media platforms, such as Instagram and Facebook, are also highly influential in women's decision-making around health behaviors [25]. Globally, 2.7 billion people use Facebook [26] and 1.0 billion use Instagram every month [27]. In Australia, approximately 3.5 hours are spent on online digital devices daily [28] and the average time spent exclusively on social media is 1.48 hours daily [29]. Modes of online engagement, and technology to support digital health resources, and ease of access are expanding rapidly [21]. With approximately 6 billion smartphone subscribers worldwide [30], opportunities to engage with almost any target market to promote behavior change have never been so numerous.

Digital health resources can promote behavior change [21,31], including in preconception populations. For example, Jack and colleagues [32,33] developed a virtual health professional to provide African American women with preconception health information and advice via computer and internet access. In a national randomized controlled trial in the United States, women in the intervention group were supported to address 50% of their identified preconception risks, significantly more than the control group [33]. This technology was tested in Australia with a multicultural sample of women aged 18-45 years [19,34]. Participants in this study, who all identified as being nonintenders, acknowledged the importance of health behaviors for preconception health and considered the resource an acceptable way to provide preconception health information and advice. However, they ultimately were not motivated to engage with a digital health resource that promoted preconception health or pregnancy [19,34]. Participants were particular about what they liked and did not like. They called for digital health resources that are accessible on smartphones (the format tested with them via a computer), easy to navigate, and tailored to meet their individual preferences. Key considerations for those developing digital health interventions are the rapid evolution of information technology and possibilities in digital health [21], trends in user engagement, and keeping up with women's preferences and expectations [19,34]. Despite the opportunities afforded by digital health, the requirements for engaging and sustainable preconception health resources are not yet fully understood. This research aims to further explore how intender and nonintender women engage with digital health resources and other online platforms, including social media, to inform the design and development of a digital health resource (or resources) to support women, both intenders and nonintenders, to make positive behavior change in relation to their preconception health. This study reports on the first phase of a larger body of participatory design research to empower women to adopt and maintain healthy lifestyle behaviors that optimize their preconception health and overall health and well-being.

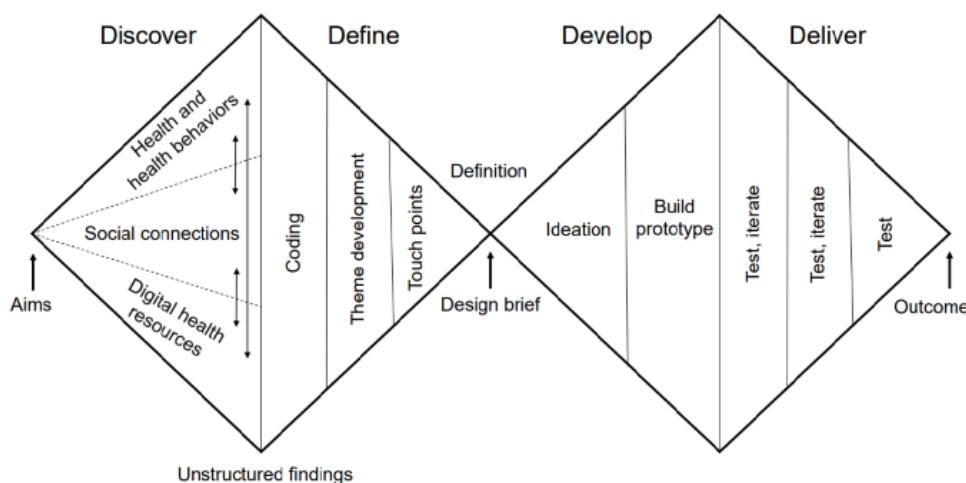
Methods

Study Design

Our experience-based codesign approach involving women and community advisors was based on the Double Diamond process, an integrated design process that focuses on contextualization and explorative processes in phase 1 and ideation and

development processes in phase 2 (Figure 1) [35]. Phase 1 is reported in this study, including a design brief with a range of considerations to scope the activities of phase 2. The anticipated output of phase 2 is a codesigned digital health resource (or resources) that engages women with knowledge and support in relation to their preconception health behaviors. Two community advisory committees guided this research from the outset.

Figure 1. Double Diamond process, adapted for use in this research.



Ethical Considerations

Ethics approval was obtained from the Monash University Human Research Ethics Committee (MUHREC reference: 28204). Participants provided informed consent via an online consent form. This full method is reported elsewhere (Walker et al, unpublished data, May 2022), and a summary is provided later.

Setting, Participants, and Community Advisors

Study participants and community advisors lived in Victoria, Australia, and were aged 18-45 years. To be eligible, they needed to identify as being an intender (planning a pregnancy in the next 2 years or had a child in the past 2 years) or as being a nonintender (not planning a pregnancy in the next 2 years, with or without children already).

Recruitment and Consent

Study participants and community advisors were recruited via advertisements sent to existing contacts at a range of women's health groups in metropolitan Melbourne and regional Victoria, Australia, and via Facebook and Twitter. Community advisors were recruited and screened for eligibility in February and March 2021. Following the first community advisor meeting, participants were recruited and screened in April and May 2021.

Data Collection

Community advisors were divided into intender and nonintenders groups based on whether they identified as being an intender or a nonintender. Four meetings for each group were held between March and October 2021. The meetings' overall objectives were to introduce the study aims, gather feedback regarding the study design and results, and seek nonbiased

guidance relating to how the interviews were conducted and phase 2 planning. The intender community advisors provided feedback in relation to the interviews being conducted with the intender participants, and the nonintender community advisors provided feedback in relation to the interviews being conducted with nonintender participants. These meetings were audio-recorded, transcribed, and added to the data set. Three in-depth interviews with each participant were conducted between June and September 2021. Interviews were designed to explore participants' lived experiences in relation to their health and desired supports for healthy lifestyle behaviors. The first interview focused on participants' perceptions of health and health behaviors, the second interview focused on social connections for health, and the third interview focused on digital health information and supports. COVID-19 restrictions meant that all meetings and interviews in this study had to be conducted online via Zoom. Meeting and interviews were audio-recorded using a Dictaphone, transcribed with the Descript transcription service, and then checked by 1 of the researchers. Community advisors and participants were de-identified with a unique participant number.

Data Analysis

Data collection and analysis occurred concurrently. This was because data collected in previous interviews informed the subsequent interviews. This process involved rapid coding to gain insights from the first interview, which informed the activities designed for the subsequent interview with a degree of personalization based on the individual responses provided by the participants. Two researchers (authors SQ, a female research assistant and dietitian, and RW, a postdoctoral research fellow and dietitian, both with expertise in women's health and

qualitative research methods) double-coded a subset of the interview 1 transcripts to develop the initial coding framework. The remaining interview 1 transcripts were coded and cross-checked intermittently for consistency. The same process was used for interviews 2 and 3, with new codes being added to the initial framework. The transcripts from community advisor meetings were double-coded using the same framework. The community advisors discussed similar topics to those discussed in the interviews, creating a situation where the same coding framework used for the interviews could be used for the community advisor transcripts. NVivo software (QSR International) supported the analyses.

A deductive process was used for theme development. Codes were mapped to 3 focus areas of the in-depth interviews (perceptions of health and health behaviors, social connection, digital health information and support) and to the 3 components of the capability, opportunity, motivation, and behavior (COM-B) framework [36]. The 2 researchers developed summary statements for each intersection between the focus areas and the COM-B system before “touch points” were identified. Touch points in experience-based codesign are positive or negative experiences that elicit an emotional response [37]. In this study, we applied the term “touch point” to crucial aspects of the product or service design that must be present for participants to initially like it, have a desire or motivation to engage with it, actually engage with it, and then allow it to be a trusted and ongoing support for behavior change. For example, a woman may initially be drawn to a digital health resource

because of its graphic design (eg, earthy tones, images of nature and well-being). She may like that the digital health resource has clear tabs for easy navigation and that the information provided is by a figure or person she relates to and trusts. Interacting with the resource may make her life easier, not harder. Touch points in this scenario may be labeled “calming,” “ease of use,” “reliability,” and “trust.” A degree of subjectivity may have been present in the identification of touch points for this study. Steps were taken to mitigate this by the 2 researchers (SQ and RW) discussing what touch points emerged as being most important to our participants with the rest of the research team. Repetition of some touch points across the intersections also indicated that they were important design considerations. The touch points generated the design brief that was scrutinized in the fourth round of community advisor meetings. Finally, themes and subthemes were derived from the summary statements and touch points.

Results

Community Advisor and Participant Characteristics

In total, 8 community advisors and 12 participants were included (Table 1), and 9 themes and 8 subthemes were derived from 124 codes, with overlap between themes (Table 2). Themes relating to digital health information and supports are reported here, while themes relating to health behaviors and social connections for health are reported elsewhere (Walker et al, unpublished data, May 2022).

Table 1. Community advisor and participant characteristics.

Characteristics	Community advisors (N=9) ^a	Participants (N=12)
Intender ^b , n (%)	3 (33.3)	6 (50.0)
Nonintender ^c , n (%)	6 (66.6)	6 (50.0)
Age (years), median (IQR)	29 (11)	31.5 (6)
Culturally and linguistically diverse, n (%)	4 (44.4)	3 (25.0)
Living with a disability ^d , n (%)	2 (22.2)	5 (41.7)
University educated, n (%)	8 (88.8)	10 (83.3)

^aOne of the community advisors only participated in 1 of the 4 group sessions.

^bIntender: planning a pregnancy in the next 2 years or had a child in the past 2 years.

^cNonintender: not planning a pregnancy in the next 2 years, with or without children already.

^dPosttraumatic stress, hearing impairment, mental health, severe endometriosis, attention deficit hyperactivity disorder.

Table 2. Summary statements, touch points, and themes (from participant and community advisor data).

	Perceptions of health and health behaviors ^a	Social connections for health ^a	Digital health information and supports
Capability for health behaviors			
Summary statement	Capability comes from a holistic understanding of health, health information, and feeling of empowerment.	Social connections and shared experiences are integral to capability.	Digital health information and supports increase capabilities for health behaviors.
Touch points	<ul style="list-style-type: none"> Health is valued. Trustworthy information. 	<ul style="list-style-type: none"> Relationships with friends and family Shared experiences Being listened to 	<ul style="list-style-type: none"> Trustworthy information Quality digital health information
Theme(s)	<ul style="list-style-type: none"> Health is multidimensional, and a few key health behaviors are valued over all others. 	<ul style="list-style-type: none"> Social connections and shared experiences build knowledge and increase confidence in decision-making. 	<ul style="list-style-type: none"> Digital health information and support need to be evidence based and reputable to increase capability.
Subtheme(s)	<ul style="list-style-type: none"> Health information can empower and disempower health behaviors. Everyday life can empower and disempower health behaviors. 	<ul style="list-style-type: none"> Looking to other sources of information when health professionals are not trusted 	N/A ^b
Opportunity for health behaviors			
Summary statement	A range of resources create opportunities for health behaviors.	Social connections are shared experiences are integral to opportunity.	Digital health information and supports increase opportunities for health behaviors.
Touch point(s)	<ul style="list-style-type: none"> Makes life easier 	<ul style="list-style-type: none"> Relationships with friends and family Shared experiences Being listened to 	<ul style="list-style-type: none"> Information and supports need to be timely and relevant. Online communities support social connections for health. Smartphone access is essential.
Theme(s)	<ul style="list-style-type: none"> Personal responsibilities prioritized over health behaviors 	<ul style="list-style-type: none"> Social connections and shared experiences increase opportunity for health behaviors. 	<ul style="list-style-type: none"> Digital health information and support need to be relevant and increase opportunity for social connection.
Subtheme(s)	<ul style="list-style-type: none"> Resources that make health behaviors easier 	<ul style="list-style-type: none"> Being listened to shared experiences are important. 	<ul style="list-style-type: none"> Ease of access and convenience are essential. Chatbots and virtual assistants may be useful but will not replace authentic social interactions.
Motivation for health behaviors			
Summary statement	A desire to feel well and live well motivates health behaviors.	We thrive when we are together.	Digital health information and supports have the potential to increase motivation for health behaviors.
Touch points	<ul style="list-style-type: none"> Pregnancy is a motivator when a pregnancy is planned or desired. Quality of life, including nature, rest, and relaxation. 	<ul style="list-style-type: none"> We learn from each other. We support each other. 	<ul style="list-style-type: none"> Clear and tailored information Variety and choice Privacy and trust Diversity and inclusion Aesthetically appealing Goal setting, tracking, and monitoring progress
Theme(s)	<ul style="list-style-type: none"> A range of factors motivate health behaviors. 	<ul style="list-style-type: none"> "We're not designed to be alone... We thrive when we're together." 	<ul style="list-style-type: none"> New digital health information and support need to be innovative to meet expectations of their target audience.

Subtheme(s)	Perceptions of health and health behaviors ^a	Social connections for health ^a	Digital health information and supports
	<ul style="list-style-type: none"> Pregnancy planning motivates behavior change. 	<ul style="list-style-type: none"> A range of motivating benefits come from social connections. 	<ul style="list-style-type: none"> New digital health information and support need to be innovative to meet expectations of their target audience.

^aReported elsewhere.

^bN/A: not applicable.

Theme: Digital Health Information and Support Need to Be Evidence Based and Reputable to Increase Capability

Participants engaged with a range of digital health resources to increase their capability, including apps, online classes, podcasts, websites, and social media. They had clear expectations of the digital health resources they engaged with, including evidence-based information, tailored advice, and the presence of a moderator on online forums. Due to an abundance of online information and “a lot of misinformation out there” (participant 3, nonintender), participants were aware of the importance of health literacy and discerning between trustworthy and unreliable information. Google was a starting point for health information searches, along with recommendations from social connections, online reviews, and a number of downloads. Participants wanted to know that other people respected and valued the information they were accessing.

In terms of resources...I did a lot of Googling. I would look up what's good, what's happening through the pregnancy cycle and what's good to be, you know, to be done during pregnancy...Um, so I did look up a few resources...I think specific applications like “Baby Centre” has some good resources, even the NHS Pregnancy Guide [National Health Service, UK]. [Participant 6, intender]

Theme: Digital Health Information and Supports Need to Be Relevant and Increase Opportunity for Social Connection

Digital health information and support on social media (mostly Facebook and Instagram) increased the participants’ opportunity to search for information, access online communities, and learn from others who had similar experiences to them. Online communities also facilitated opportunities for social connections that were considered of utmost importance to our participants. Despite many participants and community advisors being only passively involved in online discussions (eg, not posting and only reading) or engaging intermittently, these forums seemed to be highly valued.

I think for me, even though I don't post or comment, I like to be able to read other people, uh, their posts, uh, and the advice that other people provide...Yeah. So that's, that's my personality for someone who is like an introvert and doesn't talk...But it [online communities] also caters to someone who's an extrovert and likes to really ask questions and ask opinions and provide advice. [Community advisor 1]

Participants who valued online communities tended to be those most likely to experience barriers to meeting with people face to face (eg, had a chronic condition, caring for small children) or were at a time in life when their need for support was higher (eg, pregnancy).

I would definitely put an online community in my inner circle. When I fell pregnant with my oldest one, he's 6 now...I was holding on to the “What to expect when you are expecting” App...Like a lifeline, because I was terrified of what was going on. I was curious, I was all those things nervous, excited. [Community advisor 2; the term “inner circle” was used during the interviews to define those who participants relied on and trusted most.]

It's [online community] somewhere between inner circle and community, to be honest. Um, I feel like obviously a lot of [online community's] following it's my inner and broader community anyway. Um, but I feel like because we're discussing such vulnerable things and, um, people are coming back with responses saying, I understand, and I feel this, and I've been through this and everyone kind of feeling so comfortable and nurtured in that space that...I'm having conversations publicly on there that I wasn't having privately 2 years ago in my inner circle, which is really weird. But it's such a beautiful space, um, that I feel like that's kind of somewhere between inner and community. [Participant 3, nonintender]

Subtheme: Ease of Access and Convenience Are Essential

Factors that increased the participants’ opportunity to use digital health information and support were access to hardware (eg, smartphones, tablets, and computers) and cost. Participants mostly used their smartphones and were happy to pay for health apps and online programs if they were perceived to be valuable.

I tend to use the mobile phone a lot more. Um, like, you know, when I'm kind of done with work, um, I use the phone a lot more. [Participant 6, intender]

Like, I'm quite happy to pay for the, for apps or information if, if it was laid out to start with... [Participant 5, intender]

Subtheme: Chatbots and Virtual Assistants May Be Useful but Will Not Replace Authentic Social Interactions

Participants were asked about their experiences with chatbots and virtual assistants. Most had interacted with them for practical, non-health-related activities, such as booking appointments or product queries. Most reported that they would

be willing to interact with a chatbot or virtual assistant for health but described potential limitations. If participants used a chatbot or virtual assistant for health, they would need to trust they were receiving expert advice. Participants were less likely to interact with a chatbot or virtual assistant if it was not a person they were interacting with, if they did not receive timely responses, or if responses were not tailored to meet their needs.

I think you can tell when it [chatbot] is not a person...So I think that particularly from a health point of view, it maybe, sort of, needs to be very clear that's what it is. That it's not, there's not a person at the end of this chat. This is just a direction tool or something...If it was a robot, I don't think I'd use it. [Participant 2, intender]

Theme: New Digital Health Information and Support Need to Be Innovative to Meet Expectations of Their Target Audience

Participants had clear expectations of digital health information and supports they wanted. When asked about desirable features that would to motivate them to engage, the participants requested (1) resources with a clear purpose; (2) resources tailored to their needs; (3) privacy and opportunities to participate anonymously; (4) trust, openness, and honesty from other participants (fostering a sense of community); (5) diversity and inclusion; and (6) functionality that facilitates goal setting and data tracking to monitor their progress. Digital health resources also need to be visually appealing, easy to navigate, and accessible for those with hearing and visually impairments and should offer a variety of ways to engage (eg, Facebook groups, Instagram, Podcasts, and moderated forums).

I wouldn't want one resource to be all of general health, if that makes sense. Like, I would prefer it to be multiple or that resource to be more specific to women's health; or even that's very broad. Like reproductive health, for example, what would be helpful as a smaller area of the topic. [Participant 5, intender]

One of the successful things I think of these groups is that there is those multiple components. Like, you have the podcast and you have the community. Um, I don't know if either would be so successful without the other. [Community advisor 3]

In relation to preconception health, participants identified that tracking from preconception to pregnancy and birth would be helpful.

It would be cool to continue into pregnancy...So like especially spending money on an app. You don't really want to be like, "oh man, now I'm pregnant. Now I need a new app." It would be good to continue on the same thing that you can still be tracking... [Participant 4, intender]

Due to COVID-19 lockdowns, participants were working from home on their computers. The participants expressed wanting to get away from their computer screens at the end of the work day. If they were to engage with a digital health resource, they wanted to use one that seemed to be recreational.

Like it's, unfortunately it's [being online] just part of your whole day really...I just saw something on Twitter before...One of the people who has done some work with us is like, "Is anybody else just not interested in having Zoom parties?" Because by the end of a work day, I just, last thing I want to do is look at a screen... [Participant 2, intender]

Participants created a huge list of digital health information and supports that they had accessed. Some of this information and support was developed by governments (Better Health Channel, National Health Service [NHS], United Kingdom) and large organizations (Baby Centre, Royal Women's Hospital). Some of this information was developed to meet a perceived need and for commercial purposes (Keep it Cleaner, Chemical Maze, Noom), while some information and support were developed because of an unmet need and not for commercial purposes (Private Parts, Facebook groups). Participants did not list any resources that had been solely developed by health professionals or academics. In fact, some of their comments cautioned against this.

To me, um, it would need to be coming from like someone [a face or advocate] who opens the story. Like, "Hey, I'm 30 years old. I don't think I'm going to have kids. This is my situation." Um, I think that it would be quite interesting...Like, as SP was saying, like, um, there might be online forums out there, but you always search for someone who is in a very similar situation to you...I think that's why "She's on the Money" has been successful because it's run by young woman. Um, so, yeah. It just like, it cuts through a little bit more...Rather than like, "Hey, we're like, you know, from our Ivory Tower or institution..." in the messaging. Yeah. You know what I mean? [Community advisor 4]

Our community advisors also made some relevant comments in relation to the overall aims of this project to motivate women to engage with digital health resources for health behavior change.

I think that, that organic, um, like that organic genesis I think is really quite an important part. I think in terms of trust...I just like, I think that I've got a couple of friends who are involved with, um, a big breastfeeding group on Facebook called the Breastfeeding Cooperative...I think it started quite small and it's grown to be like, you know, over a hundred thousand members. And, um, you know, they've got this huge admin team now and it's massive. Um, and a lot of the women who moderate the group are doctors or nurses or like are professionals in some way, but it, it did happen very organically...It's a group that is really trusted among a lot of Australian women. But I think if it had started from like a health promotion, like deliberate, like "Let's, let's make a health promotion intervention!" I don't think it would have worked... [Community advisor 5]

What does a health promotion intervention that women trust and rely on and engage with look like?

I suppose it looks like something that you want to be a part of. Like, you want to actually be socially involved because you get something out of it...I like to feel how I give something back to that same community. And that's what makes it community rather than a classroom...I suppose, in order for them to be successful, I feel like there has to be a bit of learning, but also a bit of teaching taken on by everyone...I think you, you feel connected to them because of that shared experience. So if you create something that could generate that, that information-giving along with that social connectedness...I think you'd have a far greater buy-in from a lot of people. [Community advisor 2]

Our discussions with the community advisors and participants identified themes and touch points (Table 2) that informed the development of a design brief to inform phase 2 of this research (Multimedia Appendix 1).

Discussion

Principal Findings

Our pregnancy intender and nonintender participants were already engaging with a range of digital health resources, including social media, to optimize their preconception health, general health, and overall well-being. They actively sought health information that they considered to be evidence based, trustworthy, and relevant. Desirable attributes of digital health resources were related to convenience. Our participants were busy and wanted information and supports that made their lives easier. Online interactions that facilitated meaningful social connections for health were prioritized over simply having access to more health information. Our participants listed a range of preferences for designers to consider as they leverage off information technology, the internet, and social media to develop digital health resources that promote preconception health behaviors.

Limitations

This research had equal representation from pregnancy intender and nonintender participants who were interviewed 3 times over 3 months. This longer period of engagement allowed interviewers to delve more deeply into the participants' lived experiences, their health behaviors, and supports for health. Ongoing interaction over 3 months also facilitated trust and rapport between participants and the interviewers. Additionally, ongoing data analyses enabled the findings from one interview to inform the next interview, and interviews were tailored to individual participants. The age range of participants was a limitation of this study, with an absence of women aged from 18 to 26 years. However, this younger age group was represented in community advisor meetings, with 3 nonintender community advisors being aged less than 26 years.

Consideration needs to be given to the impact of COVID-19 in the interpretation of the results. Data collection occurred during 1 of several COVID-19 lockdowns in the state of Victoria, Australia, in 2021. The COVID-19 lockdowns impacted all health behaviors, including those considered most important by

our participants (food, exercise, and social connection) [38]. Potentially, the value participants placed on these health behaviors may have been magnified. Social connection is protective at times of stress, and perceived social support can buffer the negative impacts of isolation and loneliness [39]. Again, this may have magnified the importance participants placed on being socially connected with others. The final interview that explored participants' use of digital health information and supports occurred after many participants had been working from home or home-schooling children for approximately 18 months. This increased use of information technology for work and daily tasks may also have altered how some participants described their use of digital health resources.

Comparison With Prior Work

Digital health resources that promote health behaviors are plentiful, and women are engaging with them as it is expedient to them. This research highlighted women's dependence on commercial or perhaps less formal digital health resources, including social media, such as Facebook and Instagram. Our participants valued the opportunities these platforms created for sharing experiences and learning from others (Walker et al, unpublished data, May 2022). Individuals are increasingly turning to experience-based information and support as opposed to expertise-based information and support provided by health professionals [40]. This challenges how health promoters and designers approach the development of digital health resources that are competitive in this space [41].

Examples of the successful integration of health promotion with social media platforms can be found in the use of existing online communication platforms, such as Facebook, WhatsApp, and free online learning platforms designed specifically for laypeople [42,43]. For example, the *FeedFinder* mobile phone app supports breastfeeding women to identify, review, and share information around public breastfeeding spaces [44,45]. This digital health resource was developed in consultation with women by a multidisciplinary research team from Newcastle University, United Kingdom, highlighting the importance of user involvement in design and how some digital health interventions are more effective when targeted to communities where information is shared [44]. Another example is the use of Massive Open Online Courses (MOOCs) for learning and discussion regarding a range of topics, including health [46-48]. Developed by Monash University, Australia, the MOOC Food as Medicine provided learners with education around nutrition as well as a moderated question and discussion forum [43]. Between May 2016 and February 2018, the course attracted >81,000 learners [41]. The evaluation found that learners were open to nonexpert advice from other learners because this feedback was timely, easily accessible, and often with personal anecdotes [41]. A common feature of these examples with our research is the value users placed on opportunities to interact and learn from each other. Experience-based information and support were preferred over expertise-based information by our participants. This reinforces the need to consider the strengthening influence of online voices and the importance of sharing experiences when developing digital health resources for contemporary women [40].

Future resources to promote behavior change, digital or other, should be codesigned with target audiences to ensure they meet their specific needs and preferences and promote ongoing engagement [49]. Our particular audience targeted in this research was broad. Essentially, a public health view of the preconception period includes all reproductive-age women [2,4]. We noted more similarities than differences between our intender and nonintender participants. Social connections, including being listened to and hearing from the shared experiences of others, were paramount for all our participants' health and health behaviors (Walker et al, unpublished data, May 2022). In relation to digital health resources, participants primarily wanted resources that were easy to navigate and made their lives easier. This was confirmed with the feedback and oversight of our intender and nonintender community advisors who agreed that social connections should be integral to planning in phase 2. A systematic review of user engagement with digital health resources for mental health also found that social connections and customized content are enablers for engagement, while technical and navigation difficulties are a barrier [50]. The other touch points we identified, including privacy and the importance of images that represent quality of

life (eg, nature, rest, relaxation), were incorporated into a design brief format and shared with our community advisors for feedback. Slight but important alterations were made to the design brief after the final community advisor meeting, demonstrating the importance of community engagement throughout the research process to ensure that participant and community voices are represented accurately [51].

Conclusion

Women engage with digital health resources and other online platforms, including social media, to support their health behaviors and overall health and well-being. Women have clear expectations of what they want from digital health resources. These should be evidence based, reputable, and enable ease of access to fit in with busy lives. Social connections are paramount for women. Therefore, designers of digital health resources should consider how they can increase opportunities for women to connect and learn from each other to promote health behaviors. Codesigning digital health resources is important to successfully engage women with digital health information and support to increase their capability and create opportunities and motivation to support positive health behaviors.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Design brief to inform phase 2 of this study.

[\[DOCX File, 55 KB - formative_v6i8e39280_app1.docx\]](#)

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Abbreviations

COM-B: capability, opportunity, motivation, and behavior

MOOC: Massive Open Online Course

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Original Paper

Development and Use of a Cardiac Clinical Guideline Mobile App in Australia: Acceptability and Multi-Methods Study

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Abstract

Background: Implementation of clinical guidelines into routine practice remains highly variable. Strategies to increase guideline uptake include developing digital tools and mobile apps for use in clinical practice. The National Heart Foundation of Australia in collaboration with the Cardiac Society of Australia and New Zealand published 3 key cardiac clinical guidelines, including the Australian clinical guidelines for the (1) prevention and detection of atrial fibrillation, (2) detection and management of heart failure, and (3) management of acute coronary syndromes. To improve access and uptake for health care providers, we developed the Smart Heart Guideline App.

Objective: This study aims to evaluate the acceptability, implementation, and usability of an Australian-specific cardiac guidelines mobile app.

Methods: We used an iterative multiple methods development and implementation approach. First, we conducted a cross-sectional web-based survey with end users (n=504 health professionals) in 2017 to determine the acceptability of an Australian-specific cardiac clinical guidelines mobile app. Second, the Smart Heart Guidelines app was created using a design, user testing, and revision process. The app includes interactive algorithms and flowcharts to inform diagnosis and management at the point of care. The freely available app was launched in October 2019 on iOS and Android operating systems and promoted and implemented using multiple methods. Third, data from 2 annual national cross-sectional general practitioner (GP) surveys in 2019 and 2020 were evaluated to understand the awareness and use of the clinical guidelines and the app. Fourth, data from the app stores were analyzed between October 1, 2019, and June 30, 2021, to evaluate usage.

Results: Most health professionals surveyed (447/504, 89%) reported accessing resources electronically, and most (318/504, 63%) reported that they would use an Australian-specific cardiac guidelines app. GPs surveyed in 2019 were aware of the heart failure (159/312, 51%) and atrial fibrillation (140/312, 45%) guidelines, and in 2020, a total of 34 of 189 (18%) reported that they were aware of the app. The app was downloaded 11,313 times (7483, 66% from the Apple App Store; 3830, 34% from Google Play) during the first 20-month period. Most downloads (6300/7483, 84%) were a result of searching for the app in the stores. Monthly download rates varied. App Store data showed that people used the app twice (on average 2.06 times) during the 20 months. Many (3256/3830, 85%) Android users deleted the app.

Conclusions: Health professionals supported the development of the Smart Heart Guidelines app. Although initial downloads were promising, the frequency of using the app was low and deletion rates were high. Further evaluation of users' experience of the most and least useful components of the app is needed.

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KEYWORDS

mHealth; mobile health; apps; app; guideline; cardiovascular disease; atrial fibrillation; heart failure; heart; cardiac; cardiovascular; acute coronary syndrome; smartphone; implementation; digital health; develop; evaluate; evaluation; Australia

Introduction

Cardiovascular disease is the leading cause of death in Australia and a nationwide priority for research [1]. National clinical guidelines have been developed to inform decision-making among health professionals in the diagnosis and management of cardiovascular disease. Implementation of clinical guidelines can prevent avoidable harm, improve resource use, and reduce variation in care [2]. Despite this, implementation of clinical guidelines into routine practice remains highly variable, suboptimal, and concerning, low in some areas of health care [3]. In Australia, the National Health and Medical Research Council advises improving access and uptake of clinical guidelines by presenting content in multiple formats that are tailored to users' needs [2].

Smartphone apps are a convenient way for health professionals to access health information in a timely manner. In recent years, international organizations including the European Society of Cardiology and the American Heart Association have developed mobile apps providing digital access to their guidelines and specific apps for interactive decision support tools for real-time use in clinical practice and cardiovascular risk calculation [4,5]. Similarly, other health disciplines including anesthesiology, pediatrics, and dermatology have developed apps to improve access and adherence to guideline recommendations in clinical practice [5-8]. With the advent of "living guidelines" and its methods of continuous evidence surveillance and recommendation updates, digital authoring, and web-based publication platforms such as Making Grade the Irresistible Choice (MAGICapp) have been developed, publishing over 190 living guidelines, including the Australian guidelines for care for people with COVID-19 [9]. These developments complement a trend toward greater utilization of digital platforms and smart phone use by doctors in Australia [10,11].

The National Heart Foundation of Australia (Heart Foundation) is an independent, not-for-profit organization that funds cardiovascular research and, in partnership with the Cardiac Society of Australia and New Zealand and other organizations, publishes clinical practice guidelines and position statements in areas where guidance will have the biggest impact.

The study aim was to evaluate the acceptability, implementation, and usage of an Australian-specific mobile app to improve the awareness and use of 3 Australian cardiac clinical guidelines for the (1) prevention and detection of atrial fibrillation 2018, (2) detection and management of heart failure 2018, and (3) Australian clinical guidelines for the management of acute coronary syndromes 2016 [12-14].

Methods

Overview

We used an iterative multiple methods approach, drawing on established methods in mobile app development,

implementation, and evaluation [15]. First, we conducted a cross-sectional web-based survey of end-users to determine the acceptability of an Australian-specific mobile app to access cardiac clinical guidelines. Second, the Smart Heart Guidelines app was developed and launched on Google Play and Apple App Store (App Store) and promoted using multiple methods. Third, the app was promoted and implemented. Fourth, data from 2 annual cross-sectional national general practitioner (GP) surveys in 2019 and 2020 were evaluated to assess awareness and use of the clinical guidelines and the app. Fifth, data from the app stores were collated to evaluate app use. Each of these steps are now described.

Health Professional Acceptability Survey

A web-based survey designed for health professionals likely to use a cardiology guidelines app was developed and distributed in 2017. The survey contained 10 questions including the frequency of searching for information about the prevention or management of cardiovascular disease, methods of searching, and the likelihood of using an Australian-specific mobile app to access cardiac clinical guidelines. The survey was distributed through the Heart Foundation's social media accounts and promotion in the organization's monthly newsletter (the mailing list comprised of approximately 15000 health professionals: average open rates of 21%, 3150/15000). Survey responses informed the development of the app.

Development of the Smart Heart Guidelines App

The Heart Foundation collaborated with a global app developer, experienced with international cardiology apps in Europe and the United States. The app was created in iOS (Apple) and Android formats.

Three clinical guidelines were converted from publication in a PDF format in a peer-reviewed journal into the app. The app included the guidelines for acute coronary syndromes, atrial fibrillation, and heart failure [12-14]. The app was organized into 3 sections for each clinical guidelines and contained a main page, table of contents, interactive tools and algorithms (to support clinical decision-making), and a table of key recommendations, as shown in [Multimedia Appendix 1](#). The app was created using a design, user testing, and revision process.

The app was registered as a class 1 software-based medical device with the Australian Register of Therapeutic Goods in 2019, in accordance with national legislation [16]. Registration requirements include ongoing monitoring of safety, quality, and performance. Users had to declare that they were a health professional to download the app. The freely available (no cost) Smart Heart Guidelines app was launched on both the App Store and Google Play in October 2019.

Promoting and Implementing the App

Implementation strategies used to promote the app included printed and electronic flyers, containing a quick response code

distributed at health professional educational meetings and events. Direct email and newsletters to multiple health professional groups and paid advertising in health professional journals was used. Promotion of the app on multiple webpages associated with the clinical guidelines was also undertaken.

Annual Cross-sectional Awareness Surveys to General Practitioners in 2019 and 2020

The Heart Foundation develops and distributes a nationwide cross-sectional survey to GPs annually since 2010. These surveys collect feedback about views, attitudes, awareness and the use of Heart Foundation resources and clinical guidelines. The 2019 and 2020 surveys were distributed to a sample of approximately 4000 GPs identified from the Medical Directory of Australia [17]. The 2019 annual survey contained 24 items and was distributed and open between October and November 2019. GPs could respond on the web, using the software platform Typeform or via a paper version [18]. In 2020, the 21-item survey was only available on the web and was open from October 2020 to November 2020 [18]. Both surveys contained a combination of closed-ended questions and Likert rating scales.

Evaluation of App Usage From the App Store and Google Play

Usage data for the app was retrieved from the App Store and Google Play during the period between October 1, 2019, and June 30, 2021. Data from both app stores showed the total number of downloads of the app and the conversion rate (number of downloads divided by the number of impressions) during this period. Data from Google Play showed the retention rate (percentage of users who had not uninstalled the app from their device). The App Store report provided the number of impressions (the number of times an app appears in an App Store search), product page views (the number of times a user viewed the apps product page in the App Store), and average use (number of sessions per device divided by the total number of users).

Ethical Considerations

Heart Foundation surveys are approved through routine governance organizational processes. Data collected from the surveys were anonymized and informed consent was assumed at the time of survey participation. Therefore, there was no ethical application made for this multi-methods study.

Data Handling and Statistical Analyses

Descriptive statistics were used to summarize the health professional acceptability survey from 2017 and the GP surveys in 2019 and 2020. Google Analytics was used to evaluate app data from the App Store and Google Play.

Results

Health Professional Acceptability Survey in 2017

There were 504 respondents, from all 6 states and 2 territories in Australia. Most were nurses (198/504, 39%), allied health professionals (132/504, 26%), GPs and cardiologists (45/504, 9%), researchers (11/504, 2%), or identified as other (118/504, 23%). Respondents were from a variety of disciplines including public health (131/504, 26%), private practice (121/504, 24%), community health (86/504, 17%), research institute (55/504, 11%), private hospital (35/504, 7%), health promotion (25/504, 5%), and others (50/504, 10%). Most (447/504, 89%) reported accessing the Heart Foundation's resources electronically. Most health professionals reported using Microsoft software (246/504, 63%) Apple iOS (162/504, 32%), or Android devices (63/504, 13%). The majority of health professionals (369/504, 73%) reported they would use a mobile device (a tablet or mobile phone) to access health professional resources, although the majority (465/504, 92%) currently did not. The majority (314/504, 62%) reported that they would be likely or very likely to use an Australian-specific mobile app to access the clinical guidelines and resources.

Promotion and Implementation the App

Implementation and promotional strategies for the app are summarized in Table 1. Promotion strategies had a potential reach to over 73,000 individuals.

Table 1. Methods used to promote and implement the Smart Heart Guidelines app.

Method	Dates promoted	Recipients
Internal		
Direct email to NHFA ^a staff	November 22, 2019	90 staff members
NHFA all staff newsletter	November 27, 2019	272 staff members
External		
NHFA webpage on the Smart Heart Guidelines app	Live from November 11, 2019	6721 page views (November 11, 2019 to June 30, 2021)
NHFA newsletter to health care professionals	Monthly promotion between November 2019 and September 2020	Approximately 20,000 health care professionals subscribed
Direct email to health organizations (eg, Stroke Foundation)	November 11, 2019	69 unique IP addresses
NHFA advisory committees and guideline writing groups	November 22, 2019	40 members
Promoted in the Australian Primary Health Care Nurses Association newsletter	November 2019	Approximately 3500 members
Direct email to the CSANZ ^b	December 2019	Approximately 3000 members
Print the advertisement in the RACGP ^c newsletter	December 1, 2019	Approximately 40,000 general practitioners
Society page in <i>Heart, Lung, Circulation</i>	February 2020	>2000 cardiologist and cardiac surgeons in Australia

^aNHFA: National Heart Foundation of Australia.

^bCSANZ: Cardiac Society of Australia and New Zealand.

^cRACGP: Royal Australian College of General Practitioners.

Annual Cross-sectional Awareness Surveys to General Practitioners in 2019 and 2020

From the 4000 GPs on the distribution list, 312 GPs responded in 2019, and 189 GPs responded in 2020. Respondents'

awareness of specific cardiac clinical guidelines and reported the use of guidelines and the Smart Heart Guideline app are presented in [Table 2](#).

Table 2. Frequencies of general practitioners (GPs) who reported being aware and frequently using specific guideline resources in the annual GP surveys in 2019 (n=312) and 2020 (n=189).

Surveys	Heart failure ^a , n (%)	Atrial fibrillation ^b , n (%)	App ^c , n (%)
GP survey 2019			
Aware of the resource	159 (51)	140 (45)	Not asked
Frequently uses the resource	9 (7)	19 (6)	Not asked
GP survey 2020			
Aware of the resource	113 (60)	102 (54)	34 (18)
Frequently uses the resource	11 (6)	11(6)	10 (5)

^aGuidelines for the prevention, detection, and management of heart failure in Australia 2018 [13].

^bGuidelines for the prevention and management of atrial fibrillation in Australia 2018 [12].

^cSmart Heart Guideline app.

Data From the App Store and Google Play

During the period from October 1, 2019, to June 30, 2021, the Smart Heart Guideline app had 11,313 downloads (n=7483, 66% from the App Store; n=3830, 34% from Google Play). Data from the App Store indicated over 59,900 impressions (the number of times the Smart Heart Guideline App appeared in an App Store search) with 9000 product page views (number

of times a user viewed the apps product page in the App Store), resulting in 7483 downloads. Of these downloads, the majority (6300/7483, 84%) were a direct result of searching for the Smart Heart Guideline app in the App Store. The remaining downloads resulted from accessing the app's product page via the organization's webpage (610/7483, 8%) from browsing the App Store (n=346, 5%) or from an app referrer (a link within another app; n=214, 3%). The app had consistent conversion rates

(number of downloads divided by the number of impressions) throughout this period in both the App Store and Google Play. Data from the App Store showed that most downloads were on a mobile device (6951/7483, 93%) with fewer downloads on a tablet (532/7483, 7%). The App Store data showed low average use of the app, with an average of 2.06 sessions per user during the 20-month period. Additionally, Google Play data showed that from the 3830 downloads, most (3260/3830, 85%) resulted in user losses (app deletion by users). Download data from the App stores are presented in [Multimedia Appendix 2](#).

Discussion

Principal Findings

Following a survey among end users, which revealed that approximately two-thirds (318/504, 63%) of health professional reported being “likely” or “very likely” to use an Australian-specific mobile app to access cardiology guidelines, the Smart Heart Guidelines app was launched in October 2019. Downloads of the app during the first 20 months from users deliberately searching for the Smart Heart Guideline app in the App Store and Google Play indicate that promotional and implementation activities were useful in raising awareness of the app. The total number of app downloads (>11,000), primarily in smartphones in the first 20 months from app launch, is encouraging. However, usage data show people tended to use the app only a couple of times and many deleted the app, indicating it may not be meeting users’ needs. Responses from the 2019 and 2020 GP surveys demonstrate a consistent lack of awareness and use of clinical guidelines, despite efforts to disseminate broadly and improve accessibility, including open access publishing. Although 18% (34/189) of GPs reported awareness of the Smart Heart Guidelines app in the 2020 GP survey, fewer (10/189, 5%) reported frequently using it.

Comparisons With Prior Work

Guideline implementation is notoriously challenging [3]. Internationally, there have been mixed experiences with the development and use of clinician-facing guideline apps. The National Institute for Health and Care Excellence, United Kingdom, a major developer of clinical guidelines, launched a guideline app in 2012 only to retire it in 2018 because app use stagnated and more people were directly accessing their website for information [19]. It is important to consider the purposes of a guideline app, and if it is created for voluntary download and passive access to guideline information, it may not be meaningful to clinicians and may have low impact on practice and behavioral change. Contrastingly, apps involving more interactive and specific decision support tools may be better in improving guideline adherence and changing patient outcomes. The European Society of Cardiology Atrial Fibrillation clinical guideline app has demonstrated the value of integrating novel digital technology into clinical practice, with potential for optimizing health care professionals’ adherence to recommendations of pharmacological and interventional therapy for patients with atrial fibrillation [4]. Our App included a combination of guideline information and interactive decision support tools.

In a literature review of medical smartphone apps in clinical decision support, Watson et al [20] identified 48 trials and one Cochrane review finding that while diagnostic accuracy studies are plentiful, studies to determine whether guideline apps improve adherence to guidelines are only beginning to emerge, usually in the form of before-and-after studies, often in global health. For example, in India, in a study of over 6000 participants, a nurse - facilitated smartphone - enabled hypertension and diabetes mellitus intervention in primary care was associated with significant improvements in blood pressure and blood glucose control over 18 months [21]. The nurse examined and entered patient parameters into a mobile phone-based clinical decision support system to generate a prescription, which was reviewed by a physician [21]. In contrast, in a small randomized controlled trial of pediatric doctors in the United States in a hospital simulation study, a guideline app developed to support and drive cardiopulmonary resuscitation in real time improved guideline adherence compared with other tools including pediatric advanced life support pocket cards. The app was associated with a shorter time to first and subsequent defibrillation attempts and fewer medication errors.

A reported barrier to health professionals’ uptake of guideline apps is the lack of an international regulatory framework to ensure that the apps are evidence-based and held to a quality standard [15,22]. In Australia, therapeutic goods including medical software must be entered in the Australian Register of Therapeutic Goods, and registration of the app as a class 1 medical device may have positively influenced the uptake of the app. Studies investigating if the investment in creating and maintaining a guideline app is superior to other guideline implementation strategies are lacking [20,23]. It was beyond the scope of this study to undertake a cost-benefit analysis of the app; however, reviews of cost-effectiveness of digital health interventions in the management of cardiovascular disease are generally promising [24].

Strengths and Limitations

A strength of this study is the use of multiple methods used to identify the acceptability of an Australian-specific cardiology clinical guidelines app and comparing App Store and Google Play usage data and GP experience survey data over 2 years (2019 and 2020). The app included both guideline information along with clinical decision support tools and interactive algorithms. However, this study has limitations. First, although the acceptability survey had over 500 respondents, only a small proportion of them were GPs and cardiologists, the main intended users of the app, potentially limiting the representativeness of this sample. Second, response rates to the 2019 and 2020 surveys were low, limiting the generalizability of the results. Third, comparisons between the app’s use across the App Store and Google Play was restricted as data capture is not consistent across these commercial platforms. Fourth, we were unable to comment on health professional behavior change resulting from app use, as it was beyond the scope of this study, and alternate methods are required to understand how access to the app influenced clinical practice healthcare service delivery.

Future Directions

This formative research provides a summary of why and how an Australian-specific cardiac guideline app was developed, launched, promoted, and initially used. Future research could involve qualitative interviews with app users to explore which aspects of the app they find most and least useful and to discover any unmet needs of health professionals using the app. More tailored research into the use of clinical decision aids and support tools in the app would help better understand whether the app changes health professional behaviors and improves patient outcomes.

Conclusions

The development of the Smart Heart Guideline app, a cardiology-specific guideline app in Australia, was indicated from surveying health professionals. The app incorporated guideline information and clinical support decision aids. Although downloads of the app from among >11,000 users in the first 20 months was a promising finding, the frequency of using the app was low and deletion of the app was high. Further evaluation of the app is needed to understand the most and least useful aspects and to understand if using the app improves guideline adherence and impacts patient outcomes.

Acknowledgments

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Smart Heart App user interface.

[PNG File , 374 KB - [formative_v6i8e35599_app1.png](#)]

Multimedia Appendix 2

Number of Smart Heart guidelines app downloads by month from the Apple app store and Google Play store.

[PNG File , 26 KB - [formative_v6i8e35599_app2.png](#)]

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Abbreviations

GP: general practitioner

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Original Paper

A Psychological Support Intervention to Help Injured Athletes “Get Back in the Game”: Design and Development Study

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Abstract

Background: After a serious knee injury, up to half of athletes do not return to competitive sport, despite recovering sufficient physical function. Athletes often desire psychological support for the return to sport, but rehabilitation clinicians feel ill-equipped to deliver adequate support.

Objective: We aimed to design and develop an internet-delivered psychological support program for athletes recovering from knee ligament surgery.

Methods: Our work for developing and designing the Back in the Game intervention was guided by a blend of theory-, evidence-, and target population-based strategies for developing complex interventions. We systematically searched for qualitative evidence related to athletes' experiences with, perspectives on, and needs for recovery and return to sport after anterior cruciate ligament (ACL) injury. Two reviewers coded and synthesized the results via thematic meta-synthesis. We systematically searched for randomized controlled trials reporting on psychological support interventions for improving ACL rehabilitation outcomes in athletes. One reviewer extracted the data, including effect estimates; a second reviewer checked the data for accuracy. The results were synthesized descriptively. We conducted feasibility testing in two phases—(1) technical assessment and (2) feasibility and usability testing. For phase 1, we recruited clinicians and people with lived experience of ACL injury. For phase 2, we recruited patients aged between 15 and 30 years who were within 8 weeks of ACL reconstruction surgery. Participants completed a 10-week version of the intervention and semistructured interviews for evaluating acceptability, demand, practicality, and integration. This project was approved by the Swedish Ethical Review Authority (approval number: 2018/45-31).

Results: The following three analytic themes emerged from the meta-synthesis (studies: n=16; participants: n=164): (1) tools or strategies for supporting rehabilitation progress, (2) barriers and facilitators for the physical readiness to return to sport, and (3) barriers and facilitators for the psychological readiness to return to sport. Coping strategies, relaxation, and goal setting may have a positive effect on rehabilitation outcomes after ACL reconstruction (randomized controlled trials: n=7; participants: n=430). There were no trials of psychological support interventions for improving the return to sport. Eleven people completed phase 1 of feasibility testing (technical assessment) and identified 4 types of software errors, which we fixed. Six participants completed the feasibility and usability testing phase. Their feedback suggested that the intervention was easy to access and addressed the

needs of athletes who want to return to sport after ACL reconstruction. We refined the intervention to include more multimedia content and support access to and the use of the intervention features.

Conclusions: The Back in the Game intervention is a 24-week, internet-delivered, self-guided program that comprises 7 modules that complement usual rehabilitation, changes focus as rehabilitation progresses, is easy to access and use, and includes different psychological support strategies.

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KEYWORDS

sports; medicine; rehabilitation; sports injury; psychological support; mental health; postoperative medicine; feasibility; eHealth; mobile phone

Introduction

Background

After a serious knee injury, up to half of athletes do not return to competitive sport [1]. Athletes typically recover sufficient knee function for withstanding the physical demands of playing their sport, but an athlete's mental state is often the main hurdle to returning to sport [2]; the physical and psychological readiness to return to sport often do not coincide. The fear of reinjury is the most frequent reason reported by athletes who do not return to their preinjury sport or give up their sport after anterior cruciate ligament (ACL) injury or reconstruction [2,3]. Athletes of all ages at all participation levels can have problems with returning to sport after ACL reconstruction [1,4].

The objective of our work was to design and develop an internet-delivered psychological support program for nonprofessional athletes who are recovering from knee ligament (ACL) injury. The aim of the Back in the Game intervention is to deliver on-demand psychological support in parallel with

usual postoperative rehabilitation. The goal is to improve athletes' confidence to return to sport and subsequently improve the return to preinjury sport rate after ACL reconstruction.

Background Theory

This paper describes the processes for developing an internet-delivered program that provides psychological support for the return to sport to athletes recovering from knee ligament surgery (ACL reconstruction). *Development* refers to the entire process for arriving at an intervention to test in a randomized controlled trial. *Design* refers to the specific decisions we made about the intervention content, format, and delivery mode [5].

We adopted a blended approach [5,6] to developing and designing the Back in the Game intervention, which leaned heavily on theory- and evidence-based (United Kingdom Medical Research Council framework for developing and evaluating complex interventions [7]) approaches and target population-based (person-based [8]) approaches. O' Cathain et al's [5] taxonomy and synthesis guided the development of the eight building blocks that underpin our work (Figure 1).

Figure 1. The eight building blocks that underpin our work for developing the Back in the Game intervention.



Who Benefits From a Psychological Support Intervention?

Athletes with ACL injury expect and desire to return to sport [9-11]. Up to 9 in every 10 recreational athletes expect to return to their preinjury sport after ACL reconstruction [11,12]. Yet, fewer athletes than expected achieve their return to sport goals [1]. Psychological factors have large effects on return to sport outcomes after ACL reconstruction and larger effects on outcomes other than physical function [13,14]. Many psychological factors, including confidence, anxiety, and risk appraisal, are potentially modifiable [1,13]. Greater psychological readiness (a construct that incorporates confidence, emotions, and risk appraisal) is associated with a greater likelihood of returning to the preinjury sport [1]. Therefore, an effective intervention that provides psychological

support for the return to sport is likely to be relevant for a broad cross section of athletes.

Context of the Target Population

A biopsychosocial approach to health and rehabilitation is the dominant paradigm within which health care is delivered in the 21st century [15]. Clinicians recognize that different patients require different emphases on biological, psychological, and social elements and different emphases at different times during a course of treatment. Recovering physical function is vital for achieving return to sport goals; athletes require sufficient physical capacity for coping with the demands of playing their sport, executing their skills as desired, and staying injury-free [16].

The transition from rehabilitation to the resumption of sport after injury can be difficult. Young athletes undergoing rehabilitation get bored and lose motivation during the long

rehabilitation period [17,18]. They feel frustrated when rehabilitation does not focus on sports performance [19,20] and are concerned about their body's ability to cope with the demands of their sport [21]. Anxiety about the consequences of sustaining a knee injury again often besets athletes as they work toward returning to sport [22]. Adding to the challenge, athletes are often discharged from rehabilitation several months before attempting to return to sport. Critically, most athletes lack the support of a rehabilitation clinician during the transition back to sport.

High-quality rehabilitation aims to help athletes gradually regain knee function and physically and mentally prepare for returning to sport. The return to sport occurs along a continuum [23], beginning at injury diagnosis and concluding when the athlete is performing as desired in their chosen sport. Therefore, return to sport support should also be delivered along the same continuum.

Methods

Study Design

Our work for developing and designing the Back in the Game intervention involved systematically searching for and synthesizing available literature, designing and developing the intervention, and conducting feasibility testing. We synthesized information on the lived experiences, perspectives, and needs of active people with ACL reconstruction and the effects of psychological support interventions for improving ACL injury rehabilitation outcomes in athletes. After designing and developing the Back in the Game intervention, we conducted a 2-phase feasibility and usability study.

Lived Experiences, Perspectives, and Needs of Active People With ACL Reconstruction

To understand the issues to be addressed, based on the lived experiences, perspectives, and needs of active people with ACL reconstruction, we systematically searched electronic databases to identify qualitative research exploring the perceptions and experiences of active people with ACL reconstruction. We used the PerSPecTIF (Perspective, Setting, Phenomenon of Interest/Problem, Environment, Comparison, Time/Timing, Findings) framework [24] to construct the research question for a qualitative evidence synthesis, as follows: "From the perspective of an active person with ACL reconstruction, in the setting of completing or having completed rehabilitation, how does the phenomenon of biopsychosocial factors during recovery impact on a person's experiences and perceptions related to recovery and return to sport?" The meta-synthesis methods and results from 16 qualitative studies are outlined in [Multimedia Appendix 1](#) [9,10,17,18,25-36].

Effects of Psychological Support Interventions

To identify evidence of the effects of other psychological support interventions, we systematically searched for research addressing the following question: "What is the efficacy of psychological support interventions for improving ACL injury rehabilitation outcomes in athletes?" We identified and qualitatively summarized the major characteristics of psychological support for athletes and the consequences of

providing psychological support during rehabilitation after ACL reconstruction. The aim was to articulate a credible causal explanation for a psychological support intervention that improves the return to sport after ACL reconstruction. The review methods, as well as the specific results and quality assessments from the seven included randomized controlled trials, are outlined in [Multimedia Appendix 2](#).

Designing and Developing Back in the Game

By combining the results of qualitative and quantitative syntheses, we framed what a psychological support intervention should do and the target behaviors for achieving potential treatment outcomes. We established guiding principles to address key objectives of intervention design and important features that must be addressed to achieve the intervention objectives [8].

Ethics Approval

This project was approved by the Swedish Ethical Review Authority (approval number: 2018/45-31).

Feasibility and Usability Study

After designing the first iteration of the intervention, we completed a 2-phase feasibility testing project. Because Back in the Game was a new intervention, we wanted to ensure that it was appropriate and acceptable for athletes after ACL reconstruction. Detailed methods and results for the feasibility and usability study are in [Multimedia Appendix 3](#).

We used maximum variation sampling to recruit 11 participants for phase 1; these participants included physiotherapists, orthopedic surgeons, sports psychologists, researchers from the musculoskeletal rehabilitation field, and people with lived experience of ACL injury. For phase 2, we used strategic sampling to identify and recruit patients with recent ACL reconstruction who were aged between 15 and 30 years at the time of ACL injury, regularly played pivoting and/or cutting sports (eg, football, basketball, and floorball) prior to their injury, and intended to return to their sport. We invited 18 patients, and 7 consented to participate.

In phase 1 of feasibility testing, we focused on addressing practical issues. We sought feedback regarding technical problems with the platform that was used to deliver and display content (ie, feedback not specifically regarding the intervention content). In phase 2, we invited feedback via multiple rounds of interviews on the intervention content, look and feel of the user interface, flow and acceptability of content, frequency of content delivery, and value of the intervention.

Results

Lived Experiences, Perspectives, and Needs of Active People With ACL Reconstruction

A total of 16 descriptive themes emerged from the meta-synthesis, which we mapped to the following three analytic themes: (1) barriers and facilitators for the psychological readiness to return to sport, (2) barriers and facilitators for the physical readiness to return to sport, and (3) tools or strategies for supporting rehabilitation progress.

Athletes at all levels (ranging from amateur to professional) shared common perceptions and lived experiences of rehabilitation after ACL reconstruction (Table S1 in [Multimedia Appendix 1](#) [9,10,17,18,25-36]). Athletes wanted to play sports and saw playing sports as central to their self-identity [25,26]. They felt happy when they were playing sports [9]. However, the experience of ACL injury had often irrevocably changed how they thought of themselves and their capacity to contribute to society [27].

Anxiety and low confidence were dominant emotions. Athletes felt scared, uncertain, frustrated, and hopeless at different times during recovery and when returning to sport. Sometimes, athletes avoided tasks or activities (eg, sport-specific movements) because they lacked confidence in their knee

[9,10,17,18,26-34]. Athletes drew support, feedback, encouragement, and reassurance from people they trusted. Previous experiences of sports injury also helped athletes know what was required to recover and return to sport [17,18,25-33,35,36].

Athletes judged that quality rehabilitation programs included strategies that help build their physical and mental capacity for participating safely in sports again [9,10,17,28,29,32,34,36]. [Textbox 1](#) summarizes the key aspects of athletes' perspectives, lived experiences of rehabilitation, and needs after ACL reconstruction that informed the development and design of the intervention (Table S2 in [Multimedia Appendix 1](#) [9,10,17,18,25-36] provides a detailed summary).

Textbox 1. Evidence summary: athletes' lived experiences. Themes 1, 2, and 3 were barriers and facilitators for the psychological readiness to return to sport, barriers and facilitators for the physical readiness to return to sport, and tools or strategies for supporting rehabilitation progress, respectively.

Athletes' lived experiences

- Athletes wanted to play sports and felt happy when they were playing sports (theme 1).
- Athletes felt nervous and worried about sustaining another knee injury (theme 1).
- Athletes lacked self-confidence, self-efficacy, and self-esteem during rehabilitation (theme 1).
- Athletes knew there were risks associated with returning to sport and took active steps to manage the risk of new injury (theme 2).
- Injured athletes wanted the following (theme 3):
 - Strategies to help manage pain and injury risk
 - An understanding of their injury and what was required for recovery
 - Support from important people (eg, family, friends, physiotherapist, and coach)
 - Help with setting goals
 - Regular feedback

Effects of Psychological Support Interventions

We identified 7 randomized controlled trials for inclusion in the quantitative synthesis of the effects of psychological interventions in ACL rehabilitation (Figure S1 in [Multimedia Appendix 2](#)). The psychological support interventions with the most research attention were imagery, relaxation, and goal setting. Effect estimates are summarized in Table S1 in [Multimedia Appendix 2](#).

Textbox 2. Evidence summary: treatment approaches.

Treatment approaches

- Watching others who have experienced the injury and rehabilitation before completing rehabilitation exercises
- Learning about the ways people coped with the mental and physical challenges of rehabilitation
- Watching a carefully curated set of images designed to induce positive psychological responses toward injury and rehabilitation
- Guided relaxation
- Guided goal setting
- Guided imagery

Psychological skills training that targets coping strategies, relaxation, and goal setting might work for improving physical impairments and psychological outcomes after ACL reconstruction. It is uncertain whether imagery/visualization is helpful for injured athletes. [Textbox 2](#) outlines treatment approaches with the potential to improve health outcomes and the potential for inclusion in a new psychological support intervention.

Designing and Developing Back in the Game

A psychological support intervention for helping athletes return to sport after injury should deliver practical tools or strategies

that athletes can use to complement physical rehabilitation ([Textbox 3](#)). The intervention should (1) help injured athletes understand their injury and what is required for recovery; (2) support athletes in setting realistic goals and provide regular

feedback on progress toward athletes' goals; (3) teach athletes strategies for managing fear and anxiety, boosting low confidence and self-efficacy, and maintaining motivation and athlete identity; and (4) support athletes in establishing lifelong habits and staying healthy while playing sports. We established 5 guiding principles [8] for intervention design (Textbox 4).

Back in the Game delivers cognitive behavioral therapy plus motivational interviewing to help athletes identify negative

thoughts about the behavior of playing sports and reframe negative thoughts into positive thoughts to promote behavior change (Figure 2). The rationale for the content and delivery mode is that supporting athletes in achieving psychological readiness to return to sport while they complete usual postoperative rehabilitation helps them to more successfully transition back to the preinjury sport.

Textbox 3. Evidence summary: behaviors to target with a psychological support intervention for athletes with anterior cruciate ligament reconstruction.

Behaviors to target

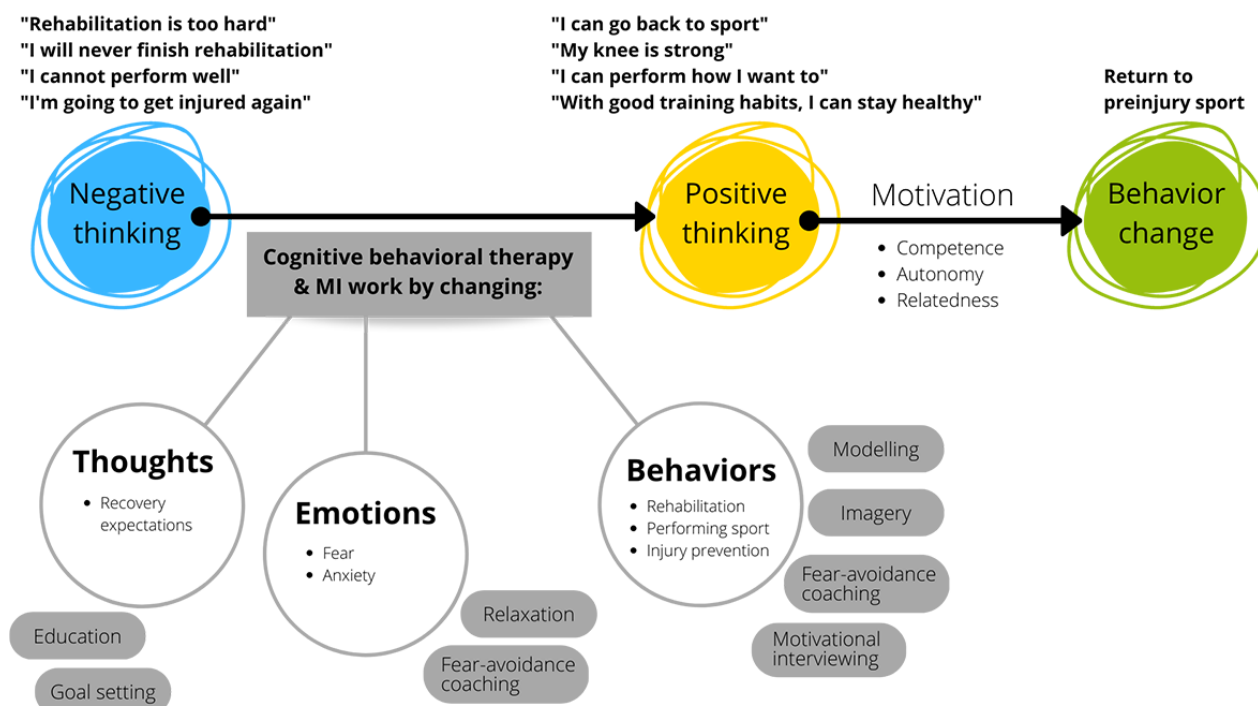
- Fear avoidance
- Setting goals
- Understanding how to recover well from injury
- Safely participating in sport
- Ongoing injury prevention
- Practicing psychological support skills (imagery/visualization, relaxation, etc)

Textbox 4. Evidence summary: guiding principles for the structure and delivery of the Back in the Game intervention.

Guiding principles

- Complement usual rehabilitation care
- Change focus as rehabilitation focus changes
- Self-guided and easy to access
- Unobtrusive and not burdensome to use
- Include a range of psychological techniques/strategies (something to meet everyone's needs)

Figure 2. Back in the Game is grounded in cognitive theory and self-determination theory and aims to facilitate return to sport behavior change. Topics that are listed in grey ovals (adjacent to "Thoughts," "Emotions, and "Behaviors") are the key contents of the intervention modules. MI: motivational interviewing.



Back in the Game is a 24-week intervention that commences in the first week following ACL reconstruction. A total of 7 modules (Figure 3) are delivered in parallel with usual rehabilitation care. The intervention mirrors the progression of rehabilitation, functions as a stand-alone eHealth intervention, and does not require monitoring or input from the clinician responsible for delivering rehabilitation. Tasks are delivered in a progressive fashion (ie, users receive a notification to log in and take action in the app every time there is new content available and up to two reminders to access the content each week) and are tailored to the stage of face-to-face rehabilitation.

Athletes choose, from a menu of different tasks, the task that best suits their needs during each intervention session.

The motivational interviewing delivered in Back in the Game focuses on athletes' confidence for recovering from their knee injury, returning to sport, returning to performance, and staying injury-free (Figure 4). Linked to each motivational interviewing question are strategies for building athletes' psychological skills in relaxation, mental imagery, education, and goal setting (Figure 4). The modules *Handling thoughts & emotions* and *Injury education* comprise tailored content that athletes can watch, read, and listen to (Figure 5).

Figure 3. Summary of the seven self-directed modules (covering psychological skills, psychoeducation, and principles of motivational interviewing) of the Back in the Game intervention. Each dot represents how often the user is prompted to complete a task in each module.

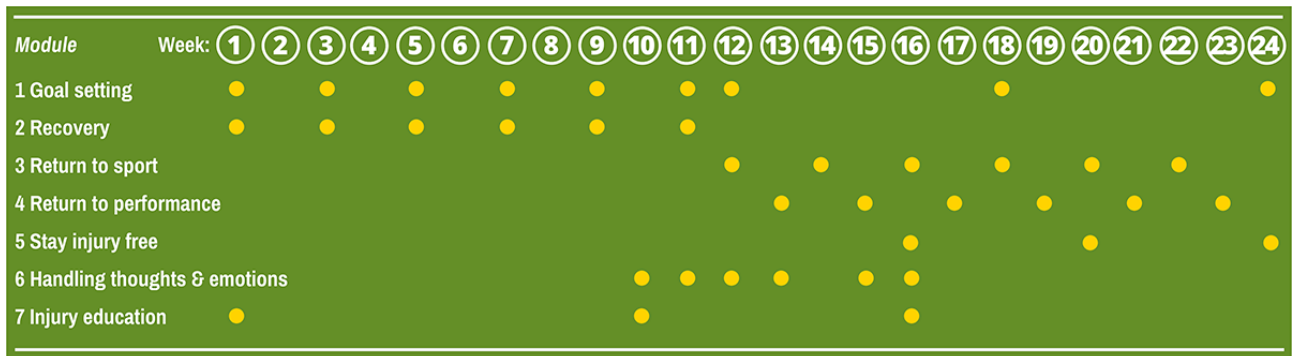







Figure 4. Overview of the "Recovery," "Return to sport," "Return to performance," and "Staying injury-free" modules plus linked cognitive behavioral therapy tasks (strategies). This screenshot is presented in the content overview video that accompanies the app introduction, which users receive when they register.

 **Building self-confidence**

Question: how confident are you about:

 Recovery?	 Return to sport?
 Return to performance?	 Staying injury-free?

Choose a strategy:






-   Relaxation
-  Mental training
-  Listen to other athletes
-  Set some goals

Figure 5. Overview of the "Handling thoughts & emotions" and "Injury education" modules. This screenshot is presented in the content overview video that accompanies the app introduction, which users receive when they register.



Feasibility and Usability Study

We worked with the content delivery platform vendor (Briteback AB, Norrköping, Sweden) to complete additional engineering tasks and implement bug fixes in response to the feedback we received in phase 1. Table S1 in [Multimedia Appendix 3](#) details the specific bugs and bug fixes. In phase 2, we identified aspects of the intervention that were satisfactory and did not require changes (Table S4 in [Multimedia Appendix 3](#)) and aspects that required specific changes/actions (Table S5 in [Multimedia Appendix 3](#)).

Users (1) thought that the intervention would add value to their physical rehabilitation, (2) found appealing content with appropriate flow, (3) appreciated receiving notifications and reminders to engage with the intervention, and (4) said that the goal-setting module was helpful. Users (1) wanted more support for starting the intervention, (2) wanted to better understand

what they had to do, and when and why they had to do certain tasks, and (3) wanted more feedback on their progress through the intervention. In response to the feasibility testing results, we added additional video and infographic content and strengthened the system for providing tailored progress reports and feedback.

Discussion

Principal Findings

Back in the Game employs a mix of psychological skills, psychoeducation, and motivational interviewing. Our blended approach to developing the intervention ensured that the content choices were informed by the prominent emotions that athletes said they felt (confidence and fear), the strategies that were tested in previous research (goal setting, imagery, relaxation, and behavior modeling), and what athletes said they needed

(support for setting goals, managing pain and injury risk, understanding their injury and what was required for physical and mental recovery, and receiving feedback on their recovery progress). A person-based approach [8] informed the decisions we made about the intervention content, format, and delivery mode (designing the intervention). This approach allows designers to understand what to do to design an attractive intervention that (1) addresses end users' needs and (2) is feasible to implement [8].

Internet-delivered psychological support works best when users feel engaged in their mental health support in real time, when the intervention employs a user-friendly interface that prioritizes multimedia, and when the intervention structure encourages users to engage in self-monitoring [37]. We embraced the recommendations for designing mental eHealth interventions and established key design principles for guiding our work.

We recommend that athletes use the Back in the Game intervention for a minimum of 30 minutes every week. It is rare for athletes to return to a pivoting sport before 6 postoperative months, and athletes are actively encouraged to delay returning to unrestricted participation in a pivoting sport for at least 9 months [16]. The intervention is designed to help athletes prepare for the return to sport; we do not expect athletes to return to their preinjury sport during the 24-week intervention period. However, we expect that some athletes will participate in a modified sport (eg, no contact and no direction changes) by the end of the intervention period.

People's beliefs, perceptions, plans, and interpretations influence their behaviors and emotions and determine how the world influences them [38,39]. Cognitive theory underpins cognitive behavioral therapy. The aim of cognitive behavioral therapy is to transform negative thoughts/thinking into positive thoughts/thinking by changing a person's thoughts, emotions, and behaviors. Cognitive behavioral therapy targets a person's interpretations and beliefs. Uncovering and changing negative thinking patterns boosts a person's self-motivation to engage in a health-promoting behavior [38]. This is the central theory underpinning the Back in the Game content. Based on the combination of cognitive theory and self-determination theory [40], we propose that when one has positive thoughts about a behavior, the motivation to engage in this behavior is enhanced, ultimately boosting the likelihood of engaging in and sustaining the behavior.

We recognized that motivation was highlighted in athletes' lived experiences of recovering from ACL reconstruction, and we incorporated self-determination theory into our framework for Back in the Game. The motivation to change one's behavior is strongest when one feels that the behavior is self-determined [40]. For the return to sport, an athlete's self-motivation to engage in a sport (ie, fulfilling return to sport goals) is driven by the following three key elements: a sense of personal control over what happens (autonomy), a belief that one has the skills and knowledge to succeed (competence), and support for achieving one's goals (relatedness) [40].

Real-world Issues

Back in the Game is a self-directed psychological support intervention that was designed to be available on-demand and be delivered via the internet (smartphone app or website). An intervention that complements physical (face-to-face) rehabilitation might be an effective tool for overcoming potential barriers to delivering effective psychological support to athletes during and after rehabilitation [37,41]. We speculate that geography, cost, and stigma are barriers that might prevent athletes from accessing the psychological support that they need to return to sport after injury. An eHealth intervention can deliver content to athletes, regardless of where they live or train, at low (or no) financial cost to the athletes, and the athletes do not need to disclose to anyone that they are accessing the psychological support content provided by an eHealth app.

For at least 2 decades, clinicians and health researchers have developed and delivered psychological treatments via the internet [42]. Digital interventions can be as effective as in-person visits to a psychologist, can deliver sustained benefits, and are probably cost-effective [43]. Using digital interventions to complement face-to-face sports injury rehabilitation is an area of growing research interest [44-46]. eHealth technology facilitates the low-cost, on-demand delivery of psychological support to injured athletes [41-43]. Smartphones are an accessible platform [47] that can be used to deliver evidence-based strategies for improving the confidence to return to sport that athletes can access anywhere at any time.

Conclusion

We describe a multifaceted approach to developing a complex eHealth intervention that considers an athlete's lived experience and context, previous work in the field, a theoretical rationale for the intervention, and input from end users to ensure an appropriate and acceptable final product.

The Back in the Game intervention is a 24-week, internet-delivered program that covers psychological skills, psychoeducation, and principles of motivational interviewing. The self-guided intervention complements usual rehabilitation, changes focus as rehabilitation progresses, is easy to access and use, and includes different psychological support strategies. End users suggested that the Back in the Game intervention met our objective of developing a psychological support intervention that was easy to access, focused on the return to sport, and complemented usual postoperative rehabilitation (ie, the intervention was appropriate and acceptable for the target population). End users had a generally positive attitude toward the intervention.

The results from the feasibility and usability testing phase confirmed that Back in the Game is an intervention that is worth testing in a definitive randomized controlled trial. The Back in the Game trial [48] commenced recruitment in 2019, and it aims to recruit 220 young athletes with ACL injury to test the effects of the Back in the Game intervention on the return to preinjury sport and level after ACL reconstruction.

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Authors' Contributions

CLA is the principal investigator and project leader. CLA was responsible for funds acquisition; intervention design, development, and production; database searching; article selection; data extraction and synthesis; the feasibility and usability study design; intervention administration; data collection, analysis, and synthesis; and the drafting, revision, and submission of the manuscript. NH was responsible for database searching, article selection, data extraction, data synthesis, and the review of the manuscript. PO and KEW were responsible for funds acquisition, project planning, intervention design and development, and the review of the manuscript. JK is the coprincipal investigator. JK was responsible for funds acquisition, project planning, intervention design and development, qualitative data extraction, the feasibility and usability study design, data synthesis, data storage, and the review of the manuscript. All authors read and approved the final version of the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Lived experiences, perspectives, and needs of active people with anterior cruciate ligament reconstruction.

[PDF File (Adobe PDF File), 424 KB - [formative_v6i8e28851_app1.pdf](#)]

Multimedia Appendix 2

Effects of psychological support interventions for improving anterior cruciate ligament injury rehabilitation outcomes in athletes.

[PDF File (Adobe PDF File), 356 KB - [formative_v6i8e28851_app2.pdf](#)]

Multimedia Appendix 3

Feasibility and usability of the Back in the Game intervention.

[PDF File (Adobe PDF File), 3122 KB - [formative_v6i8e28851_app3.pdf](#)]

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Abbreviations

ACL: anterior cruciate ligament

PerSpecTIF: Perspective, Setting, Phenomenon of Interest/Problem, Environment, Comparison, Time/Timing, Findings

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Original Paper

Adding an App-Based Intervention to the Cognitive Behavioral Analysis System of Psychotherapy in Routine Outpatient Psychotherapy Treatment: Proof-of-Concept Study

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Abstract

Background: The Cognitive Behavioral Analysis System of Psychotherapy (CBASP) is an empirically supported psychotherapeutic treatment developed specifically for persistent depressive disorder. However, given the high rates of nonresponse and relapse, there is a need for optimization. Studies suggest that outcomes can be improved by increasing the treatment dose via, for example, the continuous web-based application of therapy strategies between sessions. The strong emphasis in CBASP on the therapeutic relationship, combined with limited therapeutic availabilities, encourages the addition of web-based interventions to face-to-face therapy in terms of blended therapy.

Objective: The aim of this study was to test an app-based intervention called *CBASPath*, which was designed to be used as a blended therapy tool. *CBASPath* offers 8 sequential modules with app-based exercises to facilitate additional engagement with the therapy content and a separate exercise to conduct situational analyses within the app at any time.

Methods: *CBASPath* was tested in an open pilot study as part of routine outpatient CBASP treatment. Participating patients were asked to report their use patterns and blended use (integrated use of the app as part of therapy sessions) at 3 assessment points over the 6-month test period and rate the usability and quality of and their satisfaction with *CBASPath*.

Results: The results of the pilot trial showed that 93% (12/13) of participants used *CBASPath* as a blended tool during their therapy and maintained this throughout the study period. Overall, they reported good usability and quality ratings along with high user satisfaction. All participants showed favorable engagement with *CBASPath*; however, the frequency of use differed widely among the participants and assessment points. Situational analysis was used by all participants, and the number of completed modules ranged from 1 to 7. All participants reported blended use, although the frequency of integration in the face-to-face sessions varied widely.

Conclusions: Our findings suggest that the digital augmentation of complex and highly interactive CBASP therapy in the form of blended therapy with *CBASPath* is feasible in routine outpatient care. Therapeutic guidance might contribute to high adherence and increase patient self-management. A few adjustments, such as saving entries directly in the app, could facilitate higher user engagement. A randomized controlled trial is now needed to investigate the efficacy and added value of this blended approach. In the long term, *CBASPath* could help optimize persistent depressive disorder treatment and reduce relapse by intensifying therapy and providing long-term patient support through the app.

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KEYWORDS

Cognitive Behavioral Analysis System of Psychotherapy; persistent depressive disorder; blended therapy; internet and mobile-based Interventions; routine clinical care; eHealth; mobile phone

Introduction

Background

Up to 30% of all depressive disorders take a chronic course [1,2]. Persistent depressive disorder (PDD) is, compared with nonchronic major depressive disorder, associated with an earlier onset, a longer duration of the disorder, higher comorbidity rates of axis 1 and axis 2 psychiatric disorders, higher rates of suicidal behavior, alexithymia [3], and more childhood maltreatment [4]. Not surprisingly, treatment outcomes—both pharmacological and psychotherapeutic—are poorer, and recurrences are higher [5], often resulting in a higher frequency of treatment seeking [3]. Specific challenges in the treatment of PDD include impaired interpersonal functioning (ie, a more submissive and hostile interpersonal style), behavioral and emotional avoidance, pronounced help and hopelessness, rigid behavioral patterns, and high personal distress [3,6,7].

The *Cognitive Behavioral Analysis System of Psychotherapy* (CBASP), originally developed by McCullough [8], is, to date, the only psychotherapeutic approach that specifically targets PDD. CBASP integrates cognitive behavioral therapy (CBT) with interpersonal and psychodynamic theories and strategies [9]. The central element of treatment [10] is CBASP-specific *situational analysis*, a highly structured, multi-step interpersonal problem-solving task through which patients learn that their behavior has consequences and how to relate functionally to others. Situational analysis includes behavioral training in the form of role-playing, and the Kiesler interpersonal circumplex model [11] is used as a supplemental interpersonal strategy. At the start of therapy, formative early learning experiences are collected by creating a list of *significant others' histories*. The significant others history is then related to current interpersonal problems, initially within the therapeutic relationship. To achieve this, therapists strive for a therapeutic alliance described by *disciplined personal involvement*. Therapists regularly reveal their own feelings and reactions to patients' behavior and thus provide the foundation for corrective, healing interpersonal experiences within the therapy setting. Differences between the therapists' responses and negative experiences with significant others of the patients are emphasized using the *interpersonal discrimination exercise* (IDE).

CBASP as an outpatient treatment is an empirically supported treatment [12-15]. It has been shown to be particularly beneficial for patients with early onset [12], childhood maltreatment [16,17], and in combination with medication [14]. CBASP has also been shown to be effective in inpatient settings in open pilot studies [18-20]. However, high rates of nonresponse (40%-60%), nonremission (60%-80%), and relapse (up to 50% after 2 years) indicate the need for optimization [13,15,18,21].

Studies have shown that (1) a larger number of therapy sessions (at least 18 sessions [22]); (2) a longer treatment duration [15,22,23]; and (3) an intensification of CBASP in the sense of a dose increase through, for example, additional group therapy

or another additional therapy program [18,20] might improve therapy outcomes.

Psychotherapy resources are limited, and as CBASP requires special training, few therapists offer this treatment in routine care. Increasing CBASP therapy sessions for patients during treatment would thus result in much longer waiting times for individuals seeking this treatment. Hence, this is neither practicable nor efficient, and solutions are needed to increase the treatment dose without increasing the number of treatment sessions. This solution could then also be useful in supporting patients to maintain their treatment gains in the long term.

Internet- and mobile-based interventions (IMIs) offer high potential for psychotherapy [24]. Desktop-based IMIs have been proven to be effective and cost-efficient in delivering mental health care in numerous trials [25-27]. Guided interventions are associated with better adherence and outcomes than unguided ones [27-30]. Smartphone- or app-based IMIs have been less researched but promise to yield small to moderate effects in the treatment of depression ($g=0.33$ and $g=0.56$ [31,32]).

Research findings suggest that IMIs may also improve face-to-face therapy. In *blended therapy*, face-to-face therapy is augmented with IMIs [33]. This option of increasing the effectiveness of conventional therapy has been shown to be feasible [33-36]. The superiority of blended therapy compared with standard psychotherapy has been shown in 2 studies for mild to moderate depression, also at the 6-month follow-up [36,37]. A web-based self-management program, in combination with care as usual, also showed promising results for recurrent depression [38]. A plausible explanation for this large effect may simply be that the treatment dose was increased by adding the IMI. Another explanation could be that the more specific effect of self-directed, between-session practice and application of therapy skills in daily life contributed a significant additional benefit to an already effective therapy [39].

When conceptualizing IMIs within CBASP, the highly structured nature of the treatment and the high relevance of the therapeutic relationship but the simultaneous limitation of therapeutic availabilities suggest a blended approach to meet the needs of PDD patients. Interpersonal strategies for shaping the therapeutic relationship and behavioral training can still be applied in face-to-face sessions, whereas an IMI could support patients to elaborate and continuously apply learned CBASP strategies (eg, situational analysis) in everyday life, thus increasing the therapy dose. A total of 2 case reports of internet-based situational analysis training after CBASP inpatient treatment indicated good acceptability and feasibility [40]. Both individuals found the training helpful in transferring therapy content to everyday life.

Objective

Building on these positive first experiences, we developed an app-based intervention called *CBASPath* to be used as part of a blended CBASP therapy. The aim of this paper is to introduce

the features of *CBASPath*, describe the blended approach, and present the results of a pilot study investigating the feasibility of *CBASPath* use in routine clinical care. We examine the participants' engagement with *CBASPath*, which was blended with face-to-face sessions. Usability, app quality, and user satisfaction are important factors influencing continuous use [41]. Therefore, an additional open research question targeted participants' perceived usability, quality ratings, and satisfaction. Depression severity was observed in an exploratory manner.

Methods

Overview

To examine the feasibility of the blended *CBASPath* intervention, a single-arm, open pilot study was conducted in a routine care setting. Data were collected over a 6-month period at 4 assessment points.

Ethics Approval

The ethics committee of the Philipps University of Marburg granted ethical approval for all study procedures (file number 2019-29k).

Procedures

CBASP-certified practitioners in Germany were invited by mail to integrate *CBASPath* in their ongoing CBASP treatments in the context of the pilot study. Interested therapists received information about *CBASPath* and were instructed on how to give their patients access to it. Participants were given a link to a web-based survey [42]. Before the start of the first survey, participants were informed about study participation and app use and signed an informed consent form. Invitations for subsequent assessments were sent via email. Data were collected pseudonymously using self-generated codes to allocate assessment points. Demographic variables, self-reported diagnoses, depression severity, and prior experience with psychotherapy, as well as information on participants' current therapy and participants' attitudes toward IMIs, were assessed at baseline. Participants' engagement in *CBASPath* and depression severity were assessed 6, 12, and 24 weeks after initial use. Usability, app quality, and satisfaction with the app were assessed at week 12. A raffle of web-based vouchers for participants who took part in all the surveys served as an incentive. Manuals for therapists and patients provided suggestions for incorporating the app into the therapy. Telephone consultations for therapists were offered as needed, primarily related to study procedures and technical difficulties.

Participants

German-speaking patients who were aged at least 18 years and who were currently undergoing outpatient CBASP therapy (regardless of the stage of therapy) were eligible to participate. Additional inclusion criteria were the possession of a smartphone with internet access (Android or iOS operating system) and sufficient skills to use it, a valid email address, and willingness to take part in the web-based survey.

The *CBASPath* Intervention and Its Use in Blended CBASP Therapy

CBASPath is a CBASP-specific mobile app course integrated into the *MindDoc* app (MindDoc Health GmbH). *MindDoc* is a certified class 1 medical device that includes an adaptive monitoring system, automated feedback about the user's mental health, and courses and exercises facilitating the self-management of mental health complaints.

For the study, a designated setup of the *MindDoc* app was created, including the *CBASPath* material and additional content depending on the individual symptoms (psychoeducation about depression, mindfulness, relaxation, rumination, self-compassion, and sleep). All content could be used at the user's discretion.

The *CBASPath* material was developed specifically for this study and was accessible only to the study participants. All contents were based on the McCullough [8] concept for outpatient CBASP therapy, related treatment manuals [43,44], and a self-help book for patients with PDD [45]. We also included both CBASP practitioners and patients in the development process.

We strived to make all content as app-friendly as possible; for example, by keeping reading times short, avoiding unnecessary typing, and using interactive features. *CBASPath* includes 8 sequential modules in line with CBASP therapy and an additional module comprising 4 different step-by-step exercises for conducting personal situational analysis (interpersonal, future, and internal focus) and IDE at any time (for a detailed description, see Table 1 and sample screenshots in Figure 1). Minor adjustments to the original situational analysis and IDE exercises were made to simplify their use on the smartphone (eg, describing the situation using a meaningful heading and using multiple-choice answer options where possible).

The *CBASPath* intervention serves as an augmentation to face-to-face CBASP therapy. Although the course is primarily designed for patients to use on their own between sessions, individual exercises are closely intertwined with the content of CBASP therapy. Patients are repeatedly encouraged to discuss difficulties, success, and results of exercises with their therapist in sessions, or therapy content are followed up with the help of specific exercises (eg, on transference hypothesis). The extent to which *CBASPath* is embedded into therapy sessions can be adapted according to individual needs and the therapy stage. Intensive therapeutic guidance at the beginning in the form of a detailed introduction, specific time for questions or doubts, and concrete suggestions for suitable exercises to work on between sessions might motivate patients and prevent early attrition. Although all 8 modules are designed to be completed between sessions without therapeutic help, not reviewing completed exercises, as with analog homework, could be demotivating and have a negative impact on future use [46]. Blended use might provide additional opportunities for disciplined personal involvement, IDE, and eventually corrective relationship experiences (eg, recognition through the promotion of completed exercises and dealing with problems and doubt). Over the course of therapy, *CBASPath* should become an integral part of therapy, and therapeutic guidance can be

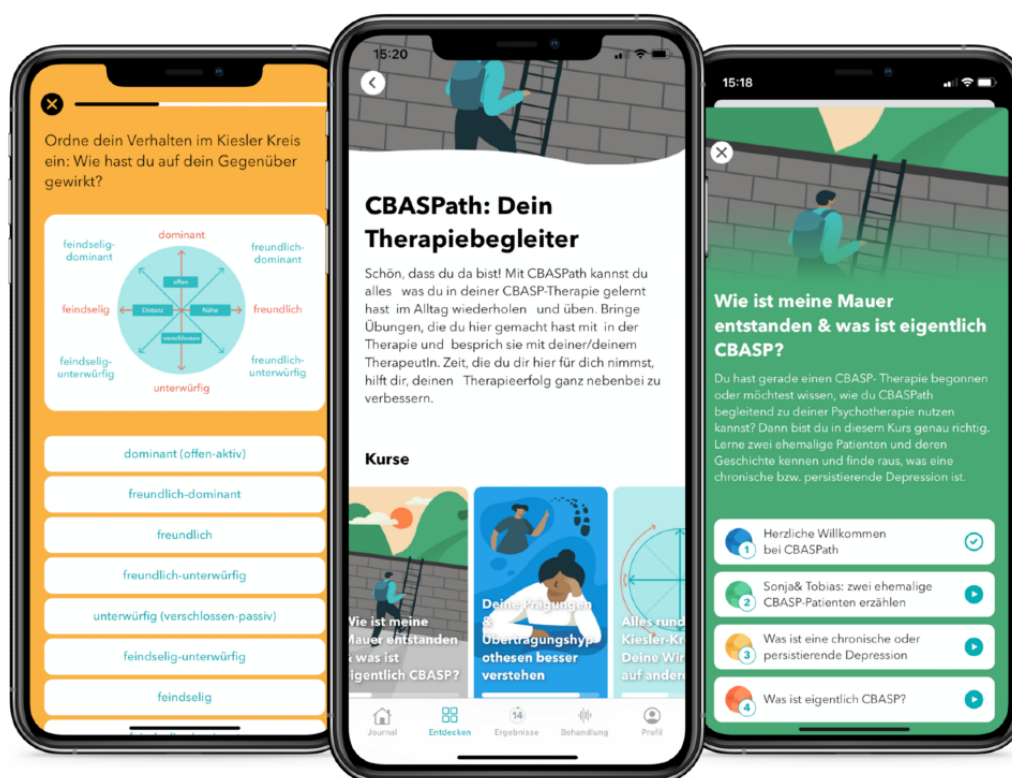
gradually faded out. After the therapy is completed, *CBASPath* can serve as a self-help tool to maintain therapeutic gains and prevent relapse. Ideally, the course is now a daily companion for the patient, which they can fall back on as needed and thus continue to incorporate CBASP skills into everyday life.

Table 1. Comparison of Cognitive Behavioral Analysis System of Psychotherapy (CBASP) components and their representation within *CBASPath*.

CBASP therapy components (disciplined personal involvement)	CBASPath content
Therapy start	<ul style="list-style-type: none"> Module 1: Information on the blended use of <i>CBASPath</i>; psychoeducation on persistent depressive disorder and CBASP; written and audio-based introduction of 2 prototype patients
Significant others history and transference hypotheses	<ul style="list-style-type: none"> Module 2: Psychoeducation on significant others history and transference hypotheses including examples of prototype patients; reflecting and journaling of personal significant others history and transference hypotheses developed in therapy
Kiesler circumplex model	<ul style="list-style-type: none"> Module 3: Psychoeducation; solidifying knowledge with interactive exercises (eg, experiencing different dimensions of the model through short videos or becoming familiar with the model by positioning celebrities in the model); hands-on exercise with reflection (eg, to try out different and unfamiliar behaviors in everyday life and to record the reaction of others in the app)
Situational analysis and training of interpersonal skills	<ul style="list-style-type: none"> Module 4: Psychoeducation on situational analysis; step-by-step training based on a prototype patient's situation presented via video and subsequent sample solutions. Module 6: Video-based empathy training; hands-on empathy exercise with reflection Situational analysis exercises: conducting personal situation analysis (3 different types of situation analysis with interpersonal, future, and internal focus)
IDE ^a	<ul style="list-style-type: none"> Module 5: Psychoeducation on IDE and "hot spot" situations; IDE training based on a prototype patient's situation and subsequent sample solutions; reflecting and journaling of personal hot spots. IDE exercise: conducting personal IDEs
Therapy completion	<ul style="list-style-type: none"> Module 7 and 8: Summarizing (and celebrating!) personal therapy successes; reflecting on helpful therapy skills as part of relapse prevention; planning further use of app as long-term support and maintenance

^aIDE: interpersonal discrimination exercise.

Figure 1. User interfaces of the *CBASPath* course from left to right: (1) Categorizing one's own behavior in the Kiesler circumplex model in the context of a personal situational analysis; (2) home screen of the *CBASPath* course; and (3) overview of different exercises in module 1.



Measures

Participants' engagement in the *CBASPath* was measured using self-report items at weeks 6, 12, and 24. Participants specified their average duration per app use in minutes, frequency of use per week, whether they conducted situational analysis and IDE, and how often *CBASPath* was used during face-to-face sessions as an additional therapy tool or for prediscussion and follow-up discussion of completed content, all regarding the last measurement time. The usability of the *CBASPath* course was measured using the System Usability Scale (SUS) [47]. The scale, which has high validity and economy, was adapted to the app context for the purpose of this study, as recommended by the author [47]. Participants' global satisfaction with the blended use of *CBASPath* was assessed using the Client Satisfaction Questionnaire adapted for internet-based Interventions (CSQ-I) [41]. Good construct validity and high internal consistency have been demonstrated [41]. The Mobile App Rating Scale [48] is the most frequently used scale for evaluating the quality and content of mental health apps. The German translation of the user version of Mobile App Rating Scale (uMARS) [49] used in this study includes 4 objective subscales (engagement, functionality, aesthetics, and information quality) and one subjective quality scale. The uMARS has good internal consistency and test-retest reliability [49]. In addition, the 16-item Attitudes toward Psychological Online Interventions Questionnaire (APOI) [50], was used to assess the participants' general attitudes toward IMIs, including a total score and 4 subscales (skepticism and perception of risk, confidence in effectiveness, technologization threat, and anonymity benefits), with higher scores indicating a more positive attitude.

Depression severity was assessed using the Beck Depression Inventory–Second Edition [51].

Statistical Analysis

Owing to the small sample size, all data collected are presented and compared at the individual case level. Mean values and SDs were calculated for the expectations toward web-based interventions, usability and quality ratings, and user satisfaction. Analyses were performed using IBM SPSS Statistics (version 27.0; IBM Corporation) for Windows. Owing to the small sample size and the fact that data on use intensity varied greatly, participants' engagement in *CBASPath* use was categorized into high, medium, and low use. High use was rated as at least twice weekly app use with a duration of at least 15 minutes of situational analysis use and at least five completed modules. Medium use was rated as once or twice a week with at least 5 minutes of situational analysis use and at least one completed module. Below this level of use was classified as low. Individual values on depression severity were visualized in a scatter plot.

Results

Participants

A total of 18 participants registered for the pilot study at baseline, of whom 5 (28%) did not participate in any further measurement time point and were therefore handled as dropouts. Another participant was excluded from data analysis as he could not download the study version of the app and could therefore not use *CBASPath*. The final study sample included 12 participants, and the final survey in week 24 was completed by 11 (92%) participants. Table 2 summarizes the baseline

sociodemographic and clinical characteristics of all participants. The sample was heterogeneous in terms of age, gender, and level of education. All patients reported depressive disorder as the treatment diagnosis. Of the 12 participants, 9 (75%) reported at least one completed psychotherapeutic treatment. All participants were in different stages of outpatient CBASP therapy when they began using the app; 50% (6/12) received CBASP group therapy, and 67% (8/12) had been in ongoing therapy for more than a year. Of the 12 participants, 10 (83%) perceived their current treatment as helpful, and 2 (17%) were

unsure. At the end of the study period after 24 weeks, of the remaining 11 participants, 3 (27%) reported having completed their outpatient treatment, and the rest were still in treatment. None of the participants reported a self-help experience with IMIs; 33% (4/12) reported a self-help experience with books. Participants' general attitudes toward IMIs can be considered positive with an average APOI total score of 48.33 (SD 3.82, range 41.00-56.00). Participants' individual APOI total scores and subscale scores are listed in [Multimedia Appendix 1](#).

Table 2. Participants' sociodemographic and clinical characteristics at baseline^a.

Participant	Age (years)	Sociodemographic data	Treatment diagnosis	Duration of the current episode (years)	Age of onset (years)	Comorbid disorders	Previous PT ^b	Setting and duration of current CBASP ^c PT	Current PT helpful
Participant 1	54	Male, married; 3 children; university degree; full-time job	MDD ^d	6	39	Dysthymia and personality disorder	More than 3 outpatient PT and 2 inpatient PTs	Outpatient group PT for >12 months	Unsure
Participant 2	46	Female; firm partnership; lower secondary education; on sick leave	MDD	4	33	None	1 outpatient PT and 1 inpatient PT	Outpatient PT for 6 to 12 months	Unsure
Participant 3	32	Female, divorced; lower secondary education; full-time job	RDD ^e	4	29	None	1 inpatient PT	Outpatient group PT for >12 months	Yes
Participant 4	27	Male; single; university degree; full-time job	MDD	8	23	None	1 outpatient PT and 1 inpatient PT	Outpatient PT for less than a month	Yes
Participant 5	32	Male; married; 1 child; upper secondary education; full-time job	Other (emotional instability)	5	21	None	None	Outpatient PT for >12 months	Yes
Participant 6	30	Male; single; upper secondary education; full-time job	MDD	6	17	None	2 outpatient PTs and 1 inpatient PT	Outpatient group PT for >12 months	Yes
Participant 7	30	Female; firm partnership; university degree; full-time job	Dysthymia	6	17	Social phobia	None	Outpatient group PT for >12 months	Yes
Participant 8	40	Female; married; lower secondary education; retired	RDD	6	17	Personality disorder and chronic pain	2 outpatient PTs and 1 inpatient PT	Outpatient PT for >12 months	Yes
Participant 9	33	Female; single; lower secondary education; not employed	Dysthymia	2	15	RDD and social phobia	3 outpatient PTs	Outpatient day clinic for less than a month	Yes
Participant 10	22	Female, single, upper secondary education, full-time job	Dysthymia	6	13	None	None	Outpatient group PT for >12 months	Yes
Participant 11	46	Male; firm partnership; university degree; full-time job	Dysthymia	4	__ ^f	None	1 outpatient PT	Outpatient PT for 6 to 12 months	Yes

Participant	Age (years)	Sociodemographic data	Treatment diagnosis	Duration of the current episode (years)	Age of onset (years)	Comorbid disorders	Previous PT ^b	Setting and duration of current CBASP ^c PT	Current PT helpful
Participant 12	62	Male; married; 3 children; lower secondary education; re-tired	RDD	5	15	None	None	Outpatient group PT for >12 months	Yes

^aAll data presented are self-reported; education level according to the International Standard Classification of Education.

^bPT: psychotherapy treatment.

^cCBASP: Cognitive Behavioral Analysis System of Psychotherapy.

^dMDD: major depressive disorder.

^eRDD: recurrent depressive disorder.

^fNot available.

General Usability, Quality Ratings, and User Satisfaction of the CBASPath Course

CBASPath's overall usability was rated with a mean total SUS score of 85.21 (SD 10.74, range 57.50-97.50) on a 100-point scale. Of the 12 participants, 8 (67%) rated *CBASPath*'s usability as excellent (SUS ≥ 85.5), 3 (25%) as good (SUS ≥ 71.4), and 1 (8%) participant rated the usability as *ok* (SUS ≥ 50.9) [52]. Participants' average satisfaction with the *CBASPath* resulted in a mean CSQ-I score of 28.00 (SD 2.26, range 24-31) out of 32 scale points, indicating high user satisfaction [41]. Users' quality ratings of *CBASPath* resulted in an average uMARS total score of 3.99 (SD 0.30, range 3.51-4.56; 1=poor to 5=excellent), indicating good quality. Approximately equally high scores were found for the subscales *function* (mean 4.10, SD 0.55, range 3.00-5.00), *aesthetics* (mean 4.03, SD 0.30, range 3.33-4.33), and *information quality* (mean 4.04, SD 0.32, range 3.50-4.50). The engagement subscale was rated at 3.80 (SD 0.50, range 3.00-4.60), and subjective app quality was 3.67 (SD 0.29, range 3.00-4.00). The individual SUS, CSQ-I, and uMARS ratings of all participants are presented in detail in [Multimedia Appendix 2](#).

Participants' Engagement With the App and in the Blended App Use Setting

All 12 participants reported using the *CBASPath* throughout the study period. Of the 12 participants, 9 (75%) reported using situational analysis within the first 6 weeks of use; as the study progressed, all participants reported using situational analysis.

In an open response field at the end of the survey, 25% (3/12) of participants noted that they had found the situational analysis particularly helpful (participants 5, 6, and 7). None of the participants reported IDE use at 6 weeks; 8% (1/12) stated using it at week 12 (participant 1), and 42% (5/12) reported IDE use at 24 weeks (participants 1, 4, 5, 6, and 8). Participants reported using *CBASPath* at least once a week to daily for 1 to 50 minutes at a time, with wide variation between individual participants and within measurement time points (see [Table 3](#) for variation of frequency of use during the study period). The most intensive use was reported at week 12: 75% (9/12) reported using *CBASPath* at least three times a week. They completed between 1 and 7 out of the 8 available CBASP modules. Owing to the small sample size and the fact that participants' engagement in *CBASPath* and blended use varied greatly, the individual use patterns were categorized into low to high use; of the 12 participants, high use could be found in 7 (58%) participants (participants 1, 2, 4, 5, 8, 9, and 12), medium use was shown by 5 (42%) participants (participants 3, 6, 7, 10, and 11), and none showed low use. All participants reported some form of blended use during the 24-week study period; however, the frequency of integration into therapy varied widely between individual participants. For example, 17% (2/12) of participants (participants 1 and 10) reported blended use in nearly every session, whereas others reported consistent blended use (participants 4 and 6) or less frequent involvement, totaling approximately 2 to 4 times (participants 12 and 11). Individual engagement in *CBASPath* and the blended use of all participants can be found in detail in [Table 3](#).

Table 3. Participants' *CBASPath* use categorized as medium and high adherence and reported blended use^a.

MTP ^b	Completed Modules, n	Duration per app use in minutes			Days of app use per week			Situational analysis use			Interpersonal discrimination exercise use			Blended use			
		Week 6 ^c	Week 12 ^d	Week 24 ^e	Week 6	Week 12	Week 24	Week 6	Week 12	Week 24	Week 6	Week 12	Week 24	Week 6	Week 12	Week 24	
High adherence																	
Participant 1	6	10	10	5	1	Daily	Daily	Yes	Yes	Yes	No	No	Yes	In every session	In >5 sessions	In every session	
Participant 2	5	50	15	15		Daily	Daily	5	Yes	Yes	Yes	No	No	No	In 1 to 2 sessions	Not at all	In 3 to 5 sessions
Participant 4	5	20	20	15	2	2	3	No	Yes	Yes	No	No	Yes	In 1 to 2 sessions	In 1 to 2 sessions	In 3 to 5 sessions	
Participant 5	5	20	20	15	4	2	— ^f	Yes	Yes	Yes	No	No	Yes	In 3 to 5 sessions	In 1 to 2 sessions	In 3 to 5 sessions	
Participant 8	6	15	20	30	1	2	2	Yes	Yes	Yes	No	No	Yes	In 1 to 2 sessions	3 to 5 times	In 1 to 2 sessions	
Participant 9	7	30	30	—	4	4	—	Yes	Yes	Yes	No	Yes	—	In 3 to 5 sessions	In 1 to 2 sessions	—	
Participant 12	7	35	15	15	2	3	1	Yes	Yes	Yes	No	No	No	In 1 to 2 sessions	Not at all	In 1 to 2 sessions	
Medium adherence																	
Participant 3	3	2	5	5	1	Daily	1	Yes	Yes	Yes	No	No	No	In >5 sessions	In 3 to 5 sessions	In >5 sessions	
Participant 6	1	1	12	15	0	4	3	No	Yes	Yes	No	No	Yes	In 1 to 2 sessions	In 1 to 2 sessions	In 3 to 4 sessions	
Participant 7	4	30	5	10	5	Daily	1	Yes	Yes	Yes	No	No	No	In 1 to 2 sessions	In 1 to 2 sessions	In every session	
Participant 10	2	10	10	15	2	5	2	Yes	Yes	Yes	No	No	No	In every session	In every session	In every session	
Participant 11	2	20	1	10	1	Daily	1	No	Yes	Yes	No	No	No	Not at all	In 1 to 2 sessions	In 1 to 2 sessions	

^aParticipants' self-reported adherence was categorized as medium and high use regarding data on completed modules, duration per app use, frequency of app use per week, and situational analysis use.

^bMTP: measurement time point.

^cRatings of week 1 to 6 after initial use of *CBASPath*.

^dRating of week 7 to 12 after initial use of *CBASPath*.

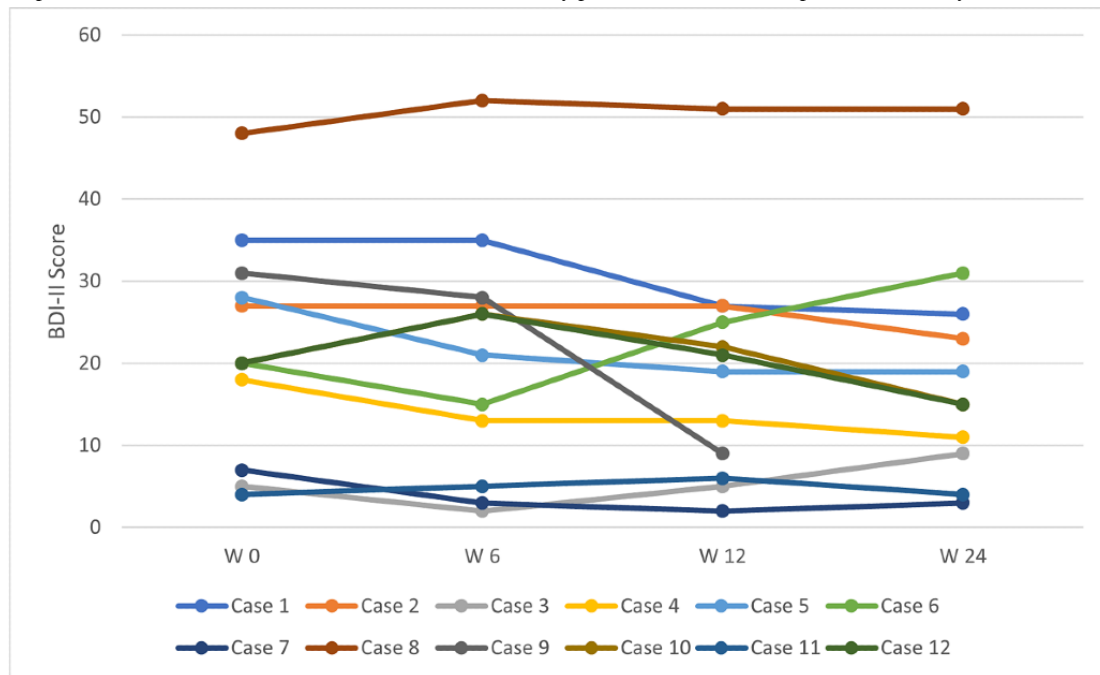
^eRatings of week 13 to 24 after initial use of *CBASPath*.

^fMissing data.

Depression Severity

Figure 2 illustrates the Beck Depression Inventory–Second Edition total scores of the 12 patients at the start of *CBASPath* use and during the course of the study. The trajectories vary considerably. Of the 12 participants, 3 (25%; participants 3, 7, and 11) had very low depression scores at the beginning of the study, which also remained at a low level during the study

period. Participant 8 showed high depression scores throughout the study period, and the depression severity of participant 6 increased after a slight improvement in the sixth week. The remaining participants (1, 2, 4, 5, and 12) showed a slight improvement in symptoms over the course of the study. Owing to pseudonymous participation, the dropout reason for participant 9 is unclear.

Figure 2. Participants' individual BDI-II scores over the course of the study period. BDI-II: Beck Depression Inventory-Second Edition; W: week.

Discussion

Principal Findings

The purpose of this study was to outline the concept and feasibility of a blended CBASP treatment in a routine care setting and investigate the usability and quality of and satisfaction with the app-based *CBASPath* course.

Our findings suggest that the digital augmentation of rather complex and highly interactive CBASP therapy in the form of blended therapy is feasible in routine outpatient care. Participants reported continuous blended use over the course of the study, good usability and quality ratings, and high user satisfaction. The positive experiences of conducting situational analysis on the web reported in another pilot study by Brakemeier et al [40] can, therefore, be extended to the app context and blended setting in this pilot study.

Usability of, Quality of, and Satisfaction With *CBASPath*

The good to excellent usability ratings indicate that working with *CBASPath* content on a smartphone is feasible and that disadvantages compared with computer-based IMIs, such as the small screen and different use patterns (eg, lower rates of user engagement), could be well compensated for by an adapted design [31]. For example, the design of the exercises was adjusted to minimize typing by using a multiple-choice format instead of text entries. To assist users who are less technology savvy in getting started, all patients were provided with written instructions for using the app, suggesting possibilities for blended use and answers to frequently asked technical questions (eg, “how do I take a screenshot?”).

The quality rating underlines the high usability of *CBASPath*. The app's functionality (including performance, ease of use, navigation, and gestural design), aesthetics (layout, graphics, and visual appeal of the app), information provided via the app

(quality, quantity, visual information, and credibility of the source), and opportunities for participant engagement (entertainment, interest, customization, and target group) were unanimously rated positive, as was subjective app quality and user satisfaction. All 12 participants would continue to use *CBASPath* by themselves and would recommend it to others; however, almost all were hardly willing to pay for the app. Considering that psychotherapy is covered by health insurance in Germany, that some health apps can be prescribed by health professionals, and that participants perceived their current therapy as mainly helpful, their willingness to spend additional money might have been limited.

CBASPath was found to be helpful by most participants in dealing with their difficulties, and they would use it again if they needed help, which again underlines the high satisfaction. A benefit through the increase of self-management skills by having independent access to digital therapy content, as found in a former study on blended therapy acceptance [53], might apply to CBASP as well and foster patients' autonomy.

Participants' Engagement With *CBASPath* and Its Blended Use

Participants' medium to high engagement with *CBASPath* and the reported blended use support the feasibility and acceptance of the presented blended modification of CBASP therapy.

The patient who did not use *CBASPath* could not install the app because of an outdated operating system on his smartphone and was therefore excluded from further analysis. *CBASPath* was continuously used over a 6-month period by at least 92% (11/12) of participants. Another participant did not participate in the final survey at the end of the 6-month study period; thus, we could not specify his use at the end of the study.

The good acceptance of blended CBASP therapy among patients is further reinforced by the fact that none of the patients in this study reported previous IMI experience but nevertheless showed

sufficient user engagement, although prior experience with eHealth is associated with higher acceptance of digital applications [54]. Although the validity of the reported use data is reduced because of the small sample size and self-reported data, it supports previous findings that therapeutic guidance for IMIs can lead to high adherence and might even reduce the risk of treatment dropout [28,33,55].

It is particularly encouraging that all participants reported using the app-based situational analysis and considered it particularly helpful, as situational analysis is a central component of CBASP therapy [43,44]. Situational analyses created in the app can be reinforced by behavioral training during the session. Moreover, good situational analysis skills were associated with better treatment outcomes in a previous study [56]. The smartphone, as a daily object, seems to be a feasible device and therefore particularly promising for transferring central CBASP skills, such as situational analysis, to patients' everyday life.

The benefit of CBASP-specific modules remains unclear as their extent of use varied widely. Most participants (8/12, 67%) had completed at least half of the 8 available modules by the end of the study period. Participants were in different stages of therapy when they started using *CBASPath*, which is why some of the modules might not have suited the respective therapy stage so that they were no longer or not yet used (eg, experienced patients may already be very familiar with their significant other's history and transference hypothesis and therefore no longer need module 2). In addition, longer reading times of some exercises of up to 15 minutes might have been an additional barrier. Brief skill-based app content is related to high and long-lasting use [57], as it reflects the typical short but frequent use of smartphones. The first 2 *CBASPath* modules could be expanded by the inclusion of hands-on exercises that prioritize *getting into the action* in addition to journaling session content and psychoeducation at a minimum. Furthermore, the low blended use of the modules because of a very flexible approach on how to embed *CBASPath* into therapy may have led therapists to recommend the modules more for independent use than incorporating them into the session. For instance, the blended use of situational analysis was advised in the written information that patients and therapists received, and modules, by contrast, were designed as self-help to bridge sessions and might therefore be less integrated into sessions. It is plausible that, in some cases, only a few modules were completed, but situational analysis was still used regularly within the blended setting.

Therapists also did not receive training for blended therapy in addition to written information; the offered telephone support was used by only one of the therapists. Training for therapists could be another way of optimizing blended use and thus improving the uptake of modules [58]. It is also suggested that the effectiveness of IMIs depends on the long-term use of an app, which can be promoted through face-to-face sessions [59].

The participants' feedback on *CBASPath* revealed options for further technical improvements that could lead to higher engagement with the course material. For example, an option to save entries directly in the app for future reference (instead of taking screenshots) was mentioned by several users. The use

of voice input may have been additionally beneficial, especially for the frequently used situational analysis exercises.

Limitations

Several limitations should be considered. Data were available only for patients who used the app. Therefore, reasons for dropout or nonuse of *CBASPath* could not be assessed, and the present results could be positively biased. Considering that participants' overall attitudes toward IMIs was rather positive, there might be a selection bias, as patients with a high general acceptance of IMIs might have been interested in participating in the study and might therefore have been particularly motivated to use the app. However, none of the participants reported experiences with blended use, and participants' general attitudes toward IMIs were similar compared with a sample with mild to moderate depression (mean 48.33 compared with mean 48.3) [50]. In addition, an affinity for smartphone use was an inclusion criterion. For more patients who are skeptical or less technologically savvy, blended use could pose additional challenges.

Furthermore, the reliability and generalizability of the results were limited because of the small sample size. Results regarding engagement and adherence should be viewed with caution because of the self-reported nature of the data collected. Objective use data should be used in subsequent studies.

Finally, there was no control of how exactly *CBASPath* was embedded in face-to-face therapy; thus, the form of blended use can vary greatly between individuals. Therefore, a subsequent randomized controlled trial (RCT) should compare manualized blended therapy with *CBASPath* with therapy without app support.

Implications and Future Directions

Overall, good usability and quality ratings, high user satisfaction, and favorable adherence to user engagement and blended use are good prerequisites for further adaption, a subsequent RCT on the efficacy, and implementation of the blended CBASP therapy concept in different routine care settings such as CBASP outpatient therapy.

A recently published RCT comparing immediate and long-term effectiveness [36] found that blended therapy could have an additional positive effect on psychotherapy for depression in terms of symptom reduction, improved therapeutic processes, and higher health-related quality of life. As an increase in therapy dose and duration seems beneficial to further improve CBASP therapy [15,20,22,60], subsequent RCT studies should further investigate whether blended CBASP therapy is also beneficial and should therefore be implemented. Future studies should include long-term follow-up assessments to evaluate whether long-term stabilization of symptoms can be achieved.

The reported use patterns and concurrent blended use appeared to be contrary in some cases. For example, when comparing weeks 12 and 24, participants 2, 3, 5, 6, 7, and 12 reported an increase in blended use during face-to-face therapy, although their user engagement with the app decreased. Therefore, further research should investigate which frequency and intensity of blended use are most effective and efficacious for different

stages of CBASP therapy. On the basis of the participants' engagement in this pilot study, it should be examined whether strong therapeutic support at the beginning, as advised in the written information (eg, by planning which modules to be worked on between sessions), can improve IMI uptake and whether intensive blended use toward the end, as observed in this pilot study (especially high in participants 1, 3, 7, and 10), might foster the use of the app as a self-help maintenance treatment after therapy. Monitoring patients' symptoms could also be a useful feedback system for therapists in making clinical decisions [38] and should be investigated more in the context of blended therapy concepts.

The fact that half of the participants received CBASP group therapy indicates the feasibility of the blended treatment approach in this setting and is consistent with earlier findings of a blended CBT group therapy for depression [61]. Of 6 patients in the blended CBASP group therapy, 2 (33%) showed high use, which, in comparison with the individual setting (5/6, 83% of patients showed high use), could indicate that the blended group therapy may be less able to encourage continuous use. Given the relatively small number of CBASP therapists, blended group therapy could be especially relevant because of higher scalability.

Replacing up to two-thirds of the face-to-face contacts with IMIs use was found to be noninferior to standard CBT treatment [62]. Therefore, blended CBASP therapy might also be promising when it comes to counteracting the treatment gap by allowing therapists to treat a larger number of patients.

As CBASP is also offered in inpatient settings [20,60], blended use as part of inpatient treatment seems promising. The use of

CBASPath as a self-help tool after successful blended therapy or for bridging therapy breaks, especially after comparatively short inpatient stays, also seems useful and should be investigated in further studies.

During recruitment, we observed that only a few interested therapists were willing to test *CBASPath* with patients. Therefore, a therapist's assessment of the feasibility of blended therapy and satisfaction with *CBASPath* should be considered to prevent potential difficulties in future studies and subsequent implementation. Further acceptance-facilitating interventions (eg, informational videos) have been proven to be effective in increasing psychotherapists' acceptance of blended therapy [63] and might help attract therapists.

Conclusions

The novel treatment approach presented here could allow further optimization of an already effective CBASP treatment and provide patients with a feasible and assessable treatment program. The blended setting itself is particularly coherent with CBASP therapy, despite its highly interactional character. However, the right frequency and optimal embedding should be further investigated to combine the best of the analog and digital worlds. Randomized controlled studies are now vigorously needed to investigate the efficacy of blended CBASP therapy and the *CBASPath* tool, with a focus on long-term follow-up to examine long-term responses. If positive, *CBASPath* could help optimize CBASP treatment in the long term and reduce relapses by intensifying therapy and providing patients with PDD with long-term therapeutic support through the app.

Conflicts of Interest

IB is the Chief Science Officer of MindDoc Health GmbH, the app manufacturer.

Multimedia Appendix 1

Participants' attitudes toward internet- and mobile-based interventions at baseline.

[DOCX File, 15 KB - [formative_v6i8e35482_app1.docx](#)]

Multimedia Appendix 2

Participants' ratings on usability, quality, and satisfaction with *CBASPath* after 12 weeks of use.

[DOCX File, 15 KB - [formative_v6i8e35482_app2.docx](#)]

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Abbreviations

- APOI:** Attitudes Toward Psychological Online Interventions Questionnaire
- CBASP:** Cognitive Behavioral Analysis System of Psychotherapy
- CBT:** cognitive behavioral therapy
- CSQ-I:** Client Satisfaction Questionnaire adapted for internet-based Interventions
- IDE:** interpersonal discrimination exercise
- IMI:** internet- and mobile-based intervention
- PDD:** persistent depressive disorder
- RCT:** randomized controlled trial
- SUS:** System Usability Scale
- uMARS:** user version of Mobile App Rating Scale

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Original Paper

Qualitative Evaluation of an Artificial Intelligence–Based Clinical Decision Support System to Guide Rhythm Management of Atrial Fibrillation: Survey Study

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Abstract

Background: Despite the numerous studies evaluating various rhythm control strategies for atrial fibrillation (AF), determination of the optimal strategy in a single patient is often based on trial and error, with no one-size-fits-all approach based on international guidelines/recommendations. The decision, therefore, remains personal and lends itself well to help from a clinical decision support system, specifically one guided by artificial intelligence (AI). QRhythm utilizes a 2-stage machine learning (ML) model to identify the optimal rhythm management strategy in a given patient based on a set of clinical factors, in which the model first uses supervised learning to predict the actions of an expert clinician and identifies the best strategy through reinforcement learning to obtain the best clinical outcome—a composite of symptomatic recurrence, hospitalization, and stroke.

Objective: We qualitatively evaluated a novel, AI-based, clinical decision support system (CDSS) for AF rhythm management, called QRhythm, which uses both supervised and reinforcement learning to recommend either a rate control or one of 3 types of rhythm control strategies—external cardioversion, antiarrhythmic medication, or ablation—based on individual patient characteristics.

Methods: Thirty-three clinicians, including cardiology attendings and fellows and internal medicine attendings and residents, performed an assessment of QRhythm, followed by a survey to assess relative comfort with automated CDSS in rhythm management and to examine areas for future development.

Results: The 33 providers were surveyed with training levels ranging from resident to fellow to attending. Of the characteristics of the app surveyed, safety was most important to providers, with an average importance rating of 4.7 out of 5 (SD 0.72). This priority was followed by clinical integrity (a desire for the advice provided to make clinical sense; importance rating 4.5, SD 0.9), backward interpretability (transparency in the population used to create the algorithm; importance rating 4.3, SD 0.65), transparency of the algorithm (reasoning underlying the decisions made; importance rating 4.3, SD 0.88), and provider autonomy (the ability to challenge the decisions made by the model; importance rating 3.85, SD 0.83). Providers who used the app ranked the integrity of recommendations as their highest concern with ongoing clinical use of the model, followed by efficacy of the application and patient data security. Trust in the app varied; 1 (17%) provider responded that they somewhat disagreed with the statement, “I trust the recommendations provided by the QRhythm app,” 2 (33%) providers responded with neutrality to the statement, and 3 (50%) somewhat agreed with the statement.

Conclusions: Safety of ML applications was the highest priority of the providers surveyed, and trust of such models remains varied. Widespread clinical acceptance of ML in health care is dependent on how much providers trust the algorithms. Building this trust involves ensuring transparency and interpretability of the model.

KEYWORDS

Clinical decision support system; machine learning; supervised learning; reinforcement learning; atrial fibrillation; rhythm strategy

Introduction

An estimated 2.3 million Americans harbor a diagnosis of atrial fibrillation (AF), and that number is expected to grow to 10 million by 2050 [1,2]. Reduction in mortality and morbidity in patients with AF is predominantly achieved by reducing stroke risk via anticoagulation (AC) [3]. However, AC does not contribute to treating the symptoms of AF or mitigating the long-term effects of living with AF, rather than affecting the sinus rhythm (SR), such as AF-induced cardiomyopathies [4]. Hence, a decision of rate control versus rhythm control must be made. Rate control involves increasing the ventricular filling time by decreasing the ventricular rate, whereas rhythm control involves re-establishment of the SR through some combination of external cardioversion, antiarrhythmic medications, or catheter ablation. The decision of rate versus rhythm control is one that has been studied for years. The data show us that there is no one-size-fits-all answer to this question, and the optimal strategy is highly reliant on individual characteristics and comorbidities of patients with AF [5-16]. The variability of these data and the differences in efficacy in various subsets of the population render the rhythm versus rate control decision a very individualized one and one that lends itself to the aid of clinical decision support systems (CDSSs).

CDSSs encompass a wide array of tools designed to augment and improve clinical outcomes [17]. These tools vary from broad aids such as literature databases [18], to decision trees that help with diagnosis [19-22], to risk stratification tools including the CHA₂DS₂Vasc and HEART scores, which estimate stroke risk in patients with AF and 6-week increase in adverse major cardiac events, respectively [23-28]. Although CHA₂DS₂Vasc and HAS-BLED (Hypertension, Abnormal renal/liver function, Stroke, Bleeding history or predisposition, Labile International Normalized Ratio, Elderly, Drugs/alcohol

concomitantly) [29] scores (the HAS-BLED score estimates risk of major bleeding for patients on AC) have been helpful in determining which patients with AF need AC, there is no CDSS to our knowledge that has been designed to help make the less straightforward AF decision concerning rate versus rhythm control. For more than a decade, the focus in CDSS has been on the development of computerized algorithms to aid in decision-making or development of computerized CDSSs (CCDSSs). A CCDSS harnesses the massive data pool, that is, the electronic health record (EHR), along with advanced computing to aid providers in making complex decisions. CCDSS development is an active field of research focusing on Bayesian networks (BN), machine learning (ML), and artificial neural networks (ANN), but clinical acceptance has lagged behind.

In this study, we introduce a novel ML framework used to create a CCDSS for rhythm management in patients with AF. The QRhythm application is a learning CCDSS that utilizes a 2-stage ML model to identify the optimal rhythm management strategy in a given patient on the basis of a set of clinical factors, in which the model first uses supervised learning (SL) to predict the actions of an expert clinician, and then applies reinforcement learning (RL) to identify the best strategy to obtain the best clinical outcome.

Providers are asked to input data pertaining to the patient in question, including age, duration of AF, history of heart failure, diagnosis of left atrial enlargement, resting heart rate, diagnosis of hypertension, BMI, and symptoms associated with their AF. Based on the answers to these questions, the algorithm predicts the frequency at which an expert would choose different rhythm control strategies including external cardioversion, antiarrhythmic medications, AF ablation, or rate control. Screenshots of the input and output screens of the application are provided in [Figures 1A](#) and [1B](#), respectively.

Figure 1. (A) Screenshot of the data input page of QRhythm. (B) Screenshot of the data output page of QRhythm. AAM: antiarrhythmic medication; AF: atrial fibrillation; AFA: atrial fibrillation ablation; EF: ejection fraction; HTN: hypertension; LA: left atrial; HR: heart rate; EXC: external cardioversion; RAC: rate control.

A.

Select all applicable

Age under 65	<input type="radio"/> Yes <input checked="" type="radio"/> No <input type="radio"/> Dont Know
First episode	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Dont Know
Heart failure (EF < 50%)	<input type="radio"/> Yes <input checked="" type="radio"/> No <input type="radio"/> Dont Know
Less than moderate LA enlargement	<input type="radio"/> Yes <input checked="" type="radio"/> No <input type="radio"/> Dont Know
Paroxysmal AF	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Dont Know
Resting HR < 50 bpm	<input type="radio"/> Yes <input checked="" type="radio"/> No <input type="radio"/> Dont Know
Not on HTN medications	<input type="radio"/> Yes <input checked="" type="radio"/> No <input type="radio"/> Dont Know
BMI < 30	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Dont Know
Symptoms of fatigue or palpitations	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Dont Know

Submit

B.

Recommendation

AF Ablation Strategy Recommended

Strategies Prediction Probability Chart for Supervised Deep Learning

Strategy	Percentage	Count
AFA	40.7%	-
AAM	38.5%	52 (38.5%)
EXC	-	-
RAC	-	-

Both the SL and RL algorithms of the QRhythm application are based on linear regression models, in which the inputs are each weighted toward prediction of each of the 4 possible treatment options: rate control, external cardioversion, antiarrhythmic medication, and ablation. The SL model is trained using stochastic gradient descent, with back-propagation of the gradient of the error, which represents the difference between the predicted treatment and what is actually selected by a treating provider, adjusted by a learning rate of 0.1. The RL model uses an algorithm called Q learning, in which the model is trained in parallel for patients in whom outcome information related to hospitalizations, stroke, and symptomatic recurrence is available in follow-up. Within the Q learning framework, the reward is calculated as $-2 \times (\text{stroke}) - (\text{hospitalization}) - (\text{symptomatic recurrence})$, and is back-propagated across each treatment, after adjustment for a learning rate of 0.01. Owing to the preliminary nature of the RL algorithm, the learning rate is one order of magnitude lower than that used in the SL algorithm. Weight updates are delivered in batches of 8 patients. The QRhythm algorithm was initialized using a combination of big data mining and chart review in the University of Colorado Health system of 100 patients diagnosed with AF,

which were used to train the SL algorithm based on the action selected by the treatment provider. The QRhythm application is now being deployed in the clinical setting, where its recommendations are being used to guide rhythm strategy decisions in actual patients. Here, it can continue training of the SL algorithm and begin training the RL algorithm as additional patient information is included.

Over time, the model will use what it has learned in the SL phase as a scaffold to slowly transition from an SL algorithm to an RL one, driven by rewards and punishments based on defined outcomes of hospitalizations, symptoms, quality-of-life scores, and changes in rhythm strategies. Rather than predicting what strategy an expert is most likely to choose, the RL edition will have the ability to suggest actions that an expert may not realize as being beneficial for the patient. Therefore, the RL edition will have the capability to improve outcomes for patients with AF when compared to standard of care. This 2-staged method was utilized by the team at DeepLearning to develop a ML model with the ability to defeat world experts in the game Go [30,31].

We used the QRhythm application as a substrate to analyze the reasons underlying apprehension toward clinical acceptance of CCDSs in general.

Methods

Ethics Approval

This study was approved by the Colorado Multiple Institutional Review Board (#20-2192).

Qualitative Assessment

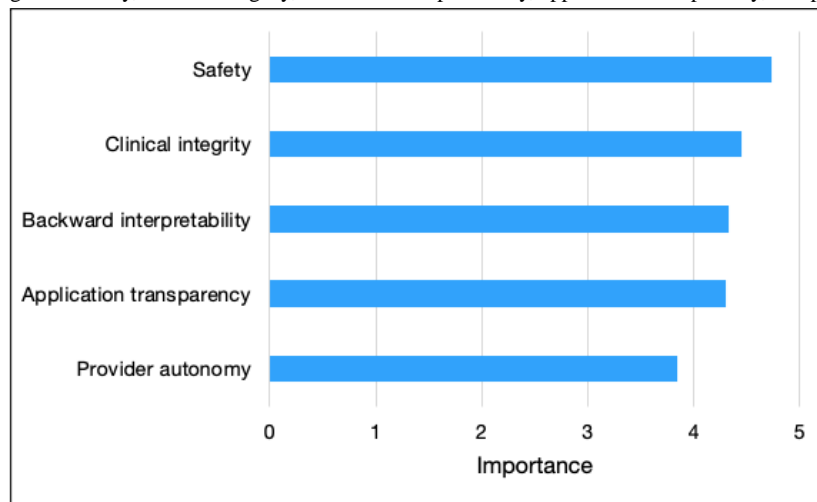
Residents, fellows, and attendings were first introduced to the QRhythm app via a brief written tutorial. The providers were asked to examine the app. They were encouraged to use the app in a clinical setting—that is, to help inform a rhythm/rate strategy for a real patient—but this was not required. They then were presented with a survey produced on REDCap. The survey was designed to assess how important the providers thought certain characteristics of the app were. They were asked to rate how important each category was on a scale of 1-5, with 1=unimportant, 2=slightly important, 3=moderately important, 4=important, and 5=very important. Other prompts asked the provider to report how firmly they agreed with a prompt, with 1=“strongly disagree,” 2=“somewhat disagree,” 3=“neutral,” 4=“somewhat agree,” and 5=“strongly agree.” Finally, those who used the app were asked to rank their areas of concern with using the app from 1=highest concern to 5=lowest concern. Data were collected on REDCap and exported to an Excel (Microsoft Inc) spreadsheet for further analysis.

Results

In total, 33 providers responded to the survey. Seven (21%) of them were attendings (postgraduate year>3), 2 (6%) were fellows, 21 (64%) were residents, and 3 (9%) chose not to identify their provider level. The providers were predominantly either internal medicine residents or attendings (n=27, 82%) with the remainder being either cardiology fellows or attendings (n=6, 18%). We feel that this mix of internists and cardiologists is valuable, as it importantly reflects providers involved in both early-stage (referrals—internists) and later-stage (treatment—cardiologists) management of AF.

Of the characteristics of the app surveyed, safety was most important to the providers, who reported an average importance rating of 4.7 out of 5 (SD 0.72) in response to the prompt “The model is not recommending anything unsafe or potentially harmful.” This was followed by an importance rating of 4.5 (SD 0.90) for clinical integrity corresponding to the prompt “The information the model is using to make predictions makes sense clinically,” 4.3 (SD 0.65) for backward interpretability (“I know the population in which the model was derived is the same as the one in which I am applying it,”), and 4.3 (SD 0.83) for application transparency (“I understand the reasoning with which the model made its recommendations”). Least important to the providers was provider autonomy with an average importance of 3.85 (SD 0.83) placed on the prompt “I am able to disagree with or challenge the recommendations of the model” (Figure 2).

Figure 2. Importance rated by survey respondents on a scale of 1-5, with 1=unimportant, 2=slightly important, 3=moderately important, 4=important, and 5=very important, with regard to safety, clinical integrity, backward interpretability, application transparency, and provider autonomy.



Of those who responded, 6 providers used the app at least once in the clinical setting; that is, they used the app to aid in developing rhythm control strategies for actual patients. Providers were not required to follow the specific recommendations of QRhythm, but merely to examine agreement and interpretability of the application, as formal testing toward hard clinical outcomes was beyond the scope of this pilot investigation. Apprehension concerning the use of the app clinically varied among these providers. In response to the prompt “I would feel apprehensive about using the QRhythm application,” 1 provider (17%) strongly disagreed, 2 (33%)

somewhat disagreed, 2 (33%) were neutral on the subject, and 1 (17%) somewhat agreed. Trust in the app similarly varied. To the prompt “I trust the recommendations provided by the QRhythm app,” 1 provider (17%) somewhat disagreed, 2 (33%) were neutral, and 3 (50%) somewhat agreed. For the most part, providers did not feel intimidated by the app. One provider (17%) strongly disagreed with the statement “the QRhythm application would be intimidating for me to use,” 4 (67%) somewhat disagreed with this statement and 1 (17%) was neutral. To the prompt, “Learning to use the QRhythm application would be easy for me,” 4 providers (67%) strongly

agreed, and 2 (17%) somewhat agreed. Finally, in general, providers felt that the QRhythm app would be helpful when taking care of patients with AF. To the prompt “Using the QRhythm application would enhance my effectiveness in patient care and AF management,” 1 provider (17%) strongly agreed, 3 (50%) somewhat agreed, and 2 (33%) were neutral.

These providers were also asked to rank their concerns regarding clinical use of the app from highest to least concern. Four providers (67%) ranked the clinical integrity of recommendations as their highest concern, 1 (17%) ranked ineffectiveness as their highest concern, and 1 (17%) ranked data security as their highest concern.

Discussion

Principal Findings

In this study, we examined the provider experience with a novel, AI-based CCDSS for rhythm management of AF. Providers generally found the application easy to use, though trust in the application was variable and apprehension toward its advice remains a concern. Our data show that safety of the recommendations provided by the app was most important to providers. This priority is followed closely by a desire for advice from a CCDSS to make sense clinically, for the provider to have knowledge of the population in which the algorithm was developed, and for transparency of the reasoning with which the app made its decision. Less important in the minds of the providers surveyed was the ability to challenge the decisions made by the app. Of those providers who used the app in the clinical setting, the accuracy of its recommendations ranked highest among their concerns.

Comparison With Prior Work

Although there are no existing CDSS for rhythm management of AF to our knowledge, there are numerous studies related to specific treatment approaches within the rate versus a rhythm control strategy decision for patients with AF. The AFFIRM trial, published in 2002, showed noninferiority in terms of mortality in rate-controlled patients compared to rhythm-controlled patients, with a trend toward increased mortality in the rhythm control group [5]. This trial subsequently guided rhythm control strategies away from the promise of improvement in mortality, and directed treatment toward improvement in symptoms alone. However, the paradigm for rhythm management may be shifting with the more recent data suggested by the EAST-AFNET 4 trial published in February 2021, which showed that early rhythm control (within a year of AF diagnosis) decreases stroke and cardiovascular mortality compared to a rate control strategy [6].

We surmise that declaring rate control as superior to rhythm control, or vice versa, however, is too sweeping a conclusion to make. Further evaluation of these data reveal that individual characteristics of patients with AF play a large role regarding the success or failure of a chosen strategy. Subsets of patients with AF, such as those with heart failure or left ventricular dysfunction, have been shown to have a mortality benefit from rhythm control [7]. Additionally, the severity of symptoms for patients with AF vary widely, and symptomatic patients

experience more relief with rhythm control than with rate control [8-12]. Conversely, factors such as atrial enlargement [13,14], age at onset of AF [15], and duration of AF (paroxysmal vs persistent vs permanent) [16] make rhythm control strategies more difficult to achieve. In other words, the decision about rate or rhythm control in patients is likely to be highly individualized, which raises the possibility that an automated CDSS could provide guidance with AI integration.

Within the category of rhythm control, various rhythm strategies exist including external cardioversion, various antiarrhythmic medications, and AF ablation. The EAST-AFNET 4 trial randomized patients into a rate or rhythm control strategy, but the protocol did not specify which rhythm control strategy was to be pursued. Patients either underwent AF ablation or were started on an antiarrhythmic agent with coincident external cardioversion, but the choice of antiarrhythmic agent was left to the provider [6]. In short, the variability in outcomes based on patient characteristics makes it difficult to generalize and extrapolate data from these studies. It does, however, lend itself to the aid of AI, which can quickly take all of these characteristics into account and provide recommendations accordingly.

The advent of EHR has brought a wealth of data to the fingertips of providers. However, the vastness of these data makes utilizing them time-consuming and clumsy for humans alone. With the aid of AI, CCDSSs aim to create interfaces that are easy to interact with, which condense this plethora of data into easily digestible visualizations to improve the quality of decisions made by providers. Multiple methods have been used to develop such technology, including BNs, ML, and ANNs. While BNs and ANNs are not presently used by QRhythm, these more sophisticated prediction algorithms could easily be incorporated in future versions to include additional types of data, such as electrocardiography (ECG) tracings, patient symptom reports, and clinic notes. The framework we have developed for QRhythm using stochastic gradient descent provides the opportunity for expansion to deep neural networks, for example, which could be used for image recognition or natural language processing to incorporate these additional data types.

ML can be broken down into 3 categories: unsupervised learning (UL), SL, and RL. UL is not used in QRhythm and will therefore not be discussed here.

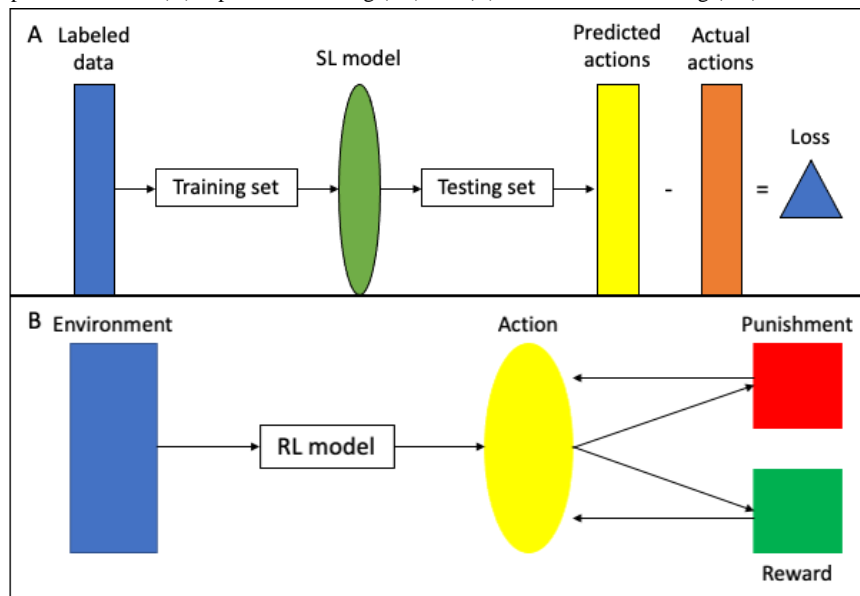
In SL, data are input to the model with associated labels; that is, data on patients who underwent a rate control strategy would be labeled as “rate control,” data for those who underwent external cardioversion would be labeled as “external cardioversion,” etc. Through application of various computer algorithms, a model is trained to recognize data associated with these labels in order to predict an outcome using a held-out “training set.” The algorithm is then applied to a second set of data known as the “testing set” or “validation set” to assess its out-of-sample generalizability and efficacy in predicting an outcome. SL comprises the initial strategy for the QRhythm application. Its learning set is a large set of charts of patients with AF. Based on these data, the model has been taught to predict the rhythm strategy most likely to be selected by an expert; for example, an electrophysiologist. SL is designed to

mimic the decisions or predictions that would be made by humans. Its efficacy is measured by the difference in the predictions made by the model compared to those made by human experts. This difference is known as the loss function. A loss of zero represents a “perfect” supervised learning model. Therefore, by definition, an SL model can only ever be as effective as the human experts against which it is compared [32-34]. SL models have been used to produce algorithms that accurately interpret ECGs [35,36]. A diagrammatic representation of SL is shown in Figure 3A.

Rather than comparing the model’s performance compared to that of a human expert as in SL, RL is driven by a system of punishments and rewards. RL is an iterative process in which

actions are made on the basis of the model’s environment. The results of each action are assessed on the basis of the outcomes of the action. Good outcomes harbor a positive value or “reward”; bad outcomes harbor a negative value or “punishment.” The model takes into account the reward or punishment that results from a certain action and uses this knowledge to inform its next action. RL models are designed to choose actions in order to maximize the reward, thus providing the best outcome possible. As the goal of RL is not merely to mimic humans, but rather to maximize outcomes, it has the potential to outperform human experts. Figure 3B shows a diagrammatic representation of an RL algorithm. An RL model has been used to aid in dosing decisions during dofetilide loading for patients with AF [37].

Figure 3. Diagrammatic representations of (A) supervised learning (SL) and (B) reinforcement learning (RL).



The advantage of ML in health care is clear; advanced computation allows for analysis of unfathomable amounts of data in infinitesimal amounts of time, which is something the most adept provider simply cannot physically achieve. More data lead to a more informed decision and, therefore, better outcomes [18,38-41]. However, the power and accuracy of ML models are irrelevant if their use is not widely adopted. AI in health care is a robust area of research, but its acceptance in everyday clinical practice lags behind. Two key obstacles standing between the development of AI for health care and its clinical use are model interpretability and trust in the technology.

Interpretability can be broken down into forward or mechanistic interpretability and backward or post hoc interpretability [42]. Forward interpretability represents the ability for a provider to walk through the input portion of the model (ie, its usability). All QRhythm users reported that using the app would be easy for them, indicating good forward interpretability. Backward interpretability represents the ability of a user to easily identify the reasoning behind the decision made by the model. Our survey respondents rated the importance of backward interpretability as 4.3 out of 5 (scale 1-5). Backward interpretability of QRhythm was less convincing; 1 (17%) user reported not understanding the reasoning underlying the decisions made by QRhythm well, 3 (50%) were neutral on the

subject, and 2 (33%) reported understanding the reasoning somewhat well.

Maybe the largest obstacle preventing clinical acceptance of AI in health care is trust. ML models require complex mathematics to be functional. As a result, the methodology underlying their decision-making is inherently murky for nonexperts in the field, leading to mistrust by those who do not understand their mechanisms. A study concerning patient apprehension toward AI in health care highlighted that one factor integral to trust in AI was safety of the recommendations made by the model [43]. These concerns were shared by our respondents who rated patient safety as the most important characteristic of the app with an importance rating of 4.7 out of 5. Asan et al [44] highlighted the importance of the transparency of a model when gaining trust. Given the black box nature of these models, achieving transparency is a difficult task. To do so, steps such as furthering education concerning ML in the health care field and providing accessible and understandable explanations of models should be taken.

Limitations

QRhythm is in the beta testing phase of operation and currently relies heavily on the SL model for recommendations owing to the need for interactive training of RL. Time and increased

deployment are needed to improve the accuracy of the recommendations of the model, and additional research is needed to identify a training environment that is safe but also provides meaningful opportunities to apply a computer algorithm in clinical care decisions. Importantly, our work has uncovered the challenges with integration of software development lifecycles, which generally proceed best in a bottom-up, just-in-time development life cycle as employed in the Agile development process, with the necessary top-down guidance from clinical studies and expert opinion. Development of a CDSS that not only provides usability but also meaningful predictions toward an improvement in clinical outcomes is the ultimate goal, and this work represents an important first step.

Conclusions

In summary, we introduced a novel ML-based model first utilizing SL and then RL to aid in the decision-making process for rhythm strategy for patients with AF. We asked providers to respond to a survey to assess apprehensions regarding the acceptance of such a model for widespread use in clinical practice. Our results show that interpretability and trust of a model are key to acceptance, and providing transparent explanations underlying model reasoning and ensuring the safety of model recommendations are key aspects to improving interpretability and trust.

Acknowledgments

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Data Availability

The survey and raw data used for this study are available as supplemental information.

Conflicts of Interest

None declared.

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Abbreviations

AC: anticoagulation

AF: atrial fibrillation

AI: artificial intelligence

ANN: artificial neural network

BN: Bayesian network

CCDSS: computerized clinical decision support system

CDSS: clinical decision support system

ECG: electrocardiography

HAS-BLED: Hypertension, Abnormal renal/liver function, Stroke, Bleeding history or predisposition, Labile International Normalized Ratio, Elderly, Drugs/alcohol concomitantly

EHR: electronic health record

ML: machine learning

RL: reinforcement learning

SL: supervised learning

SR: sinus rhythm

UL: unsupervised learning

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Original Paper

Development of a Dynamically Tailored mHealth Intervention (What Do You Drink) to Reduce Excessive Drinking Among Dutch Lower-Educated Students: User-Centered Design Approach

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Abstract

Background: The high prevalence and adverse consequences of excessive drinking among lower-educated adolescents and young adults are public concerns in the Netherlands. Evidence-based alcohol prevention programs targeting adolescents and young adults with a low educational background are sparse.

Objective: This study aimed to describe the planned process for the theory- and evidence-based development, implementation, and evaluation of a dynamically tailored mobile alcohol intervention, entitled *What Do You Drink* (WDYD), aimed at lower-educated students from secondary vocational education and training (*Middelbaar Beroepsonderwijs* in Dutch).

Methods: We used intervention mapping as the framework for the systematic development of WDYD. It consists of the following six steps: assessing needs (step 1), formulating intervention objectives (step 2), translating theoretical methods into practical applications (step 3), integrating these into a coherent program (step 4), anticipating future implementation and adoption (step 5), and developing an evaluation plan (step 6).

Results: Reducing excessive drinking among Dutch lower-educated students aged 16 to 24 years was defined as the desired behavioral outcome and subdivided into the following five program objectives: make the decision to reduce drinking, set realistic drinking goals, use effective strategies to achieve drinking goals, monitor own drinking behavior, and evaluate own drinking behavior and adjust goals. Risk awareness, motivation, social norms, and self-efficacy were identified as the most important and changeable individual determinants related to excessive drinking and, therefore, were incorporated into WDYD. Dynamic tailoring was selected as the basic intervention method for changing these determinants. A user-centered design strategy was used to enhance the fit of the intervention to the needs of students. The intervention was developed in 4 iterations, and the prototypes were subsequently tested with the students and refined. This resulted in a completely automated, standalone native app in which students received dynamically tailored feedback regarding their alcohol use and goal achievement via multiple sessions within 17 weeks based on diary data assessing their alcohol consumption, motivation, confidence, and mood. A randomized controlled trial with ecological momentary assessments will be used to examine the effects, use, and acceptability of the intervention.

Conclusions: The use of intervention mapping led to the development of an innovative, evidence-based intervention to reduce excessive alcohol consumption among lower-educated Dutch adolescents and young adults. Developing an intervention based on theory and empirical evidence enables researchers and program planners to identify and retain effective intervention elements and to translate the intervention to new populations and settings. This is important, as *black boxes*, or poorly described interventions, have long been a criticism of the eHealth field, and effective intervention elements across mobile health alcohol interventions are still largely unknown.

Trial Registration: Netherlands Trial Registry NTR6619; <https://trialssearch.who.int/Trial2.aspx?TrialID=NTR6619>

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KEYWORDS

alcohol consumption; excessive drinking; lower-educated students; adolescents; young adults; dynamic tailoring; mobile health intervention; intervention mapping; health promotion

Introduction

Health and Behavioral Problem

Alcohol is one of the most commonly used substances among adolescents and young adults in the European Union. Nearly half (43.8%) of adolescents aged 15 to 19 years are current drinkers, and this prevalence increases (58%) among young adults aged 20 to 24 years. Among these groups, 51.1% (adolescents) and 54.5% (adults), drink alcohol excessively on at least one occasion per month [1]. Excessive drinking is defined as heavy drinking (ie, drinking more than the recommended weekly consumption) and binge drinking (ie, drinking more than the recommended amount on 1 occasion [2]). It is well established that excessive drinking has various negative consequences regarding health, social relationships, academic performance, and finishing school [1]. It increases the risk of (physical) violence, drunk driving, injuries, risky sexual behavior, episodic memory deficits, the development of alcohol use disorders [1,3], tissue damage in the body [4], and various forms of cancer [5].

Excessive Drinking

In the Netherlands, various studies have shown that adolescents and young adults engage in excessive drinking [6-8]. For instance, 66% to 70% of adolescents and young adults engage in heavy drinking [8]. In the Netherlands, heavy drinking is defined as drinking more than what is proposed in the low-risk guidelines [9], in which adolescents (aged 15-17 years) are recommended to drink no alcohol and adults are recommended to drink no alcohol or, in any case, ≤ 1 standard drink per day. In addition, 14% to 19% of young adolescents and adults engage in binge drinking [8]. This is defined as drinking more than 4 (for women) or 6 (for men) standard alcohol units on 1 occasion at least once per week [10].

Need for Alcohol Interventions Among Lower-Educated Students

From a public health perspective, there is an urgent need to develop and evaluate alcohol interventions that target lower-educated adolescents and young adults. When completing secondary education, students in the Netherlands can follow 3 levels of education: the lowest level is secondary vocational education and training (*Middelbaar Beroepsonderwijs* [MBO] in Dutch), the intermediate level is higher professional education (*Hoger Beroepsonderwijs* in Dutch), and the highest level is higher education (*Wetenschappelijk Onderwijs* in Dutch). In this study, we refer to students who follow a lower educational level as MBO students. MBO schools prepare students for the labor market or continuing education. In the academic year 2021-2022, there were 61 MBO schools in the Netherlands, with 504,300 students [11]. Regarding adolescents (students

aged 16-18 years), 21% of the students who followed a lower educational level drank >10 glasses of alcohol on a weekend day [6]. Regarding young adults, the majority of young adults who followed a lower educational level drank alcohol in the past 12 months (63.1%), 42.7% engaged in heavy drinking, and 6.5% engaged in binge drinking [8]. Most interventions are targeted at higher-educated students [12-14]; these are mostly brief interventions, these interventions have shown modest effect sizes, and use effective techniques such as motivational interviewing, personalized feedback, identification of risk situations, and goal setting. However, interventions that effectively reduce excessive drinking among lower-educated students are still lacking, and thus, effective mechanisms that can be applied in these interventions are still largely unknown [15].

This Study

This study aimed to describe the planned process for the theory- and evidence-based development, implementation, and evaluation of a dynamically tailored mobile intervention, entitled *What Do You Drink* (WDYD), targeting Dutch lower-educated adolescents and young adults who engage in excessive alcohol drinking. WDYD is based on the self-determination theory (SDT) [16] and self-regulation principles [17]. SDT states that autonomous motivation (ie, feeling that one's behavior can be chosen), competence (ie, feeling confident and competent), and relatedness (ie, feeling related to and understood by others) are key targets for behavior change [18]. Regarding self-regulation, people go through the following three phases: (1) forethought, in which they prepare for behavior change via self-motivational beliefs and goal setting; (2) performance, in which they use strategies to reach goals and monitor their behavior; and (3) self-reflection, where they evaluate used strategies and learn from success or failure [17]. The developmental process is elaborated by following the six steps of the intervention mapping (IM) protocol [19], which include assessing needs (step 1), defining performance and change objectives (step 2), defining theory- and evidence-based methods and practical applications (step 3), producing the program (step 4), defining a program implementation plan (step 5), and defining a plan for process and effect evaluation (step 6). These steps are described in detail later.

Methods

We first describe the final intervention, followed by a description of the step-by-step systematic development of the intervention.

WDYD Intervention

WDYD is a dynamically tailored mobile intervention to reduce excessive drinking among Dutch lower-educated adolescents

and young adults. WDYD is an 18-week intervention consisting of 10 sessions. It starts with a weekly session (weeks 0-5), followed by sessions every 2 weeks (weeks 7 and 9) and finally every month (weeks 13 and 17). In each session, the participants can choose from a couple of exercises that have been preselected to meet their needs, based on their activities and recordings in the app. The app consists of 39 different exercises in the form of mini-interventions and 22 brief videos in the form of role model stories. Screenshots of the intervention are provided in Figures S1-S16 in [Multimedia Appendix 1](#).

In the first session of WDYD, the program was introduced, and users gave an estimation of their weekly alcohol consumption, received normative feedback on alcohol consumption (ie, own consumption compared with the Dutch guidelines [20]), and answered a question on whether they will take the challenge of reducing their alcohol consumption (*yes or no, I am not in the mood or no, I do not want that or no, or I am not sure I can*). Those who answer *no* receive a movie and can choose 1 of 2 mini-interventions targeting mood, motivation, or self-confidence (depending on their answer) and are asked again, after the mini-intervention, whether they want to reduce their alcohol consumption; those who answer *yes* to the first or second question are asked to plan how much they would like to drink for each day of the next week, can view a movie, and can choose 1 of 2 mini-interventions targeting planning. The session ends with a date and proposed time for the next session. Users who have set a goal to reduce their drinking are informed that they will be asked to fill out a diary daily for the next week. When users chose not to reduce their alcohol consumption, a similar intervention was repeated in the following sessions. Users who did not set a goal after 3 sessions were offered the option to continue with WDYD, take a break for 3 weeks, or stop receiving invitations for sessions.

When users chose to set an alcohol reduction goal in one of the sessions, they received daily reminders to fill out a diary to monitor their alcohol consumption (which was based on alcohol consumption of the previous day), current mood, the importance of reaching their self-set goal (to assess motivation), and perceived confidence in reaching that goal (to assess self-confidence). In addition, the follow-up sessions consisted of an overview and feedback of goal progress of the past week based on the 7 preceding diaries, the option to view a movie and to choose 1 out of 2 mini-interventions tailored to their personal situation based on their diary input (ie, when participants did not meet the goal for at least two days and mood, importance, or self-confidence had a low score), and the option to adjust their goal and consequently viewing a movie and choosing 1 of 2 mini-interventions targeting planning. In addition to the sessions, users received a notification and could select 1 of the 2 mini-interventions targeting relapse prevention (when they had not reached their goal for 3 consecutive days after having reached at least five goals). When users had not reached their goal for the last 3 consecutive days and their mood was low, they received a notification and could select 1 of 2 mini-interventions targeting mood. When users reached their goal for several days, they received positive reinforcement messages, and when they did not fill out diaries for a couple of days, they received compliance-enhancement messages. These,

as well as reminders for the sessions, were offered via push notifications. In the home menu, 4 exercises were always readily available as well as 2 movies based on role modeling. For each session, participants received an invitation (at 7:30 PM or at a time chosen by participants) and 3 reminders via push notifications in case a session was not started or ended (ie, days 1, 4, and 7). The invitation for the diaries was sent via push notification at 11 AM, and a reminder was sent at 5 PM on the same day; the diary was available for 1 day, so participants were not able to fill out earlier diaries (approximately 1-minute completion time per diary).

The WDYD app consisted of 5 menus. The first menu showed participants when the next session was scheduled, the exercises they could perform, and movies they could view between sessions. The second menu showed the participants which exercises were their favorites. The third menu was the diary. The fourth menu provided an overview of alcohol intake in the week based on the diary input. Finally, the fifth menu was a profile page, in which participants could view their registration details, read a brief explanation regarding WDYD, and decide whom to contact via email in case of questions regarding the app. Screenshots of WDYD are provided in Figures S1-S16 in [Multimedia Appendix 1](#).

Systematic Development of WDYD

WDYD was systematically developed using IM [19], and a user-centered design [21] was applied, closely involving the target group in the intervention development. IM is used to provide a systematic and detailed description of the development of WDYD. The IM protocol provides a framework for the development of health promotion programs. It describes a step-by-step procedure that supports effective decision-making and the proper use of theory and empirical evidence. Each step has a different focus and approach for the use of evidence and theory [19].

IM Steps

Step 1 of IM consists of a needs assessment. In this step, the health problem, behavioral and environmental causes of this problem, and related determinants are identified. In addition, the overall intervention goals, which are the desired outcomes, are defined. These health problems and causes have already been described in the *Introduction* section, and the related determinants are described in the *Results* section (IM step 2).

In step 2, the program objective and desired behavioral outcome were defined. As part of this step, the performance objectives of the behavior were formulated, functioning as the subbehaviors that underlie the program objective and behavioral outcome. Next, the changeable determinants associated with the behavioral outcome were identified. Combining the performance objectives with the determinants resulted in change objectives. Change objectives are defined as statements of what the target population should learn to change to achieve the desired behavioral outcome.

In step 3, theory- and evidence-based methods were linked to the change objectives for the behavioral outcome. Subsequently, practical applications were selected and designed to deliver theory- and evidence-based methods. Practical applications are

specific techniques for the practical use of theory- and evidence-based methods in ways that fit the target group and the context in which the intervention will be delivered. The parameters for use under which the method would be effective were considered in the selection of practical applications.

In step 4, the practical applications of the intervention methods were translated into program production. The intervention materials were developed and produced in four iterations according to user-centered design to ensure it fits the needs of users [21]: (1) analyze user needs via design and concept testing, (2) test a web-based static prototype, (3) test a web-based working prototype, and (4) test the concept intervention. In each iteration, the MBO students were asked to provide input and feedback for the next iteration.

In step 5, a plan for adoption and implementation was defined, including a program that would influence the behavior of individuals who would make decisions regarding adopting and using the program. Finally, in step 6, the plan for the effect and process evaluation of the intervention is discussed [19].

Ethics Approval

This study was approved by the Ethical Committee of the Faculty of Social Sciences of Radboud University Nijmegen (number ECSW2016-1403-390).

Results

Behavioral Outcome, Performance Objectives, Determinants, and Change Objectives (IM Step 1)

Behavioral Outcome

The objective of the program is *to reduce excessive drinking among Dutch lower-educated students aged 16 to 24 years*. The desired behavioral outcome of the WDYD intervention was formulated as follows: *Dutch lower-educated students aged 16 to 24 years drink within the normative limits of the Dutch National Health Council for low-risk drinking* [20]. This implies zero alcohol consumption for adolescents (aged 16-17 years), and for adults (aged 18-24 years), it implies a mean alcohol consumption that will not exceed 7 (for women) or 14 (for men) glasses of standard alcohol units per week and, in case of binge drinking, ≥ 4 (for women) or ≥ 6 (for men) standard alcohol units on 1 occasion after having received the intervention [10].

Performance Objectives

As part of the systematic development approach (IM step 2 [19]), we defined the performance objectives of the behavior (subbehaviors that underlie the program objective and behavioral outcome). The intervention targets are based on self-regulation principles [17], which break down behavioral outcomes into subgoals. Performance objectives were formulated in the order of the behavior change process, including deciding to reduce alcohol consumption, setting goals, using strategies to achieve drinking goals, and monitoring and evaluating one's own alcohol drinking behavior. The performance objectives are presented in [Table 1](#).

Table 1. Matrix of the change objectives of the dynamically tailored mobile *What Do You Drink* intervention to reduce excessive alcohol drinking among lower-educated students (aged 16-24 years) in the Netherlands.

Performance objective	Determinant			
	Risk awareness	Motivation	Self-efficacy	Social norms
1. Make the decision to reduce alcohol drinking	Acknowledge the long-term and short-term risks of alcohol drinking; be aware of responsible drinking norms	Understand misconceptions regarding positive expectancies of alcohol consumption; acknowledge the advantages of drinking less at short and long term; express the importance of drinking less or responsibly	Express confidence to reduce alcohol drinking	Experience positive norms from peers to reduce alcohol drinking
2. Set realistic drinking goals	Acknowledge the urge to set realistic drinking goals; be aware of drinking norms	Feel committed to self-set goals	Express confidence in setting realistic drinking goals	Communicate regarding realistic drinking goals with peers or buddy; ask for help from peers or buddy in setting realistic drinking goals
3. Use effective strategies to achieve drinking goals	Be aware of challenging situations	Feel motivated to achieve drinking goals	Express confidence in achieving drinking goals	Communicate regarding drinking goals with friends or peers or family or buddy; resist social pressure to drink more than the self-set goals; learn from others how they effectively reduce drinking
4. Monitor own drinking behavior	Be aware of own drinking behavior	— ^a	—	—
5. Evaluate own drinking behavior and set goals				
5.1. If successful, maintain reduced alcohol drinking or adapt goal (for further reduction)	Recognize congruence and discrepancy between own drinking behavior and set goals; acknowledge the urge to maintain reduced alcohol drinking or adapt goal	Feel that reducing their goal is (socially) rewarding	Express confidence in maintaining reduced alcohol drinking or adapt goal	—
5.2. If unsuccessful (lapse), revise used strategies in reducing alcohol drinking or adapt drinking goal	Recognize congruence and discrepancy between own drinking behavior and set goals	Feel motivated to revise used strategies to reduce alcohol drinking; feel motivated to adapt drinking goal after lapse	Express confidence to deal with tempting or challenging situations; express confidence to manage negative feelings	Learn from others how they cope with lapses and revise used strategies to reduce alcohol drinking and adapt drinking goals

^aNot available (missing data; there were no change objectives made for the combination of this performance objective and determinant).

Determinants

A systematic literature search resulted in 4 changeable determinants of excessive drinking among adolescents and young adults: risk awareness, motivation, self-efficacy, and social norms. These are related to the key targets of SDT for behavior change (ie, autonomous motivation, competence, and relatedness) [16,18]. First, those who drink excessively usually underestimate their amount of drinking as well as the short- and long-term effects of excessive drinking [22-24]. According to the precaution adoption process model [25], awareness of the risk involved in performing a particular behavior is crucial in taking the first step toward behavioral change. Therefore, increasing risk awareness may be an effective mechanism for reducing alcohol consumption.

Second, intrinsic motivation is a risk factor for excessive drinking among young adults [26]. A Dutch study targeting alcohol reduction among adolescents and young adults was not

effective for lower-educated students because they were particularly unmotivated to change their behavior [27]. This was probably due to the focus on higher-educated students and those ready to reduce excessive drinking in the intervention. Increased motivation to drink alcohol also influences drinking behavior. For instance, a study showed that motivations to drink alcohol that included positive outcomes of drinking (eg, socializing and having fun) was related to more drinking [28]. Increasing intrinsic motivation to reduce drinking through an intervention that suits the needs of the target group and decreasing motivation to drink alcohol by focusing on socially evoked alcohol drinking might be effective mechanisms for behavioral change. On the basis of the SDT [16], intrinsic motivation is a key factor in the adaptive self-regulation of behavioral change. In addition, increasing intrinsic motivation to reduce drinking among adolescents and young adults who drink excessively is shown to decrease alcohol consumption

[29,30]. Therefore, increasing intrinsic motivation may be an effective mechanism for reducing alcohol consumption.

Third, self-efficacy is related to alcohol drinking [26]. Young adults with low self-efficacy to refuse alcohol drinking are more likely to engage in heavy drinking [31]. Drinking refusal self-efficacy is shown to be affected by mood [32]. A negative mood seems to contribute to a lowered drinking refusal self-efficacy, resulting in more maladaptive drinking behaviors, such as uncontrolled excessive drinking [33]. High perceived self-efficacy in refusing alcohol drinking is shown to result in less high-risk drinking behaviors [34]. In addition, drinking refusal self-efficacy is affected by self-efficacy expectations regarding dealing with social pressure. Thus, enhancing self-efficacy may be an effective mechanism for reducing alcohol consumption.

Feeling confident in dealing with social pressure leads to a decrease in alcohol consumption and binge drinking [27]. Social norms, the fourth determinant, also comes into play. Social pressure plays a role in excessive drinking among young adults [35,36], with social norms perceived by peers in particular [24,37]. Thus, not only feeling more confident in coping with social pressure but also addressing the social norms that correspond with this pressure could function as changeable factors in decreasing excessive alcohol consumption. Thus, enhancing self-efficacy may be an effective mechanism for reducing alcohol consumption.

Change Objectives

To define the change objectives, the performance objectives were combined with the determinants, resulting in specific goals that would enhance the behavior change process during the intervention (eg, *express confidence to reduce alcohol drinking*). Table 1 depicts the matrix of the performance objectives, with the change objectives specified per determinant in the WDYD intervention. Regarding risk awareness (determinant), when making the decision to drink less alcohol (performance objective 1), an example of a change objective is that one should be aware of the short- and long-term risks of alcohol drinking and of responsible drinking norms. Regarding intrinsic motivation (determinant), to set realistic drinking goals (performance objective 2), an example of a change objective is that one should feel committed to their self-set goals. Regarding self-efficacy (determinant), when using effective strategies to achieve drinking goals (performance objective 3), an example of a change objective is that one should express confidence in achieving drinking goals. Regarding social norms, when using effective strategies to achieve drinking goals (performance objective 3), an example of a change objective is that one should communicate their goals with others or learn from others how they effectively reduce drinking.

Selection of Methods and Practical Applications (IM Step 3)

Theory- and Evidence-Based Methods

Next, we selected theory- and evidence-based methods and their corresponding practical applications for the intervention (IM step 3) [19]. Multimedia Appendix 2 provides an overview of the theory- and evidence-based methods that we selected based

on the change objectives presented in Table 1. Dynamic tailoring, or just-in-time adaptive intervention (JITAI), was selected as the overarching method. It ensures not only personalization of feedback to the individual but also adaptation based on variations in time. In other words, methods can be tailored to the situation of a person based on psychological and behavioral changes over time [38,39]. Dynamic tailoring is based on the principle of timing of the right type and amount of support. This requires monitoring of the individual. Dynamic tailoring or JITAI has been more effective than nondynamic tailoring or non-JITAI [39,40]. The parameters for use under which tailoring is effective are that the intervention is tailored to determinants related to behavior change or relevance (eg, age, sex, and alcohol consumption). These were applied; the determinants are described in IM step 2, and the messages are tailored to users' age, sex, and current alcohol consumption based on input from the diaries.

We used theory- and evidence-based methods derived from self-regulation [17] theories as the broad umbrella, as these target performance objectives directly, including self-monitoring [41], behavioral feedback, and goal setting [42]. These methods have been found to be effective in reducing alcohol consumption [12,43]. Furthermore, these self-regulatory methods can cause participants to see the discrepancy between their alcohol drinking goal and behavior, leading to increased risk awareness. Other methods applied to increase awareness include normative feedback and personalized risk information [44].

To increase motivation, we used methods based on motivational interviewing and self-reward. Motivational interviewing [45] is an effective method for alcohol reduction interventions targeting adolescents and young adults [14,46]. Self-reward has not yet been properly examined as an effective method for changing behavior [47], but it has shown promising effects on promoting behavior change and maintenance of physical activity [48] and fruit consumption [49].

To improve self-efficacy in coping with difficult alcohol-related situations, we included methods such as coping planning and relapse prevention. Problem solving is associated with a reduction in excessive alcohol consumption [50], which includes coping planning and relapse prevention [51]. Self-efficacy was also increased through self-persuasion [52] and stress management [53]. Self-persuasion can reduce alcohol consumption compared with direct persuasion (ie, providing arguments) [54]. Research has shown that stress management can reduce negative emotions and alcohol consumption among students [55].

To address social norms, modeling and social support were incorporated into the intervention. Modeling [56,57] has been shown to be effective when normative information on the alcohol consumption of peers (eg, negative attitude toward excessive drinking) is given [58]. Social support [59] has not yet been properly examined as an effective method for reducing alcohol consumption. In the context of alcoholics anonymous, it has been suggested as an effective mechanism in promoting a sober lifestyle [60] and has also been shown to be an effective method in various health behavior change interventions [61].

Practical Applications

The practical application of the chosen methods as part of WDYD is presented in [Multimedia Appendix 2](#). Here, we provide examples of the practical applications and the parameters for use under which the methods are effective. First, we provide 2 examples regarding performance objective 1 (*making the decision to reduce drinking*). To increase users' awareness of possible drinking norms (change objective), targeting the determinant *risk awareness*, the method *normative feedback* will be applied keeping the parameter for use in mind, that is, the feedback needs to be individual, follow the behavior in time, and be specific [62]. In the practical application, users will receive information regarding their own alcohol consumption compared with alcohol drinking guidelines [20] (Figure S1 in [Multimedia Appendix 1](#)). To target the determinants *motivation and self-efficacy*, the method *motivational interviewing* was used by means of several practical applications in the app while maintaining the parameters for use, such as a supportive relationship with the client combined with the evocation of change talk in a manner that is collaborative, evocative, autonomy supporting, and exploring rather than confronting, educating, authoritative, and explanative [62]. The practical applications of this are a value clarification, importance and confidence rulers, identifying personal strengths, and looking forward and back. For example, to allow users to express the importance of drinking less (change objective for determinant *motivation*), the practical application *values clarification* was used to explore among users important values and to evoke change talk by examining among users how these fit with reducing their alcohol consumption. In addition, upon the interest of the user, examples of values among peers and how these values relate to reduced drinking were provided (Figures S2-S5 in [Multimedia Appendix 1](#)).

Second, 2 examples of practical applications for performance objective 2 (*set realistic drinking goals*) are described. App users chose their alcohol drinking goals based on their preferences and abilities to achieve their goals. Users were encouraged to set smart goals that were specific, measurable, achievable, relevant, and time bound. The app provided different exercises to achieve these drinking goals. To enhance expressing confidence in setting realistic drinking goals (change objective), targeting the determinant *self-efficacy*, the method *goal setting* was practically applied by asking users to set drinking goals based on their consumption during the previous week and checking whether the set goals are realistic (Figure S6 in [Multimedia Appendix 1](#)). The reference period (ie, alcohol consumption in the past week) and checking whether the set goals were realistic were included to adhere to the parameters for use of goal setting (ie, users feel committed to their goal, and goals are difficult but available within the individual skill level [62]). To stimulate communication regarding realistic drinking goals with peers or a buddy and to ask for help in setting realistic drinking goals by peers or a buddy (change objectives), targeting the determinant *social norms*, the method *mobilize social support* was chosen. The parameter for the use of mobilizing social support is, that support for behavior change is positive and includes caring, trust, openness, and acceptance, [62]. This was practically applied by stimulating users to choose

a buddy among their friends who could help them reduce alcohol consumption and to specify how they can help (Figures S7-S10 in [Multimedia Appendix 1](#)).

A total of 3 examples of practical applications with regard to performance objective 3 (*use effective strategies to achieve drinking goals*) are described. To promote resistance to social pressure to drink more than the self-set goals and learning from others how they effectively reduce drinking (change objectives), targeting *self-efficacy*, the method *modeling* was practically applied by showing videos and role model stories with tips and tricks from peers on how they reduce alcohol drinking and how they say no to alcohol, keeping in mind the parameters for use of modeling (ie, the user can identify with the model, and the model needs to be a coping model who provides their own solutions [62] (Figures S11 and S12 in [Multimedia Appendix 1](#)). To promote feeling motivated to achieve drinking goals, targeting the determinant *motivation*, the method *self-reward* was practically applied by an exercise focusing on how and when to reward yourself. The parameter for use is that self-praise or self-reward is prompted if there has been effort or progress in performing the behavior [63]. This was applied by asking users to select a behavioral achievement (eg, reaching their goal for alcohol consumption for 1 day, 3 days, or a week) and to link a reward to this achievement.

Regarding performance objective 4 (*monitor own drinking behavior*), an example of a practical application of the method *self-monitoring* to enhance awareness of one's own drinking behavior (change objective), targeting the determinants *risk awareness and motivation*, was an alcohol drinking diary, along with a mood diary. The parameters for the use of self-monitoring are that the monitoring must be of a specific behavior, that the data must be interpreted and used, and that the reward must be reinforced to users [62]. This was applied by prompting users to fill in their diary on a daily basis, specifying how many glasses of alcohol they drank yesterday and how they are feeling today. They could also indicate how important they think it is to reach their alcohol goal for that day and how much confidence they have in reaching that goal. Users received a notification for the diary at 11 AM and a reminder at 5 PM when they did not fill in their diary to promote the use of the diary. The app contained a separate page where users were able to see their diary and progress regarding their alcohol drinking goals. If users reached their drinking goals for a couple of days in a row, a positive reinforcement of progress toward goals was prompted (Figures S13 and S14 in [Multimedia Appendix 1](#)).

With regard to performance objective 5 (*evaluate own drinking behavior and set goals*), 2 examples of practical applications are provided. To promote recognition of congruence and discrepancy between own drinking behavior and set goals (change objective), targeting the determinant *risk awareness*, the method *behavioral feedback* was applied. The parameter for use is that feedback needs to be individual, follow the behavior in time, and be specific [62]. This was applied by showing the user the discrepancy between the set goals and drinking behavior in glasses per day of the past week in a graph (Figure S15 in [Multimedia Appendix 1](#)). To stimulate users expressing confidence in maintaining reduced alcohol consumption or adapting goals (change objective), targeting the

determinant *self-efficacy*, the methods *relapse prevention* and *planning coping responses* were applied. The parameter for use is that high-risk situations are identified and coping responses are practiced. This was applied with exercises focusing on learning from lapses (eg, drinking too much on 1 occasion) and how to get back on track. For example, in an exercise, users are stimulated to identify high-risk situations (ie, where, with whom, their thoughts, feelings, and consequences) and to learn coping responses (ie, helping thoughts and responses). They can also see an example of a peer who describes a high-risk situation and plans a coping response.

Program Production of WDYD (IM Step 4)

WDYD was systematically and iteratively developed in 4 phases with the active involvement of lower-educated students to examine what fits their needs (IM step 4) [19], following user-centered design principles [21]. WDYD was developed by the Research Institute for Applied Sciences (Nederlandse organisatie voor Toegepast-Natuurwetenschappelijk Onderzoek), Trimbos Institute, and Radboud University Nijmegen, and the software for WDYD was developed by Newstory. Students from 2 MBO schools participated in the iterative development of WDYD. They were recruited via a contact person at each school (ie, a teacher). The students involved in the development were diverse in terms of sex, age, and alcohol consumption. Their inputs were included in the following version and were consecutively pretested. Participants received a gift voucher as a reward for their participation in the pretests. An advisory board of relevant stakeholders (Trimbos Institute, Dutch MBO Council, MBO's Nova College and Deltion College, Dutch Foundation Testjeleefstijl, Open University Heerlen, Maastricht University, and Radboud University Nijmegen) offered recommendations for the program design, implementation, and evaluation. WDYD was developed in 4 phases and pretests. The aim of the pretests was to evaluate the preferences of the students, that is, their needs and requirements for the program and their preferred strategies with regard to layout and future use (eg, channel, frequency, and duration). After each pretest, feedback was processed in the prototype, and the prototype was further developed based on recommendations.

The first pretest of WDYD was a concept test consisting of a scenario of the program and mock-ups of possible strategies used for improving motivation, self-efficacy, mood, and planning and for preventing relapse. This concept was tested through 4 focus group interviews with students who engaged in excessive drinking (N=23 students). The mean age of the participants was 17 (range 15-21) years, 52% (12/23) were male, and they varied according to study type (social care: 6/23, 26%; car engineering: 5/23, 22%; audiovisual: 3/23, 13%; aviation and service: 3/23, 13%; legal service: 2/23, 9%; photography: 2/23, 9%; executive secretary: 1/23, 4%; and enforcement: 1/23, 4%). The concept was positively evaluated with a mean grade of 7.1 on a 10-point scale (1=very bad to 10=excellent; range 6.5-8.5). Students were positive regarding the variety of methods used and the tone of voice in that they experience an autonomous choice to reduce their drinking. They perceived the Dutch guidelines [9] (no alcohol for adolescents and maximum 1 standard drink per day for adults) as somewhat unrealistic, and most students indicated that they did not want to reduce alcohol

consumption. They experienced feelings of shame in using a program to reduce their alcohol consumption and did not feel the need to ask for help to reduce their consumption; they indicated that it is important that WDYD can be used individually and privately, and they suggested that an app may be a good solution for that. Participants indicated that privacy in the use of the program is crucial, as it accounts for the experience of freedom or autonomy of choice (with regard to the decision to reduce alcohol drinking as well as which program parts they want to use and when). Suggestions for further development were to enhance personal relevance (eg, information regarding the purpose and target group of the program, key focus on coping with challenging situations and empowerment instead of therapeutic focus, and information regarding the consequences of alcohol drinking), language (ie, avoiding therapeutic language and explaining difficult terms, such as binge drinking), guarantee privacy of use (ie, preference for the program to be used via an app and not wanting to share program content with others), and duration and frequency (ie, they wanted to spend a maximum of 15 minutes per week on the program; this may be a couple of times per week to, for example, monitor drinking; they wanted to use it until they drank less or reached their goal). This concept test resulted in a production document in which the features, functionalities, and requirements of WDYD were stated based on the students' recommendations on the first prototype.

The second pretest consisted of the evaluation of a web-based, static prototype in 5 focus group interviews, in which the prototype was evaluated individually (students could scroll through the pages via a link on their phone and write down their notes), both individually and classically (the prototype was presented via a beamer), or vice versa. These mock-ups were presented as several pages, illustrating the process of navigating through the app. The questions focused on the practical applications of the behavior change methods in the app (eg, exercises, diaries, and notifications) and the design. The sample consisted of 57% (33/58) male students, the participants' mean age was 18.4 (range 16-22) years, and they drank on average 10 glasses of alcohol per week (range 0-56 glasses). More than half of the sample (30/58, 52%) engaged in binge drinking at least once a week and drank >7 glasses of alcohol weekly (30/58, 52%). The app was evaluated with a mean grade of 7.0 on a 10-point scale (1=very bad to 10=excellent; range 4-8.5). Students were positive regarding the design, user-friendliness, and monitoring of their drinking behavior. The app was evaluated as very user intuitive: it was clear what they needed to do and how they could do it. Some of the exercises were unclear, especially the titles, pictures, or icons, and the texts were evaluated as too long. Although we explained difficult words (ie, binge drinking), students struggled to read them, so they were better avoided. In addition, participants preferred use of pictures, icons, and shortened texts. They also suggested using videos for more variety and providing them with notifications for completing the diary. They recommended reducing the amount of text, explaining some exercises more clearly, using more and better suitable pictures, and using swiping to navigate through the different pages of the exercises (instead of the next or previous page buttons). These

recommendations were processed into a third prototype of the app.

The third pretest consisted of an evaluation of a web-based working prototype of the app via an individual interview (N=3 students). Participants were asked to download the app on their phone and use it daily for a couple of days (including the weekend). After this, they were called for an evaluation. The questions were focused on unclarity, navigation, content, usability, and overall impression. A total of 67% (2/3) of the students were male, the mean age was 17.3 (range 16-18) years, they drank an average of 9 glasses of alcohol per week (range 5-12 glasses), 67% (2/3) of the students drank >7 glasses per week, and no participants engaged in binge drinking (ie, 2 of the male students drank 5 glasses per day on 2 consecutive days of the weekend). The prototype was positively evaluated with a mean grade of 7.3 on a 10-point scale (1=very bad to 10=excellent; range 6-8). The students were positive regarding the design, navigation, language, and interactive nature of the app. They were also positive regarding the ease of use and time for participation. They suggested further reducing the amount of (informative) texts and improving the visibility of the role model videos. These recommendations were processed in the fourth prototype of WDYD.

The fourth pretest consisted of an evaluation of the full product (ie, the working WDYD app) in individual interviews (N=4 students). Students used the prototype in the form of a mobile app for at least eight days so that they could have received the baseline questionnaire, 2 sessions, and notifications to fill out their diary daily. After this period, they were called for an evaluation. The interviews focused on the usability and content of the app. The mean age of the sample was 18.3 (range 17-19) years, and 50% (2/4) of the students were male. They drank on average 5.3 glasses of alcohol weekly (range 3-8), 25% (1/4) drank >7 glasses per week, and 25% (1/4) engaged in binge drinking at least once a week. The app was evaluated very positively with a mean grade of 8.2 (1=very bad to 10=excellent; range 7.8-8.5). At the start, students had somewhat low expectations of the app, but they were positively surprised: they were positive regarding informativity, design, user-friendliness (ie, ease of use and time needed to participate), language (ie, understandable), notifications (amount and type), and freedom of choice they experience within the app (eg, the option to view a video and the option to choose 1 out of 2 exercises). The number of notifications was evaluated as good, but there was room for improvement: 1 participant received the notification although they had already filled in the diary, and 2 participants received a reminder although they had already filled in the diary; this needs to be improved in the next version. The preference for the use of the weekly overview (ie, a graphical overview of their alcohol consumption of the week based on the diary input) varied; some participants evaluated it as informative, whereas others preferred the use of the diary as informative in itself and indicated that a weekly overview was not needed. The weekly overview was maintained in the diary, and users could decide for themselves whether to use this overview. The feedback was perceived as somewhat brief, but this was not changed because they only experienced 2 out of the 10 sessions, and during the

preceding pretests, the amount of feedback was perceived as too much.

Suggestions for improvements were processed into the final version of WDYD, which was used for the randomized controlled trial.

Implementation Plan of WDYD (IM Step 5)

To ensure successful implementation (IM step 5) [19] of WDYD, the target group was intensively and iteratively involved in the developmental process of the intervention, following user-based design principles [21]. Students from 2 MBO schools participated in 4 different pretests (refer to the Program Production of WDYD subsection). In addition, 2 classes of MBO students in media design developed short videos in which role models (ie, students) provided tips and tricks to reduce their alcohol consumption and to deal with challenges. These videos were developed in sprint sessions (writing a plan, developing scripts, and refining the videos), in which students received feedback from their teacher and 2 developers of WDYD and made refinements to the plan, scripts, and videos. This resulted in 22 videos that were incorporated into WDYD as part of several exercises.

The intervention was developed and implemented in collaboration with the Trimbos Institute. The Trimbos Institute was the owner of WDYD from the start, as they manage the knowledge network for e- and m-mental health in the Netherlands. This enhanced the opportunity for a broad implementation of WDYD and integration in interventions already used by the Trimbos Institute nationally.

Several strategies have been implemented to specifically stimulate the sustained use of WDYD. Notifications were used to invite and remind participants to fill in their diary, participate in a session, and keep up with their alcohol drinking goals (positive reinforcement messages). This way of prompting a review of progress toward goals is associated with a reduction in alcohol consumption frequency [58]. In light of behavioral maintenance, motivational interviewing was applied to establish a working alliance and to increase intervention engagement, intrinsic motivation, and confidence for change [45]. WDYD not only consisted of several motivational interviewing exercises (such as values clarification, importance and confidence ruler, identifying personal strengths, looking forward, and looking back) but also applied principles of motivational interviewing. These principles were autonomy support (ie, by providing participants as much choice as possible, eg, to provide them with the chance to plan the time to the next session, to provide the choice to view a video, and to choose 1 out of 2 exercises), partnership (ie, the input of participants in the diaries and sessions was the point for departure of the sessions, and participants were stimulated to provide their opinion or solution in the exercises), acceptance and compassion (ie, feedback via push notifications or sessions were written empathetically and personal, without coercion or blame), and evocation (ie, the point of departure for feedback within WDYD was the input of the participant in the diary and sessions; the exercises included in WDYD were interactive, and participants were encouraged to elaborate on their own motivation, confidence, planning strategies, mood, and relapse prevention strategies). In addition,

dynamic tailoring was implemented to elicit behavior change, but it was also used to prevent intervention fatigue and, therefore, induce sustained use [15,38] by withholding from intervening when a user is not receptive to the intervention (eg, when a user does not fill in the diary repeatedly, no exercise will be offered).

Evaluation Plan of WDYD (IM Step 6)

To evaluate the effectiveness of WDYD (IM step 6) [19], a study protocol was written, and a 2-arm randomized controlled trial was planned (trial registration: Netherland Trial Registry NTR6619 [64]). The goal was to randomly assign participants to the intervention group (ie, WDYD intervention) or the control group (ie, no intervention). The participants were recruited via a web-based lifestyle monitor for MBO students [65]. Students who drank alcohol excessively according to the monitor were invited to participate in the study. The eligibility criteria for participation in the study were (1) drinking excessively, that is, drinking more than the low-risk drinking guidelines recommended for adolescents (aged 16-17 years) to drink no alcohol and for adults to drink a maximum of 1 (women) or 2 (men) glasses of standard alcohol units daily, or (2) binge drinking, that is, drinking ≥ 4 (for women) or ≥ 6 (for men) standard alcohol units on 1 occasion [20]. In addition, participants had to be aged ≥ 16 years at the time they signed up, have to be computer or internet literate, and have to provide their informed consent before participation in the study.

The primary outcome measures were excessive drinking (yes or no), binge drinking (yes or no), and the mean weekly alcohol consumption. The secondary outcome measures were intrinsic motivation and self-confidence toward reducing alcohol consumption and the mood of the participant. Outcomes were assessed at baseline, week 9, and week 33 by using web-based surveys and ecological momentary assessments [66]. The ecologic momentary assessments will consist of brief daily diary measurements, assessed every 6 weeks for 7 consecutive days, ending after 33 weeks (ie, weeks 1, 7, 13, 19, 25, 31, and 33 after baseline). Participants in the intervention group will evaluate WDYD in a web-based survey at week 9 after baseline, and they will receive questions on overall acceptability (mean grade), usability of the app, information supplied, and design principles behind the app.

Discussion

Principal Findings

This study provides a comprehensive and detailed description of the rationale and plan for the development, implementation, and evaluation of WDYD, a dynamically tailored mobile health intervention. WDYD was developed to reduce excessive drinking among lower-educated adolescents and young adults in the Netherlands. The IM protocol was followed for the development of WDYD [19]. Furthermore, a user-centered approach was applied in designing the intervention [21].

Contribution of IM

Poorly described interventions, or *black boxes*, have long been criticized in the eHealth field [67,68]. Treatment rationales within empirical papers are often briefly described in the

methods section, where the theoretical framework, delivery, behavior change techniques, and content of the intervention are addressed to a limited extent [19]. The IM approach resulted in a systematically developed intervention by using theory-driven and evidence-based methods. The proper description of behavior change techniques and their practical applications in WDYD contributed to the replicability of the intervention. Furthermore, it can inspire researchers to design new interventions [69].

WDYD was developed in response to an earlier web-based, brief, single-session version of WDYD. This older version showed nonsignificant results for lower-educated adolescents and young adults (aged 16-24 years) and pointed out specific recommendations for improvement [27]. For instance, the new version of WDYD included exercises for students not ready to reduce excessive drinking and implement known conditions for the effectiveness of motivational interviewing (eg, autonomy support, evoking change talk, and partnership) and a nonjudgmental tone of voice [45]. The new version of WDYD was a longer and more intensive intervention, which included multiple sessions to facilitate improvement in intrinsic motivation for change as well as goal striving and persistence [17]. It was based on effective interventions using these strategies [70,71]. The IM protocol is useful for revising and updating existing interventions and provides an opportunity to account for earlier study flaws and limitations.

User-Centered Design

A user-centered design is crucial to maximize the fit of the intervention with the target group [72]. The user-centered design approach resulted in the intensive involvement of the target group in the developmental process of WDYD. The 4 pretests demonstrated how involving the target group led to an increasingly suited intervention, resulting in more positive evaluations of the app. After every pretest, the app was adjusted according to the feedback and recommendations of the target group. This led to changes in the design that would have been easily missed if the target group was not involved in the developmental process. For instance, the pretests indicated that students struggled with difficult wordings (eg, binge drinking), so they were avoided as much as possible. Another example was that students preferred the use of brief textual feedback in the app, alternate textual feedback with pictures and icons, and enhanced variability by including videos. Therefore, we decided to let students develop videos themselves, which included the role model stories of students who provided tips to reduce their alcohol intake and deal with challenges. In addition, textual feedback was rewritten in a terse style, and pictures and icons were added.

Limitations

There are some limitations regarding the developmental process of WDYD. First, the sample sizes of the 2 final pretests were small. Moreover, not all pretests included excessive drinkers only, as the focus of these tests was on evaluating usability and intuitive use. This may explain why participants in the final 2 pretests evaluated the app as more positive (mean grades of pretests 3 and 4 were 7.3 and 8.2, respectively, compared with pretests 1 and 2, which were 7.1 and 7.0, respectively). Therefore, the results of the final 2 pretests should be interpreted

cautiously. However, having only a handful of students in the qualitative evaluation allowed for in-depth interviews, addressing all facets of the app. Second, the final pretest indicated some flaws with regard to the notifications (eg, notifications for the diary were sent although participants had already filled in the diary). This was resolved and thoroughly tested before implementation in the trial. Third, lower-educated students appeared to be a very challenging target group; on the one hand, students indicated in the pretests that they preferred a brief intervention, to spend a maximum of 15 minutes of their time for the intervention per week, that the textual feedback was as brief as possible, and that the intervention included as much freedom of choice as possible. Therefore, we provided students with several options (eg, viewing a video and choosing 1 out of 2 tailored exercises). On the other hand, as an

intervention developer, intervention time is essential for inducing behavior change, and providing users with freedom of choice increases the risk of lower exposure. In addition, personal relevance of the app remained a problem throughout the pretests; even in the fourth pretest, the expectations of students of the app were low, but when participating, they were surprised by the app and perceived it as informative and supportive.

Conclusions

It can be concluded that IM and user-centered design are useful means to develop an evidence-based and theory-driven intervention to reduce excessive drinking among lower-educated students. The target group of lower-educated students who drink alcohol excessively needs more attention in future research to design well-suited and effective interventions.

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Authors' Contributions

HvK, PvE, CV, JK, and MK developed the *What Do You Drink* intervention. HvK, RA, PvE, and CV wrote the paper. MK and JK provided feedback on drafts of the paper. All authors read and approved the manuscript for publication.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Screenshots of the *What Do You Drink* intervention.

[[DOCX File, 1609 KB](#) - [formative_v6i8e36969_app1.docx](#)]

Multimedia Appendix 2

Methods and practical applications of WDYD.

[[DOCX File, 31 KB](#) - [formative_v6i8e36969_app2.docx](#)]

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Abbreviations

- IM:** intervention mapping
 - JITAI:** just-in-time adaptive intervention
 - MBO:** Middelbaar Beroepsonderwijs
 - SDT:** self-determination theory
 - WDYD:** *What Do You Drink*
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Original Paper

The Effectiveness of Web-Based Psychotherapy to Treat and Prevent Burnout: Controlled Trial

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Abstract

Background: Burnout is a hidden productivity killer in organizations. Finding a solution to efficiently measure and proactively prevent or rehabilitate employees with burnout is a challenge. To meet this unabated demand, companies and caregivers can focus on proactive measures to prevent “Burnout as an Occupational Phenomenon.”

Objective: We aimed to address effectiveness, reliability, and validity of the empowerment for participation (EFP) batch of assessments to measure burnout risk in relation to the efficacy of web-based interventions using cognitive behavioral therapy (CBT) and floating to improve mental health and well-being. We introduced three risk assessments: risk for burnout, risk of anxiety, and risk for depression.

Methods: We used an interventional, empirical, and parallel design using raw EFP psychometric data to measure the effectiveness of web-based therapy to reduce the risk of burnout between a control group and web-based therapy group. A total of 50 participants were selected. The rehabilitation and control groups consisted of 25 normally distributed employees each. The rehabilitation group received therapy, whereas the control group had not yet received any form of therapy. IBM SPSS was used to analyze the data collected, and a repeated measures ANOVA, an analysis of covariance, a discriminant analysis, and a construct validity analysis were used to test for reliability and validity. The group was selected from a list of employees within the My-E-Health ecosystem who showed a moderate or high risk for burnout. All assessments and mixed-method CBT were web-based, and floating was conducted at designated locations. The complete EFP assessment was integrated into a digital ecosystem designed for this purpose and therapy, offering a secure and encrypted ecosystem.

Results: There was a statistically significant difference between pre- and postassessment scores for burnout. The reliability of the burnout measure was good (Cronbach $\alpha=.858$; mean 1.826, SD 3.008; Cohen $d=0.607$; $P<.001$) with a high validity of 0.9420. A paired samples 2-tailed test showed a good t score of 4.292 and $P<.001$, with a good effect size, Cohen $d=0.607$. Web-based therapy reduced the risk for burnout in participants compared with the control group. Tests of between-subject effects show $F=16.964$, a significant difference between the control group and the web-based therapy group: $P<.001$, with movement between the group variables of 0.261 or 26.1% for the dependent variable.

Conclusions: This study suggests good reliability and validity of using web-based interventional mixed methods CBT to reduce the risk of burnout. The EFP batch of web-based assessments could reliably identify morbidity risk levels and successfully measure clinical interventions and rehabilitation with consistently reliable results to serve as both a diagnostic and therapeutic tool worthy of major research in the future.

Trial Registration: ClinicalTrials.gov NCT05343208; <https://clinicaltrials.gov/ct2/show/NCT05343208>

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KEYWORDS

risk for burnout; effectivity of web-based therapy; Proactive Occupational Health; presenteeism; work-related stress

Introduction

Measuring Burnout

Burnout within the workplace is a major problem in recent times; therefore, this paper aimed to show that early web-based identification and intervention are effective in addressing this demand. Bucci and Berry [1] argued that the digital revolution is evolving at an unstoppable pace. They also accept that the explosion of digital technology and mental health care is under greater pressure to path digitally mediated interventions and services. Nonetheless, Hollis et al [2] believe that “digital technology has the potential to transform mental health care by connecting patients, services and health data in new ways. Digital web-based applications can offer patients greater access to information and services and enhance clinical management and early intervention through access to real-time patient data.” However, both Hollis et al [2] and Bucci and Berry [1] agree that there are substantial gaps in the evidence base underlying these technologies.

A meta-analysis carried out by Duijts et al [3] showed that predictors of sickness can be used in a homogeneous manner to identify presenteeism. Presenteeism relates to those who choose to remain at work, even though they are not physically or psychologically well, thereby impacting productivity, team dynamics, workflow, and the bottom line [4,5]. A literature review also revealed that key work factors associated with psychological ill-health and absence in staff were associated with long work hours, work overload and pressure, lack of control, lack of participation in decision-making, poor social support, and unclear management and work roles [4,5].

Michie and Williams [6] showed that sickness absence was associated with a poor management style. In the same report, they also showed that successful interventions used training and organizational approaches to increase participation in decision-making, problem solving, and communication techniques, as well as additional support and feedback for individuals. They concluded that many of the work-related variables associated with high levels of psychological ill-health were potentially amenable to change.

Smith and Beaton [7] raised the need for an accurate assessment of psychosocial changes in working conditions [7]. They also stressed the need for these measurements to focus on the collection of data at baseline, and if possible, a follow-up time point.

Over the years, many complex attempts have been made to measure burnout. These include, but are not limited to, assessments for job satisfaction and performance in 1991 [8], development of a measure of workplace deviance in 2000 [9], the World Health Organization’s Health and Work Performance Questionnaire in 2003 [10], the Stanford Presenteeism Scale in 2005 [11], the Utrecht Work Engagement Scale in 2002 [12], and others. What is evident and common in all the above measures is that they are static and retroactive in nature; they

lack continuity in understanding an individual over time and within their changing environments. According to Michelsen [13,14], a reliable and valid methodology to support individual psychological safety and engagement needs continuity in its construct. He suggests that individual measures need to have the ability to monitor individuals within their environment, over time, and dynamically show deviations, mean scores, and trends covering a broad spectrum of issues that affect psychological well-being, engagement, and participation in a myriad of situations within the workplace.

Originally designed in early 2001, as a psychosocial monitoring tool used to assess employees undergoing transformational change initiatives within their companies [13], the empowerment for participation (EFP) battery used today has seen numerous upgrades, from its original paper format to a digital (HTML) version in 2007, to the fully interactive web-based ecosystem used currently. The assessments were accessed via a secure and encrypted web-based ecosystem.

The *EFP assessment battery* consists of 4 assessments and a 360° mirror feedback assessment when objective feedback is required (not addressed herein). All assessments are scored using the visual analog scale (VAS), which consists of a straight line with a beginning and end point; for example, very good to very poor. As the slider moves from left to right, the text positioned at either end of the line increases as the opposite end decreases. The position at which the slider stops is represented by a number from 0 to 20. The slider can be moved in either direction or in accordance with the assessed feels regarding that specific question. To minimize the clustering of points around a preferred numeric value or description as used by Likert-type assessment scales, no visible numeric values or intermediate points are visible or seen by the assessed. The *Journal of Behavior Therapy and Experimental Psychiatry* showed that the VAS scales used enable simple and rapid assessment of the state of anxiety and exhibit superior psychometric properties [15].

The *EFP Motivation Assessment* consists of 20 VAS questions (Cronbach $\alpha=.939$) and aims to show the level at which the individual’s motivation lies. It measures an individual’s motivation in areas such as transparency (openness), meaning, identification, balance, teamwork, stimulation, self-esteem, participation, and engagement among others. Validation analysis showed that 95.9% of the original grouped cases were correctly classified, 93.2% of cross-validated grouped cases were correctly classified (effect size=0.881; Wilks lambda=0.106; $P<.001$), and good group centroid separations from low motivation to high motivation were noted, indicating an excellent measure [14].

The *EFP Stress Assessment* consists of 20 VAS questions (Cronbach $\alpha=.887$) and aims to show the level of an individual’s stress level by measuring several stressors and symptoms in areas such as communication, knowledge, conflict, justice, values, safety, and health in the workplace. Earlier analysis showed good validity, where 91.8% of the original grouped

cases were correctly classified, 89% of cross-validated grouped cases were correctly classified (effect size=0.913; Wilks lambda=0.072; $P<.001$), and good group centroid separations from low stress to highly stressed were noted, indicating an excellent measure [14].

The EFP *Defense Routines Assessment* consists of 20 VAS questions (Cronbach $\alpha=.870$). The purpose here is to map and understand an individual's defense routines and the ability to engage in work and life effectively and openly. The concept of defense mechanism was driven by Freud [16] in 1923, where more difficult-to-handle associations are considered to exist in the so-called primary process (subconscious process), usually considered as an antagonistic relation to the secondary process (conscious processes). Rather, the *Defense Routines Assessment* uses redefinition by Neisser [17] of these processes, where they are not perceived as antagonistic but instead as essential to each other. This suggests that the secondary process provides opportunities to process primary material through an appreciation of the routines that the individual creates as a defense. According to Senge [18] and Michelsen [13], defense routines are habits created to protect us from threats to our self-image and identity. Therefore, these routines provide protection against our deepest assumptions. The *Defense Routines Assessment* aims to measure these routines in areas such as guilt, flexibility, forgiveness, communication, conflict, control, and rationality. Michelsen [13] showed that 97.3% of the original grouped cases were correctly classified, 94.5% of cross-validated grouped cases were correctly classified (effect size=0.891; Wilks lambda=0.103; $P<.001$), and good group centroid separations from low defense routes to moderate defense routes were noted, indicating a very good measure [14].

The EFP *Perpetual Motivation Positioning* assessment consists of 50 VAS questions (Cronbach $\alpha=.944$), divided into seven subscales: (1) knowledge, (2) external demands, (3) social environment, (4) health and safety, (5) self-expectations, (6) openness, and (7) self-esteem. The assessment is presented in a visual spider-gram for easy visual identification of areas in conflict. For example, deviations or anomalies with external demands, self-expectations, and social environments are usually associated with those persons exhibiting psychological challenges or some degree of burnout. The purpose of the assessment is to gain insight into a person's boundaries, participation and adaptability, trust, creativity, openness, and more. In an earlier analysis of the EFP assessment, statistical validation showed that 100% of the original grouped cases were correctly classified, 97.3% of cross-validated grouped cases were correctly classified with an effect size of 0.908 (Wilks lambda=0.084; $P<.001$), and good group centroid separations from low adaptability to high adaptability were noted, indicating an excellent measure [14].

The *Risk for Burnout* report has 30 questions that make up the risk assessment (Cronbach $\alpha=.928$; $P<.001$ partial eta squared=0.900; Cohen $d=0.900$). They were compiled from the EFP batch of questions as follows: (5) motivation; (5) stress; (5) defense routines; (0) knowledge; (6) *Perpetual Motivation Positioning* external demands; (0) social environment; (2) health and safety; (3) self-expectancy; (0) openness; and (2) self-esteem. There are four subdimension measures: (1) external

demands, (2) self-expectancy, (3) depersonalization, and (4) symptoms. All questions are VAS formatted with values ranging from 0 to 20 and a total accumulated score ranging from 0 to 600. The purpose of the risk assessment scale is directly associated with preventive care and proactive cognitive behavior therapy (CBT), used to address any identified trends or associated risks. Because My-E-Health is a registered company health care provider, this EFP Risk for Burnout (EFPRB) measure has served and proven its reliability and validity in preventing workplace-related psychological ill-health, indicating an excellent measure [14].

To avoid psychological and central tendencies and to increase the reliability and validity of the burnout measure, several measures were taken during the year. First, individuals taking the assessments are not limited to symptomatically related questions for specific diagnoses; rather, they take holistic and situation-based questions regarding their general environmental well-being and how they feel within that context. Second, all questions are VASs, and lastly, there are embedded control questions to check for similar question variance anomalies.

There are five risk levels of burnout in the EFPRB assessment—risk levels are provided in relation to the total score or the mean score following a linear guide: 0 to 99 points (mean 0-3.300)=no evidence of burnout, 100 to 199 points (mean 3.333-6.6333)=low risk for burnout, 200 to 299 points (mean 6.6667-9.9667)=moderate risk for burnout, 300 to 399 points (mean 10.00-13.300)=high risk for burnout, and 400 to 600 points (mean 13.3333-20)=burnout. These have proven to be statistically significant in previous studies ($N=73$)—risk for burnout: Cronbach $\alpha=.928$; $P<.001$; partial eta squared=0.900, Cohen $d=0.900$ (Michelsen, 2021 [4]). It has excellent content validity: internal validity of $P>.93$ and external validity of $P>.91$ [4].

Prevention or Rehabilitation Interventions

Measuring and identifying burnout risks and implementing preventive measures early are simpler than retroactive approaches. Retroactive or burned-out cases are those with a high degree of causal and symptomatic reactions already embedded into one's behavior and specifically related to their individual burnout. This requires immediate support for staff-off or sick leave. In some cases, up to 2 years. Understanding these nuances is just part of the complex equation used to evaluate the causes leading to mental health exhaustion and their symptomatic effects on the individual [4].

Internet-based therapy using CBT is now considered an effective way to treat a range of psychological disorders [19,20]. Michelsen [4] suggested that a solution can be found by merging a measurement, causal and symptomatic identification instrument, and an interactive web-based solution to improve access and efficacy in treatment.

Naturally, efficacy in treatment requires many approaches to be discussed herein, namely accessibility, psychological safety (both psychological and data-driven), chemistry (patient and caregiver), an interactive web-based environment to enhance cognitive awareness of self, and a measurement system to

demonstrate patient and counselor treatment progress and empowerment.

Web-based (24/7) access provides the employee with a patient-centric ecosystem with access to a multimodal caregiver team (various specialties from a health coach, psychotherapist, psychologist, medical doctor, counselor, dietician, and others), where the individual can and even choose their care team from available caregivers. The My-E-Health ecosystem provides this type of multimodal access, and it opens the caregiver team's booking calendar to the patient so that the patient can easily book appointments as needed.

Psychological safety should be provided for both the individual and the health care teams. According to a study by Grailey et al, in 2021 [21], a health care team requires a shared belief of psychological safety to allow for interpersonal risk taking, improve innovation, and reduce errors through team InterVision. The My-E-Health model conducts weekly InterVision. Therefore, a multimodal web-based health care team can provide psychological safety via team connectedness designed around a consensus-driven patient-centric system used by My-E-Health. In 2021, Hunt et al [22] showed that psychological safety is an important component of safe and effective patient care in mental health services. Patient psychological safety is as important as the outcome of the health care team. According to Fathers and Stevens [23], it is important to make a patient's experience positive. They also believe that good communication (combining visual, verbal, and written communication to best convey the treatment message) is of greatest importance as well as accessible and correct information and that caregivers should speak clearly not rushing the patient but adapting to the patient's pace. Maintaining a patient's dignity, integrity, and privacy is a vital component of psychological safety [23]. Psychological safety includes the use of a secure and encrypted web-based framework in which secure conversation tunnels can be built between the patient and caregivers. Understanding that one's personal data are always kept private and not shared with persons outside of the care team also supports this. Aggregate data, quality assurance, and oversight are fundamentally important for all stakeholders. This is also supported by InterVision and consensus among the multimodal teams in an internal weekly session.

According to Laughton-Brown [24], chemistry between counselors (any member of the health care team) and employees (patients) is of primary concern, as a trusting relationship is fundamental to good therapy. Facilitating this chemistry can be enhanced by the psychological safety offered by the multimodal care team. This can be improved during the initial web-based therapy (providing feedback on the results of the assessments) through cognition by connecting the visual cortex (visually recognizing and concurring with one's status) and accepting it by validating how the patient feels. This content validation uses the cognitive dissonance theory to connect the subjective situational environment (experience by the patient) to their status and well-being.

Therapy and sick leave are recommended for individuals assessed to be "burned-out," and they are immediately placed into the company rehabilitation program. Employees fluctuating

between the lower two categories on the EFPRB scale (no evidence and low risk) require no additional care and continue their normal quarterly feedback sessions with their health coaches. However, individuals that show a "Moderate Risk for Burnout" level enter a modified web-based rehabilitation program to address identified concerns and receive the necessary guidance to build the needed coping skills to address said issues. Employees falling into the "High Risk for Burnout" category enter an individually designed intervention or proactive rehabilitation program, usually all 3 of the components described herein.

Interactive and Integrated Web-Based Environment

The advantage of the web-based environment over that of traditional clinical settings is that it can be interactive and integrate a myriad of digital and visual tools and various media. Marikyan et al [25] also believe that connecting the dots using cognitive dissonance in technology adoption is rapidly becoming the norm. For web-based therapy systems to be as effective as possible, an interactive ecosystem that provides users with the ability to adapt treatment models to the needs of the patient, and not the reverse. Furthermore, patient-validated assessments can monitor progress if assessed monthly during treatment. Michelsen [4] believes that visual and cognitive recognition and interactivity among the patient, caregiver, and interactive environment help empower the individual [4].

Web-based tools can be used to enhance clinical therapy sessions by providing interactive solutions, as used in Gestalt therapy, to demonstrate possible patient cognitive distortions, dissonance, and self-awareness and visually illuminate areas that may inhibit self-empowerment. These tools can be used in one or a combination of various psychological disciplines (CBT, acceptance commitment theory, and dialectical behavioral therapy and psychodynamic, interpersonal, and transpersonal) and can transform how future web-based mental health ecosystems can work. Finding a workable and sustainable solution that can proactively monitor and positively impact mental health and the effects of burnout will ultimately support systemic evidence-based interventions to identify and manage presenteeism [14].

Methods

Recruitment of Participants

The participants were employees of contracted companies within the My-E-Health company health care and well-being platform. Both the control and therapy groups were gainfully employed and belonged to the My-E-Health company health care program. Their ages ranged from 22 to 68 (mean 43.28, SD 11.317 years) with homogeneity. The study consisted of 28 (56%) males and 22 (44%) females with a mean of 1.44 and SD of 0.501, suggesting good homogeneity. At the time of their assessment, employees had been working at specific positions for 12 months to 16 years.

The control group (n=25, age: mean 42.92, median 41.00, SD 10.71 years) consisted of 11 men (44%) and 14 women (56%). The treatment group (n=25, age: mean 43.64, median 41.00, SD 12.10 years) consisted of 17 (68%) men and 8 (32%) women.

This Study

The aim of this study was to evaluate the effectiveness of web-based therapy in addressing and lowering the risk of employee burnout among randomly selected employees in 4 private companies located in Sweden and the United Kingdom. The hypothesis is that, compared with the control group, the intervention group will demonstrate decreased levels of burnout and that these improvements will remain after 6 months. The research questions of this study were as follows:

1. Is web-based therapy effective in reducing existing burnout?
2. Is web-based therapy effective in reducing the risk for burnout for participants compared with the control group?

Clinical Trial Design and Criteria

This study was approved by the Regional Ethics Committee in Lund, Sweden, in 2017 and began before clinical trial registration. This interventional and empirical study examined the effectiveness of web-based CBT in reducing burnout. A parallel study of a control group was conducted. Both the intervention therapy group and the control groups were selected from a list of employees within the My-E-Health company health care ecosystem that had been assessed on the EFP Burnout Scale to have “Moderate Risk of Burnout,” “High Risk of Burnout” or with “Burnout.” Inclusion criteria include the following: (1) a moderate or high risk for burnout; (2) employees with a current burnout diagnosis from a hospital or outpatient or psychiatric clinic; (3) a fully employed person with a member organization; and (4) no other inclusion criteria. The exclusion criteria were (1) no evidence of burnout on the EFP scale, (2) low risk of burnout on the EFP scale, (3) unemployed persons, and (4) no other exclusion criteria. The inclusion group (n=50) consisted of a control group (n=25) and interventional therapy group (n=25).

The postassessment value was used as the dependent variable. The control group consisted of 25 normally distributed employees (n=25) who had not yet received any form of therapy but only received feedback related to their EFP assessment scores and a therapy group (n=25) consisted of those who received interventional CBT. Both groups were required to validate the pretest and posttest EFP assessment results. Repeated measures ANOVA and analysis of covariance (ANCOVA) analyses were performed using the SPSS (IBM) program.

Intervention Package Used to Reduce Moderate and High Risk for Burnout

The therapeutic package developed by My-E-Health for the treatment of employees, health care professionals, and patients with moderate-to-high risk for burnout consists of three components:

1. The web-based test battery, known as the EFP assessment and the Risk Assessment for Mental Exhaustion (identify the risk level for burnout) and many of the causal aspects related to that risk level.
2. Web-based therapy that is either proactive or preventive in nature or retroactive and encompasses mixed-methods therapy using a mix of CBT, acceptance commitment

theory, dialectical behavioral therapy, transpersonal and psychodynamic therapy, as well as mindfulness techniques such as mindfulness walks (isolating the sensors independently during a walk) and other parasympathetic bottom-up or top-down strategies. These help to bring the patient into the present while addressing both the sympathetic response (fight or flight response) and parasympathetic response (rest or relax and digest response) approaches, also complemented with daily routines to stimulate natural hormone release.

3. Flotation REST (Restricted Environmental Stimulation Technique) completed at any of many floating centers internationally, a minimum of 10 floating sessions 2 to 3 times weekly (depending on the level of exhaustion) for 4 to 5 weeks. Each floating session was followed by a web-based therapy session.

One purpose of the *first component* (EFP) is to detect the severity, early symptoms, and associated causes that lead to a risk for burnout. This facilitates preventive and proactive treatment while at work and not waiting until someone is on sick leave. Another aim was to provide an adequate description of problems (symptomatic and causal in nature), irrespective of severity, for appropriate treatment methods to be introduced and for proper monitoring and evaluation. The psychometric assessments included in the EFP represent a compilation of a range of well-tested test techniques, which are also found in other psychological tests. The EFP batch assessment uses a new approach in that it uses well-tested techniques that have been combined into a whole, where the different parts are allowed to mirror and deepen the understanding and correlation with each other to provide a better overall assessment of an individual's psychological challenges, causes, hurdles, or conditions. Here, individuals can connect with their coach, caregiver, or multimodal team, complete their psychometrics (as needed in therapy or at least on a quarterly basis) and receive live, interactive, face-to-face feedback about their results.

The *second component*, the web-based therapy or mental health coaching program, focuses on improving the individual's situational awareness and understanding of the present, to addressing any cognitive distortions or cognitive dissonance and empowering a path forward. This is accomplished by using an interactive web-based ecosystem as well as learning to identify and listen to their signals and using “mixed methods CBT” and mindfulness to activate their visual cortexes to empower themselves to change. The phase can also include activities designed to help individual patients listen to their bodies and nervous systems (sympathetic and parasympathetic) and to naturally manage hormonal stimulation via daily routines [26-33]. International studies show that web-based counseling combined with CBT (in all its forms) and associated decluttering activities such as mindful-walks, yogic breathing, meditation, yoga, yin yoga, yoga nidra, visualization, aroma therapy, hot shows, cold therapy, and much more, can be used effectively for a variety of clinical problems [34-37]. There are many different relaxation techniques, such as meditation, Tai-Chi, yoga, and qigong [38]; nonetheless, these methods often require long and regular practice before the benefits become apparent. Therefore, a combination of relaxation exercises to activate the

parasympathetic nervous system and an effective and well-known method to reduce physiological and psychological responses to stress and anxiety [39] is needed. Reducing stress with stress-reduction therapy and relaxation training to increase a sense of “mindfulness” usually involves many hours of practice. It is also understood that people with the greatest need for relaxation training are also those having the toughest time in implementing and completing such training [40].

Posttherapy treatment includes continuity with web-based quarterly feedback, which has proven to be an effective way to solidify treatment and prevent relapse. Nonetheless, the evidence for web-based CBT and other methods is well investigated (Carlbring et al, 2018 [40]) and need not be further discussed here. For patients with a moderate-to-high risk of burnout, this phase starts and coincides with the third component.

In contrast, *the third component*, the flotation REST, may not be as well known; therefore, it will be described in more detail below. In step 2, we focus on the treatment of clinical and symptomatic parameters affecting the patient. These include interactive situational analysis of the patient in relation to their holistic self: causes and empowering solutions to empowerment and symptomatic therapy. This can include decluttering exercises to help reduce the constant onslaught of stimuli that activates the autonomic nervous system (sympathetic and parasympathetic nervous systems) and many others. It is well known that a heightened state of stimuli leads to an overactive amygdala signaling the hypothalamus and autonomic nervous system to be on guard or in “Fight or Flight” mode [41]. This state increases involuntary body functions such as blood pressure, pulse, dilation of the blood vessels, and breathing caused as the adrenal glands stimulate a hormone called epinephrine (adrenaline) and secrete it into the blood [41]. Consequently, the hypothalamus and pituitary gland (HPA axis) triggers the release of blood sugar (glucose and fats) as well as the activation of various corticosteroids. This, in turn, affects an individual’s circadian rhythms, sleep, fatigue, and behavior. Patients exhibiting various degrees of stress, anxiety, depression, or burnout usually find themselves in a heightened state, an exhaustive state, or somewhere in between [42]. Step 3 flotation REST or float therapy acts as a break to the sympathetic nervous system by activating the parasympathetic nervous system (producing the rest, relax, and digestive state) by eliminating extra stimuli, muscle tension, stress, and more coming from within or from the situational environment facing the patient [43].

Flotation REST was first introduced by Dr John Lilly in 1954 as an isolation tank to help isolate persons from gravity, the onslaught of external stimuli. Experiences of Dr Lilly with weightlessness and high-altitude flight and isolation also seem to coincide with the meditative experiences of Robert A Monroe, the founder of The Monroe Institute, and his meditative experiences related to monotonous low-frequency stimuli in the exploration of human consciousness leading to a state of rest or relaxation. Both the aforementioned practiced isolation and a form of deep meditation.

Benson [44] argued that the positive effects derived from these various relaxation techniques may be due to deep relaxation,

which simultaneously triggers the so-called a relaxation response (RR). Yogic breathing techniques can also improve the transition effectiveness after entering the tank to achieve a state of relaxation [45]. It is also well known that individuals in a state of acute crisis are not, as a rule, susceptible to rehabilitation efforts, so catching challenges early and combining the 3 proactive components within the intervention program where individuals can benefit from more professionally oriented interventions, creating distance and learning the necessary coping skills to manage daily challenges [45].

Relax Response

Relax response (RR) is identified as the physiological opposite of the “fight-flight response” or stress response [46]. RR is associated with instantly occurring physiological changes, including reduced sympathetic nervous system activity; reduced metabolism; and lowered heart rate, blood pressure, and respiratory rate [45,47]. Activation of the parasympathetic nervous system deactivates corticosteroid effects and improves recovery, improves sleep quality [42], and further creates less dependency on alcohol and psychoactive medications, while increasing the sense of control and efficacy in stressful situations [48].

Currently, techniques are used to induce relaxation and trigger RR. Many symptomatic pharmacological treatments rarely succeed in successfully treating stress-related disorders [49].

Ben-Menachem [50] believed that two main factors were necessary to trigger RR: (1) reduced sensory stimulation and (2) decreased body movement. Flotation REST triggers RR (parasympathetic nervous system) by removing many of the negative stimuli by introducing effortless deep relaxation in a weightless, dark isolated floating pod [50]. It has been shown that the effect of a rehabilitation program diminishes if delayed too long. Introducing rehabilitation efforts at an earlier stage using proactive relaxation therapy, in conjunction with mixed methods CBT, for those displaying a moderate-to-high risk of stress, anxiety, or burnout [14], ensures faster recovery.

The floating pod or floating chamber was filled to a height of approximately 20 cm with lukewarm water (approximately 35 °C-36 °C or 95 °F-96.8 °F) mixed with a magnesium sulfate to water specific gravity ratio of 1.25:1. The chamber can be either a large room designed for patients with claustrophobia or a pod that resembles an egg shape. The patient literally floats like a cork in a weightless environment during their floating sessions. Some patients have likened it to the safety of a womb before birth. Some spas that use floating tanks may use soft music during a floating session; nonetheless, no music is played if one is in therapy. Tanks are equipped with soft lights; however, the patients turn them off when comfortable. Sensory isolation is achieved when decluttering emerges, and an individual finds mindfulness by intuitively and visually moving into the primary process [43]. In psychology, this is referred to as the primary process. As decluttering, breathing, and meditating take hold and the patient achieves the here-and-now or present, the secondary process emerges for a more mature style of thought. In some cases, patients may fall asleep during this phase. Professor Kjellgren has shown in her research that it is restful and psychologically beneficial to experience recurring episodes

of just “being in the present weightlessness state” induced by a flotation tank [51].

The flotation tank is constructed such that the participant has full control and can stop when they wish to. The lid is easily opened from the inside as well as from the outside. By pressing the buttons inside the tank, the participant could turn on a light in the tank or call for the staff. The water salinity is remarkably high, which provides a good carrying capacity. The high buoyancy in combination with the low water level (approximately 30 cm or 12 inches in depth) provides additional psychological safety (needed for the parasympathetic nervous system to activate) and security. The water is automatically circulated and filtered through a 5- μ m filter and processed via a UV light system before and between the floats. Each participant floats in a safe and clean environment. At the same time, it must be emphasized that flotation REST is a “mild” form of REST, and there are no reports in the literature on hazards or problems to patients.

Jonsson [52] showed that these techniques can trigger RRs even in patients with severe anxiety (generalized anxiety disorder), depression, posttraumatic stress disorder [52], and burnout.

Ethics Approval

The study protocol was approved by the Regional Ethical Board in Lund, Sweden (Dnr 2017/761). All personal data were anonymized, all cases were provided with identification tags, and all individual identifying information was excluded before any research and when the data were transferred into the matrix used for statistical analyses.

Procedures for Assessment, Collection, and Data Analyses

Data were extrapolated from the organizations in the My-E-Health program. All employees agreed to the co-ownership of the data and participated in the research. All individuals have approved our General Data Protection Regulation (GDPR) regulations and responsibilities and are currently or were members of our company health care program. A total of 73 ($n=50$) employees took 100 batches of EFP assessments. However, for the purpose of this study, only the first and last assessments will be used. Employees were informed about the ongoing research and the objectives of the studies, anonymity, and confidentiality of the survey.

Because all assessed individuals entering the My-E-Health EFP platform were unknown upon entry (as little information was known about them before their assessments, no prequalification or demographics were applied, and no individual categorization or adjustments were made), they should be considered one large cohort. There was only one contingency, and all assessed individuals within this study were full-time employees. Their

assessments were subjective and purely based on how individuals interpreted their own situational environment, health, and well-being. Personal data were strictly kept private between the individuals and their counselors or caregivers. No information was made available to employer organizations other than the aggregate data pertaining to their company.

Procedure, Access, Measures, and Web-Based Treatment

For web-based therapy to reach its full potential, individual integrity, privacy, solid measures with reliability and validity, and an interactive framework are necessary. Naturally, the web-based ecosystem needs to provide psychological safety where individuals can feel safe, access an encrypted “Private Space,” and receive live video feedback within an interactive environment. The EFP batch is accessed via a web-based ecosystem designed to proactively support individuals in their eHealth needs. Here, individuals can connect with their coach, caregiver, physician, or psychologist; complete their psychometrics (as needed or at least on a quarterly basis); and receive live counseling about their results. All communications were encrypted and performed within a secure (Health Insurance Portability and Accountability Act– and General Data Protection Regulation–compliant) framework to protect individual integrity. Any identified deviations can be addressed early together with the caregiver or certified counselor, using the inbuilt CBT framework.

The EFP assessment battery consists of the 4 assessments discussed earlier. All assessments are scored using the VASs, consisting of a straight line with a beginning and end point; for example, very good to poor (Figure 1). As the slider moves from left to right, the text positioned at either end of the line increases as the opposite end decreases. The position at which the slider stops is represented by a number from 0 to 20. The slider can be moved in either direction or in accordance with the assessed feels regarding that specific question. To minimize the clustering of points around a preferred numeric value or description as used by Likert-type assessment scales, no visible numeric values or intermediate points are visible or seen by the assessed. The *Journal of Behavior Therapy and Experimental Psychiatry* showed that the VAS-A scales used below enable a simple and rapid assessment of the state of anxiety and exhibit superior psychometric properties (Abend et al, 2014 [15]).

Figure 1 shows an EFP assessment question scored using the VAS, consisting of a straight line with a beginning and end point: very good to poor in this example. The VAS line has hidden values to minimize central tendencies. The button can be moved in either direction, either left or right based-upon how an individual may feel, and the scale variables increase or decrease proportionally.

Figure 1. Visual analog scale used in assessments.

Statistical Analysis Requirements

Several assumptions that needed to be met before running the analysis of the pre- and posttest data were made. The ANCOVA will control for the pretest values to analyze the posttest values and examine whether there is a significant difference between the control group and the therapy group while controlling for the pretest values. ANOVA requires an assumption of normality where both the pretest and posttest are normally distributed.

ANCOVA Assumptions

To run an ANCOVA, 2 assumptions must be met to ensure that the covariate meets the requirements to run the ANCOVA. The first assumption is that the pretest cannot be statistically significantly different across the levels of the independent variables of the group. ($n=50$; control group, $n=25$, and web-based therapy group, $n=25$). This means that there was no difference between the control group and the treatment group for the pretest or initial assessment test.

The procedure used a general linear model univariate analysis to check whether the covariates met the requirements to run the ANCOVA. Assumption test 1, testing between-subject effects using the pretest for burnout as the dependent variable, showed no significant difference between the groups for burnout ($P>.07$), thereby passing the first assumption.

The second assumption is the homogeneity of the regression test between the subjects' effects. The dependent variable is the posttest assessment for burnout, and the covariate is the pretest assessment for burnout, where the group was the fixed factor. To pass this assumption, the group times the pretest for burnout cannot be significant. The results showed a nonsignificant result of $P>.13$, thereby meeting the homogeneity of the regression condition and passing the requirements needed to move forward with an ANCOVA.

ANOVA Assumptions

There are 4 assumptions that need to be met to complete a repeated measures ANOVA with normality being the most important, where both the pretest and posttest are normally distributed:

The dependent variable should be interval or ratio data.

1. The participants are randomly sampled from the population.
2. The dependent variable is normally distributed in the population at each level of the independent variables.
3. The variability in the difference between any pair of groups should be the same as that between any other pair of groups.

The test for normality showed no missing values and that the data did not exhibit statistically different normality values for both the pretest and posttest (Kolmogorov-Smirnov test=0.200), confirming the null hypothesis. Shapiro-Wilk analysis for normality for the burnout pretest ($P=.69$) and for the burnout posttest ($P=.17$) confirmed that we could. This result confirms that the null hypothesis can be accepted (or cannot be rejected).

A descriptive analysis showed acceptable burnout pretest (skewness=-0.179 and kurtosis=-0.565) and burnout posttest (skewness=0.027 and kurtosis=-1.057) values for skewness and kurtosis. The EFP pretest assessment for burnout showed a normal distribution ($n=50$; mean 7.62, SD 2.90). The EFP posttest assessment for burnout showed ($n=50$; mean 5.80, SD 2.612). There were no outliers, and both pre- and posttest EFP assessments showed a normal distribution.

Paired samples statistics showed group mean scores for the pretest for burnout at mean 7.624 with an SE of 0.41008 and posttest mean 5.7980 with an SE of 0.36946, meeting the assumption to run the ANOVA. Paired samples correlations showed no correlation, 0.408 and $P<.003$ to meet the assumption needed to run ANOVA. Therefore, all 4 assumptions for running the ANOVA were met.

Normality was not violated, and the assumptions for both the ANCOVA and ANOVA were met.

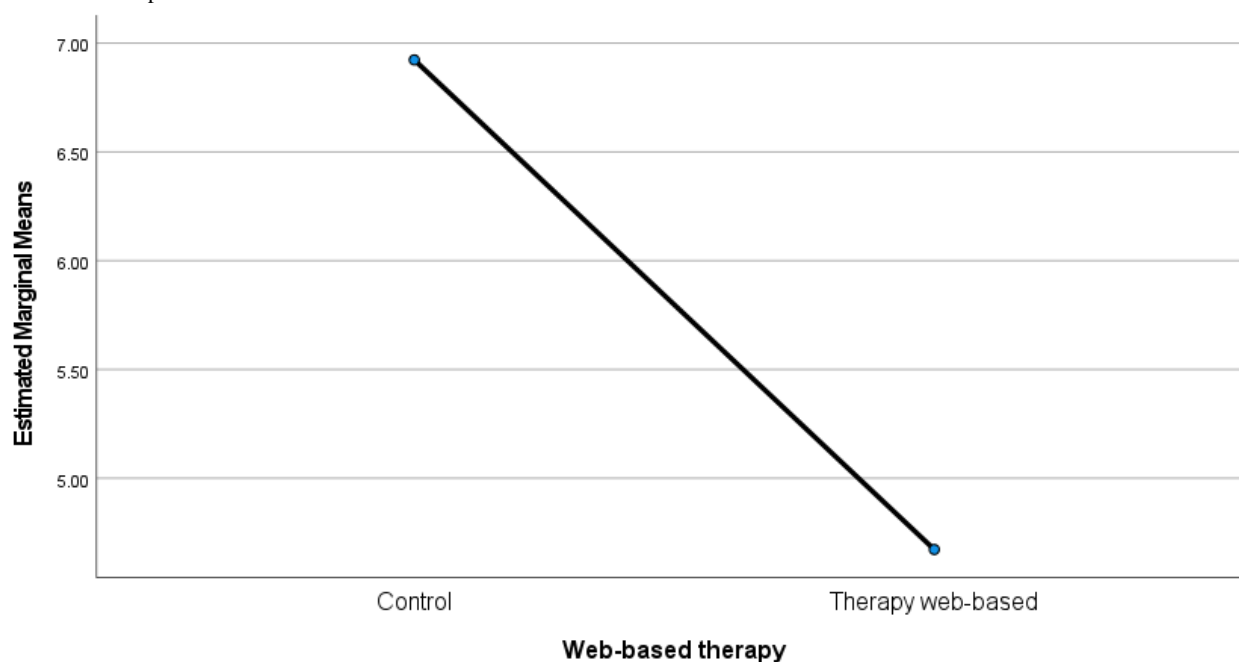
Results

Overview

The results are organized into four sections: an ANCOVA, a repeated measures ANOVA, reliability for internal validity using discriminant statistics, and external content validity analysis.

A descriptive output of the ANCOVA showed a clear difference in the mean scores for the control group, mean 6.572, SD 2.54 and the web-based intervention CBT group, mean 5.024, SD 2.49 where a lower score represents a lower risk for burnout. In controlling the pretest assessment for burnout scores, the between-subject effects group analysis showed statistically significant differences between the groups on the posttest assessment for burnout: $F=12.624$, $P<.001$, and a partial eta squared (0.212) or membership difference between the groups of 21.2% (Figure 2).

Figure 2 presents the estimated marginal means for the posttest assessment for burnout between the groups, which shows a significant drop in the risk for burnout for the intervention CBT web-based therapy group as opposed to the control group.

Figure 2. Pretest and posttest results.

Covariates appearing in the model are evaluated at the following values: Burnout.Mean.Intl=7.6240

Repeated Measures ANOVA

When running a repeated measures ANOVA, the paired samples test showed good results (t score of 4.292; $P < .001$ with a good effect size Cohen $d = 0.607$) obtained from the mean average 1.826 divided by the SD 3.008. The paired samples effect sizes for the pretest (Cohen $d = 0.607$, 95% CI 0.302-0.906) and posttest (Cohen $d = 0.602$, 95% CI 0.300-0.899) also showed good effect sizes.

Using the general linear model ANOVA between subjects to analyze the difference between the pre- and posttest scores as a dependent variable and the $n = 50$ group (the control and intervention CBT group) as the fixed factors, with the posttest assessment for burnout as the covariate, the descriptive statistics for the univariate analysis of variance showed a significant difference in the mean scores for the control group (mean 0.304, SD 2.085) versus the intervention CBT web-based group (mean 3.348).

The Levene test of equality of error variances tests the null hypothesis that the error variance of the dependent variable is equal across the groups. Burnout difference based on mean (Levene_{1,48} = 3.629; $P = .06$). Burnout difference based on median

(Levene_{1,48} = 2.354; $P = .13$). This fails the assumption; therefore, the null hypothesis can be accepted.

Tests of between-subject effects (Table 1) show that $F = 16.964$ and a significant difference between the control group and the web-based therapy group: $P < .001$ with an effect size or movement between the group variables or change of 0.261 or 26.1% for the dependent variable.

An independent-samples t test, with the difference in burnout scores between the groups, where the difference in score becomes the dependent variable and the group the fixed factor is presented in Table 2. Group statistics for the independent-samples t test using the difference in burnout scores as the dependent variable showed a large mean difference for the control group (mean 0.3040) and the web-based therapy group (mean 3.3480). This is confirmed when the equal variances assumed are calculated using the Levene test for equality of variances ($F = 3.629$; significance = .063; t_{48} test = -0.4.119; $P < .001$; CI -4.5299 to -1.5580).

Table 2 shows a clear burnout difference between the control group and the intervention group.

Table 1. Tests of between-subject effects shows a 26.1% difference between the groups (dependent variable: burnout difference).

Source	Type III sum of squares	<i>df</i>	Mean square	<i>F</i> value	Significance <i>P</i> value	Partial η^2
Corrected model	115.824 ^a	1	115.824	16.964	<.001	0.261
Intercept	166.714	1	166.714	24.417	<.001	0.337
Group	115.824	1	115.824	16.964	<.001	0.261
Error	327.732	48	6.828	N/A ^b	N/A	N/A
Total	610.270	50	N/A	N/A	N/A	N/A
Corrected total	443.556	49	N/A	N/A	N/A	N/A

^a*R* squared=0.261 (adjusted *R* squared=0.246).

^bN/A: not applicable.

Table 2. Burnout difference between the control group and the intervention group (N=50).

Burnout difference	Participants, n (%)	Values, mean (SD)	Values, SE
Control	25 (50)	0.3040 (2.08536)	0.41707
Web-based therapy	25 (50)	3.3480 (3.05070)	0.61014

Reliability

Cronbach α was used to measure the internal reliability, where a Cronbach α of $\geq .70$ is considered acceptable, Cronbach α of $\geq .80$ is considered good, and an Cronbach α of $\geq .90$ is considered excellent. The coefficient α for international reliability showed good results (N=50; Cronbach α = .858; mean 1.826, SD 3.008; Cohen *d* = 0.607; *P* < .001).

Internal Validity Using Discriminant Statistics

The discriminant validity showed significant reliability and validity. Predicted group membership between the control group and the therapy group classifications was conducted on the pretest and posttest assessments for burnout and three EFP assessments—stress, motivation, and anxiety, as follows:

1. Pretest (78% of original grouped cases were correctly classified; effect size=0.733; Wilks lambda=0.711; *P* < .003). Subject matrix function pooled within-groups correlations between discriminating variable and standardized canonical discriminant functions the variable ordered by absolute size of correlation within function shows the following: stress pretest assessment <0.023, motivation pretest assessment >−0.281, anxiety posttest assessment >0.520, and burnout >0.423. Functions at group centroids functions shows the control group

at −0.625 and the web-based therapy group at 0.625. There were no mission or out-of-range variables.

2. Posttest (70% of original grouped cases were correctly classified; effect size=0.682; Wilks lambda=0.784; *P* < .02). Subject Matrix function pooled within-groups correlations between discriminating variable and standardized canonical discriminant functions the variable ordered by absolute size of correlation within function shows the following: stress posttest assessment <0.814, motivation posttest assessment >−0.668, anxiety posttest assessment >0.495, and burnout >0.598. Functions at group centroids functions shows the control group at 0.514 and the web-based therapy group at −0.514. There were no mission or out-of-range variables.

External Validity

An external construct validity question was asked after the pretest EFP and posttest EFP assessments. This study aimed to establish whether the measured results corresponded to how they felt at that point. All participants (the web-based therapy group and the control group) were asked to accurately validate (0-100) how they really felt in relation to the assessment results. All participants answered both validation questions, resulting in a (median=0.95 or >0.9414) construct validity for the pretest and a >0.9420 for the posttest (Table 3).

Table 3. Frequency table showing content validity results where each employee validates and confirms the accuracy of their assessed results to how they feel. A visual analog scale (VAS) is presented to the assessed employees, and they are prompted online to validate their scores. This is done during the web-based session with their counselor. The accuracy (validity) and correctness of the assessment measures for both preassessment for burnout (0.9414) and postassessment for burnout (0.9420) showed excellent content validity.

	Pretest burnout	Pretest accuracy	Posttest burnout	Posttest accuracy
Participants, N				
Valid	50	50	50	50
Missing	0	0	0	0
Values, mean (SD)	7.6240 (2.89972)	94.14 (5.322)	5.7980 (2.61249)	94.20 (5.379)
Values, median	8.0500	95.00	5.8000	95.00
Skewness	-0.179	-0.606	0.027	-0.590
SE of skewness	0.337	0.337	0.337	0.337
Kurtosis	-0.565	0.023	-1.057	-0.040
SE of kurtosis	0.662	0.662	0.662	0.662
Percentiles				
25	5.5000	90.00	3.3250	90.00
50	8.0500	95.00	5.8000	95.00
75	9.9750	100.00	7.8000	100.00

Discussion

Principal Findings

The proverb “prevention is better than a cure” cannot be truer in the case of employee burnout. All individuals within this construct were affected by it. It is well proven that burnout can destroy a person’s ability to engage in work and life [4,14]. Burnout affects productivity within the workplace and directly affects company presenteeism rates [5]. Low productivity rates can also be correlated with employee defense routines [13,51].

Companies spend billions of US Dollars on preventive maintenance each year in efforts to maintain their physical machinery and equipment but very little on preventing unseen personnel burnout. Similar to machines that break when a part is not changed in time, productive employees experience burnout when their need to recharge is ignored [14,17,53]. In a *Harvard Business Review* article “1 in 5 Employees Is Highly Engaged and at the Risk of Burnout,” Seppälä and Moeller (2018 [54]) described how a company’s most important resource, their highly motivated employees, are at risk for burnout. These motivated employees are the ones that you repeatedly turn to, because they are dependable and efficient, and they always do the work. This affects work, colleagues, teamwork, innovation, creativity, and company continuity. Stress, anxiety, and psychosocial risks are widely recognized as major challenges to occupational health and safety, and these include stress, anxiety, depression, and burnout, which are all engagement killers that cost companies more than US \$1 trillion annually [4,5,13,14,55].

As time and space continue to implode, companies increasingly depend on highly engaged employees. A company’s drive to increase output not only drives them to turn a blind eye to the needed or required employee maintenance but they also tend to ignore, all so frequent, signals by reframing those signals into

resilience training to further increase the output of their highly engaged workers. Companies literally play Russian roulette with the mental health of their most valued employees.

Addressing this problem requires the same discipline as your car service or any other scheduled maintenance. When an engine signal light comes on in your car, you take your car in for service. If you show signs of any risk for burnout, you should also take yourself in for tune-up or service. Preventive maintenance requires good tools to measure tolerances, deviations, and acceptable levels to operate sustainably. Unfortunately, today, there are many fancy-looking well-being or mental health apps on the market with 0 validity and reliability. Their flashy content looks good and they cost almost nothing in return, and as the old saying goes, “you get what you pay for” cannot be more from the truth. It is easy to provide a simple PDF one-page problem analysis without providing a solution or services to support companies in their preventive efforts is another whole story.

It has been shown that preventive and proactive treatment can reduce a person’s risk of burnout, and the chances that the differences occur through random error alone cannot be considered. This study found a statistically significant difference, showing that web-based therapy reduces the risk for burnout.

If used correctly, coaches, therapists, psychologists, and medical personnel can effectively reduce costs by proactively engaging with clients. The benefits of using the My-E-Health approach with the EFP batch mean that intervention can begin at an early phase when psychosocial challenges are in their infancy. This alone will reduce both the cost and effort needed to prevent the “slippery slope effect” into work-related burnout, as well as an individual’s personal pain.

Nevertheless, this full-service method can be used to proactively measure, identify, and treat other mental health challenges, such

as anxiety, depression, and posttraumatic stress disorder. Therefore, broader use of the EFP batch as a measure of psychosocial situational well-being is highly plausible.

Limitations

The study was registered in ClinicalTrials.gov on April 25, 2022, and not preregistered, as it was already approved by the Swedish Regional Ethics Committee in 2017; therefore, the authors do not see this as a limitation, but some might. Although there was an acceptable sample size of $N=50$ with an effect size of Cohen $d=0.607$, larger sample sizes are always desirable in clinical studies. In addition, published materials related to the prevention and rehabilitation of burnout are a limiting factor; however, this can be seen as an opportunity for clinicians and researchers to assess the clinical effectiveness of early identification and rehabilitation in future studies.

Conclusions

Although there are many internet-based intervention studies on stress-related issues, few have addressed burnout. This original study suggests the effectiveness of web-based intervention therapy in reducing the impact of burnout in the workplace. It

also provides good evidence for the use of web-based tools in prevention and early identification to measure company exposure and the risk of employee burnout. The EFP batch of web-based assessments can reliably assess company morbidity risk levels and successfully measure clinical interventions and rehabilitation, thereby reliably serving as both a diagnostic and therapeutic tool worthy of major research in the future.

Web-based therapy is effective in reducing burnout. Reliability of the burnout measure was good (Cronbach $\alpha=0.858$; mean 1.826, SD 3.008; Cohen $d=0.607$; $P<.001$) as well as the instrument validity (0.9420). A paired samples test showed a good t score of 4.292 and $P<.001$, with a good effect size Cohen $d=0.607$.

Web-based therapy was effective in reducing the risk for burnout in participants compared with the control group. Tests of between-subject effects showed $F=16.964$ and a significant difference between the control group and the web-based therapy group: $P<.001$, with movement between the group variables or change of 0.261 or 26.1% for the dependent variable. Therefore, after controlling for pretest, is there a statistically significant difference between the levels of the independent variables?

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Data Availability

The SPSS data file for this study is available as a supplementary file. Researchers can also contact the authors for related materials.

Conflicts of Interest

None declared.

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Abbreviations

- ANCOVA:** analysis of covariance
- CBT:** cognitive behavior therapy
- EFP:** empowerment for participation
- EFPRB:** EFP Risk for Burnout (extracted from the EFP assessment)
- REST:** Restricted Environmental Stimulation Technique
- RR:** relaxation response
- VAS:** visual analog scale

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Original Paper

A Novel Hospital-to-Home System for Children With Medical Complexities: Usability Testing Study

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Abstract

Background: Children with medical complexity (CMC) are a group of young people who have severe complex chronic conditions, substantial family-identified service needs, functional limitations, and high health care resource use. Technology-enabled hospital-to-home interventions designed to deliver comprehensive care in the home setting are needed to ease CMC family stress, provide proactive and comprehensive care to this fragile population, and avoid hospital admissions, where possible.

Objective: In this usability testing study, we aimed to assess areas of strength and opportunity within the DigiComp Kids system, a hospital-to-home intervention for CMC and their families and care providers.

Methods: Hospital-based clinicians, family members of medically complex children, and home-based clinicians participated in DigiComp Kids usability testing. Participants were recorded and tasked to think aloud while completing usability testing tasks. Participants were scored on the metrics of effectiveness, efficiency, and satisfaction, and the total usability score was calculated using the Single Usability Metric. Participants also provided insights into user experiences during the postusability testing interviews.

Results: A total of 15 participants (5 hospital-based clinicians, 6 family members, and 4 home-based clinicians) participated in DigiComp Kids usability testing. The participants were able to complete all assigned tasks independently. Error-free rates for tasks ranged from 58% to 100%; the average satisfaction rating across groups was $\geq 80\%$, as measured by the Single Ease Question. Task times of participants were variable compared with the task times of an expert DigiComp Kids user. Single Usability Metric scores ranged from 80.5% to 89.5%. In qualitative interviews, participants stressed the need to find the right fit between user needs and the effort required to use the system. Interviews also revealed that the value of the DigiComp Kids system was in its ability to create a digital bridge between hospital and home, enabling participants to foster and maintain connections across boundaries.

Conclusions: Usability testing revealed strong scores across the groups. Insights gained include the importance of tailoring the implementation of the system to match individual user needs, streamlining key system features, and consideration of the meaning attached to system use by participants to allow for insight into system adoption and sustainment.

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KEYWORDS

usability testing; digital health; children with medical complexities; children; chronic disease; pediatrics; health care; parenting; virtual health; care provider; youth; family needs; home care; usability

Introduction

Background

Children with medical complexities (CMCs) have a significant disease burden, including neurological impairment and organ dysfunction [1]. Medical advances have led to many CMC living longer than would previously have been possible with the added support of technologies such as ventilators and feeding tubes [2]. International epidemiological data indicate that CMC commonly constitute <1% of all children in a given population [1,3,4]; however, Canadian data show that this fraction of the population accounts for up to one-third of pediatric health-related expenditures [1]. Within the current care model, CMC have, on average, 5 or more inpatient hospital stays per year, with a median of 38 days [5]. In addition to the expertise of their acute care hospital teams and specialists, families of technology-dependent CMC often require specialized home care nursing [6]; however, health professional support for this population is fragmented in terms of home and specialist care, with considerable variation in the provision of these services by region. Many regions lack adequate numbers of specialized pediatric home care nurses trained to care for CMC, and specialist care is often episodic, separated geographically from hospital and home care, and lacks integration in terms of communication and documentation with other care systems [6,7].

To reduce poor outcomes such as unmet health care needs as well as emergent and repeated hospitalizations of CMC, care models are needed that emphasize care coordination (organized care with a clear division of responsibility [5]), timely access to urgent care, and a focus on proactive, comprehensive care, as opposed to care that is reactive and episodic [8]. In other complex populations such as frail older people and adults coping with cancer, hospital-to-home models of care using technology-enabled digital health care systems have successfully been used to decrease unmet health needs and unplanned hospitalizations [9,10].

Although technology-enabled digital health care systems can theoretically help bridge the gap between hospital and home and improve outcomes in CMC, this area remains largely underexplored for this population. Despite the relatively low number of studies in this area, research has shown promise in easing the burden of care on CMC families and reducing poor outcomes such as reducing urgent and in-person health care delivery. For example, preliminary data from a virtual hospital-to-home intervention for CMC consisting of vital sign monitoring and virtual communication with a hospital-based clinical team showed a 42% reduction in emergency department visits per patient per month and a 26% reduction in inpatient admissions, with a 95% patient satisfaction rating [11]. Another virtual intervention program involving unrestricted access to a specialist health care team for parents of CMC via telephone, email, telemedicine, and in-person consultations demonstrated an increase in total health system encounters but a decrease in in-person home and clinic care [12]. These early studies demonstrate that virtual care models can indeed improve outcomes for CMC; however, the lack of scalable, standardized

virtual care models, despite these promising results, suggests that a deeper exploration of factors influencing adoption, scalability, and spread is warranted.

Usability Testing

Usability testing studies assist in understanding the interactions between people and technology to investigate the ease of use, learnability, and perceived benefits and challenges of novel systems according to diverse end user groups (those for whom a technology or product is ultimately designed) [13]. The granularity of these studies provides detailed usability information that informs larger concepts such as intervention adoption, scale, and spread. The metrics of effectiveness, efficiency, and satisfaction are widely accepted as important components in the composite concept of usability and should be incorporated into usability measurement and reporting [14]. In addition, qualitative user experience data provide valuable insight into user behaviors, perspectives, needs, and desired outcomes from technology systems, helping to inform the relevance and acceptance of the technology by end users [15]. In this study, we aimed to investigate the usability of a virtual hospital-to-home health system for CMC and their families, called DigiComp Kids (Cloud DX technology).

DigiComp Kids Intervention

The DigiComp Kids intervention uses the Cloud DX Connected Health System and consists of a hospital clinician portal and a home-based kit designed to communicate with one another. The hospital clinician portal is intended to enable hospital-based clinical teams to review biometric data and health information submitted by families and home-based clinicians as well as to send health information to home-based kits to facilitate home-based care management decision-making. Hospital-based clinicians can review submitted patient vital sign measurements, photos, and survey responses; configure individual vital sign parameters and alerts for each patient; send and receive secure messages with family members and home-based clinicians; send health-related documents to families and home-based clinicians such as care plans or medication schedules; schedule and initiate video calls with families and home-based clinicians; and document patient care information directly within the hospital clinician portal. The home-based kit is intended for use by CMC family members and their home-based clinicians to transmit biometric data and health information to hospital-based clinical teams as well as to receive health information sent by hospital-based clinical teams. Components of the home-based kit include a Samsung tablet, a Bluetooth-enabled pulse oximeter with heart rate monitoring capabilities, and a dual tympanic-temporal infrared thermometer. Kit components facilitate remote monitoring of biophysical parameters such as body temperature, heart rate, oxygen saturation, and respiratory rate (manual measurement); submission of responses to health-related monitoring questions; direct upload of photos to the cloud-based patient chart; real-time connection with hospital-based providers via video link and secure text messaging; and virtual appointment scheduling.

The DigiComp Kids system was designed with hospital-based clinicians, CMC families, and home-based clinicians to allow for comprehensive team-based care for CMC in the home

setting. Details of the design methodology are available in detail in a previously published manuscript [16]. The aim of the DigiComp Kids system is to connect hospital-based clinical teams with CMC families and their home clinicians to proactively monitor CMC health needs and respond to them in a timely manner. By better connecting families with home- and hospital-based clinicians, the DigiComp Kids system has been designed to facilitate safe care at home for CMC.

Objectives

The objective of this usability testing study was to assess areas of strength and opportunity within the DigiComp Kids system according to hospital-based clinicians, medically complex children and their family members, and home-based clinicians. During this early formative stage, the results from this usability testing study will assist in making further improvements to the DigiComp Kids system during the preclinical implementation phase.

Methods

Ethics Approval

The Hamilton Integrated Research Ethics Board (HiREB Project #8324) approved this study. All participants provided informed consent before engaging in usability testing.

Setting, Recruitment, and Participant Groups

Usability testing took place entirely virtually because of the need for physical distancing and research regulations in place during the COVID-19 pandemic. In usability testing studies, the engagement of 4 or more participants per group is typically sufficient to detect >80% usability problems [17]; thus, we recruited 6 family members, 4 home-based clinicians, and 5 hospital-based clinicians, for a total of 15 usability testing participants. All participants resided in Southern Ontario, and usability testing was conducted between November and December 2020.

Hospital-based and home-based clinicians were recruited via the networks of various members of the study team (MB, NC, AL, MHM, and SR). Emails were sent to distribution lists and individual contacts known to be working with CMC in either hospital or home settings. The included clinicians spoke and read English, had at least 3 months of experience caring for CMC in hospital or home settings, and provided informed consent to participate. Hospital-based clinicians included a system navigator, complex care nurse practitioner, and 3 registered nurses working with CMC populations. Home-based clinicians included registered nurses and a registered practical nurse working directly with CMC in home settings as well as a clinical nurse specialist whose role is to support the provision of home care by offering remote clinical support.

Family participants were recruited by a clinical member of the study team (AL) and a CMC family partner on the study team (SR). The included family participants lived in the Southern Ontario area, had a child that met the definition of medical complexity [18], spoke and read English, and provided informed consent for both themselves and their child to participate. In

this study, all recruited family members were mothers of medically complex children.

Procedures

Our usability testing procedure incorporated both quantitative and qualitative measures via standardized usability testing and individual participant interviews to capture user effectiveness, efficiency, satisfaction, and user experience.

Training

Overview

All participants received DigiComp Kids intervention training using the Connected Health System through a dedicated virtual session. Before training, participants received either an at-home Connected Health System kit (family members and home-based clinicians) or access to the hospital Connected Health System clinician portal (hospital-based clinicians) as appropriate. All participants also received an electronic standardized training manual developed by the lead author of this study (MB) to guide the training session. The purpose of the training sessions was to orient participants to the DigiComp Kids program using the Connected Health System and its features and to allow participants to navigate the system and ask questions. Participants were given a general background on the project and the way that the home- and hospital-based systems interact, before being specifically trained on the relevant components for their group, as detailed in subsequent sections.

Hospital-Based Clinicians

Hospital-based clinicians were trained in the use of the hospital clinician portal. Training was guided by a standardized training manual that clinicians could refer to as needed throughout the training and testing sessions. Training topics included patient vital sign alert management and configuration; communication with families and home-based clinicians via secure chat messages and video calls; patient home-based care scheduling, including changes to care plans, medications, and required data entry from families or home-based clinicians; and direct documentation within the cloud-based platform. All tasks were demonstrated by the trainer (MB) via remote screen sharing, and participants were subsequently given the opportunity to practice tasks to solidify their information retention and application.

Families and Home-Based Clinicians

CMC family members and home-based clinicians were trained in the use of the at-home DigiComp Kids kit. Practice kits were delivered to family and home-based clinician participants before training. Similar to the hospital-based clinician training, home-based training was guided by a standardized training manual provided to participants for their use throughout the training and testing sessions. Topics for participant training included tablet log-in and setup; sending and receiving secure chat messages; viewing and undertaking scheduled vital signs assessments, photos, and surveys; and locating shared documentation such as care plans and medication orders. Participants were guided through tasks by the trainers (MB and NK) over video and were encouraged to follow along and participate with their kits before the testing session took place.

Testing

Testing for all participants was scheduled either immediately following or as soon as possible after the training sessions within a few days. All testing sessions were audio-visual recorded using videoconferencing software to facilitate the review and scoring of usability testing sessions at a later time.

Hospital-Based Clinicians

Following the training session, hospital-based clinicians participated in an individual virtual testing session facilitated by a moderator (MB). Testing sessions began by reminding the participants that usability testing was intended to test the DigiComp Kids system and approach usability training and not their performance or abilities as clinicians. Participants were given an opportunity to ask questions and were reminded that there would be a scheduled break during testing, but that they could request additional breaks at any time.

Next, participants were asked to think aloud during usability testing. Thinking aloud involves participants concurrently performing a task while verbalizing what comes to mind during the performance of that task [19]. The purpose of thinking aloud is for the moderator to gather relevant data on specific issues of usability, such as system navigation issues, areas of frustration or obscurity, or confusion around the workflow when using the system.

Hospital-based clinicians were asked to complete a series of usability testing tasks guided by a standardized testing protocol. Tasks within the protocol represented the core competencies for the hospital clinician portal, including locating patient information; responding to changes in patient vital signs; and communication, documentation, and scheduling of patient tasks such as surveys and video calls. Usability testing tasks for hospital-based clinicians are listed briefly in [Textbox 1](#) and in further detail in [Multimedia Appendix 1](#).

Textbox 1. User testing tasks for hospital-based clinicians.

Tasks

- Task 1: Verbalize vital signs readings and any generated alerts for last assessment
- Task 2: Change Emma's heart rate parameters from 0 (low) to 80 (high) bpm to 90 (low) to 130 (high) bpm
- Task 3: Request a video call with Emma's family
- Task 4: Add a note to the oxygen saturation reading from this morning
- Task 5: Add assessment to chart with actions taken
- Task 6: Schedule a video call with Emma's family in 4 hours
- Task 7: Change Emma's risk stratification to "medium"
- Task 8: Change the "Wellness Survey" from being sent once weekly to being sent every day for 5 days
- Task 9: Send a chat message to Emma's family

To add realism to the usability test, the participant tasks were conducted in the context of a simulated patient case. The fictional patient used for this case was a 2.5-year-old girl diagnosed with spinal muscular atrophy type 1, named Emma. Participants were introduced to Emma as their patient and provided clinical information on her condition, such as her main clinical issues (generalized low muscular tone and respiratory impairment) and the technical support used (portable oxygen and suction machine) to maintain her well-being at home. At prespecified time points, hospital-based clinicians were given new information about their patient case to indicate the progression of the patient scenario over time. Participants were asked to respond to information and updates on their patients given by the moderator throughout the testing process by following the clinical protocols that were taught during their training session. Further details of the patient are available in [Multimedia Appendix 2](#).

Families and Home-Based Clinicians

CMC family members and home-based clinicians each participated in an individual usability testing protocol facilitated by a moderator (MB or NK). Think-aloud procedures were explained to the participants, as described earlier, and all

participants were given the opportunity to ask questions before beginning their testing sessions. In contrast to the hospital-based clinician participants, usability testing sessions for family members and home-based clinicians did not take place within the context of a patient case but rather focused on undertaking day-to-day tasks related to caring for CMC using the DigiComp Kids home-based technology kit. During these sessions, family members and home-based clinicians were invited to imagine the use of a home-based technology kit with a medically complex child to which they provided care. For realism, family members were also given the option of applying peripheral vital sign devices (eg, pulse oximeter and thermometer) to their children, depending on their comfort level. The content of home-based clinician and family member usability testing sessions focused on device setup and log-in, peripheral vital sign device application and use, submission of clinical information such as responses to survey questions and photos to a simulated hospital-based clinical team, location of information sent by a simulated hospital-based team, and determination of required daily tasks using the scheduling function. Usability testing tasks for home-based clinicians and family members are listed briefly in [Textbox 2](#) and in further detail in [Multimedia Appendix 3](#).

Textbox 2. User testing tasks for family members and home-based clinicians.

Tasks

- Task 1: Set up and turn on the tablet
- Task 2: Log-in to the tablet
- Task 3: View and interpret pending measurements and surveys using red asterisk
- Task 4: Complete or describe temperature measurement
- Task 5: Complete or describe oxygen saturation measurement
- Task 6: Complete and submit Wellness Survey
- Task 7: Find and read out the up-to-date list of child’s medications
- Task 8: Take and submit a photo using the tablet

Interviews

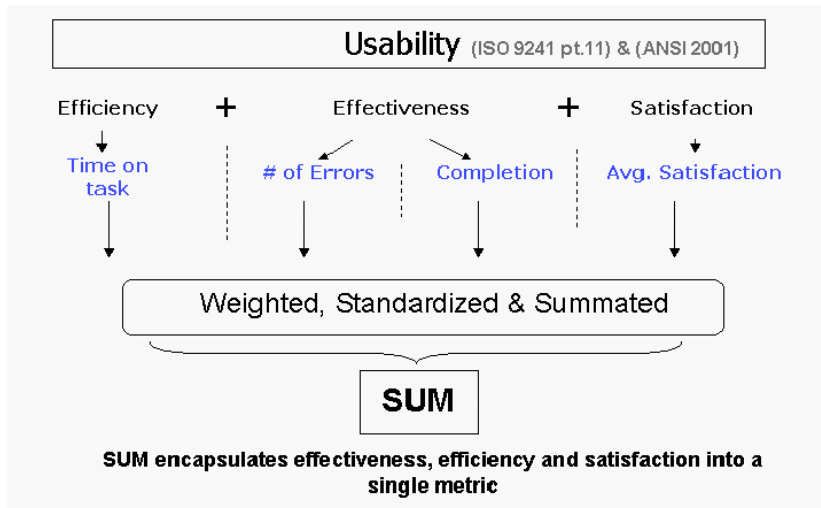
Immediately following the individual testing sessions, each participant was interviewed about their experience of participating in DigiComp Kids usability testing. The purpose of the qualitative data collection in this study was to improve our understanding of the usability of *DigiComp Kids* by triangulating quantitative usability metrics with user experience data from interviews [20,21]. A semistructured interview guide was developed using constructs from a holistic framework to improve the uptake and impact of eHealth technologies [21]. Specifically, the constructs used to guide the interview questions were those of “technology”—the hardware and software comprising the DigiComp Kids system; “people”—the participants themselves and other individuals specified by the participants; and context—the social, cultural, and physical

environment in which the system is situated [21]. Across these categories, questions were designed to solicit areas of ease, frustration, and future improvement. Probing questions were used to encourage elaboration and clarification of participants’ responses where needed. Interview sessions were audio recorded using videoconferencing software. The interview guide can be found in [Multimedia Appendix 4](#).

Measures

Usability is a composite measure comprising task completion, error rate, task time, and satisfaction score metrics [22]. Each of these measures was collected for each task that a user attempted during DigiComp Kids usability testing, with the goal of combining these measures into a Single Usability Metric (SUM) or SUM score [22] (Figure 1).

Figure 1. SUM model (reproduced from Sauro and Kinlund [22]). SUM: Single Usability Metric.



Task completion, error rates, task times, and satisfaction were calculated and standardized following the methods detailed by Sauro and Kinlund [22]. Task completion scores represented the ratio of successful task completion by participants to task attempts. Error rates were computed by dividing errors committed by the task error potential (number of participants multiplied by the number of subtasks per task) to account for multiple possible errors committed by the same participant on the same task. This value is subtracted from one to calculate the error-free rate, enabling it to be combined with other

usability metrics into a summative score [22]. Task times and satisfaction scores were standardized by computing Z scores. To achieve this, a specification limit was set to represent an acceptable score. The specification limit for task time was the time it took an expert user to complete the task, multiplied by 1.5 [23], and for satisfaction, a value of 5.6 was used on the 7-point Single Ease Question satisfaction scale [24,25]. Detailed formulas for the usability measures can be found in [Multimedia Appendix 5](#) [22-25].

Data Management and Analyses

Quantitative Analysis

Microsoft Excel [26] v 16.3 was used for all quantitative statistical analyses. Descriptive statistics were used to summarize participants' demographic data, child diagnostic information (family members), and professional work experience (clinicians).

In addition to reporting usability metrics by user group and task, Sauro and Kinlund [22] demonstrated that the constructs of efficiency, effectiveness, and satisfaction can be represented using a single SUM. Using SUM, usability as a construct is represented as a single score, making it intuitive to interpret without sacrificing the precision of using all 4 variables [22]. To construct the SUM, standardized metrics (task completion, error rates, task satisfaction, and task times) were averaged to create a single, summated score. This single score represents the overall usability of the DigiComp Kids system, equally weighted for the metrics of task completion, error rates, satisfaction, and task times.

Qualitative Analysis

Audiotaped interviews were transcribed verbatim, and the lead author (MB) proofread the transcripts to ensure accuracy. A qualitative descriptive approach was used to analyze the data. Initially, the 3 transcripts were read several times by 3 authors with qualitative training (MB, NK, and NC) before meeting to develop a coding scheme. The coding scheme was developed deductively using theoretical concepts from a holistic framework, including technology, people, and context [21]. This initial coding scheme was used to independently double-code 4 transcripts (MB and NK or MB and NC) using the Dedoose data management software and thematic analysis techniques [27,28]. Team members met to discuss preliminary findings and refine the coding structure. The remainder of the

transcripts was coded by one author (MB or NK), and the authors met to discuss emerging themes.

Multiple measures were used to maintain rigor during the qualitative analysis. First, 1 author (NC) with qualitative expertise guided the qualitative data collection and analysis processes, approving methodological decisions before they were carried out. Second, all authors involved in the qualitative portion of the project (MB, NK, and NC) met weekly during the qualitative analysis process and were contacted via email between meetings to review the progress and discuss methodological issues. Process meetings were particularly helpful when major methodological milestones were encountered, for example, when defining and refining the code tree or when developing emerging themes. The process of peer review and triangulation of ideas helps establish confirmability in decisions [29]. Finally, a detailed audit trail was kept throughout the analysis process, documenting reflexive memos, meeting notes, coding and thematic decisions, and methodological processes.

Results

Demographics

Hospital-Based Clinicians

A total of 5 hospital-based clinicians participated in usability testing using the clinician portal (Figure 2). All participants were female, and the majority were employed full time and educated at a bachelor's or graduate degree level. One participant was identified as a system navigator, and the rest were registered nurses or nurse practitioners. The average length of clinical practice among participants was 12 years, with 5 years practicing in CMC populations. The hospital-based clinician's demographic variables are presented in Table 1.

Figure 2. Clinician portal.



Table 1. Hospital-based clinician characteristics (n=5).

Characteristics	Values
Gender (female), n (%)	5 (100)
Ethnicity, n (%)	
Asian	1 (20)
White	3 (60)
Unspecified	1 (20)
Role, n (%)	
Registered nurse	3 (60)
Nurse practitioner	1 (20)
System navigator	1 (20)
Practice area, n (%)	
Pediatrics	2 (40)
Complex care	3 (60)
Length of clinical practice (years), mean (SD)	12 (10.6)
Length of clinical practice with complex populations (years), mean (SD)	5 (2.3)

Family Members and Children

A total of 6 family members participated in usability testing using the Connected Health Kit (Figure 3). Overall, 4 CMC participated in usability testing with their family members, and 2 family members simulated usability testing tasks because their children were unavailable during the testing time. All participating family members were female, and most were White and married. Most family members were educated at university

level and working full time or on leave. The experience level of family members using tablet technology was evenly distributed from “somewhat experienced” to “expert.” The medically complex children of family members in this study were mostly male and White and aged between 2 and 7 years. CMC had 4 to 6 diagnosed chronic conditions and relied on a wide range of assistive technologies for support, as presented in Table 2.

Figure 3. Components of the home-based kit.

Table 2. Family member and child characteristics.

Characteristics	Values, n (%)
Family members (n=6)	
Gender (female)	6 (100)
Ethnicity	
Asian	1 (17)
White	5 (83)
Number of children	
1	1 (17)
2	2 (33)
3	1 (17)
4	2 (33)
Highest level of formal education	
College diploma	1 (17)
Bachelor's degree	3 (50)
Professional degree	1 (17)
Postgraduate certificate	1 (17)
Employment status	
Unemployed	1 (17)
Part-time	1 (17)
Full-time	2 (33)
On leave	2 (33)
Experience using tablet technology	
Somewhat experienced	2 (33)
Very experienced	2 (33)
Expert	2 (33)
Children (n=6)	
Gender	
Female	2 (33)
Male	4 (66)
Ethnicity	
Asian	1 (17)
White	5 (83)
Age (years)	
2-4	3 (50)
5-7	3 (50)
Number of chronic conditions	
4	2 (33)
5	2 (33)
≥6	2 (33)
Assistive technology	
Enteral or parenteral feeding tube	5 (83)
Home oxygen	5 (83)
Mobility devices	3 (50)

Characteristics	Values, n (%)
Noninvasive ventilation	3 (50)
Invasive ventilation	2 (33)
Tracheostomy	2 (33)
Cerebrospinal fluid shunt	1 (17)
Long-term intravenous line or port	1 (17)
Communication devices	1 (17)

Home-Based Clinicians

A total of 4 home-based clinicians participated in the usability testing. All home-based clinicians were White women who were employed in contract or part-time positions by community

agencies or CMC families. The average length of clinical practice among participants was 14 years, with 12 years spent practicing CMC populations. The demographic characteristics of home-based clinicians are presented in [Table 3](#).

Table 3. Home-based clinician characteristics.

Home-based clinicians (n=4)	Values
Gender (female), n (%)	4 (100)
Ethnicity (White), n (%)	4 (100)
Role, n (%)	
Registered nurse	2 (50)
Registered practical nurse	1 (25)
Clinical nurse specialist	1 (25)
Practice area, n (%)	
Complex care	3 (75)
Home or community care	3 (75)
Emergency department	1 (25)
Neonatal intensive care	1 (25)
Length of clinical practice (years), mean (SD)	14 (16.0)
Length of clinical practice with complex populations (years), mean (SD)	12 (16.9)

User Performance

The scores for task completion, error-free task rates, task satisfaction, and task times are presented by the end user group

in [Tables 4-6](#). SUM scores are presented for each task as well as the overall score per user group.

Table 4. Hospital-based clinician performance.

	Completion	Error-free rate	Satisfaction	Time	Single Usability Metric score
Task 1	1.00	0.80	0.9660	0.5675	0.8334
Task 2	1.00	0.85	0.9963	0.7549	0.9003
Task 3	1.00	1.00	0.9963	0.5199	0.8791
Task 4	1.00	0.97	0.9990	0.9878	0.9884
Task 5	1.00	0.93	0.8980	0.7580	0.8973
Task 6	1.00	0.92	0.8665	0.9798	0.9416
Task 7	1.00	1.00	0.9663	0.9999	0.9991
Task 8	1.00	0.70	0.3400	0.4350	0.6188
Task 9	1.00	1.00	0.9990	0.9994	0.9996
Score, mean (SD)	1.00 (0)	0.9078 (0.105)	0.8919 (0.212)	0.7780 (0.227)	0.8953 (0.119)

Table 5. Family participant performance.

	Completion	Error-free rate	Satisfaction	Time	Single Usability Metric score
Task 1	1.00	1.00	0.9987	0.6915	0.9226
Task 2	1.00	1.00	0.8577	0.3613	0.8048
Task 3	1.00	1.00	0.9987	0.9946	0.9983
Task 4	1.00	0.98	0.9222	0.8531	0.9392
Task 5	1.00	0.94	0.9987	0.9545	0.9744
Task 6	1.00	1.00	0.7734	0.6879	0.8653
Task 7	1.00	0.78	0.2327	0.3936	0.6010
Task 8	1.00	0.89	0.9806	0.4880	0.8394
Score, mean (SD)	1.00 (0)	0.9487 (0.079)	0.8453 (0.261)	0.6780 (0.246)	0.8681 (0.127)

Table 6. Home-based clinician performance.

	Completion	Error-free rate	Satisfaction	Time	Single Usability Metric score
Task 1	1.00	0.94	0.6879	0.2358	0.7153
Task 2	1.00	1.00	0.9893	0.9099	0.9748
Task 3	1.00	1.00	0.8159	0.2148	0.7577
Task 4	1.00	1.00	0.9990	0.8708	0.9675
Task 5	1.00	1.00	0.6664	0.7486	0.8538
Task 6	1.00	1.00	0.9990	0.5636	0.8909
Task 7	1.00	0.67	0.6844	0.3121	0.6658
Task 8	1.00	0.58	0.6554	0.2420	0.6202
Score, mean (SD)	1.00 (0)	0.8987 (0.172)	0.8058 (0.160)	0.5122 (0.298)	0.8057 (0.136)

DigiComp Kids usability testing revealed strong usability across end user groups with respect to task completion, errors, end user satisfaction, and task time. The average total SUM for hospital-based clinicians was 89.53%; family participants scored 86.81% across tasks, whereas home-based clinicians scored 80.57%. In terms of the individual score components, participants in all groups achieved task completion scores of 100%. Error rates varied (range 58%-100% error free), with participants achieving perfect scores across some tasks, whereas other tasks proved more complex and drew many errors. In general, participants committed more errors on tasks in which more steps were required to complete them (eg, task 8 for hospital-based clinicians). Participant satisfaction, as measured by the Single Ease Question, was generally high, with all groups, on average, reporting satisfaction scores of 80% or higher. A direct positive correlation was observed between the error-free rates and satisfaction scores. In general, simpler tasks (ie, those with fewer error opportunities) were more likely to be completed error free than more complicated tasks, and those tasks that were completed without errors by participants had higher satisfaction scores than those in which participants committed many errors. Task times varied across groups and were consistently the lowest scores of the 4 usability measures.

Qualitative Findings

Thematic analysis of qualitative interview data generated 5 themes: fostering and maintaining team connections across

boundaries; finding the right fit between user needs and required effort; improving system efficiencies and eliminating redundancies; making the system work in daily life; and reflecting on current and future technology needs.

Fostering and Maintaining Connections Across Boundaries

An important value highlighted in the co-design process for DigiComp Kids was that the system should aim to foster a sense of cohesion and connection between hospital-based clinicians, families, and home-based clinicians. During qualitative interviews, this aspect of the DigiComp Kids system was touched on by 12 of 15 participants, highlighting its importance. For example, 1 parent participant relayed:

Like, we were going to have an NG tube and we were going to come home with it and like having someone to walk us through, like doing those kinds of things that freak me out right now. I don't want to do that... I don't have the confidence of me to be listening to see if it went in. But if that [video call] was a possibility that would like totally ease my stress, like if she pulled out an NG tube that it would, um that somebody would be there to walk me through it.
[Parent 002]

For this participant, the possibility of remotely connecting with a clinician meant easing her stress while performing the procedure for her child at home. Similarly, hospital-based

clinicians agreed that connecting with families at home would enable them to play a more supportive role for the child and the family:

I think that this also provides reassurance to families when they're calling clinicians or emailing clinicians and they're unsure of when they're going to get a response. It might make families feel better. Even when it's an initial discharge say from the NICU and a technology dependent kid and there's a lot of anxiety on whether they'll be able to reach clinicians or whether they live really far away geographically. They'll have this one-on-one support depending on the hours. [Hospital 012]

For families and care teams situated in different geographic areas, having access to a communication channel via a remote system can help break down boundaries and facilitate team cohesion and support.

Finding the Right Fit Between User Needs and Required Effort

Family members and hospital-based clinicians spoke of the need for the DigiComp Kids system to be implemented using flexible protocols that allow users to titrate their use of the system up or down as needed. Family members commented that CMC has labile medical conditions, resulting in a continuum of disease severity and subsequent health needs, depending on the manifestation of their conditions. The participants commented that the right fit between the user and the system would need to be struck to balance daily user requirements with self-identified user needs. One family member shared the importance of making the tool worthwhile to use:

Adding in another thing as another day-to-day task, that kind of seems like a bit much. If it was a point of time where we were trying to track something or a point where we were trying to wean him off the vent and we really wanted to zoom in on something, some numbers, I could see it being a daily thing... I'm trying to think of how it would be used as more tool rather than another chore, task to do with a complex kid. [Parent 001]

Similarly, another family member spoke of the need for system use to add value to their lives as a motivation to adopt the system:

But having the unit open and on every day, unless it's for a specific reason, it sounds really selfish but I feel like we would just open and use it if we needed something dealt with, not just so the team could find information of how normal our day is going. If that makes sense? [Parent 002]

The fit or balance of required effort versus user needs was touched on by most participants as an important factor in whether they could envision adopting the DigiComp Kids system as part of their daily care routine.

Improving System Efficiencies and Eliminating Redundancies

In terms of improving system efficiency and eliminating redundancies, 5 participants spoke to the potential for the DigiComp Kids system to streamline and accelerate the timing of communication between clinicians. Using DigiComp Kids to enable multiple clinicians to view real-time patient data and communicate necessary changes in a timely fashion was seen as an important care improvement. For example, 1 home care clinician said:

Because [the hospital-based clinicians] are able to end up getting changes right away... rather than, for families what they would do is they would call the hospital, that they would page someone and then depending on how busy the person, [or] the team is, sometimes it takes a bit longer to answer that call or get back. [Home care 007]

The DigiComp Kids system was seen as a strategy to accelerate necessary changes to care plans by allowing families, home-based clinicians, and hospital-based clinicians to view data in real time as patient changes are taking place. Other important factors for streamlining communication that arose in the interviews were ease of access to information and system interoperability, as detailed by the following participant:

I think this is so great. Honestly if everyone could just use this and have access to this, everyone's life would be so much easier. Nurses, specialists, complex care teams, homecare, like I do not understand why we we're are on so many different platforms for one patient. [Home care 009]

Finally, participants also pointed out areas for improvement in the DigiComp Kids system that would further improve its usefulness with regard to streamlining team communication and work processes. For example:

When you have interdisciplinary groups, you're like well I need this person to be able to address this issue and they might not be present at the time. I think that's always the challenge in team communication, trying to get messages to people and you know in hospital, it's like flagging charts and paging. So, if there was some way to flag people, that we need their attention, that would be really useful. [Hospital 011]

Participants contributed important insights with respect to the context in which the DigiComp Kids system would be implemented and made suggestions on how the system could be further optimized to enable efficiency and eliminate redundancies.

Making the System Work in Daily Life

The fourth theme generated from the participant interviews was "Making the system work in daily life." Facets of this theme include envisioning how the DigiComp Kids system would fit into daily workflows for families and clinicians as well as the practicality of using the system in real life. For example, parents spoke of the advantage of using the DigiComp Kids system to

provide a thorough report and history of the child to different care providers:

And the more I kind of say it, the more excited I get about the idea of having it on my phone. Because even just pulling up, you know going to an appointment or having to go to the hospital or even just in a complex care appointment, being like, this is what he's currently doing. This is our history, our results history. Or I've taken subsequent pictures, check out this camera roll of all of the things I've documented for you. [Parent 003]

This parent envisioned using the system as a “one-stop” documentation hub that would be accessible from their phone to share with different health care providers. Similarly, hospital-based clinicians spoke of envisioned positive changes in their workflows while using the system.

I think the live feature of chats, of getting notified when things are happening in the home is fantastic in comparison to our regular phone call where a message is left or an email where a message is left. And you only get to it at the end of the day. Whether clinicians get notified during these events that are occurring. I think it's great. [Hospital 012]

Streamlining workflows to enable families and clinicians to easily access information and engage in real time with each other was viewed as a potential advantage of the DigiComp Kids system. These real-time connections were discussed as having the potential to facilitate proactive patient care and earlier intervention in case of patient deterioration. Finally, participants again assisted in contextualizing the proposed workflows for the intervention and identifying the necessary backups and safeguards in case of unforeseen issues:

The other thing would be a power failure, if you like potentially were working in an environment like, you'd have to have a back-up. Like if it did work for your routine documentation, you'd have to have a protocol for all your back-up um, documentation. But I guess just if you don't have working power or working internet or data, I guess through the iPad then it may not function properly. [Home care 008]

Reflecting on Current and Future Technology Needs

The fifth and final theme generated from the interview data was participant reflections on how DigiComp Kids might fit with their current and future technology needs. One home care nurse highlighted how the DigiComp Kids system might enable families and clinicians to have a clear understanding of disease progression to enable proactive care planning:

I think the result dashboard probably would be helpful so that we can see changes over time. I'm thinking like specifically if they have some sort of progressive disease or something that affects let's say their breathing and their respiratory system. I think it would be helpful to those numbers over time and allow people to make decisions based on those numbers. [Home care 010]

The DigiComp Kids system tracks and trends patient disease progress over time, enabling families and care providers to accurately understand current needs and forecast anticipated future needs. Importantly, the system can do this without adding additional charting for families who are already busy taking care of medically complex children. One parent commented:

I do a really bad job of tracking things. And so, having something that kind of does it for me and keeps it all together in one spot. We're one of the few families that choose not to have nursing, so I don't even have nursing charts. So, if somebody were to ask me... I can tell you what his normal oxygen levels are, and his normal heart rate is because I see it every night. But I have no idea what his blood pressure is or anything, not a clue. Because we don't have nursing and I just don't keep track. [Parent 005]

Ongoing tracking of disease progression was deemed an important part of providing anticipatory and proactive care, ultimately benefiting medically complex children, their families, and health care providers alike.

Discussion

Principal Findings

This study was conducted to assess the usability of the DigiComp Kids intervention using the Cloud DX Connected Health System. By conducting usability testing, areas of strength and opportunity can be identified in virtual health innovations before large-scale clinical implementation.

The DigiComp Kids intervention using the Connected Health System attained high usability scores across groups, with SUM scores achieved by hospital-based clinicians, family participants, and home-based clinicians placing them in the 97th, 93rd, and 80th percentiles, respectively, in relation to SUM scores across all technology industries [30]. In addition, consistent with the definition of usability by Sauro and Kinlund [22], we noted a direct positive correlation between task error-free rates and task satisfaction.

Qualitative participant feedback highlighted favorable aspects of the DigiComp Kids system, such as its ability to connect home-based and hospital-based clinicians across geographic boundaries, to eliminate inefficiencies in care processes, and to encourage more proactive tracking of disease progress and planning for future needs. In addition, the participants assisted in contextualizing the intervention with regard to their daily lives and workflows, highlighting areas where the system could be further refined to improve the fit between user needs and system requirements.

Interpretation

The DigiComp Kids intervention outranked most reported intervention SUM scores across the technology industries. We hypothesized that part of our high usability scores stems from the DigiComp Kids intervention, which has been co-designed alongside hospital-based clinicians, family members of CMC, and home-based clinicians. By intentionally building the system with the needs of our end users in mind, the co-design process

may have contributed to the intervention achieving high SUM scores across the end user groups. Of particular interest is one component of the total SUM score, the task completion score, which was 100% across all usability participants. This score is well above the average task completion rate for technologies from usability literature, which is 78% [31]. It is possible that our task completion rates were falsely inflated due to user belief bias, whereby participants believed that the task they were being asked to complete in the simulated testing environment was indeed achievable and therefore tried harder to complete the assigned task than they might have in a real-life scenario [32]. Although we cannot determine whether user belief bias influenced our task completion scores, they should be interpreted with caution.

Qualitative interview data yielded insights beyond reflections on immediate usability testing procedures. As participants were questioned about the value of using the DigiComp Kids intervention in their daily lives, many responded by transcending their immediate circumstances, reflecting on what meaning the intervention would hold for them in the short term and long term. For example, some family participants were able to envision DigiComp Kids as part of their future daily lives, with their children in worse health than they were presently. The meaning of the system for these parents seemed to lie in its ability to create a digital bridge between hospital and home for families in need of support, either now or in the future. Evaluating the utility of a system by envisioning the role of technology in one's future circumstances is a view supported by the literature on digital technology adoption, in that users may change their perceptions of technology value and meaning over time as their circumstances change [33]. These findings highlight the need for those responsible for implementing technological innovations such as the DigiComp Kids system to interpret user feedback in context, paying particular attention to the meaning that participants place on technology in their present and future lives. Consideration of these user perspectives allows for insight into the factors that affect technology adoption, abandonment, or sustainment [34].

Comparisons With Prior Work

The results from DigiComp Kids usability testing using the Connected Health System built on previous usability studies by highlighting the critical roles of multimethod data collection in usability testing, consideration of the critical role of human factors, and the role of virtual health systems in connecting patients, families, and clinicians across traditional geographic barriers, as detailed below.

DigiComp Kids usability testing resulted in relatively high SUM scores across the end user groups. Despite this, the interview findings gathered from end users in our study assisted in identifying areas for improvement in the DigiComp Kids intervention. As emphasized by the DigiComp Kids study participants, the process of implementing virtual health interventions requires attention to be paid to the subjective needs of end users, together with the goals of the intervention and system requirements. These subjective needs are often best gathered using qualitative techniques, which help distill user experience data essential to assessing end user acceptance. This

finding aligns with the literature, in which subjective user needs gathered via qualitative techniques illuminate distinct and important insights into end user acceptance. For example, in a study on the comparative effectiveness of 3 virtual health media for communicating health information to parents, the authors found no significant differences in the knowledge retention or efficiency of parents using each of the 3 tools; however, subjective feedback revealed a strong preference for one tool over the other 2. Similar to the qualitative results generated by family members in DigiComp Kids, parents in this study desired a tool that was simple, trustworthy, efficient, and provided practical information on condition management [35]. These qualities were important to parents in this study and were found to influence parents' perceptions of the usability of different media, separate from quantitative metrics of usability that were collected [35]. This study highlights the importance of gathering both quantitative and qualitative information from end users, as each may offer different insights into end user preferences and overall usability. In our study, gathering qualitative experience data helped contextualize the intervention and raised issues for system improvement that otherwise may not have been uncovered until full-scale implementation.

A second important finding of the DigiComp Kids usability testing was the critical role of human factors in virtual health system usability. Human factors, or the ways in which people interact with technology, have a critical impact on the success of virtual innovations [36]. In our study, participants engaged in 2 tasks wherein icons or functions that they were required to access were hidden, either within another icon on the tablet or in a different section of the clinician's portal. For instance, in task 7 for family and home-based clinicians (find and up-to-date medication lists), the folder that participants were required to locate was hidden within another folder. Conversely, all other icons that the participants were asked to find were accessible through paths from the main screen. Similarly, when hospital-based clinicians undertook task 8 (changing the schedule of the Wellness Surveys to be sent to participants), they needed to navigate from the individual patient profile to the main hospital clinician portal before being able to access the survey scheduling function, whereas all other clinician tasks were accessible through the individual patient profile. These 2 tasks resulted in high error rates, and low satisfaction ratings were corroborated by frustration voiced by participants in the qualitative interviews. Similar results have been reported in other usability studies. For example, in a study in which the authors tested the usability of patient portals for parents of children with chronic diseases (ie, cystic fibrosis, diabetes, and arthritis) using scenario-based usability testing and think-aloud protocols, high error rates and low completion scores resulted when information was located in a different place than participants expected [37]. Similarly, a systematic review examining the usability of eHealth interventions for adolescents with juvenile idiopathic arthritis found that adolescents using an iPod touch to input pain data made more errors, required more time per task, and reported that the device had a lower satisfaction rating than either computer-assisted or paper-based data entry [38]. This direct relationship between system ease of use and task performance emphasizes the importance of

understanding human factors within formative usability testing procedures when innovating in the virtual health sphere [34].

Finally, of particular importance to DigiComp Kids participants was their ability to connect with remote clinicians in different geographic locations. In a similar usability study, McGillion et al [39] examined the usability of a postoperative hospital-to-home remote automated monitoring intervention and found that being able to connect remotely with care team members was invaluable, particularly for patients experiencing acute recovery. As was the case in our study, patient participants expressed a sense of security in knowing that a clinician would be able to monitor their postoperative progress and be reachable, should it be required [39]. Similarly, in a study evaluating an online symptom monitoring intervention for families of children with life-limiting illnesses, the authors reported increased parental empowerment over time in the study, demonstrating the value of digital technologies in supporting parents caring for their children at home [40]. This theme reinforces the important role that virtual health technologies can play in transcending traditional barriers to providing and receiving health care, such as physical location, while offering patients and families additional support in their home environments. This point may be particularly important for patients and families with frequent or intensive health care requirements, such as those with complex chronic conditions.

Limitations

One potential limitation of this study was the lack of diversity in the participant samples. All participants in this study were English-speaking females, and the majority were White. Although the prevalent groups included in this study (ie, primary caregivers for children and nurses) have historically been predominantly female, the inclusion of male participants may have yielded different results. The inclusion of non-English-speaking participants was not possible at the time of this study because of the limitations of the study team. In addition, family participants were well educated and at least “somewhat experienced” using tablet technology; thus, our results may not be reflective of family members with lower education or less experience with tablet computing. Although the objective of a usability testing study is not to generalize results to a broad population but to uncover areas of usability

strength and opportunities to make refinements, it is possible that the inclusion of a more diverse group of participants would have yielded different results and perspectives.

Another potential limitation of this study is that the collection of data related to the SUM metric and its components may have missed information that other scales capture. Our choice to collect data on effectiveness, efficiency, and satisfaction was guided by the accepted usability standards [14], which are well captured in the SUM. However, other scales, such as the Net Promoter score [41] and the Standardized User Experience Percentile Rank Questionnaire [42], capture data that we did not, such as participant ratings of trust and credibility of the intervention. We are confident that some of these data were captured in qualitative interviews; however, we did not collect quantitative data related to them.

Finally, the task completion rates across all groups were 100%, as presented in Tables 4-6. This may represent a user belief bias in our results, such that participants may be more likely to believe that the task they are being asked to complete is indeed achievable in a simulated testing scenario. Alternatively, because participants were trained in the DigiComp Kids system use immediately before usability testing, perfect task completion scores may simply represent increased training material retention by participants because of the short interval between training and testing times.

Conclusions

The implementation of virtual health system solutions for CMCs and their families is an important initiative in providing comprehensive care in the home setting. This usability testing study offered valuable insights into the preclinical implementation phase of the DigiComp Kids intervention using the Connected Health System. Examples of such insights include the importance of tailoring the implementation of the system to match individual user needs, streamlining system features in key areas to allow for intuitive system use with the fewest steps required to complete tasks, and investigating and considering the meaning attached to system use by participants to allow for insight into system adoption and sustainment. Taken together, these findings emphasize the importance of formative virtual health system testing to uncover challenges early and refine interventions to suit the needs of end users.

Conflicts of Interest

MHM is involved in several studies that Cloud DX provides in-kind support to, including the PVC-RAM trials, VERDICT, VERDICT-2 and VISION-2. The authors have no further conflicts to declare.

Multimedia Appendix 1

Hospital usability testing tasks.

[DOCX File, 27 KB - [formative_v6i8e34572_app1.docx](#)]

Multimedia Appendix 2

Usability testing patient case.

[DOCX File, 22 KB - [formative_v6i8e34572_app2.docx](#)]

Multimedia Appendix 3

Usability tasks for home-based clinicians and family members.

[\[DOCX File , 26 KB - formative_v6i8e34572_app3.docx \]](#)

Multimedia Appendix 4

Interview guide.

[\[DOCX File , 19 KB - formative_v6i8e34572_app4.docx \]](#)

Multimedia Appendix 5

Formulas for usability metrics.

[\[DOCX File , 25 KB - formative_v6i8e34572_app5.docx \]](#)

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Abbreviations

CMC: children with medical complexity

SUM: Single Usability Metric

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Original Paper

Design and Formative Evaluation of a Virtual Voice-Based Coach for Problem-solving Treatment: Observational Study

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Abstract

Background: Artificial intelligence has provided new opportunities for human interactions with technology for the practice of medicine. Among the recent artificial intelligence innovations, personal voice assistants have been broadly adopted. This highlights their potential for health care-related applications such as behavioral counseling to promote healthy lifestyle habits and emotional well-being. However, the use of voice-based applications for behavioral therapy has not been previously evaluated.

Objective: This study aimed to conduct a formative user evaluation of Lumen, a virtual voice-based coach developed as an Alexa skill that delivers evidence-based, problem-solving treatment for patients with mild to moderate depression and/or anxiety.

Methods: A total of 26 participants completed 2 therapy sessions—an introductory (session 1) and a problem-solving (session 2)—with Lumen. Following each session with Lumen, participants completed user experience, task-related workload, and work alliance surveys. They also participated in semistructured interviews addressing the benefits, challenges and barriers to Lumen use, and design recommendations. We evaluated the differences in user experience, task load, and work alliance between sessions using 2-tailed paired *t* tests. Interview transcripts were coded using an inductive thematic analysis to characterize the participants' perspectives regarding Lumen use.

Results: Participants found Lumen to provide high pragmatic usability and favorable user experience, with marginal task load during interactions for both Lumen sessions. However, participants experienced a higher temporal workload during the problem-solving session, suggesting a feeling of being rushed during their communicative interactions. On the basis of the qualitative analysis, the following themes were identified: Lumen's on-demand accessibility and the delivery of a complex problem-solving treatment task with a simplistic structure for achieving therapy goals; themes related to Lumen improvements included streamlining and improved personalization of conversations, slower pacing of conversations, and providing additional context during therapy sessions.

Conclusions: On the basis of an in-depth formative evaluation, we found that Lumen supported the ability to conduct cognitively plausible interactions for the delivery of behavioral therapy. Several design suggestions identified from the study including reducing temporal and cognitive load during conversational interactions, developing more natural conversations, and expanding privacy and security features were incorporated in the revised version of Lumen. Although further research is needed, the promising findings from this study highlight the potential for using Lumen to deliver personalized and accessible mental health care, filling a gap in traditional mental health services.

KEYWORDS

voice assistants; behavioral therapy; problem-solving therapy; mental health; artificial intelligence; user evaluation

Introduction

Artificial intelligence (AI) has provided new opportunities for human interactions with technology for care delivery [1]. These include remote monitoring, mobile health apps (eg, chatbots), and the use of a wide variety of sensors for remote monitoring and surveillance. Of the recent innovations, personal voice assistants that rely on AI-based platforms such as Amazon's Alexa, Google Home, Cortana, and Siri have transformed how humans search for information, with recent reports suggesting that nearly 30% of search queries rely on voice-based input [2]. Broad adoption of such platforms lends support for their potential utility in health care-related applications such as behavioral counseling to promote healthy lifestyle habits and emotional well-being [3,4]. However, current health care-related applications of voice assistants are generally rudimentary, and few of them have been developed for delivering evidence-based therapies or have been subjected to careful evaluation (eg, to inform development or for their effect on clinical or behavioral outcomes) [5]. To this end, we developed and evaluated Lumen, an end-to-end voice-based virtual coach that was developed as a stand-alone Alexa application. Lumen delivers evidence-based problem-solving treatment (PST) for patients with mild to moderate symptoms of depression and anxiety.

Lumen, by design, is different from the current spectrum of voice-based health applications that primarily support web-based information-seeking activities [4]. Studies on such information-seeking activities performed on voice assistants have focused on the quality and content of voice assistant responses for several topics including health behavior and lifestyle [6,7], mental health, interpersonal violence, addiction help [8,9], patient and consumer safety risks [10], vaccines [11], postpartum depression [12], medication names [13], and sexual health [14]. The findings across these studies consistently highlight the shortcomings associated with the quality of the information retrieved during these voice-based searches. For example, Bickmore et al [10] found that Siri, Alexa, and Google Assistant platforms and their underlying algorithms were effective in completing only 43% of requests regarding situations that required medical expertise, and 29% of the responses could have resulted in some degree of patient harm [10]. Other applications, mostly preliminary prototypes, have been developed for assessment and support. These applications have been used for delivering visual acuity tests [15], support for coping with chronic disease [16], and for nutritional planning [17]. However, it is important to note that these applications have largely lacked outcome assessment or incorporation of behavioral therapy [4]. Although text-based behavioral therapy applications (eg, chatbots) have shown promise in mitigating psychiatric disorders [18,19], several challenges exist including long-term adherence and engagement limited to younger age groups [20]. Therefore, it is plausible that voice-based therapy delivery may mitigate some of these issues.

In this paper, we describe the design and formative evaluation of Lumen, with the following research objectives: (1) to characterize the user experience, task-related workload associated with interactive communication, and participant alliance with delivered treatment and (2) to identify and describe user perspectives including the benefits, challenges, and barriers to Lumen use and recommendations for design improvements.

Methods

In the following sections, we describe the design components of Lumen, its features, and the mixed methods study that was conducted.

Lumen

Lumen is a virtual voice-based coach that delivers an evidence-based, 8-session PST program for patients with mild to moderate depression and anxiety. The first 4 PST sessions were conducted weekly, followed by 4 biweekly sessions. Each PST session lasted approximately 45 minutes to 1 hour. Lumen was designed to align with the evidence-based PST program.

Lumen's design was based on two overarching principles: (1) providing cognitively plausible conversations, that is, aligning Lumen's conversations with the cognitive processes of human communicative interactions [5] and (2) alignment with the principles of evidence-based PST. This PST program was previously tested and delivered with a human coach [21]; Lumen incorporates essential components of the treatment protocol for coaching and monitors progress using surveys and ecological momentary assessments. All Lumen design components are delivered in an integrated environment, coordinated through the voice-only platform and associated mobile tools (Figure 1 provides an overview of the components of Lumen and their interactions).

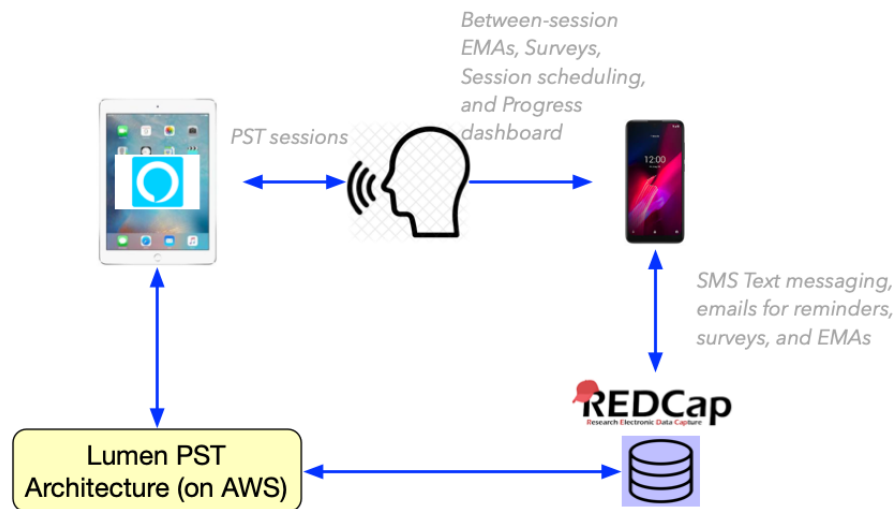
Developed on Amazon's Alexa platform, Lumen's architecture incorporates an intelligent conversation manager that manages the content, structure, and flow of interactive conversations between a patient and Lumen and a context manager that incorporates context awareness into the conversations. Using underlying AI capabilities of the Alexa platform, the conversation manager uses user verbal input to provide appropriate, synchronous responses, aligned with PST's treatment guidelines. PST content and conversational structure were designed in consultation with master PST trainers and PST experts.

The context manager provides contextual awareness to the interactions by incorporating user input from surveys and ecological momentary assessments (delivered asynchronously through mobile apps) and treatment progression and continuity (eg, review of patient problems and action plans from a previous session; Sections A and B in [Multimedia Appendix 1](#) provide additional details of the Lumen architecture and features).

We followed an iterative user-centered design process, comprising brainstorming sessions with software engineers, interaction designers, psychiatrists, and researchers; prototype

development on the Alexa platform; and several iterations of internal testing.

Figure 1. User interaction with Lumen for problem-solving treatment (PST) sessions highlighting the various components. AWS: Amazon Web Services; EMA: ecological momentary assessment.



Participants and Study Design

Participants for this formative evaluation were recruited from the recently completed Engaging Self-Regulation Targets to Understand the Mechanisms of Behavior Change and Improve Mood and Weight Outcomes (ENGAGE-2) trial (ClinicalTrials.gov, National Clinical Trial#03841682), in which a PST-certified health coach delivered integrated collaborative care for depression and obesity to intervention participants, whereas those in the control group received usual care. A convenience sample (91/106, 85.8%) of ENGAGE-2 participants was contacted for assessing their interest in participating in a study with a virtual PST coach. Of these 91 participants, 26 (28%) expressed interest and consented to participate. Of the 26 participants, 17 (65%) had prior PST experience (ie, part of the ENGAGE-2 intervention group) and 9 (35%) did not have prior PST experience (ie, part of the ENGAGE-2 control group).

This was an observational study, with each participant completing 2 Lumen sessions: an *introductory* first session (termed S1; n=26) and a *problem-solving* second session (termed S2; n=24, missing 2 of the 9 ENGAGE-2 control participants). The 2 sessions represented the overarching structure of the 8-session, evidence-based PST evaluated in a previous trial [21]; S1 represented an initial overview session, and S2 represented a problem-solving session that was repeated in sessions 2 to 8 during the evidence-based PST.

In S1, Lumen provides a program overview, provides a detailed introduction to the PST process and behavioral activation, and guides the participant to create a list of problems to address in subsequent sessions. In S2, Lumen guides the participant through the steps of problem-solving: identifying a problem to address, setting a goal, brainstorming possible solutions, evaluating the pros and cons of each solution, selecting a solution to implement, and developing an action plan to carry out before the next session. S2 concludes with behavioral activation coaching, where Lumen assists participants with

selecting a social, physical, and pleasant activity to partake before the next session.

The full Lumen PST program included 6 more problem-solving sessions that followed the same structure as S2; this was the rationale for testing only 1 problem-solving session during this formative evaluation. As such, the purpose of the 2-session approach was to conduct a representative evaluation of all Lumen sessions and to evaluate whether there were differences in participant experience and interactions between the sessions.

Ethics Approval

The study was approved by the institutional review board of the University of Illinois (IRB#2020-0918). All participants provided written consent.

Procedure

Consented participants were provided access to the Lumen S1 and S2 skills via the Alexa application and were given instructions on how to enable the skills on the Alexa app on their personal phones or mobile devices. All user interviews were conducted remotely by a trained research coordinator using the Zoom (Zoom Video Communications) videoconferencing platform. Participants were first provided with a brief overview of the study purpose, and their access to the Lumen skill (designed as a private skill, which was available by invitation only) was verified. During the session, a research coordinator went through a list of tips to effectively communicate with Lumen and answer any questions. After this, participants were instructed to turn off their video, and audio recording via Zoom was enabled from this point. Participants then opened the Alexa app and said “Open Lumen Coach” to begin their Lumen session. During their Lumen sessions, the trained note taker took notes of any deviations from the session script or any technical problems.

After each Lumen session, the coordinator followed a semistructured interview script that included the following

components. First, participants were asked to walk through their interaction experience with Lumen during their completed session, reflecting on what worked, what did not, and challenges they faced. Although the same procedure was followed for both Lumen sessions, interview questions varied slightly from S1 to S2 to inquire about session-specific content. Interview questions after S1 focused on participants' impressions of Lumen, suggestions for improving Lumen, evaluating the usefulness of tips on how to communicate with Lumen, and impressions of the PST overview. Interview questions after S2 included questions about participants' impressions of Lumen that were different from S1, delivery of PST by Lumen, and factors affecting their likelihood of Lumen use in the future. S1 and S2 were conducted several days apart, and participants had access to the specific sessions only a day or so before the session.

After the interviews were completed, participants were emailed a link to 3 brief postinterview surveys related to user experience, workload, and the collaborative relationship between the participant and Lumen (User Experience Questionnaire Short Version [UEQ-S] [22], NASA Task Load Index [TLX] [23], and Working Alliance Inventory–Technology Version [WAI-Tech] [24]).

Audio recordings of the interviews (26 for S1 and 24 for S2) were transcribed using the Trint audio transcription software for subsequent analysis. All (26/26, 100%) postinterview surveys were completed after S1, and 95% (23/24) postinterview surveys were completed after S2.

Data Analysis

Data analysis included coding of interview transcripts using thematic analyses and descriptive summaries of user experience, task load, and WAI-Tech surveys.

Coding of Transcripts

All interview transcripts were coded using an inductive thematic analysis to characterize the participants' perspectives regarding their interaction with Lumen [25] (Section E in [Multimedia Appendix 1](#) provides the interview guide). This approach involved the following stages: first, 2 coauthors (CRR and EAK) read the interview transcripts to familiarize themselves with the content. Next, a set of "open codes" was created to characterize the content and context discussed in the interviews (ie, inductive coding) [26]. These initial codes were compared across the transcripts to identify repeated and interrelated subthemes. Similar subthemes were grouped over multiple review sessions to develop a set of 6 overarching themes. All responses were coded; some responses were assigned multiple codes, in an order of relevance; however, only the primary assigned code was used for all analyses. Two coauthors (EAK and CRR) independently coded a set of 5 transcripts with a high degree of interrater agreement (Cohen κ ranged from 0.83 to 1 with mean 0.93, SD 0.07). Discrepancies were resolved through discussions with the first author (TK). Subsequently, all remaining transcripts were coded.

Surveys

From the UEQ-S survey, pragmatic quality and hedonic quality scale values were calculated by rescaling the survey responses to the range -3 to 3 and calculating item means within each scale using the UEQ-S Data Analysis Tool [27]. Pragmatic quality refers to the task- or goal-related interaction qualities (eg, efficiency, perspicuity, and dependability) that a user aims to reach when using the product. Hedonic quality refers to the aspects related to pleasure or fun (eg, stimulation and novelty) while using the product. Values <-0.8 represent a negative evaluation, between -0.8 and 0.8 represent a neutral evaluation, and >0.8 represent a positive evaluation on each scale.

The NASA TLX rating sheet was administered assuming similar weights for each of the 5 task load items (except for physical demand, which was not considered, as it was irrelevant to Lumen): mental demand, temporal demand (eg, being rushed), effort, frustration, and performance. Each item was then rescaled to the range 5 to 100 by multiplying the raw score by 5.

From the WAI-Tech survey, three 12-item subscale (task, goal, and bond) scores and an overall score were calculated as item means within each subscale. The task subscale reflected how responsive Lumen was to the participant's focus or need; the goal subscale reflected the extent to which goals were important, mutual, and capable of being accomplished; and the bond subscale reflected the degree of mutual liking and attachment [24]. A higher overall score reflected a more positive rating of the working alliance.

Given that the 2 sessions focused on 2 primary structural components of PST sessions—a session overview and a problem-solving session—we compared whether there were differences in the user experience, task load, or work alliance between these sessions. To this end, scores on each of the scales between S1 and S2 were compared using paired t tests. Analyses were conducted using SAS (version 9.4; SAS Institute Inc); statistical significance was defined by 2-sided $P < .05$. Additional analyses comparing PST-experienced and PST-naive participants can be found in Section F in [Multimedia Appendix 1](#).

Results

General Characteristics

Among the 26 participants, 20 (77%) were female, 19 (73%) were racial or ethnic minorities ($n=13$, 50% Black; $n=6$, 23% Hispanic) with an average age of 43.9 (SD 11.9) years, 10 (38%) had a high school or some college education, and 14 (54%) had an annual family income of $<US \$55,000$ ([Table 1](#)). Participants with previous PST experience (17/26, 65%) and those without previous PST experience (9/26, 35%) did not differ in age, race, income, or educational status, although 65% (11/17) of the participants with previous PST experience and 100% (9/9) of the participants without PST experience were female ($P=.04$).

Table 1. Baseline characteristics by prior problem-solving treatment (PST) experience.

Characteristic	All Lumen formative evaluation participants (N=26)	Participants with prior PST experience (n=17)	Participants without prior PST experience (n=9)	P value
Age (years), mean (SD)	43.9 (11.9)	42.6 (13.2)	46.3 (9.2)	.46
Female, n (%)	20 (77)	11 (65)	9 (100)	.04
Race or ethnicity, n (%)				
Non-Hispanic White	4 (15)	3 (18)	1 (11)	.34
African American	13 (50)	9 (53)	4 (44)	.34
Asian or Pacific Islander	1 (4)	1 (6)	0 (0)	.34
Hispanic	6 (23)	2 (12)	4 (44)	.34
Other (eg, decline to state or multirace)	2 (8)	2 (12)	0 (0)	.34
Education, n (%)				
High school or general education or less	2 (8)	1 (6)	1 (11)	.95
College—1 year to 3 years	8 (31)	5 (29)	3 (33)	.95
College—≥4 years	10 (38)	7 (41)	3 (33)	.95
Post college	6 (23)	4 (23)	2 (22)	.95
Income (US \$), n (%)				
<35,000	7 (27)	4 (23)	3 (33)	.32
35,000 to <55,000	7 (27)	3 (18)	4 (44)	.32
55,000 to <75,000	5 (19)	4 (23)	1 (11)	.32
≥75,000	7 (27)	6 (35)	1 (11)	.32

User Experience, Task Load, and Working Alliance

Participants had a positive evaluation (values >0.8) for pragmatic (S1: mean 1.3, SD 1.2 and S2: mean 1.4, SD 0.9), hedonic (S1: mean 1.0, SD 1.1; S2: mean 1.2, SD 1.0), and overall (S1: mean 1.2, SD 1.0; S2: mean 1.3, SD 0.8) qualities related to their user experience with Lumen for both sessions. There were no statistically significant differences between the 2 sessions ($t_{22}=0.37, 0.00, \text{ and } 0.25$ and $P=.71, .99, \text{ and } .80$ for pragmatic, hedonic, and overall scores, respectively).

Across both sessions, participants encountered medium (approximately 50) across the mental (cognitive), effort, frustration, and performance dimensions of the NASA TLX scale. There were no statistically significant differences between

S1 and S2 (Table 2). However, participants rated as having experienced more temporal workload in S2 (mean 52.0, SD 29.1) than S1 (mean 36.5, SD 23.2; $P=.03$), suggesting feeling rushed during their interaction with Lumen in S2.

The scores on the 7-point WAI-Tech survey for task (S1: mean 5.2, SD 0.9; S2: mean 5.3, SD 0.9), bond (S1: mean 4.9, SD 1.0; S2: mean 4.7, SD 1.0), and goal (S1: mean 5.0, SD 0.9; S2: mean 5.1, SD 0.9) subscales were moderately high, indicating that Lumen-based PST sessions were perceived to be aligned with the participants' needs, addressing their potential goals and the degree of mutual liking. There were no statistically significant differences between both sessions on the task, goal, and bond scales or the overall scores (Table 3).

Table 2. Paired *t* test results comparing NASA Task Load Index scores between sessions 1 and 2.

Question	Session 1 (n=26), mean (SD)	Session 2, (n=23), mean (SD)	<i>t</i> test (<i>df</i>)	<i>P</i> value
How mentally demanding was the task? (<i>mental demand</i> ^a)	42.7 (25.0)	53.9 (26.1)	-1.80 (22)	.09
How hurried or rushed were you in the pace of the task? (<i>temporal demand</i>)	36.5 (23.2)	52.0 (29.1)	-2.37 (22)	.03
How hard did you have to work to accomplish your level of performance? (<i>effort</i>)	36.0 (23.4)	42.8 (18.9)	-1.44 (22)	.16
How insecure, discouraged, irritated, stressed, and annoyed were you? (<i>frustration</i>)	31.9 (22.0)	38.5 (24.6)	-0.95 (22)	.35
How successful were you in accomplishing what you were asked to do? (<i>performance</i>)	34.6 (23.1)	37.2 (23.3)	-0.37 (22)	.71

^aItalicized text shows the various categories of the NASA Task Load Index scales.

Table 3. Paired *t* test results comparing task, goal, and bond subscales of the Working Alliance Inventory–Technology Version between sessions 1 and 2.

Scale	Session 1, mean (SD)	Session 2, mean (SD)	<i>t</i> test (<i>df</i>)	<i>P</i> value
Task subscale	5.2 (0.9)	5.3 (0.9)	0.11 (22)	.92
Bond subscale	4.9 (1.0)	4.7 (1.0)	1.49 (22)	.15
Goal subscale	5.0 (0.9)	5.1 (0.9)	-0.32 (22)	.75
Overall scale	5.0 (0.9)	5.0 (0.9)	0.56 (22)	.58

User Perspectives of Lumen

On the basis of the thematic analysis, we identified 6 categories that highlighted key user perspectives regarding Lumen. This included (total, N=536 coded themes across all categories; % of each category across all transcripts): (1) comparing Lumen with a human coach (ie, a human-AI comparison; 200/536, 37.3%), (2) task load experienced during Lumen interactions (102/536, 19%), (3) perception of PST delivered by Lumen (82/536, 15.2%), (4) user suggestions for improving Lumen (81/536, 15.1%), (5) natural language understanding of Lumen (44/536, 8.2%), and (6) technical issues (27/536, 5%) that were encountered during the 2 Lumen sessions (detailed descriptions of each of these categories along with exemplary quotations are provided in Table 4).

Comparisons of Lumen with a human coach included several aspects: potential flexibility, ease of accessibility of Lumen for those who cannot attend face-to-face appointments, and cost-related advantages. Participants also highlighted the nonhuman nature of the interaction, describing the lack of changes in tone, emotion, instant feedback, and desiring a “more personalized human touch.” Nevertheless, nearly all participants described the potential advantages related to Lumen’s accessibility, allowing those in need for therapy easily access a coach at any time:

...the fact that the flexibility of it, the fact that I could be at home, where I could be in my car, or that, you know, I could take a moment and stop at work and go in a quiet room instead of having to, you know, actually go out and, you know, go to a building, find parking, all of the inconveniences that come with [face-to-face] appointments...

In addition, and importantly, participants with previous PST experience expressed that the Lumen sessions were similar to the human coach sessions that they had previously engaged in.

Participants also highlighted the workload associated with Lumen sessions, sometimes describing the difficulty in pausing sessions to collect thoughts as they worked through the steps of PST. This was especially the case in S2, where participants were required to brainstorm multiple solutions to a problem and then list the pros and cons of each solution. The workload challenges identified were related to pacing of the sessions (temporal load) and the amount of information that was directed at the participants (cognitive load). One of the participants explained that the short time to respond made them “feel pressured to come up with something ...[...]. But she [Lumen] did ask if I needed more time, but when I was responding my answers, I [still] felt like it was a short time and I almost felt cut off.”

Participants described their perceptions of the PST program or structure as well as Lumen’s role in delivering PST. Their comments highlighted the importance of the PST stepwise structured approach and Lumen’s PST coaching that enabled them to create goals that could have been overwhelming:

If my goal is truly trying and I have a problem, I just feel overwhelmed. I don’t know how to attack it. Well, Lumen supplies that. It breaks it down. It pulls all of the jumbled information out of my head, leaves the emotion behind and helps me lay out a plan for essentially attacking the problem without the emotional stress of it.

Participants provided several suggestions for improvement. This included further personalizing the PST sessions, creating

embodied avatars for Lumen, incorporating a friendlier voice, and investigating ways for reducing the task load associated with the interactions. One of the most insightful aspects was several participants highlighting the importance of cognitive “offloading” [28]. This was especially aligned with the need to reduce the cognitive load associated with conversational interactions, especially during the problem-solving session (S2), where participants had to identify and work through a problem, set a goal, identify and evaluate possible solutions, and then devise a structured action plan to address the problem. Participants also suggested the need for visualizing their tasks, either digital or paper-based, that would help in organizing their thought processes and saving the notes for future interactions,

as highlighted in the following quote: *“If it would have a way in app, I mean, [...] but like a way to help me, a way to help track for me what my progress is.”*

Although there were a few instances of technical issues where the participants’ verbal responses were not comprehended by Lumen because of issues related to accent or ambient noise, these issues were minimal and most users noted the ease of interaction, as described in the following quote: *“I was pretty much impressed with how easy was to use and, you know, it wasn’t intimidating at all.”* Additional examples of Lumen interactions including problem-solving conversations are provided in Section D in [Multimedia Appendix 1](#).

Table 4. Coding categories, their description, and examples from the interviews.

Coding category (spread ^a , %)	Description	Example from data
Interactive task load (78%)	Participant description of the demands of interacting with Lumen. Includes: <ul style="list-style-type: none"> • Temporal load (pace of interactions, whether there was ample time to provide a response) • Cognitive load (density of content and length of sessions) 	<ul style="list-style-type: none"> • “I felt kind of rushed when it was like time to, like, think through and write things” (3502) [Temporal load] • “Sometimes it’s telling you a lot of things. So, for a user, it’s hard...You’re not looking at somebody. So, you’re really, really having to concentrate and pay attention, so if by any chance you miss something, then you kind of get lost” (1213) [Cognitive load]
Natural language understanding (46%)	Participant description of challenges that Lumen faced with understanding participants’ verbal responses. Includes: <ul style="list-style-type: none"> • Spoken comprehension (breakdowns due to Lumen’s comprehension) • Accent or enunciation issues (eg, understanding names) 	<ul style="list-style-type: none"> • “I think it was difficult to provide the prompts that were requested, and I suspect that depending on the person’s accent or if they’re from—if maybe their English isn’t exactly clear, there may be some language issues” (5457) [Spoken comprehension and accent or enunciation issues]
Comparison with human coach (100%)	Comparison of Lumen to a human coach. Includes: <ul style="list-style-type: none"> • Naturalness of voice or tone (presence or absence of emotion) • Interactive engagement in conversation (whether Lumen was conversational) • Lumen’s tone or inflection (identifying when Lumen was asking a question vs making a statement) • Lumen vs human PST^b content (comparing depth of help Lumen provided relative to human in delivery of PST) • Perceived Lumen benefits or drawbacks (pros and cons of receiving PST from Lumen relative to human, eg, accessibility, availability, and comfort with disclosure) 	<ul style="list-style-type: none"> • “...just robotic. Like, I’m talking to like a machine robot. That’s my initial thought. But at the same time, not in the way that it’s like dumb, but in that it’s like very scientific and not very like human.” (6132) (Naturalness of voice or tone) • “I think initially for me, what may be missing that I picked up on right away is the human interaction component. [...] a human as opposed to talking to like a device or a computer [...] So, I don’t know how differently it’ll be the more I become engaged with it.” (3498) [Interactive engagement in conversation] • “When I spoke with [the human coach], I found myself venting, if I may, and going in every which direction, whereas Lumen forces me to stay very rigid, and sometimes when going through problem solving, the emotional release of going in every which direction, direction, rather than going straight and narrow feels a lot more comfortable.” (3831) [Lumen vs human PST] • “it allows accessibility to people who can’t travel or maybe they feel anxious around talking to another person. So, it eliminates like class, it eliminates race, it eliminates sex. It eliminates sort of those prejudice that could happen in like a person-to-person to person setting.” (6132) [Perceived Lumen benefits]
PST features in Lumen (78%)	Description of the PST features as delivered by Lumen. Includes: <ul style="list-style-type: none"> • Program structure or format (feedback around the stepwise PST process) • Virtual PST coaching (describing Lumen’s role in the PST process) 	<ul style="list-style-type: none"> • “You know, I think if I’m if I am if my goal is truly trying and I have a problem, I just feel overwhelmed. I don’t know how to attack it. Well Lumen supplies that. It breaks it down. It pulls all of the jumbled information out of my head, leaves the emotion behind and helps me lay out a plan for essentially attacking the problem without the emotional stress of it.” (3831) [Program structure or format and virtual PST coaching]

Coding category (spread ^a , %)	Description	Example from data
User recommendations (62%)	Participants' recommendations for: <ul style="list-style-type: none"> Lumen improvements (ideas for functions or features in the user interface) Interacting with Lumen (tips for others to have an effective session with Lumen) 	<ul style="list-style-type: none"> "I would tell them that like, so like you're talking to a computerized app, so make sure you're speaking clearly and slowly and like follow directions in order to get what you're what you need from it." (6132) [Interacting with Lumen] "I would say as a part of the app, have basically have the binder already inside the app and then maybe have a link to a principal PDF for those who want to do that." (6023) [Lumen improvements] "I think it would be kind of cool, especially with it being linked with Alexa is if it had the ability to pick up key-words. So, like if I, you know, saying like I need to work on my diet or trainer or whatever, that somehow it was able to tap into some of those keywords. And while it's talking back to me saying, you know. You know, we've looked into like some trainings in your area. We are going to send you emails of, you know, something like that that would be like really great or hear from information regarding blah, blah, blah, blah, blah." (3498) [Lumen improvements] "She could be better if she if I could see it, even though is a mechanical thing or robot, I want to see Lumen, so I know how Lumen it looks...I'd rather see the person I'm talking to, even though [it] is a machine or whatever it is I would rather see, you know." (7323) [Lumen improvements]
Technical issues (36%)	Technical issues that were experienced by participants during the sessions. Includes: <ul style="list-style-type: none"> Breakdowns in conversation 	<ul style="list-style-type: none"> "Well, I was a little confused when it just stopped. It was still on the app. [...] And then it just completely shut the app." (3470) [Breakdowns in conversation]

^aSpread refers to the percentage of transcripts (total=50) that the coding category was present.

^bPST: problem-solving treatment.

Discussion

Principal Findings

We designed and developed a virtual voice-based coach, Lumen, which delivers an evidence-based PST program for depression and anxiety. To the best of our knowledge, Lumen is one of the first voice-based virtual coach application for delivering behavioral therapy. In contrast to prior research that has primarily used voice assistants in web-based information-seeking tasks, Lumen delivers therapy aligned with the goals and principles of an empirically validated PST program. In this developmental evaluation, participants found the Lumen virtual coach to have high pragmatic usability and user experience, with limited task load during interactions. Participants also highlighted the considerable advantages of Lumen including the on-demand accessibility to a virtual therapist and the delivery of a complex PST task with a simplistic structure and organization for achieving therapy goals. Moreover, although the second session required increased user input, there were no marked differences in effort or interaction quality, except for temporal load (associated with the pace of the conversations), which was highlighted by the participants in their interviews. In addition, the participants highlighted the lack of personalization and deep engagement in the conversation and the relative lack of emotional engagement in the conversations.

Comparison With Prior Work

PST, traditionally delivered by human coaches in face-to-face or phone-based settings, has been developed on mobile platforms [29]. However, similar to other text-based mobile apps, participant engagement with mobile PST platforms has been challenging [30]. To this end, Lumen offers a novel, voice-based mechanism for seemingly naturalistic voice interactions, potentially replicating interactions with a therapist. As previously described, much of the prior work has relied on evaluating the quality health information-seeking tasks using voice-based personal assistants (eg, [8,9]). Moreover, many of the previously developed applications have been preliminary prototypes (eg, [15]) that lacked extensive evaluation or outcome assessment. To the best of our knowledge, this is one of the first fully functional voice-based applications that provides end-to-end support for behavioral therapy (in this case, PST).

Design Changes

Several design changes were incorporated in response to participants' suggestions. To reduce the temporal and cognitive load (ie, reducing the pace of conversations), we incorporated multiple functionalities within Lumen. First, we split longer conversations (especially in S1, where Lumen provided an overview of the PST) into multiple shorter conversations to reduce the mean length of conversations between Lumen and the participant. Such shorter conversations allow for more interactive turns and have been shown to improve the common

ground and engagement between conversational partners [5,31-34]. Second, we developed functionality that allowed participants to repeat, pause, and resume conversations. This allowed participants to ask Lumen to repeat instructions if they could not keep up with the content or to pause conversations in situations where they needed to take a break. Finally, we slowed the pace of the conversations to reduce temporal demand.

In addition, based on suggestions, we also developed a workbook to accompany Lumen in both physical and digital forms. The workbook includes content corresponding to the PST and simple worksheets for taking notes and facilitating brainstorming problem-solving goals, developing and evaluating potential solutions, and creating action plans. Such a cognitive aid helps in externalizing the thought processes [28,35,36] and creating a record for follow-up after the session. Recording and brainstorming with tools also affords cognitive benefits, especially with older adults, such as prospective memory regarding the goals and action plans that were created [37]. We also developed several features linked to Lumen to further integrate contextual aspects regarding the user including their current status and progress. For example, participants can track their progress by viewing their completed sessions and responses to the Patient Health Questionnaire-9 and General Anxiety Disorder-7 surveys on a user dashboard. Similarly, responses on the Patient Health Questionnaire-9 and General Anxiety Disorder-7 surveys were integrated into the Lumen session and reviewed during the session to help participants monitor the level of their depressive and anxiety symptoms.

Finally, we heeded several privacy and security considerations for pragmatic implementation and testing in a real-world setting within the context of a planned pilot randomized clinical trial. To this end, we will afford trial participants access to the Lumen skill within the Amazon Alexa app on a fully encrypted and locked down iPad, with timed exits for nonuse. This allows for preventing accidental recording issues that have been reported regarding the use of voice-based smart devices (Section B, [Multimedia Appendix 1](#)). The iPad-based delivery is aligned with the concept of using a stand-alone “device as a therapist” for the planned trial. However, additional considerations regarding voice-based profile verifications and security considerations are necessary for a wider, pragmatic use of Lumen as a daily therapy tool.

Despite these changes, several aspects of Lumen’s design and interaction are limited by current AI-based voice technology. In particular, the natural language understanding challenges of voice-based technology are well documented [10]. These include difficulties in parsing tone, accent, and pronunciation in spoken language, creating breakdowns in conversation and making it functionally impossible to have a free-form, open-ended conversation with these devices. In addition, current technology is also not able to discern differences in emotion or other verbal cues that are easily interpreted in face-to-face human conversations [5]. With ongoing improvements in technology, these challenges are likely to be mitigated over time, allowing for continued improvement of Lumen for optimized user experience.

Limitations

This mixed methods formative research study had several limitations. The study was based on a small sample of users (N=26) who used Lumen in a relatively controlled environment. However, participants were engaged in 2 sessions and performed the Lumen interactions without external support. Only 2 sessions were evaluated with participants, and as such, we could not characterize participants’ experience with the entire 8-session PST program. However, structurally, sessions 2 to 8 mirror the S2 evaluated in this study. It is likely that participants will become more or less comfortable with the Lumen interactions in the later sessions. Given the formative and controlled nature of this study, we could not assess the impact of the various measures (ie, task load and work alliance) over time. We will be able to determine such longitudinal effects in our ongoing pilot clinical trial. Sessions were attended by a research coordinator and a trained note taker. It is not known whether their presence influenced the participants’ use of Lumen or their responses to the interview questions.

Notwithstanding those technological and research limitations, the findings from the formative evaluation and the subsequent improvements in design and functionalities position Lumen to be a “minimum viable product” that is highly acceptable to participants, appears to veridically reflect PST content, and is ready for potential real-world pilot testing. Recruitment has been completed for the pilot clinical trial (ClinicalTrials.gov, NCT# 04524104) in which 63 adults with mild to moderate depressive and anxiety symptoms have been randomized in a 2:1 ratio to the Lumen intervention or the wait-list control group and followed for 4 months. The objectives of the pilot trial are 3-fold: (1) to determine the feasibility and acceptability of the Lumen virtual coach for delivering the 8-session PST program; (2) to assess neural target engagement by comparing changes in the amygdala and dorsal lateral prefrontal cortex in functional neuroimaging between the Lumen intervention and wait-list control groups; and (3) to examine the relationship between neural target engagement and changes in self-reported measures of mood, coping, and psychosocial functioning. The pilot trial will provide the preliminary data needed to accelerate the clinical and translational research on this novel digital psychotherapy and to catalyze future development and definitive efficacy clinical trials.

Conclusions

With a goal of overcoming the lack of empirical evidence for AI-based voice applications in behavioral therapy, we developed a voice-only virtual coach, Lumen, for delivering PST. The findings from the formative evaluation highlight feasibility, accessibility, and favorable user experience. Suggestions for more natural conversations and better contextual support have resulted in an improved, minimally viable product. Lumen is being tested in a clinical trial to evaluate its neural mechanism of action and therapeutic potential in depression and anxiety. If successful, Lumen can be a viable voice-based therapist offering a realistic and cognitively plausible verbal interaction for personalized and accessible mental health care, filling a gap in traditional mental health services.

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Data Availability

Deidentified data from this study are not available in a public archive. Deidentified data from this study will be made available (as permissible according to institutional review board standards) by emailing the corresponding author.

Authors' Contributions

TK, CRR, NEW, JMS, and JM conceived the study; TK, CRR, EAK, and NL collected the data; TK, CRR, EAK, NL, and NEW were involved in the preliminary analysis; and all authors participated in the interpretation of the results, writing of the manuscript, and critical review. All authors approved the final manuscript for submission.

Conflicts of Interest

TK is a paid consultant for Pfizer, Inc outside of this work. JM is a paid scientific consultant for Health Mentor Inc (San Jose, California, United States). OAA is the cofounder of KeyWise AI and serves on the advisory boards of Blueprint Health and Embodied Labs. The other authors report no conflicts of interest.

Multimedia Appendix 1

Details of the Lumen architecture and user interaction patterns with Lumen.

[[DOCX File, 456 KB - formative_v6i8e38092_app1.docx](#)]

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Abbreviations

AI: artificial intelligence

ENGAGE-2: Engaging Self-Regulation Targets to Understand the Mechanisms of Behavior Change and Improve Mood and Weight Outcomes

PST: problem-solving treatment

TLX: Task Load Index

UEQ-S: User Experience Questionnaire Short Version

WAI-Tech: Working Alliance Inventory–Technology Version

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Original Paper

Delivering an mHealth Adherence Support Intervention for Patients With HIV: Mixed Methods Process Evaluation of the Philippines Connect for Life Study

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Abstract

Background: The Philippines HIV epidemic is one of the fastest growing epidemics globally, and infections among men who have sex with men are increasing at an alarming rate. Connect for Life Philippines is a mobile health (mHealth) intervention that supports antiretroviral therapy (ART) adherence in this key population through individualized voice calls and SMS text messages.

Objective: The objective of this process evaluation is to assess the intervention reach, dose delivered and received, fidelity, and acceptability and to describe contextual factors affecting the implementation of an mHealth adherence support intervention for patients on ART in a clinic in Metro Manila, Philippines.

Methods: A mixed methods process evaluation approach was used in an observational cohort study. Quantitative data sources for the process evaluation were call and SMS text message logs obtained from the mHealth platform and questionnaires collected at 12-, 24-, and 48-week study visits. Qualitative data were collected from process reports and through a series of focus group discussions conducted with a subset of participants during the intervention development phase, after an initial 8-week pilot phase, and at the end of the study.

Results: The 462 study participants received 31,095 interactive voice calls and 8234 SMS text messages during the study. Owing to technical issues, intervention fidelity was low, with only 22.1% (102/462) of the participants receiving reminders via voice calls and others (360/462, 77.9%) receiving only SMS text messages during the intervention. After 48 weeks in the study, 63.5% (293/462) of the participants reported that they would be quite likely or very likely to recommend the program to a friend, and 53.8% (249/462) of the participants reported that they benefited quite a bit or very much from the intervention. Participants who were on ART for <6 months at the beginning of the study and those who received the daily or weekly pill reminders were more likely to report that they benefited from the intervention ($P=.02$ and $P=.01$, respectively).

Conclusions: The Connect for Life intervention had high participant satisfaction and acceptability, especially among those who received high dose of the intervention. However, poor reliability of local telecommunication networks had a large impact on the intervention's usability, fidelity, and dose received.

KEYWORDS

mobile health; mHealth; adherence; HIV; antiretroviral therapy; process evaluation; Philippines; men who have sex with men; MSM; mobile phone

Introduction

Background

The HIV epidemic in the Philippines is one of the fastest growing epidemics globally, with 207% increase in new HIV infections and 388% increase in AIDS deaths from 2010 to 2020. In 2020, an estimated 73% of people living with HIV in the Philippines knew their status and 44% of people living with HIV were on antiretroviral therapy (ART) [1-4]. In 2 studies of cohorts of patients with HIV in Manila, 84% to 90% of patients who started ART had achieved viral suppression [4,5]. Most new and existing HIV infections occur among men who have sex with men (MSM) [3]. Improving treatment coverage, retention, adherence, and viral suppression are key to slowing the spread of HIV in the Philippines. Unfortunately, widespread stigma, lack of knowledge, and barriers to accessing care pose a challenge to engaging patients in testing and ensuring high levels of adherence to ART and retention in care [6-8]. High rates of first-line treatment failure, loss to follow-up, and suboptimal treatment adherence lead to poor outcomes in many patients with HIV in the Philippines [9,10].

This paper describes the process evaluation of a mobile phone technology for health (mobile health [mHealth]) intervention for people living with HIV in Metro Manila, Philippines. To support ART adherence, the intervention, Connect for Life, provided patients with HIV with individualized voice calls and SMS text messages, pill reminders, appointment reminders, symptom reporting, health tips, and adherence feedback.

The Connect for Life platform was developed by Janssen Global Public Health, and before adaptation for the Philippines, its versions were piloted in India and Uganda. The mMitra (mobile friend) project in India aimed to improve maternal health outcomes through health messages to pregnant women [11,12]. The Treatment Advice using Mobile Alerts project in India [13,14] and Call for Life Uganda [15,16] supported ART adherence among people living with HIV.

Process Evaluation of mHealth Interventions

As mHealth technologies have become widespread in low-income and middle-income countries, mobile phone interventions have become increasingly popular in the global health and development sectors as an inexpensive and efficient way to communicate and deliver services. Several trials have shown that mHealth approaches show potential for improving self-management of chronic diseases, including adherence to HIV medications [17-21], whereas systematic reviews show mixed outcomes of mHealth interventions and highlight the need for more rigorous evaluation methods and longer follow-up periods in mHealth studies [22-31].

Trials assessing mHealth adherence interventions for HIV often do not include process evaluations to examine the fidelity and

quality of the intervention delivery, causal mechanisms for the health outcomes, contextual factors affecting the delivery, and costs to implement [29,32,33]. For mHealth interventions, current guidance suggests that practitioners should also include a minimum set of information about the content, context, and technical features of the intervention, including aspects such as ease of use, content quality, privacy and security, service quality, personalization, and perceived enjoyment [34-37].

Process evaluations of SMS text messages and interactive voice response systems (IVRSs) have examined fidelity, reach, dose delivered, and user satisfaction for projects ranging from water and sanitation to prevent diarrheal disease [38]; airline pilot fatigue [39]; and prevention of weight gain, smoking, or HIV among young people [40-42]. A systematic review of mHealth projects in Africa found that in projects where acceptability and usability of mHealth technology among participants was measured, it was generally high. However, infrastructure issues (unreliable network and internet and electricity access) were frequently cited as key challenges in delivery [24].

The success of mHealth projects in achieving the intended health outcomes is almost entirely dependent on the adaptation and delivery of the intervention in local contexts. Having a complete understanding of the implementation process of an mHealth intervention can enable practitioners to interpret the outcomes and replicate the intervention in other contexts. Therefore, we performed a process evaluation alongside the Connect for Life Philippines prospective cohort study. The process evaluation examined the fidelity, dose delivered and received, reach, usability, acceptability, and cost of the Connect for Life Philippines intervention.

Methods

Recruitment

The study was conducted at the Sustained Health Initiatives of the Philippines (SHIP) Clinic, a low-cost, private facility in Metro Manila, a city with approximately 13 million people in the predominantly Catholic country of the Philippines.

SHIP Clinic provides HIV primary care and wraparound services to approximately 900 people living with HIV. Approximately 98% of SHIP's clients are MSM, with an average age of 30 years at initial consultation. Most are full-time or part-time employees. The clients come from all regions of Metro Manila, and some live in other provinces.

Recruitment into the Connect for Life study occurred in person at the study site between October 2016 and December 2017. As patients checked in for their routine clinic visits, the study coordinator approached all patients seated in the clinic waiting room, briefly introduced the study following a recruitment script, elicited their interest in participating, screened them for

eligibility, completed the informed consent process, and provided a brief orientation to the intervention.

Connect for Life Mobile Phone ART Adherence Support Intervention

The study team worked with IT specialists and public health professionals from Janssen Global Public Health, University of the Philippines, and local IT companies to develop the content and functionality of the Connect for Life mHealth platform (Figure 1). Connect for Life is a technology built on the Mobile Technology for Community Health (MOTEC; Grameen Foundation) open-source software platform [43]. It enables health facilities to connect to patients via their mobile phones through IVRS call flows or SMS text messages. As Connect for Life works through phone calls and SMS text messages, it does not require the user to have a smartphone, install an app, or have mobile internet connection. This makes it accessible to a wide range of users in the Philippines, where, in 2015, mobile phone penetration was high, but smart phone coverage and internet access were low (with 113 mobile subscriptions per 100 people, 99% of the population reached by network coverage, and 22% of the population owning a smart phone) [44-46].

The study team tailored the Connect for Life platform for the Philippine context. Some existing features were retained, such as reminders sent on the recipient's preferred days and times, health tips, and symptom screening. New features were developed, such as medical record functionality and adherence feedback scores. Clinicians at the study site developed new

content for the voice and SMS text messages, which were recorded by a local voice talent agency. During the formative study and intervention development stage, a series of focus groups were conducted to engage with patients at the clinic about their adherence behaviors and preferences for configuration and content, and their feedback was incorporated to ensure that the intervention was tailored to the target population [47-49].

The Connect for Life system was installed in a secure cloud server environment and linked to a local telecom provider through application programming interface integration to execute calls and SMS text messages. A local IT service provider was contracted to monitor server functionality, install software updates, and troubleshoot technical issues. The Connect for Life software developers provided in-depth technical training and software documentation to the local IT provider and training for the clinical staff on how to use the Connect for Life web-based platform.

The intervention development process was guided by the Behavior Change Wheel and the Capability Opportunity Motivation–Behavior model developed by Michie, Atkins, and West [50-52]. Behavior change techniques related specifically to ART adherence were informed by the information-motivation-behavioral skills model of ART adherence [53]. Each service in the intervention package was designed to address ≥ 1 of the 3 main components that drive behavior in the Capability Opportunity Motivation–Behavior model, as outlined in Figure 2 [47,48].

Figure 1. Connect for Life Philippines mobile health intervention functions. ART: antiretroviral therapy; IVRS: interactive voice response system; PIN: personal identification number.

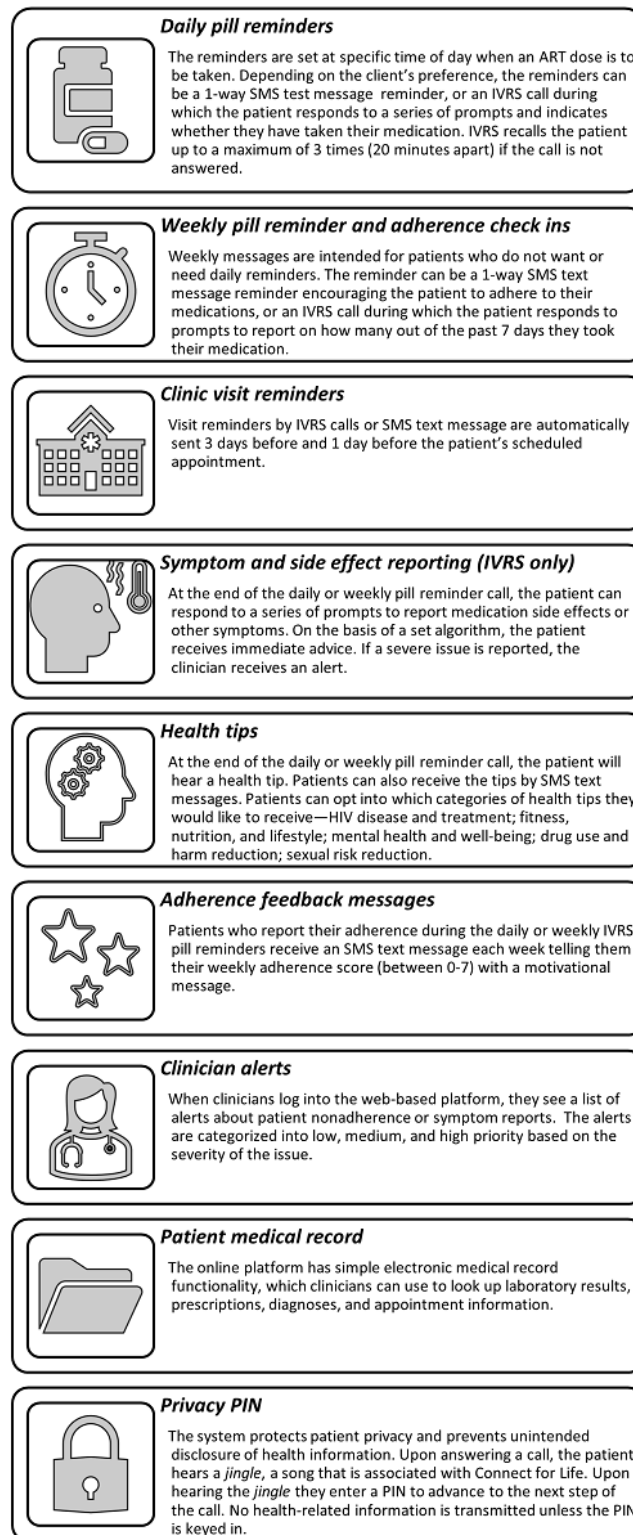
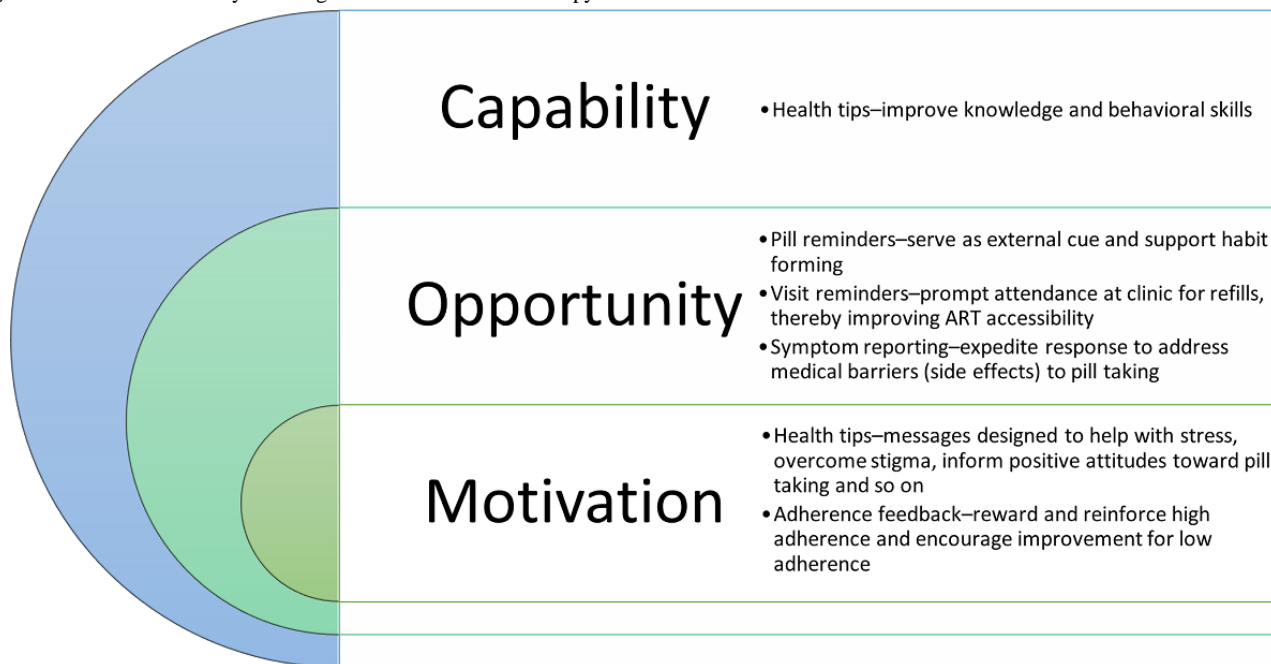


Figure 2. Intervention theory of change. ART: antiretroviral therapy.

Data Collection and Analysis

A mixed methods approach was used with qualitative data embedded in the experimental design of the 48-week prospective cohort study [54]. The design allowed us to assess participants' use of and experience with the system and use quantitative and qualitative analyses to generate complementary data about acceptability, usability, and the impact of contextual factors on the intervention.

The process evaluation measures were based on the framework proposed by Linnan and Steckler [55], which defines the approach to adequately describe the context, reach, dose (delivered and received), acceptability, and fidelity of the intervention. Additional aspects related to reporting on mHealth technology were included based on guidance from the mHealth Evidence Reporting and Assessment checklist [36].

The process evaluation questions, tools, methods, and data sources are described in [Multimedia Appendix 1](#).

To measure the fidelity and dose of intervention delivery, records from the mHealth platform detailing the services received by each participant were exported. To understand the usability and acceptability of the intervention, participants completed self-administered paper-based questionnaires at 3 time points during the study. Where questionnaires had blank or missing fields, all available data points were included in the analysis. Data distributions were explored to categorize the responses to the questionnaires. Associations between acceptability of the intervention and independent variables (time point, treatment experience, and reminder frequency) were calculated using chi-square tests. Data analysis was conducted using Stata 15.

Qualitative feedback was collected in several ways: routine monthly process reports from clinicians to document implementation successes and challenges, comments recorded on the acceptability questionnaires, and a series of focus group

discussions (FGDs). The study team conducted 2 FGDs with a total of 12 participants during the intervention development phase in 2016. In early 2017, a total of 2 additional FGDs were conducted with 5 participants after an 8-week pilot phase. Finally, in 2018, during the final 2 months of the study, 3 FGDs were conducted with 15 participants. The FGDs were transcribed, transcripts were manually coded using a deductive coding methodology to group responses by topic areas in the FGD guide, subtopics were assigned through line-by-line coding, and data were consolidated in a structured template that enabled identification of salient themes. Results from the FGDs in the formative and pilot phases informed the content and structure of the intervention and helped to identify implementation issues early in the project [47].

Ethics Approval

Ethics approval for the study was obtained from the University of the Philippines Manila research ethics board (protocol number 2016-265-01) and the London School of Hygiene and Tropical Medicine (reference number 11631). All participants provided written consent before inclusion in the study.

Results

Study Population and Intervention Delivery

Process Evaluation Questions 1 and 2: Reach and Recruitment

Of approximately 675 patients receiving ART services at the study site during the recruitment period, 485 (71.9%) were approached by the study coordinator while attending a routine visit at the clinic, 464 (68.7%) were interested in learning about the study, and 462 (68.4%) met the eligibility criteria and consented to participate.

Reasons for refusal (21/485, 4.3%) included no need or desire for adherence support, not wanting to receive messages or calls on their mobile phone, privacy concerns, and frequent travel

out of the country. Of the 0.4% (2/464) of the patients who were excluded, one was ineligible because he did not speak English and the other did not have a mobile phone.

All but 1 of the participants in the study (461/462, 99.8%) identified as male, and 98.5% (455/462) were MSM. The mean age at enrollment was 32.4 (SD 5.7) years. University or postgraduate studies had been completed by 85.9% (397/462) of the participants, and 91.3% (422/462) were employed or enrolled in university, which reflects the higher-than-average socioeconomic status of patients at the study site, a private fee-for-service clinic.

At the time of enrollment, 92.2% (426/462) of the participants were already taking ART and 7.8% (36/462) had not yet started. Of those already taking ART, perfect adherence of 100% of doses taken in the last 30 days was reported by 52.1% (222/426) of the participants, 95% to 99% adherence was reported by 26.6% (113/426), 90% to 94% adherence was reported by 12.7% (54/426), and adherence of <90% was reported by 8.7% (37/426).

Participants were followed for 48 weeks, during which time 91.1% (421/462) of the participants were retained for the study duration and active on ART at the study site, 0.6% (3/462) had withdrawn from the study but were still in care, 0.6% (3/462) had died, 3.9% (18/462) had defaulted from treatment, and 3.7% (17/462) had transferred to another clinic.

Process Evaluation Question 3: Fidelity

The process evaluation found that the fidelity of the intervention was low. The planned intervention consisted of daily IVRS pill

reminder calls for all participants in the first 6 months of ART and weekly IVRS calls for those on ART for >6 months. During the study, only 22.1% (102/462) of the participants received the IVRS intervention, whereas 72.7% (336/462) received a scaled-down SMS text message version of the intervention. The reasons for the small proportion of participants receiving the voice calls were technology-related challenges described in the *Usability and Context* section.

Process Evaluation Questions 4 and 5: Dose Delivered

Of the 462 participants, 95 (20.6%) participants received a combination of voice calls and SMS text messages, 336 (72.7%) received SMS text messages only, 7 (1.5%) received voice calls only, and 24 (5.2%) received neither.

The 22.1% (102/462) of the participants who opted for IVRS services received a total of 30,940 calls during their study enrollment period (Table 1). During the calls, participants listened to 3980 health tips. Only 2 symptom or side effect reports were made. An average of 303 calls were made per participant, which included repeat reminder calls (up to 3 calls per day) if the initial call was unanswered. Of all the scheduled outgoing IVRS calls by the Connect for Life system, only 0.14% (44/31,095) of the calls failed to initiate owing to a software or platform issue.

The 93.3% (431/462) of the participants who opted for SMS text messages received 8234 messages in total: 2468 (29.97%) adherence feedback, 417 (5.06%) health tips, 2272 (27.59%) pill reminders, and 3077 (37.37%) visit reminders.

Table 1. IVRS^a and SMS text message services provided.

Services	Participants who received the service (N=462), n (%)	Total number of calls and messages delivered after enrollment (N=30,940 calls; N=8234 SMS text messages), n (%)	Number of calls and SMS text messages per participant, mean (SD)
IVRS calls (n=102)			
Any	102 (22.1)	30,940 (100)	303 (324.3)
Listened to health tip	69 (14.9)	3980 (12.86)	58 (80.1)
Reported symptoms or side effects	2 (0.4)	2 (0.01)	1 (0)
SMS text messages (n=431)			
Any	431 (93.3)	8234 (100)	19 (49)
Adherence feedback	70 (15.2)	2468 (30)	35 (17.3)
Health tip	11 (2.4)	417 (5.1)	38 (45.7)
Pill reminder	10 (2.2)	2272 (27.6)	227 (187.3)
Visit reminder	428 (92.6)	3077 (37.4)	7 (4)

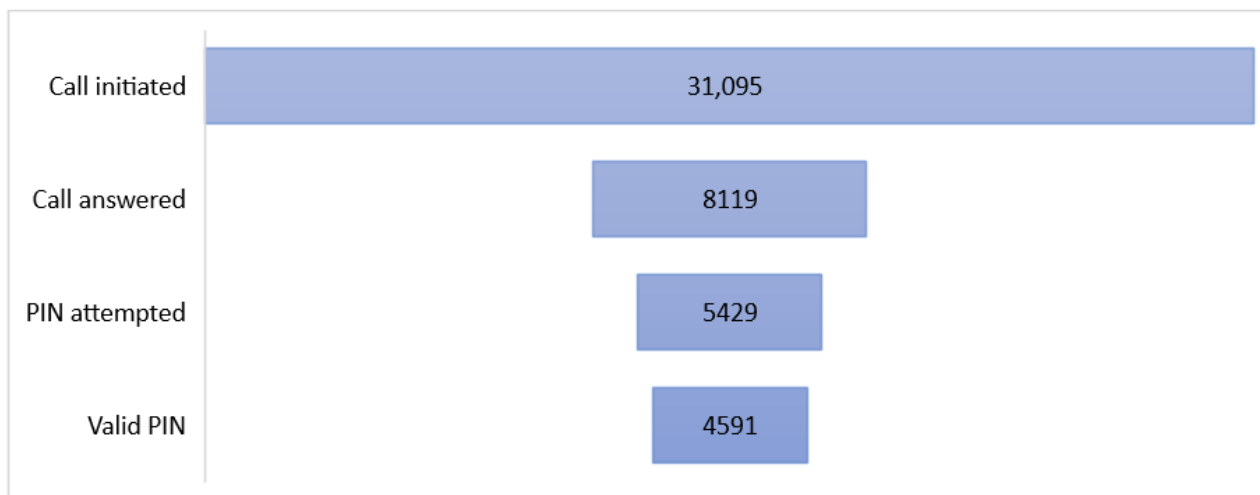
^aIVRS: interactive voice response system.

Process Evaluation Question 6: Dose Received

Including setup calls during the visits, of the 31,095 outgoing calls made by the Connect for Life system, 8119 (26.11%) were answered by the participants. To listen to the message, the

participant had to enter their personal identification number (PIN). A PIN attempt was recorded for 66.87% (5429/8119) of the calls that were answered, and the PIN was entered successfully in 84.56% (4591/5429) of the PIN attempts (Figure 3).

Figure 3. Interactive voice response system calls made and outcomes. PIN: personal identification number.



Of the 2690 calls that were answered and no PIN was entered, an estimated 1846 (68.62%) went to voicemail. This estimate was based on the number of seconds the call was connected before it was automatically terminated by the software (approximately 140 seconds).

Experiences of Participants and Providers

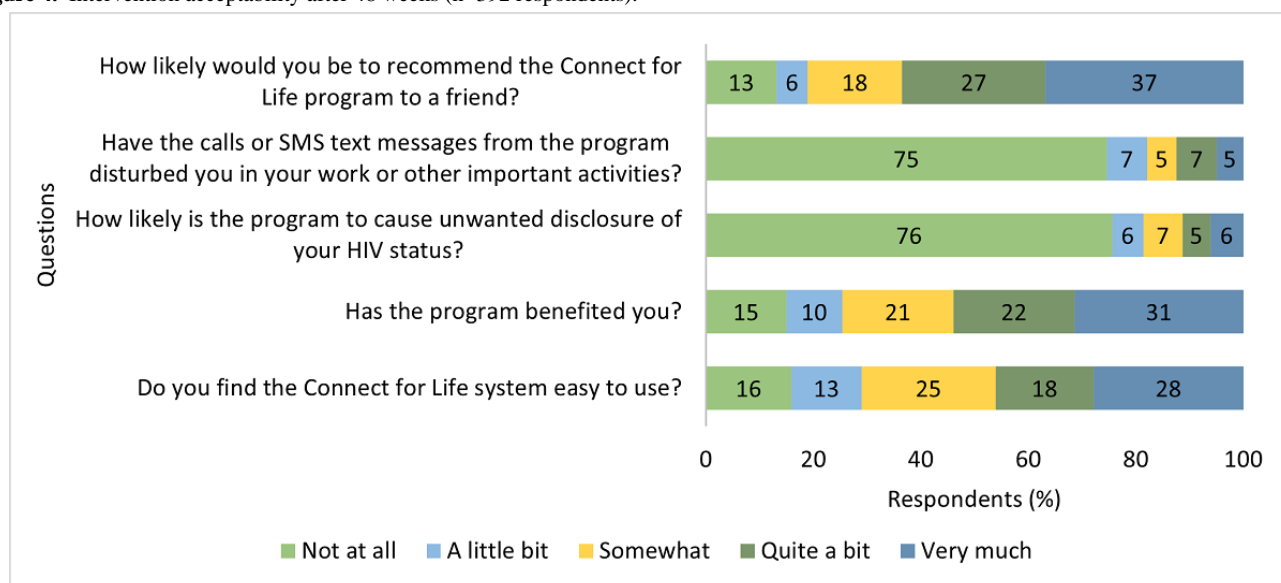
Process Evaluation Questions 7 and 8: Usability and Context

The biggest technology challenge that the project faced was frequent dial tone multifrequency (DTMF) malfunction during IVRS calls. This was reported by study participants and observed by the study staff during the process of activation of the IVRS service. During the DTMF malfunction, the system was unable to recognize the tones as users pressed number keys

on their phones, resulting in invalid PINs or inability to navigate the IVRS menus. DTMF failure was suspected during an estimated 32.08% (2605/8119) of calls that were answered by participants (1767/2605, 67.83% of the answered calls where no PIN was entered and 838/2605, 32.17% calls where an invalid PIN was entered). Enrollment was temporarily suspended, and an investigation of the issue found that the DTMF malfunctions were related to the telecommunication infrastructure rather than the Connect for Life platform; therefore, it was not possible for the study team to correct the issues.

Only 46.1% (159/345) of the participants reported that they found the Connect for Life system quite easy or very easy to use (Figure 4), indicating that ease of use can be improved.

Figure 4. Intervention acceptability after 48 weeks (n=392 respondents).



The provider’s experience with the system was largely positive. In monthly process reports, clinicians reported that the medical record functionality facilitated easy access to laboratory results, medication history, diagnosis, and other information, which had previously been recorded in Microsoft Word documents and

paper charts. Clinicians also reported that the alert function, which flagged patients with poor adherence or side effects for the clinician to follow up, was overwhelming to use. The symptom reporting alerts were useful, but these alerts were “buried” in a long list of alerts about missed doses and missed

clinic visits. This occurred when participants failed to answer calls and responded to the IVRS prompts, which triggered alerts for nonadherence, resulting in high numbers of inaccurate alerts for missed doses. Clinicians recommended reviewing and updating the criteria for generating alerts.

Clinic staff also observed that across the clinic, participant compliance with attending appointments on the scheduled date and time improved from 17% before the study to >30% after the implementation of Connect for Life. They attributed this improvement to the visit reminders sent through SMS text messages. The improved on-time visit attendance saved staff time and effort by reducing the need to call patients and reschedule appointments.

Process Evaluation Question 9: Acceptability and Satisfaction

Acceptability

Acceptability questionnaires were collected at 3 time points (426/462, 92.2% completed at the 12-week visit; 335/462, 72.5% at the 24-week visit; and 392/462, 84.8% at the 48-week visit). Acceptability levels are summarized in [Figure 4](#).

After 48 weeks in the study, 63.5% (221/348) of the participants reported that they would be quite likely or very likely to recommend the program to a friend, and 53.9% (187/347) of the participants reported that they benefited quite a bit or very much from the intervention.

Some participants reported concern over privacy and inconvenience, with 12.4% (43/347) of the participants reporting that the messages and calls disturbed them quite a bit or very much during their work or other important activities and 11.3% (39/345) of the participants stating it was quite likely or very likely that the intervention could cause unwanted disclosure of HIV status. Social harm monitoring was conducted at each study visit and no instances of disclosure were reported.

Associations between acceptability and several independent variables were explored.

Time on Study

There was no strong evidence of difference in the acceptability indicators at different time points after enrollment. The proportion of participants who reported that the intervention benefited them quite a bit or very much was 45.2% (128/283) at the 12-week study visit, 54.3% (188/346) at the 24-week visit, and 53.9% (187/347) at the 48-week visit ($P=.51$).

Time on Treatment

Among participants who had started ART <6 months before enrollment in the intervention, after 48 weeks, 65% (39/60)

reported that the intervention benefited them quite a bit or very much, compared with only 51.6% (148/287) of the more experienced participants who had been on ART for >6 months at the time of enrollment ($P=.02$).

Frequency of Service

People who received daily or weekly pill reminders were much more likely to report that the intervention benefited them compared with those who did not receive pill reminders. This trend was consistent across all time points. At the 48-week visit, 70% (21/30) of the participants who received weekly pill reminder and 64% (9/14) of those who received daily pill reminder reported that they benefited quite a bit or very much from the intervention compared with only 51.5% (157/305) of those who received no reminders ($P=.01$).

There was no evidence of difference between those receiving daily and those receiving weekly pill reminders in terms of acceptability of the frequency of pill reminders or participants' likelihood to recommend Connect for Life to a friend. Of those who received daily pill reminder, 14% (11/78 observations) said that there were "too many" reminders, whereas 7% (4/58 observations) of those who received weekly pill reminder said that there were "too many" reminders ($P=.29$). At week 48, a total of 80% (24/30) of the participants who received weekly pill reminders were quite likely or very likely to recommend to a friend, compared with 64% (9/14) of those who received daily pill reminders and 61.4% (188/306) of those who received no reminders ($P=.30$).

Other Factors

No association was observed between viral load suppression or HIV knowledge score and intervention acceptability.

Qualitative Feedback From FGDs and Adherence Questionnaires

Qualitative data were collected to facilitate better understanding of participants' experiences with the system and the contextual and motivating factors influencing the use, acceptability, and usability of the intervention.

The key findings from the acceptability questionnaires and the FGDs at the end of the study were that the intervention was received positively, and participants believed that the intervention should continue after the study ended. Several main themes emerged—the importance of personalized reminders, technical challenges and usability issues, desire for health tips, and importance of social support as part of HIV care ([Textbox 1](#)).

Textbox 1. Main themes from focus group discussions (FGDs).**Personalized reminders**

- Participants liked that the intervention was highly personalizable, enabling them to select the frequency and time of calls or SMS text messages and the topics of health tips. Preferences for voice calls and SMS text messages varied. Participants also reported that they found the visit reminders and pill reminders to be helpful for their adherence; however, most patients were using their own alarms or pill boxes as adherence tools. Several participants who only received the visit reminder service expressed interest in trying the pill reminders and health tips after hearing the feedback from participants who received those components of the service:

It is an advantage being reminded at work especially when you get busy so you would not miss to take your medicine on time.

Receiving pill reminder call on a weekly basis made me more aware of the time and I think it is more beneficial to those who has tight schedule. But in my end, I never forget a dose with the aid of alarm clock.

For me, the two times [visit] reminder is fine. Actually, it is very helpful on reminding me on my next visit. There are times that I got surprised receiving the text because I already forgot that I have a follow-up visit.

Technical challenges

- Participants who received the calls described challenges with entering their personal identification number and with navigating the interactive voice response system (these challenges were owing to failure of the dial tone multifrequency technology) and more broadly about the hassle of responding to the prompts in the calls. Even when the call went unanswered, it still served as a prompt to take medication:

In the evening, I don't know how to use the PIN so whenever I received the call (usually an international number) and hear the music, I already know that it is the pill reminder call. I actually can't go through the IVR because I don't know exactly when I need to enter the PIN... On the other hand, the call itself serves as an alarm to take my meds though I was not able to answer or enter my PIN.

Health tips

- Participants expressed that although they use the internet to find health information, they trusted health tips from Connect for Life more, because the information was vetted by their health care provider. They liked that the health tips included information on a range of related health topics, such as nutrition and mental health, in addition to the HIV basics. However, some participants were unwilling to receive tips via SMS text message because of concerns about privacy, and some stated that they knew someone who they could ask for health information:

In general, I think it is better that the health tips are coming from Sustained Health Initiatives of the Philippines and recommended by health care professionals. It would be more reliable as compared to information in the Google.

It's like trivia for today, even you are on meds for a long time already.

Social support

- Almost all FGD participants mentioned the importance of human connection. Several participants mentioned that they would prefer to connect to a live person in addition to electronic information, especially regarding symptom management. Participants stressed the role of support from their health care providers or other patients in helping them to understand more about living with HIV:

I would like to suggest having someone to reach to answer a not so relevant question like if I have stomach-ache and I want to know if it is connected to my meds or a side effect versus to searching in Google which is sometimes inaccurate.

Exchange of experiences [is important] especially to the new patient so they would know what to do. They would feel that they are not alone, because you won't know how to avoid feeling self-pity. At least with a support group they have someone to communicate with.

Process Evaluation Question 10: Cost

A description of the types of expenses involved in the implementation and the approximate costs from the Philippines setting are shown in [Table 2](#).

Table 2. Costs involved in the intervention.

Aspect	Description	Cost
Cloud hosting of solution	The database and software require hosting on RDS ^a and EC2 ^b server instance. The cost of a monthly or yearly subscription depends on the amount of storage needed and payment schedule. Our database includes data for approximately 700 patients.	US \$50 per month
VOIP ^c provider	This may be the local telecommunications company (eg, Vodacom and Globe) or a specialist service provider.	PHP 0.50 (US \$0.01) per SMS text message or PHP 5 (US \$0.10) per minute for voice calls
Local service provider IT support	IT support monitors the server, VOIP functionality, and software updates and manages users' log-ins. Our local IT support provides up to 20 hours of support monthly and charges an hourly rate for additional support.	PHP 10,000 (US \$200) per month
Staff	An administrative clerk, counselor, or other cadre of staff will allocate time and effort to enroll patients on the system, activate their services, monitor alerts, and update details.	Cost varies (0.1-0.5 FTE ^d of administrator)

^aRDS: relational database service.

^bEC2: Elastic Compute Cloud.

^cVOIP: voice over IP.

^dFTE: full time equivalent.

Discussion

Principal Findings

During the study, >31,000 IVRS calls and 8000 SMS text messages were sent to 462 study participants. The Connect for Life system was acceptable to both participants and providers. Participants liked that the intervention was highly personalizable, enabling them to select the frequency and time of calls or SMS text messages and the topics of health tips. Feedback on the pill reminders, visit reminders, and health tips was very positive. Participants appreciated that health tips covered a variety of topics beyond HIV basics. The FGDs revealed that acceptability of the weekly adherence scores and symptom reporting functionalities of the intervention was low, as these 2 functions required lengthy navigation of the IVRS menu.

Owing to technical issues, the intervention was not implemented as originally intended, with only 22.1% (102/462) of the participants receiving the IVRS pill reminder intervention and others receiving a scaled-back SMS text message intervention. When the technical issues were first identified, enrollment in the study was paused for 3 months, while the study team assessed the cause of the issue. Ultimately, the issue of DTMF malfunction was attributed to issues in the telecommunications system that neither the telecommunications provider nor the Connect for Life developers could resolve. When enrollment was resumed, participants were provided SMS text messages rather than IVRS services. Despite the technical challenges, acceptability remained high, and only 0.6% (3/462) of the participants withdrew from the study. Following the study, the frequency of technical issues has decreased significantly, and the study site has continued to provide the service. Currently, pill reminder calls are a routine service for all new patients undergoing ART.

Notably, the technical challenges experienced in delivering the intervention were related to navigating the IVRS menu and made it difficult to distinguish whether the issues raised with

ease of use or overall satisfaction were related to the technical challenges (ie, the dial tones were not recognized when keyed in) or to the product design (ie, IVRS menus were very complicated). The accuracy of the adherence scores in the weekly feedback SMS text messages was dependent on successful navigation of the IVRS process. This type of feedback may have been better delivered via a smart phone app rather than an IVRS setup. The interactive component of the IVRS system was an important aspect of the study design, which was not effectively evaluated in this study owing to the low number of participants who received this part of the service, warranting ongoing monitoring and future studies.

The scaled-back intervention provided everyone with visit reminders, which addressed part of the theory of change by improving medication accessibility through timely refills, but did little to prompt pill-taking, habit forming, and improvements in health knowledge. Individuals who received a high dose of the intervention (daily or weekly pill reminders) were more likely to recommend the intervention to others, suggesting that the planned intervention was more acceptable than the scaled-back version.

Our analysis of dose received shows that the call answer rate was low, with only 26.24% (8119/30,940) of outgoing calls answered, which is reflective of a preference for SMS text messages and chat services among the target population. The requirement of a PIN reduced exposure to the intervention, which was mostly owing to technological challenges. After experiencing technical difficulties several times, many participants stopped answering the calls. However, some mentioned that the phone ringing at the set time each day served as an effective adherence reminder.

Privacy considerations were paramount, with 11% (51/462) of the participants reporting that they had concerns about the potential for disclosure of their HIV status. Therefore, in situations where entering a PIN is a barrier to intervention exposure, practitioners can consider adapting the content to

eliminate potentially sensitive health information and delivering the service with no PIN requirement.

Ultimately, the study showed the importance of choosing technologies that can function in local contexts. In low-resource settings, it may take time to scale-up technologies that will be quick to roll out in high-resource settings. Practitioners must identify service providers with appropriate capacity and ensure that patients have the skills and motivation to use the intervention. Conducting an iterative process with several pilot stages is advantageous, as it enables practitioners to identify the problems with functionality and adapt the intervention before scaling up.

An important aspect of the intervention was that, through this regular contact from the clinic, participants felt cared for and felt that their health care provider was concerned about their well-being. This social support was a key motivator for adherence. Participants requested to be able to speak to someone about side effects or for social support, suggesting that an intervention that links calls to counselors more effectively may be an area for future evaluation.

Comparison With Previous Studies

The Connect for Life Philippines intervention was adapted from the same platform used for Call for Life Uganda and mMitra and Treatment Advice using Mobile Alerts in India. Acceptability was high in all 3 settings [11,16]. However, there were differences in the preferences and use patterns of the participants in the Philippines setting compared with those in Uganda and India. The Philippines had a high preference for SMS text messages over voice calls and a low call answer rate. The Connect for Life Philippines and Call for Life Uganda projects experienced similar challenges with network instability issues in the early stages [16].

Similar to Connect for Life and Call for Life, other mHealth interventions for people living with HIV have shown improvements in ART adherence, even where participant response rates (ie, dose received) are low [29,31,56]. For example, the PositiveLinks app used by people living with HIV in Virginia, United States, had response rates of <40% to most app prompts, but participant retention in care, CD4 results, and viral suppression improved significantly [57]. There is an important distinction between adherence to the intervention (ie, calls, app prompts, and device use) and adherence to medication.

Strengths and Limitations

A strength of the Connect for Life platform is its scalability; the project can easily be expanded to cover a large number of sites and patients with great cost efficiency, if those facilities have access to computers and internet connectivity. To deliver the project at scale, creation of content in regional languages will be an important consideration. The platform is adaptable, as the local IT provider can add and remove new data fields and update the SMS text message content, voice files, and call flows. However, changes to the functionality of the software or interoperability with other systems will require support from the software developers at Johnson and Johnson Global Public Health. The Philippines Department of Health has plans to implement electronic reporting systems for HIV services at an

aggregated level. If the department is ever to implement a patient-level electronic medical record, interoperability with Connect for Life will be an important consideration to ensure delivery at scale.

A strength of this process evaluation study is the mixed methods and participatory approach. The study used prospectively collected quantitative data on participants' responses to the intervention and qualitative feedback from questionnaires, monthly process reports, and FGDs. The evaluation included the users of the intervention, clinical service providers, and developers of the technology platform.

The methodology addressed all key components in process evaluation for public health interventions and studies (context, reach, dose delivered, dose received, fidelity, implementation, and recruitment) [55]. Furthermore, the study included information on the technology platform, infrastructure, security, and cost, as guided by the mHealth Evidence Reporting and Assessment checklist developed by the World Health Organization mHealth Technical Evidence Review Group [35].

A limitation of our approach was that the evaluation was conducted by the same study team responsible for planning and implementing the intervention, rather than by independent evaluators. Other limitations included the convenience sampling strategy for participants in the FGDs and the low participation in the focus groups. Although the study team approached many individuals to participate, it was a challenge to identify those who were willing owing to reluctance to disclose their HIV status in a group. Furthermore, owing to transportation challenges, there was low attendance among those who confirmed their intention to participate in the groups.

Incomplete data may have affected the interpretation of the results. Of the 462 participants in the study, 440 (95.2%) attended the final study visit at week 48, and 89.1% (392/440) of them completed the questionnaire during the final visit. There may be differences in the experiences of participants who transferred out, died, withdrew from the study or were lost to follow-up, attended but did not complete the questionnaire, and completed the questionnaire.

This study focused on MSM in Metro Manila, and the study population was urban and highly educated. Participants may have had alternative adherence reminders, including self-set phone alarms and email alerts. Therefore, the results are not broadly generalizable to other contexts.

Conclusions

mHealth interventions are useful to support adherence, as they have low replication costs and are highly adaptable to specific cultural contexts. On the basis of the findings of this process evaluation, we can guide practitioners implementing mHealth interventions to support medication adherence to consider the following recommendations:

1. The intervention should allow the participant to personalize the service based on their preferences for delivery by SMS text message or voice calls, timing of messages and calls, and selection of content.

- Limit the complexity of the IVRS menus to reduce the “hassle” factor and likelihood of technical failures. If the navigation of menus is a key aspect of the intervention, consider using an app or a chatbot instead of, or in addition to, an IVRS system.
 - Consider how to use the mHealth intervention to facilitate human interaction. For example, certain responses to the intervention may prompt counselor-, clinician-, or peer support.
 - Ensure that the roll out of an existing mHealth technology in a new setting is an iterative process that includes robust process evaluation methods. Rigorous pilot-testing is needed to ensure technical function. Work plans should include ample time and budget for adaptation of the technology.
- The Connect for Life mHealth intervention to support adherence to ART had high participant satisfaction and acceptability. However, the feasibility of the intervention was dependent on the reliability of local telecommunications networks, and poor reliability of the local mobile networks had a large impact on the intervention’s usability, fidelity, and dose received.
- The process evaluation allowed us to better understand the preferences and use patterns of mHealth services by MSM in the Philippines. This will enable the effective scale-up of mHealth services for this key population, which is essential in the context of the dual HIV and COVID-19 pandemics, where more services must be delivered virtually.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Process evaluation methodology.

[[DOCX File , 19 KB - formative_v6i8e37163_app1.docx](#)]

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Abbreviations

ART: antiretroviral therapy
DTMF: dial tone multifrequency
FGD: focus group discussion
IVRS: interactive voice response system
mHealth: mobile health
MOTECH: Mobile Technology for Community Health
MSM: men who have sex with men
PIN: personal identification number
SHIP: Sustained Health Initiatives of the Philippines

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Original Paper

Exploring Factors Associated With Mobile Phone Behaviors and Attitudes Toward Technology Among Adults With Alcohol Use Disorder and Implications for mHealth Interventions: Exploratory Study

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Abstract

Background: Alcohol use disorder (AUD) is associated with severe chronic medical conditions and premature mortality. Expanding the reach or access to effective evidence-based treatments to help persons with AUD is a public health objective. Mobile phone or smartphone technology has the potential to increase the dissemination of clinical and behavioral interventions (mobile health interventions) that increase the initiation and maintenance of sobriety among individuals with AUD. Studies about how this group uses their mobile phone and their attitudes toward technology may have meaningful implications for participant engagement with these interventions.

Objective: This exploratory study examined the potential relationships among demographic characteristics (race, gender, age, marital status, and income), substance use characteristics (frequency of alcohol and cannabis use), and clinical variables (anxiety and depression symptoms) with indicators of mobile phone use behaviors and attitudes toward technology.

Methods: A sample of 71 adults with AUD (mean age 42.9, SD 10.9 years) engaged in an alcohol partial hospitalization program completed 4 subscales from the Media Technology Usage and Attitudes assessment: *Smartphone Usage* measures various mobile phone behaviors and activities, *Positive Attitudes* and *Negative Attitudes* measure attitudes toward technology, and the *Technological Anxiety/Dependence* measure assesses level of anxiety when individuals are separated from their phone and dependence on this device. Participants also provided demographic information and completed the Epidemiologic Studies Depression Scale (CES-D) and the Generalized Anxiety Disorder (GAD-7) scale. Lastly, participants reported their frequency of alcohol use over the past 3 months using the Drug Use Frequency Scale.

Results: Results for the demographic factors showed a significant main effect for age, *Smartphone Usage* ($P=.003$; $\eta_p^2=0.14$), and *Positive Attitudes* ($P=.01$; $\eta_p^2=0.07$). Marital status ($P=.03$; $\eta_p^2=0.13$) and income ($P=.03$; $\eta_p^2=0.14$) were associated only with the Technological Anxiety and Dependence subscale. Moreover, a significant trend was found for alcohol use and the *Technological Anxiety/Dependence* subscale ($P=.06$; $R^2=0.02$). Lastly, CES-D scores ($P=.03$; $R^2=0.08$) and GAD symptoms ($P=.004$; $R^2=0.13$) were significant predictors only of the *Technological Anxiety/Dependence* subscale.

Conclusions: Findings indicate differences in mobile phone use patterns and attitudes toward technology across demographic, substance use, and clinical measures among patients with AUD. These results may help inform the development of future mHealth interventions among this population.

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KEYWORDS

mobile phone use patterns; substance use; alcohol; technological attitude; alcohol use disorder; demographic differences; anxiety; depression; mobile phone; patient attitude

Introduction

Background

Many chronic health problems are associated with alcohol use disorder (AUD), including stroke, high blood pressure, heart disease, cancer of the esophagus, liver, and colon [1-3]. AUD is also related to a plethora of psychological and behavioral problems [3]. According to the 2019 National Survey on Drug Use and Health, prevalence rates of AUD among US adults show that 14.1 million have this disorder [4]. Approximately 88,000 people die annually from alcohol-related diseases [4,5], making it a significant public health concern. Accordingly, an objective of alcohol treatments is to help patients abstain from alcohol use.

Long-term abstinence has been shown to improve various complications of alcohol-related diseases [6]. Abstinence maintenance is intricately linked with the successful completion of the initial days following alcohol cessation, when individuals tend to experience elevated anxiety, depression, and cravings for alcohol and are thus at high risk for a relapse occurrence [7,8]. Patients at this stage tend to report low self-efficacy to effectively manage daily triggers for alcohol consumption [9,10]. Consequently, fundamental strategies to facilitate the acquisition of sobriety and long-term maintenance requires real-time interventions that provide individuals with ongoing support and the necessary skills to manage relapse risk factors [9,10]. Mobile phone technologies are among the recommended platforms to augment public health impact [11,12] and can be harnessed to increase reach and dissemination of multifaceted approaches designed to effectively address both cognitions and behaviors associated with AUD.

The wide availability of mobile phone or smartphone ownership (97%) and frequent app usage (80% in the past 30 days) among US adults [13,14] provides an opportunity for researchers to reach this population at scale. Traditional face-to-face substance use intervention programs are inherently limited in their ability to assess and treat real-time risks that can occur in the individual's day-to-day environment [11]. Moreover, low engagement and high attrition are common among traditional substance use treatment interventions with this population, particularly among patients in early recovery [11,15,16]. Smartphone-delivered interventions have shown promising results in increasing engagement and improving outcomes with mental health and behavioral health treatments, although most mHealth studies lack any theoretical framework [11,17,18]. For example, a recent review shows efficacy of mHealth alcohol use interventions, but results remain mixed overall [11].

According to Golbert et al [11], strengthening the rigor of this emerging research requires applying theoretically informed approaches and the use of randomized controlled trials (RCTs) to adequately assess the effect of these new interventions [11]. To our knowledge, there are 2 theory-informed, smartphone app delivered interventions for adults with AUD being conducted [19,20]. While these studies could help determine the efficacy of these technology-based approaches for improving alcohol use outcomes, essential to their success is an understanding of how individuals with AUD use their mobile phone in their daily lives and their attitudes toward technology, which may have an effect on participants' engagement with these interventions.

Studies conducted with general populations have demonstrated variability in mobile use patterns across demographic subgroups (eg, men vs women, White vs non-White, and married vs single) [21,22]. Correspondingly, these findings have been used to inform the development of mHealth approaches addressing barriers and facilitators for behaviors that are more likely to appeal to particular groups [21,22]. Similar assessment studies with individuals with AUD may provide guidance for the development of mHealth intervention approaches in different subgroups of this population, such as those with higher levels of comorbid affective symptoms (eg, anxiety and depression). Because mHealth interventions with individuals with AUD is a developing research area, examining predictors of smartphone use and attitudes toward technology is an important step toward advancing this work.

Objectives

This study explores mobile use behaviors and attitudes toward technology among adults with AUD receiving outpatient treatment. In addition to demographic characteristics (eg, age, gender, and marital status), mental health factors (eg, anxiety and depression symptoms), which are highly relevant to this population [23,24], were also examined as potential correlates of mobile phone behaviors and attitudes toward technology. Moreover, a potential effect of the level of alcohol use on mobile phone behaviors and attitudes toward technology was explored.

Methods

Participant Recruitment and Study Design

Participants were recruited from an alcohol and drug partial hospitalization program at a private hospital in the Northeastern United States. This program provides an abstinence-based and cognitive-behavioral treatment. Patients attend 3-4 groups per day (eg, relapse prevention, drink, drug refusal skills, goal-setting, etc), daily individual counseling with a mental

health worker, and medication management with an attending psychiatrist. Adult patients were approached by research staff to determine their interest in participating in a study designed to develop or test a 12-week smartphone app for increasing physical activity engagement among adults in early recovery from alcohol. Recruitment occurred in 2 phases: as part of an open pilot and then subsequently as part of a RCT. Data collected as part of the baseline assessment from each of these phases were examined in this paper.

Ethics Approval

The study was approved by the Institutional Review Board at Butler Hospital (IRB# 1604-003).

Measures

Demographic information was collected for race, age, ethnicity, gender, marital status, income, and education.

Media and Technology Usage and Attitudes (MTUA) Scale

The MTUA is a 50-item scale with 15 subscales. In this study, we administered 4 subscales: *Smartphone Usage*, *Positive Attitudes Toward Technology*, *Negative Attitudes Toward Technology*, and *Technological Anxiety/Dependence*. Each subscale has been shown to have strong validity and reliability [25]. The *Smartphone Usage* subscale consists of 7 items assessing the frequency, on a 10-point frequency, ranging from 1=never to 10=all of the time, of engaging in various smartphone activities (eg, texting, emailing, taking pictures). The other 3 subscales are measured based on a Likert-type scale, ranging from 1=strongly agree to 5=strongly disagree [25] and assess different attitudes toward technology: (1) *Positive Attitudes* subscale (an item is “I feel I get more accomplished because of technology”), (2) *Negative Attitudes* subscale (an item is “new technology makes life more complicated”), and (3) *Technological Anxiety/Dependence* subscale measures anxiety that resulted from individuals being away from their phone (an item is “I get anxious when I don’t have my phone with me”).

The Drug Use Frequency Scale

The Drug Use Frequency Scale is a self-report instrument consisting of 10 items that measure the frequency of use for different substances over the past 3 months [26]. Participants reported their frequency of alcohol use (and use of other substances) using a 7-point Likert-type scale ranging from 0=not all to 7=every day. A score of ≥ 5 indicates a high frequency of substance use [26].

Generalized Anxiety Disorder 7-item (GAD-7)

The GAD-7 scale consists of items that reflect the diagnostic symptom criteria for this disorder (eg, “feeling anxious, nervous, and on edge”) based on the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition [27]. Participants are asked to indicate how often in the last 2 weeks they were bothered by the different symptoms. Response options are 0=not at all to 3=nearly every day. Items 1-7 are summed to provide a total score [27].

The Center for Epidemiologic Studies Depression (CES-D) Scale

CES-D is a 20-item self-report measure that assesses the presence of depression symptoms experienced over the past week [28]. Each item is measured on a 4-point Likert-type scale that indicates the frequency of depression symptoms ranging from 0=rarely or none of the time to 3=most or all of the times. A sum of scores is calculated for this measure [28].

Statistical Methods

Overview

Frequencies for the following demographic characteristics were examined in the combined data set from the 2 trials (open pilot and RCT): race, marital status, age, gender, ethnicity, education, employment, and income. There were missing data for variables (eg, employment, education, and income) not collected in the open pilot study.

Sample Characteristics and Development of Subgroups

Sample size constraints for the variables race and marital status allowed for comparison between being White and non-White and married/living with a partner vs single/divorced/widowed. For age, a median split approach was used to create 2 age groups: ≥ 43 years and ≤ 44 years. Less than 1% of the sample reported an ethnic identity, and hence group comparisons were not feasible. Employment status was coded into 2 groups: employed vs unemployed/retired/disabled. For education, the groups were high school/some college versus college degree/advanced degrees. Annual income was reported by 39 participants and was coded into 2 categories: \leq US \$75,000 and \geq US \$75,000.

Preliminary Analyses

Chi-square tests were used to explore potential proportion difference among race, gender, age (independent variables), and marital status, education, employment, and annual income (dependent variables). A series of ANOVA models evaluated mean differences for the abovementioned 7 demographics and the 3 dependent variables, GAD-7, CES-D, and alcohol use.

Primary Analyses

ANOVA evaluated demographic differences for each of the 4 MTUA subscales. Separate linear regression analyses were used to explore a potential association between anxiety (GAD-7) and depression (CES-D), alcohol use (independent variables), and each of the MTUA subscales (dependent variables). In addition to statistical significance, partial eta-squared (η_p^2), R , or $R^2\beta$ values were used, as appropriate, to demonstrate the level of association between the independent variables and dependent measures [29,30].

Results

Sample Description

The majority of participants identified as White (56/70, 80%), others identified as non-White (14/70, 20%), and over half of the participants were men (36/62, 58%). Nearly half of the sample was aged ≤ 43 years (30/61, 49%), while 51% (31/61)

of participants were aged ≥ 44 years. Participant age range was 20-64 (mean 42.89, SD 10.9) years. Fifteen participants were married/living with a partner (15/40, 38%), and 25 (63%) were single/divorced/widowed. For education, 43% (17/40) of participants were in the high school/some college category, and 57% (23/40) were in the college degree/advanced degrees group. Moreover, 56% (27/48) of the sample was employed, and 12% (25/48) were unemployed/retired/disabled. Furthermore, 67% (24/39) of participants reported an annual income of \leq US \$75,000, while 39% reported an annual income of \geq US \$75,000. The distribution of alcohol use variables showed that 37%

(26/71) of the sample reported consuming alcohol for “5-6 days a week” over the past 3 months. A higher number of participants (33/71, 47%) reported consuming alcohol “every day” over the past 3 months.

There were no statistically significant differences for race, gender, age and marital status, education, employment, and annual income (Table 1).

Moreover, there were no statistically significant relationships between the demographics and the GAD-7, CES-D, and alcohol use variables (see Table 2).

Table 1. Statistics for the seven demographic subgroups.

	Race			Gender			Age		
	Chi-square (<i>df</i>)	Partici-pants, n	<i>P</i> value	Chi-square (<i>df</i>)	Partici-pants, n	<i>P</i> value	Chi-square (<i>df</i>)	Partici-pants, n	<i>P</i> value
Marital status	1.307 (1)	40	.74	0.365 (1)	39	.74	0.062 (1)	38	.54
Education	1.687 (1)	40	.37	0.843 (1)	39	.52	0.001 (1)	38	.62
Employment	0.036 (1)	40	.62	0.530 (1)	33	.47	0.516 (1)	38	.75
Annual income	0.399 (1)	39	.66	0.542 (1)	38	.51	0.016 (1)	37	.90

Table 2. Inferential statistics on the associations among demographics, generalized anxiety, depression, and alcohol use.

	GAD-7		CES-D		Alcohol use	
	<i>F</i> test (<i>df</i>)	<i>P</i> value	<i>F</i> test (<i>df</i>)	<i>P</i> value	<i>F</i> test (<i>df</i>)	<i>P</i> value
Race	0.480 (1,65)	.49	0.741 (1,61)	.74	0.003 (1,68)	.96
Gender	0.592 (1,56)	.45	0.417 (1,53)	.52	3.705 (1,60)	.06
Age	0.269 (1,55)	.78	0.796 (1,52)	.38	0.269 (1,59)	.61
Marital status	1.188 (1,36)	.28	0.617 (1,33)	.44	0.0001 (1,38)	>.99
Education	0.226 (1,36)	.64	2.075 (1,33)	.16	0.780 (1,38)	.38
Employment	1.969 (1,34)	.51	1.957 (1,34)	.17	1.696 (1,36)	.20
Annual income	0.447 (1,37)	.51	1.527 (1,32)	.23	0.510 (1,37)	.48

MTUA Subscales and Demographic Characteristics

Smartphone Usage Subscale

Smartphone usage scores were significantly different between the 2 age groups ($F_{1,69}=10.87$; $P=.002$; $\eta_p^2=0.14$). Participants

aged ≤ 43 years had a higher mean score on this measure (mean 29.46, SD 5.07) than those aged ≥ 44 years (mean 24.35, SD 7.67). There were no significant relationships for the subscale and the other demographic variables. Detailed information can be found in Table 3.

Table 3. Inferential statistics for the demographics, Media Technology Usage and Attitudes subscales, and clinical characteristics.

	<i>Smartphone Usage</i>		<i>Positive Attitude</i>		<i>Negative Attitude</i>		<i>Technological Anxiety/Dependence</i>	
	<i>F test (df)</i>	<i>P value</i>	<i>F test (df)</i>	<i>P value</i>	<i>F test (df)</i>	<i>P value</i>	<i>F test (df)</i>	<i>P value</i>
Demographics								
Race	0.911 (1,68)	.34	0.071 (1,68)	.79	0.190 (1,68)	.66	0.548 (1,67)	.46
Gender	2.353 (1,60)	.13	0.847 (1,60)	.36	0.058 (1,60)	.81	0.106 (1,60)	.75
Age	10.87 (1,69)	.002	4.819 (1,69)	.03	0.493 (1,68)	.49	0.788 (1,69)	.79
Marital status	0.374 (1,38)	.55	2.629 (1,38)	.11	0.352 (1,37)	.56	5.468 (1,38)	.03
Education	0.065 (1,38)	.80	3.368 (1,38)	.07	2.586 (1,37)	.12	1.084 (1,38)	.30
Employment	0.153 (1,46)	.70	6.196 (1,46)	.02	0.164 (1,45)	.69	1.257 (1,46)	.27
Annual income	0.403 (1,37)	.53	0.585 (1,37)	.45	0.583 (1,36)	.45	6.196 (1,37)	.02
Clinical characteristics								
Generalized Anxiety Disorder	2.194 (1,65)	.14	0.868 (1,65)	.36	0.331 (1,64)	.57	5.135 (1,65)	.03
Epidemiologic Studies Depression Scale	3.554 (1,62)	.06	2.194 (1,65)	.14	0.113 (1,62)	.74	9.024 (1,62)	.004
Alcohol use	0.525 (1,69)	.47	0.374 (1,69)	.54	0.046 (1,68)	.83	3.640 (1,69)	.06

Positive Attitudes Subscale

Positive attitudes toward technology were significantly different between the 2 age groups, ($F_{1,69}=4.819$; $P=.03$; $\eta_p^2=0.07$). Specifically, younger participants, aged ≤ 43 years, had a greater positive attitude toward technology (mean 22.75, SD 3.90) than those in the older age group, aged ≥ 44 years (mean 20.94, SD 2.63). As shown in Table 3, there were no significant relationships for this subscale and the other demographic variables.

Technological Anxiety/Dependence Subscale

Marital status was associated with *Technological Anxiety/Dependence* ($F_{1,38}=5.468$; $P=.03$; $\eta_p^2=0.13$). Participants who were married reported less anxiety when separated from their phone and less dependence on their device (mean 8.26, SD 3.43) compared to the single, divorced, widow group (mean 10.48, SD 2.54). In addition, differences in scores on the *Technological Anxiety/Dependence* subscale were also observed between the income groups ($F_{1,37}=6.196$; $P=.02$; $\eta_p^2=0.14$). Individuals with an annual income of \leq US \$75,000 had greater technological anxiety or dependence on their phone (mean 10.63, SD 2.28) versus those with an annual income of \geq US \$75,000 (mean 8.27, SD 3.65). There were no significant relationships between the 2 subscales and the other demographic variables (see Table 3).

MTUA Subscales and Anxiety and Depression Symptoms

Anxiety was a significant predictor of *Technological Anxiety/Dependence* scores ($F_{1,65}=5.135$; $P=.03$). The correlation coefficient ($R=0.27$) shows a positive linear relationship between the 2 variables. Anxiety symptoms accounted for 8% ($R^2=0.08$) of variance in *Technological Anxiety/Dependence* scores. A

significant β coefficient of .22 ($t=2.266$; $P=.03$), suggesting a one-unit increase of 0.22 in reported anxiety and dependency on technology for every 1-point increase in anxiety, as measured by the GAD-7 scale. Significant findings were not found between anxiety and *Smartphone Usage* ($F_{1,65}=2.194$; $P=.14$), *Positive Attitude* ($F_{1,65}=0.868$; $P=.36$), and *Negative Attitude* ($F_{1,64}=0.331$; $P=.57$).

Depressive symptoms were also a significant predictor of *Technological Anxiety/Dependence* subscale scores ($F_{1,62}=9.024$; $P=.004$). The correlation coefficient ($R=0.36$) shows a positive and linear relationship between the 2 variables. Depression symptoms account for 13% ($R^2=0.13$) of variance in the *Technological Anxiety/Dependence* measure. A significant β coefficient of .36 ($t=3.004$; $P=.004$) was noted, indicating for one-unit increase in depression, there is a .36 increase in technological anxiety/dependence. A near significant trend was noted between depression symptoms and *Positive Attitude* ($F_{1,62}=3.554$; $P=.06$). Results for the other subscales were as follows: *Smartphone Usage* ($F_{1,62}=1.316$; $P=.26$) and *Negative Attitude* ($F_{1,61}=0.113$; $P=.74$).

MTUA Subscales and Alcohol Use

Frequency of alcohol use in the past 3 months and reported anxiety when being away from one's mobile phone or being dependent on this device showed a near significant trend ($F_{1,69}=3.640$; $P=.06$; $R^2=0.02$). Results for the other subscales were as follows: *Smartphone Usage* ($F_{1,69}=0.525$, $P=.47$), *Positive Attitudes* ($F_{1,69}=0.612$, $P=.54$), and *Negative Attitudes* ($F_{1,68}=0.046$, $P=.83$).

Discussion

Principal Findings

This study provides an examination of mobile phone use behavioral patterns and attitudes toward technology among a sample of adults with alcohol use disorder (AUD) in early recovery. Demographics, anxiety and depressive symptoms, and alcohol use were associated with smartphone usage and attitudes toward technology. These results may provide insights into the development of mobile phone delivered intervention (mHealth) approaches for individuals with AUD.

Relative to older patients with AUD, those aged ≤ 43 years reported higher rates of smartphone usage and were more likely to have positive attitudes about media use. Specifically, younger patients had greater reliance on their mobile phone to complete various tasks, such as using apps, searching for directions, and browsing the web and reported a more positive view of these activities. These results are consistent with previous studies demonstrating a strong association between being a younger age and greater reliance on this device to complete many daily tasks—aided by easy access to the internet—compared to older adults [21,22]. High usage of mobile apps has been shown to be associated with perceived importance in facilitating the accomplishment of targeted goals using these platforms [21,22].

Therefore, this younger subgroup of patients may be very receptive to using a smartphone app to help during early recovery, and mHealth strategies consistent with how this group uses their phone are likely to be more acceptable and engaging. For example, a mobile phone app with a “resource” feature on AUD may provide a menu of information on the psychophysiological impact of this disorder, effective treatments, including strategies for managing risks for relapse, such as environmental triggers, depression, anxiety, and cravings [1,2,4]. Given existing barriers to treatment and the impact of chronic alcohol use on long-term memory and cognitive functioning [6], ready access to this information in moments of greatest need (eg, high-risk situations) may be critical toward improving alcohol treatment outcomes.

Our findings also demonstrated that single/divorced/widowed participants indicated greater anxiety without their phone or feeling more dependent on this device than those who were married/living with a partner. A previous study assessing mobile phone use behaviors among a nonclinical population has shown overall similar results [21]. It is possible that individuals with AUD who do not live with a partner are more likely to rely on their phone to remain connected with family members or friends. Therefore, when developing technology-supported approaches for individuals with AUD not living with partners, app features that allow participants to easily connect with others may be desirable. For example, apps that contain message boards that allow communication between users or being able to use certain *keywords* (eg, “struggling”) to immediately connect with a clinician to receive additional support to address emerging barriers or experiences could be an attractive app feature in this subgroup individuals.

Moreover, participants with an annual income of \leq US \$75,000 also showed higher anxiety without their phone or were more dependent on their device. A Pew Research Center report on mobile phone usage and annual income conducted between 2013 and 2021 showed individuals of this income bracket as being more smartphone-dependent than their higher-income counterparts [13]. While it is not clear what contributes to the difference in dependency on smartphones between income groups, this report found individuals of this income level are more likely to be “smartphone only internet users” and less likely to own other devices (eg, a computer or iPad) [13]. It is possible that lower financial resources indicate greater increased reliance to on this device to complete many and different tasks. Moreover, AUD is more prevalent among socioeconomically disadvantaged groups than those of a higher income level [31,32]. This intersection has been associated with a higher prevalence of many chronic conditions, such as liver disease, type 2 diabetes, hypertension, and some cancers, compared to the general population [2,33,34]. The current evidence shows that low-income adults with AUD are significantly dependent on their mobile phone and thus suggests the potential acceptability of mHealth programs among this subgroup. Accordingly, researchers have the opportunity to deliver both clinical and behavioral health intervention approaches that address cognitions and behaviors salient in increasing sobriety and thereby decreasing associated health risks among this group. For example, engagement in physical activity or yoga has shown to be beneficial as an adjunctive tool in treatments for AUD [35-37]; however, these interventions are small and are typically delivered in person and over many months. Accordingly, mHealth approaches have the potential to reach a large section of this group and promote sobriety on a large scale.

Lastly, the study findings showed that anxiety and depression symptoms were significant predictors of *Technological Anxiety/Dependence* scores, although they accounted for minimal variance ($R^2=0.08$ and 0.13 , respectively). Nevertheless, anxiety and depression symptoms are highly prevalent among individuals with AUD, and mobile phone app programs that would allow participants to track their symptoms may provide insights into trends associated, such as the relationship between anxiety or depression symptoms and alcohol cravings. Additionally, an app feature that could enable participants to share this type of information with their provider could help inform treatment decisions. However, more research is necessary to determine whether media anxiety and phone dependency may, in fact, be contributing toward an increase in anxiety and depression symptoms in this population.

Limitations and Future Work

An important limitation of this study is the lack of heterogeneity with respect to participant ethnicity, preventing an assessment of a potential relationship between a particular ethnic group and mobile phone or media constructs. For example, Latinx populations have increased incidence rates of AUD that may be linked to minority stress and socioeconomic status [31, 32]. Assessment of mobile use behaviors among Latinx adults with AUD is an important research area to determine the potential receptiveness of mHealth substance abuse treatment approaches

in this group. Accordingly, more research is needed to extend the current understanding of the nature or frequency of mobile phone usage and views of this technology across different demographic subgroups with AUD. In addition, participants enrolled in this study were interested in using a smartphone app to help them increase their physical activity in early recovery. It is possible that the results of this study may not generalize to the broader AUD patient population. Moreover, future studies with a larger sample size with AUD is needed to assess these relationships. Despite these limitations, the findings may help inform future mHealth approaches that can be used to augment addiction treatment in individuals with AUD. Aligned with the goals of precision medicine, mHealth approaches that are

tailored to specific individuals needs and characteristics may be more effective in improving overall treatment outcomes.

Conclusions

Notwithstanding these limitations, the study findings provide insight into the relationship between age, marital status, income, depression, and anxiety on empirical constructs for mobile phone use behaviors in adults with AUD. Moreover, the study results provide knowledge into mHealth approaches that are likely to appeal to the needs of different demographic adult subgroups with AUD. Our findings accentuate the need to fully understand individuals' mobile phone use and attitudes toward technology to evaluate their potential influence on the level of engagement with mHealth interventions in different adult groups with AUD.

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Conflicts of Interest

None declared.

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Abbreviations

AUD: alcohol use disorder
CES-D: Epidemiologic Studies Depression Scale
GAD-7: Generalized Anxiety Disorder 7-item
mHealth: mobile health
MTUA: Media Technology Usage and Attitudes
RCT: randomized controlled trial

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Original Paper

Feasibility of Conducting Long-term Health and Behaviors Follow-up in Adolescents: Longitudinal Observational Study

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Abstract

Background: Machine learning uses algorithms that improve automatically through experience. This statistical learning approach is a natural extension of traditional statistical methods and can offer potential advantages for certain problems. The feasibility of using machine learning techniques in health care is predicated on access to a sufficient volume of data in a problem space.

Objective: This study aimed to assess the feasibility of data collection from an adolescent population before and after a posterior spine fusion operation.

Methods: Both physical and psychosocial data were collected. Adolescents scheduled for a posterior spine fusion operation were approached when they were scheduled for the surgery. The study collected repeated measures of patient data, including at least 2 weeks prior to the operation and 6 months after the patients were discharged from the hospital. Patients were provided with a Fitbit Charge 4 (consumer-grade health tracker) and instructed to wear it as often as possible. A third-party web-based portal was used to collect and store the Fitbit data, and patients were trained on how to download and sync their personal device data on step counts, sleep time, and heart rate onto the web-based portal. Demographic and physiologic data recorded in the electronic medical record were retrieved from the hospital data warehouse. We evaluated changes in the patients' psychological profile over time using several validated questionnaires (ie, Pain Catastrophizing Scale, Patient Health Questionnaire, Generalized Anxiety Disorder Scale, and Pediatric Quality of Life Inventory). Questionnaires were administered to patients using Qualtrics software. Patients received the questionnaire prior to and during the hospitalization and again at 3 and 6 months postsurgery. We administered paper-based questionnaires for the self-report of daily pain scores and the use of analgesic medications.

Results: There were several challenges to data collection from the study population. Only 38% (32/84) of the patients we approached met eligibility criteria, and 50% (16/32) of the enrolled patients dropped out during the follow-up period—on average 17.6 weeks into the study. Of those who completed the study, 69% (9/13) reliably wore the Fitbit and downloaded data into the web-based portal. These patients also had a high response rate to the psychosocial surveys. However, none of the patients who finished the study completed the paper-based pain diary. There were no difficulties accessing the demographic and clinical data stored in the hospital data warehouse.

Conclusions: This study identifies several challenges to long-term medical follow-up in adolescents, including willingness to participate in these types of studies and compliance with the various data collection approaches. Several of these challenges—insufficient incentives and personal contact between researchers and patients—should be addressed in future studies.

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KEYWORDS

Fitbit; wearables; health tracker; survey; adolescents; psychosocial; long term; follow-up; feasibility; artificial intelligence; machine learning; posterior spine fusion; operation; surgery

Introduction

Physicians and public health workers are often asked to make predictions on patient health outcomes after specific medical and surgical treatments. Over the years, many medical specialties have created prediction models to identify treatments that optimize patient health outcomes [1,2]. In general, these systems are based on traditional logistic regression models that use a limited set of clinical and physiological variables.

Machine learning (ML) uses statistical learning to uncover complex nonlinear relationships among data. ML identifies patterns from big data sets and, subsequently, enables researchers to predict outcomes [3]. Discovering nonlinearities in the data is how ML techniques such as neural networks can complement traditional statistical methods for analyzing complex medical problems, such as presurgical, intrasurgical, and postsurgical outcomes [4].

Recent advances in wearable technology, as well as improvements in data mining capability, have allowed physicians to gain access to a wide variety of patients' physiologic, behavioral, and psychological data that can be used to build ML models [5,6]. Wearable technology enables the repeated or continuous digital measurement of different types of parameters. Typically, the real-time measurement of the 4 basic vital signs (ie, temperature, heart rate, respiration rate, and blood pressure) is limited to a single event over several months, most often during a visit to a primary care physician. Wearables enable the longitudinal measurement of these and other parameters with high precision [7]. Similarly, wearables can provide approximate information about sleep patterns, differentiating wake from sleep [8], as well as accurately measuring step count and activity duration [9].

There are few studies evaluating the feasibility of the various data collection methods in this context. There are still substantial barriers to the widespread use of wearable technology and web-based surveys in clinical research among adolescents. Although most of the technological barriers have been addressed in the last decade, patients' compliance with wearing the tracking devices as well as patients' fatigue from repeated communications with the care team are still major challenges. Reports from commercial studies indicate that 50% of new users of wearables and 74% of new users of health apps stop using them within 2 weeks [10]. Patient participation is often related to the extent of how they feel the clinical study they initially agree to participate in can actually meet their needs, fulfill their expectations, and align with their goals [11,12]. In general, patient attitude is often tied to perceived usefulness in long-term studies [13].

Given these considerations, this study evaluated the feasibility of monitoring health parameters in adolescents prior, during, and 6 months after a posterior spine fusion (PSF) operation. We assessed patients' adherence with wearing a health tracking device, answering web-based surveys, and filling out paper surveys. We also evaluated the feasibility of data extraction from the hospital data warehouse and the aggregating of the extracted data with data from the original electronic medical record (EMR).

Methods

Recruitment and Study Population

Patients were approached at the time of their evaluation in the orthopedic surgeons' office once they had been scheduled for a PSF operation and evaluated to determine whether they met the inclusion criteria, which included the following.

- Patients with idiopathic scoliosis scheduled for PSF surgery at Johns Hopkins All Children's Hospital
- Patients of both sexes, aged 12 to 19 years
- Participants, parents, or legal guardians with reliable Wi-Fi or a cellular internet access data plan
- Participants, parents, or legal guardians with a compatible Bluetooth smartphone or home computer
- Completion of written informed consent by participants, their parents, or legal guardians
- Participants and parents were able to understand the instructions to upload data

Once the consent to participate in the study was obtained, we distributed a Fitbit device with the corresponding instructions on its use and downloaded the information onto a secure website for subsequent data analysis.

Data Sources and Study Variables

Data were collected from the following sources: (1) wearable devices (Fitbit Charge 4), (2) hospital data warehouse, (3) electronic surveys, and (4) paper pain diaries.

Adherence

We defined adherence to the protocol as patients who answered at least 75% of the Qualtrics surveys and wore the tracking device at least 75% of the time.

Fitbit Data

Patients received a Fitbit Charge 4 (Fitbit) at the time of enrollment. The Fitbit Charge 4 is a lightweight, noninvasive wearable tracking device that reports daily step count, vigorous activity minutes, heart rate, and sleep patterns to the user's smartphone or computer. The study team asked the patients to sync the device on a daily basis. We created personal Fitbit accounts linked to Fitabase (Small Steps Labs), a Health Insurance Portability and Accountability Act-compliant, encrypted, and password-protected portal that aggregates data from the Fitbit server for easier extraction. We collected the following data from Fitabase: daily steps, time spent asleep (minutes/day), and heart rate (beats/minute). Data captured by the Fitbit were synced to the patient's personal device using the Fitbit app and subsequently stored on the central cloud-based Fitbit cloud services. The Fitabase portal extracted the patient-level data from the Fitbit cloud services.

GPS function was disabled by default by the study coordinators, and study participants were advised not to alter this functionality on their device or smartphone app.

EMR Data

A variety of demographic and physiologic data are stored in the EMR. Johns Hopkins All Children's Hospital has built a

physiologic data warehouse that stores inpatient physiologic data in a long-term storage solution. The system comprises data captured from operating rooms and specific patient care areas throughout the hospital. For the purpose of this study, we retrieved age, sex, medications, and pain scores. Once data were extracted from the hospital data warehouse, they were stored in a REDCap research database (REDCap Consortium). Data were collected before, during, and for 6 months after the PSF operation.

Psychosocial Data

To identify psychosocial difficulties or barriers to recovery from surgery, psychosocial surveys were administered to patients via the QualtricsXM web-based software platform (SAP America Inc) before, during, and 3 and 6 months post-PSF surgery. We used the following validated surveys: Pain Catastrophizing Scale [12], Patient Health Questionnaire [13], Generalized Anxiety Disorder Scale [14], and Pediatric Quality of Life Inventory [15]. The survey data were collected and stored using REDCap.

Pain Diary Data

Patients completed a daily paper diary documenting pain levels and analgesic medications. These data were manually inputted and stored in REDCap.

Statistical Analysis

Continuous variables were summarized with means, SDs, and ranges (minimum to maximum), and categorical variables were summarized with counts and percentages. Statistical comparisons between compliant and noncompliant groups were evaluated with 2-tailed *t* tests for independent samples, and 2-sided *P* values <.05 were considered statistically significant. Statistical analyses were performed using the *Pandas* and *NumPy* Python packages (Python Software Foundation).

Ethics Approval

This study was reviewed and approved by the Johns Hopkins All Children's Hospital Institutional Review Board (IRB00211758). Written consent was obtained from the parents and study participants.

Results

In total, 2 orthopedic surgeons evaluated 108 patients with a diagnosis of idiopathic scoliosis between October 2020 and September 2021. Of the 108 patients scheduled for a PSF surgery, 84 (77.7%) were approached. Of the 84 patients approached, 32 (38%) were enrolled in the study. The reasons why we were not able to enroll the other patients approached are listed in [Table 1](#).

[Table 1](#) lists the reasons why 62% (52/84) of the patients who were approached were not enrolled in the study. Of the 52

patients not enrolled, 25% (n=13) did not meet the inclusion criteria. In 46% (n=24) of the patients, we were not able to reach out on time to enroll them or there was not sufficient time to establish at least 2 weeks of baseline values prior to the scheduled surgery because of staffing limitations.

At the time of writing, of the 32 enrolled patients, 13 (41%) have completed the 6-month follow-up period, and 3 (9%) are still in the process of completing the follow-up. The remaining 16 (50%) patients dropped out during the follow-up period and did not complete the study. [Table 2](#) lists the reasons why patients did not complete the 6-month study period. Patients dropped out of the study on average 17.6 (SD 7.2; range 6-31) weeks from the day of surgery ([Table 3](#)). Of the 16 patients who dropped out of the study, the average age was 14 (SD 1.3; range 12-17) years, and there were 10 (62%) girls and 6 (38%) boys. Of the 16 patients who completed the study, there were 11 (69%) girls and 5 (31%) boys, and the average age was 14.8 (SD 1.9; range 13-18) years. There was no statistical difference between the 2 groups (*P*=.80) with respect to age and sex distribution. We defined noncompliant patients as those who did not complete the Qualtrics survey at least 75% of the time.

Of the 32 enrolled patients, 12 (38%) were considered noncompliant because they failed to complete the Qualtrics survey at least 75% of the time. However, 1 of them completed the Fitbit portion of the study. The remaining 11 patients stopped synchronizing the device within 1 to 5 months after the surgery.

Of the 13 patients who completed the follow-up, 12 (92%) patients were consistent in wearing the Fitbit at least 75% of the time during the day ([Table 4](#)). Their adherence was constant over the 6-month study. Additionally, 11 (85%) patients were also compliant in wearing the Fitbit at least 75% of the time at night for the duration of the study ([Table 4](#)).

Of the 13 patients who completed the follow-up, 9 (69%) completed the Qualtrics questionnaires throughout the entire study, and only 4 (31%) completed the Qualtrics questionnaires at least 75% of the time over the study period ([Table 5](#)).

The follow-up involved paper-based surveys to assess pain scores and the use of analgesic medications. None of the 13 patients who have completed the study were compliant with completing the pain paper diary during the study period.

We were able to retrieve the pain scores from the hospital data warehouse. These data were manually matched with those recorded in the patients' EMR, and no discrepancies were found between the 2 databases. We collected additional demographic and clinical data, including the daily morphine equivalent doses of opioids administered and amount of blood transfusions (data not shown).

Table 1. Reasons why patients were not enrolled in the study.

Reason	Patient (N=84), n (%)	Detail
Not meeting inclusion criteria	13 (15)	Either above or below study age limits
Unable to operate Fitbit	5 (6)	Mental delay or Spanish-speaking only
Eligible for the study but denied participation	10 (12)	N/A ^a
Researchers missed enrollment encounter	19 (23)	Limited staffing
Not sufficient time to obtain baseline values	5 (6)	Changes in surgery scheduling

^aN/A: not applicable.

Table 2. Reasons why patients dropped out of the study once they were enrolled.

Reason	Patient (N=32), n (%)
Completed study	13 (41)
Still enrolled	3 (9)
Parents asked to stop	2 (6)
Lost Fitbit	2 (6)
Noncompliant	12 (38)

Table 3. Duration of patients' participation in the study before dropping out prior to the 6-month (26 weeks) follow-up. There was 1 patient who never started the study even though she signed the written consent form.

Patient number	Study participation (week), n
1	9
2	21
3	26
4	31
5	11
6	10
7	14
8	6
9	24
10	23
11	26
12	19
13	16
14	15
15	12
16	18

Table 4. Patients' adherence with wearing Fitbit devices during the day and night. Data reflect the percent of time patients wore the Fitbit during the first and second study periods (1-3 and 4-6 months, respectively).

Study period, percentage of time wearing the Fitbit	During the day (N=13), n (%)	During the night (N=13), n (%)
1-3 months		
100%	11 (85)	5 (38)
75%	1 (8)	6 (46)
50%	1 (8)	2 (15)
25%	0 (0)	0 (0)
4-6 months		
100%	7 (54)	6 (46)
75%	5 (38)	5 (38)
50%	1 (8)	1 (8)
25%	0 (0)	1 (8)

Table 5. Number of patients who responded to the Qualtrics surveys over the study period.

Percentage response to Qualtrics surveys	Patient (N=13), n (%)
100%	9 (69)
75%	4 (31)
50%	0 (0)
25%	0 (0)

Discussion

Principal Findings

The goal of this study was to assess whether it is possible to collect meaningful and reliable clinical data over extended periods of time from adolescents who needed a surgical procedure using different techniques. This was the preliminary phase of a project that will use ML to predict outcomes after complex surgical procedures in children and adolescents.

This study showed that it is possible to conduct long-term health outcome assessment in adolescents using tracking devices and web-based apps that allow repeated surveys of populations. The study confirmed that there are multiple obstacles to conducting and completing this type of study. The willingness of adolescents and parents to participate and complete the surveys are major limiting factors. It was not surprising to find that adolescents were more compliant with completing electronic surveys than paper surveys.

Comparisons With Prior Work

There are few data on children and adolescents' willingness to participate in clinical trials as well as their use of tracking devices and electronic surveys.

We faced several challenges when conducting this study. We encountered problems enrolling patients in the study. Once patients were enrolled, there was a relative high number of dropouts. Only 38% of the patients we contacted agreed to be enrolled in the study, and once enrolled, only 50% of them completed the study.

Adult studies have shown that provider and patient factors are common barriers to patients' enrollment in clinical studies. A lack of time and resources often prevent physicians from being involved in patients' enrollment [14,15]. The presence of a strong, trusting relationship between physicians and patients is often a determining factor in patients and parents' willingness to participate in a study [16]. The fear of experimentation and medical mistrust are common barriers to participation in clinical studies [17,18]. Privacy concerns may have also played a role in parents' decision not to participate in the study. Our low number of enrolled patients might be attributed to the lack of direct contact between the principal investigator and patients, as patients were contacted by research personnel who were not directly involved in the patients' care. Similarly, the lack of personal contact between the researchers and patients may have influenced the large number of dropouts.

The feasibility of using ML techniques is predicated on the access to patients' data and building reliable data sets. We collected data prior, during, and after the hospital stay of adolescents who underwent a PSF operation. We used paper-based surveys, electronic surveys, wireless-enabled wearable technology, and hospital-based data warehouse to collect patients' data. The goal was to acquire a broad set of data, including numerical, categorical, time-series, and text data.

Peer-reviewed research on the use of Fitbit devices found that the device is reliable for tracking daily activity in healthy young adults [19]. Barriers to wearing tracking devices have been reported in the literature. Many of the issues reported in early studies have been addressed by the manufacturer as new devices are now waterproof and new batteries provide long intervals between recharges. With respect to monitoring sleep, devices

such as Fitbits are not a substitute of polysomnography. However, there is consensus among researchers that devices such as Fitbit can provide gross estimates of time spent sleeping [8]. It is still controversial whether they can offer an accurate reading of the sleep stages [20]. The new generation Fitbits can provide a much wider set of information.

We were able to retrieve the number of steps and the number of minutes the patients spent sleeping from the Fitabase.

It was interesting to notice that the patients who remained in the study for 6 months were also very compliant with wearing the Fitbit. The patients who were not compliant with answering the Qualtrics surveys were also not compliant with wearing the Fitbit, with the exception of 1 patient. This seems to indicate that they dropped out because of a general lack of interest in continuing with the study and not because of the specific burden of complying with either the Qualtrics survey or wearing the Fitbit.

A potential draw back on the long-term use of these tracking devices is the novelty factor, with waning interest in wearing these devices after a couple of weeks [21,22]. Our overall patients' adherence with constantly wearing the Fitbit was similar to their adherence with answering the Qualtrics surveys. Further analysis and possibly creating focus groups will help the understanding of these differences in adolescents' behaviors.

The widespread introduction of EMRs has allowed clinician, administrators, and researchers to have rapid access to a wealth of patients' demographic and clinical data. EMR data can be transferred into clinical and research registers independently from registry purposes. We were able to collect data we consider to be relevant in this pilot feasibility study. There are challenges to this methodology, with the main concern being the accuracy of the data inputted into the EMR and registries. Authors have suggested creating some form of data curation to review and assess data quality. For the purpose of this study, we collected demographic and numerical data while the patients were hospitalized, with the majority of the data automatically recorded by hospital monitor devices. The only self-reported data were the pain scores, where nurses used a numeric scale to document

the patients' pain levels during the hospital stay [23]. We confirmed the accuracy of the process by manually verifying the EMR with the data extrapolated from the hospital warehouse.

It was not surprising to observe a low adherence to filling out the follow-up paper diary documenting the patients' pain level and use of analgesic medications. Recent surveys have shown that approximately 75% of adolescents own a smartphone [24]. The same survey highlighted how teenagers prefer texting to talking to their peers. In addition, there is also some evidence that adolescents prefer electronic books to paper books [25]. These findings may explain why our patients were compliant with answering electronic surveys but did not complete the paper surveys. Additionally, a very demanding schedule where patients were asked to report daily pain scores and medications used for 6 months may have caused survey fatigue.

Limitations

There are a few limitations to this study. The relatively low percentage of patients willing to participate and then comply with the study requirements may have introduced a selection bias. The lack of data on pain levels throughout the study has resulted in the inability to make correlations between pain levels and behaviors.

Conclusions

This preliminary study showed that it is possible to conduct long-term studies and evaluate the different aspects of adolescents' behaviors and outcomes of health interventions using wearable devices and web-based surveys. These technologies may substantially lower the cost of conducting this type of research.

This study confirmed that there are barriers to engaging relatively healthy adolescents and keeping them interested in participating in this type of long-term study.

Further studies are needed to identify better ways of informing patients and their families of the relevance of these long-term studies. Researchers should also design strict reminder schedules including periodic texts, phone calls, and emails and consider rewards to keep patients engaged in these long-term surveys.

Conflicts of Interest

None declared.

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Abbreviations

- EMR:** electronic medical record
ML: machine learning

PSF: posterior spine fusion

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Original Paper

Predictors of the Acceptance of an Electronic Coach Targeting Self-management of Patients With Type 2 Diabetes: Web-Based Survey

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Abstract

Background: Type 2 diabetes (T2D) is a lifestyle-related disease whose prevalence increases with age. Diabetes self-management through mobile health (mHealth) apps enables patients with T2D to improve their health. According to the Technology Acceptance Model (TAM), technology acceptance (ie, intended use) is necessary to ensure mHealth can be implemented successfully. Therefore, the specific acceptance requirements of patients with T2D should be considered.

Objective: This cross-sectional study aims to examine the extent to which different TAM predictors are associated with the acceptance of a diabetes app including an electronic coach (eCoach; Iris app) among patients with T2D.

Methods: Using a web-based survey, data on 92 patients with T2D (mean age 62.76 years, SD 8.29 years) were collected. Acceptance of the Iris app with the TAM predictors (ie, perceived usefulness, perceived ease of use, social influence, perceived self-efficacy, perceived security, prior usage experience, perceived health, and propensity of data/information sharing) was assessed. Further, control variables (ie, gender, age, education, ethnicity, household, BMI, amount of years with diabetes, diabetes-related complaints, and medication use) were assessed.

Results: Multiple linear regression analyses showed that acceptance of the Iris app was positively associated with perceived usefulness ($\beta=.57, P<.001$), social influence (subjective norm; $\beta=.20, P=.004$), and willingness to share data ($\beta=.25, P<.001$). In addition, acceptance regarding the Iris app was higher among patients with T2D with overweight ($\beta=.23, P=.01$) or obese BMI ($\beta=.21, P=.01$). The model explained 75.8% of the variance in the acceptance of the Iris app by patients with T2D. In addition, perceived usefulness of the Iris app was positively related to perceived ease of use ($\beta=.32, P<.001$), subjective norm ($\beta=.26, P=.004$), perceived control ($\beta=.19, P=.03$), willingness to share data ($\beta=.20, P=.01$) regarding the Iris app, and perceived security regarding general use of apps/smartphone/internet ($\beta=.15, P=.04$). The model explained 58.2% of the variance in patients' perceived usefulness about the Iris app.

Conclusions: Among patients with T2D, the belief that the use of the Iris app is helpful/beneficial, the willingness to share their Iris app data, and others' approval of using this app can stimulate the acceptance of this app. In addition, the belief that the use of (health) apps is reliable and secure, the belief that the use of the Iris app is easy to use, a higher perceived capability and personal control with using this app, the willingness to share their Iris app data, and others' approval of using this app can stimulate the perceived usefulness of such an app. These TAM predictors explained a high variance in acceptance and perceived usefulness of the Iris app. Implications for practice are addressed.

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KEYWORDS

mobile health; type 2 diabetes; self-management; eCoach; Technology Acceptance Model

Introduction

Background

Type 2 diabetes (T2D) is a global public health problem leading to increased mortality and morbidity risk. Furthermore, T2D can affect patients socially and economically [1]. The prevalence of this chronic disease is high and still increasing [2,3]; in particular, people older than 50 years are at an increased risk [4-6]. In addition, T2D prevalence is higher among people with low socioeconomic status (SES) [7]. Empirical evidence indicates that a healthier lifestyle (eg, eating healthy and more physical activity) and monitoring blood glucose levels may improve the health status of patients with T2D and reduce health complications of diabetes [5,8]. For societal, economic, and ethical reasons, increasing demands are made on individuals to self-manage their own health and to maintain a healthy lifestyle. Patients with T2D are supposed to take control over their life and health, and diabetes self-management is therefore crucial [9].

For patients with T2D, mobile health (mHealth) apps can be a valuable tool to support self-management [9,10]. In general, the advantages of mHealth apps include a wide reach of people, and tailored and timely health information, education, and support [11]. Regarding T2D, many apps have been developed over the past years, which focus on supporting self-management and education of patients with T2D to promote a healthy lifestyle and health [4,11,12]. However, the elements of these apps vary, and may include insulin management applications, wearable blood glucose meters, automated SMS text messages, health diaries, and virtual health coaching [11]. The meta-analysis of Greenwood et al [9] showed that apps including components of 2-way communication, personalized data, and tailored education and feedback contributed most to an improved HbA1c (also referred to as glycohemoglobin or hemoglobin A1c, an indicator of adequate diabetes management). Previous empirical studies showed that the usability and efficacy of these T2D apps vary to a great extent [13]. Technology acceptance is crucial to ensure mHealth, such as these T2D apps, can be implemented as planned, and thus understanding the requirements for this acceptance is very important. The few empirical studies that examined the predictors of patients' acceptance of diabetes management showed that predictors based on extended versions of the Technology Acceptance Model (TAM; [14]) explained a high variance (around 60%) in patient's intention to use diabetes management apps, which is a proxy for acceptance [15]. To anticipate the development of the Iris (T2D) app, which is intended as an electronic coach (eCoach) to support self-management of patients with T2D, the aim of this study is to determine which predictors are associated with acceptance of this specific app (for a description of the Iris app, see the "Methods" section).

Prior Research

The TAM [14] is one of the most prevailing, dominant theoretical models that has been frequently applied to predict

consumer acceptance of health technology such as mHealth [16]. The TAM is based on social-cognitive models such as the Theory of Planned Behavior [17,18], Diffusion of Innovations Theory [19], and Social Cognitive Theory [20]. According to the original TAM, behavior (in this case, using the Iris app) is determined by behavioral intention, which is a proxy for acceptance. Furthermore, the following 2 major cognitive predictors, perceived usefulness and perceived ease of use, directly predict acceptance of health technology such as the Iris app. Perceived usefulness refers to an individual's belief that the use of this technology is helpful/beneficial, whereas perceived ease of use refers to an individual's belief that this technology is easy to use [14,16].

In the course of the years, the original TAM has been modified by extending it with additional predictors. Several extended TAM models have been proposed. For example, the Unified Theory of Acceptance and Use of Technology (UTAUT; [21,22]) included social influence (ie, subjective norms) as another important cognitive factor that predicts acceptance of health technology. Subjective norms refer to an individual's belief of how other people, especially the people whom they trust and resort to, will evaluate them when using the technology [21]. In addition, Cialdini [23] has emphasized the importance of social norms and made a distinction between injunctive norms (ie, an individual's belief of what most other people approve of) and descriptive norms (ie, an individual's belief of what most other people typically do). Thus, social influence in the TAM can refer to injunctive and descriptive social norms, where subjective norms are a person's perception of injunctive norms of relevant other persons [24]. The UTAUT [21], Senior Technology Acceptance Model (STAM; [25]), and an extension of the TAM by Fathema et al [26] included perceived self-efficacy/behavioral control as a cognitive factor predicting perceived usefulness, perceived ease of use, and acceptance. Perceived self-efficacy/control refers to an individual's belief to successfully handle technology and personal control over technology [26]. Other examples of extended versions of the TAM included perceived security and trust (ie, the extent to which a user believes that a particular service is secure), prior usage experience with mobile phones and eHealth, perceived health (ie, self-management of diabetes), and willingness to share data (ie, willingness to share personal information/data; eg, [16,21,25,27-40]). Although several predictors have been proposed according to (extended) TAM models, only a few empirical studies examined TAM predictors of diabetes management apps and showed support for these predictors [15]. Nevertheless, empirical studies that tested the TAM predictors regarding acceptance of T2D eCoaching apps, specifically, are lacking. Previous studies focused predominantly on the usability and efficacy of T2D apps [13] or used a qualitative approach to examine the acceptance of diabetes apps (eg, [41]).

Study Objective

The aim of this study was to examine the predictors associated with the acceptance of the Iris app for patients with T2D. According to (extended) TAM models, we hypothesize that the

following predictors are positively associated with acceptance of the Iris app: perceived usefulness, perceived ease of use, social influence (ie, descriptive and subjective social norms), perceived self-efficacy/behavioral control, perceived security, prior usage experience, perceived health, and willingness to share data. In line with others (eg, [21,24]), we included the following control variables: sociodemographic factors (ie, gender, age, education, ethnicity, household) and health-related factors (ie, BMI, amount of years with diabetes, diabetes-related complaints, and medication use).

Methods

Participants

Participants provided informed consent prior to completing the 20-minute survey. Inclusion criterion was men and women with T2D who had a smartphone that they used regularly. We used convenience sampling. Recruitment took place from July to November 2018 through an advertisement on the website of the Dutch Diabetes Association [42], through flyers handed out at the National Diabetes Challenge festival in Amsterdam (September 2018), and through a Facebook advertisement in November 2018. The online survey was an “open survey” that was voluntary and accessible for individuals who received, through these advertisements and flyers, the link to the study information and survey online. In total, 97 participants filled out the online survey. The individuals who provided digital informed consent filled in all items on the questionnaire. Thus, the participation rate equaled the completion rate. As a reward, participants received an online web shop voucher of €10 (US \$10.43).

Procedure

The recruitment materials included a link that referred interested individuals to the study information online (including information about the duration of the survey, incentive, data storage, the research team, and the purpose of the study) and a subsequent consent page. Following digital consent, participants could continue to fill in the survey. The 20-minute survey consisted of questions regarding their experience with (diabetes) apps and their willingness to share health information with others. Privacy and anonymity of the participants were guaranteed.

The Anticipated App Iris

The Iris app is a dynamically tailored intervention that provides personalized diet and physical activity advice, as well as behavioral support. Users start with intake: First, users fill out health data (eg, BMI, medication usage, HbA1c). Second, users can decide whether they are willing to work on a physical activity or diet goal. To provide personalized dietary advice, users are asked to rate from different food products (eg, fruits, vegetables, sugar-sweetened beverages) their average intake per week (quantity per day and number of days per week). Similarly, when users select a physical activity goal, they are

asked to rate their activities on a general week (physical activity toward work, at work, around the house, leisure time, and sports). Based on the health data, users are provided with a recommended diet (Mediterranean, low carbohydrate, or low caloric diet). Based on the dietary intake or physical activity data, users are provided with feedback on what food categories or physical activities are compliant with the recommended intake, and which categories could be improved. Next, users can self-set a specific daily or weekly goal (eg, eating 2 pieces of fruit for 3 days).

When a goal is set, a user will be asked to daily assess whether they have reached their goal, and assess their goal motivation, goal competence, and mood (each on a 3-point scale: negative, neutral, or positive). The app includes a monitoring page, where people can monitor the number of times they reached their goal for 7 days. In addition, based on whether a goal was (partly) reached or not, each week a user is provided with (positive) feedback on their performance. Furthermore, based on the daily diary data, the most important barriers for not reaching a goal are assessed (motivation, competence, planning, or mood), and a tailored intervention is recommended to overcome the barrier, based on an effective behavior change technique.

Measurements

The majority of the measurements were self-constructed and based on theoretical reasoning (original and modified versions of the TAM), empirical studies (eg, [16]), and the results of the 3 focus group interviews we conducted regarding the barriers and facilitators to use the Iris app (n=23 patients with diabetes). The outcome variable was technology acceptance. Predictors of technology acceptance included perceived usefulness, perceived ease of use, social influence, perceived self-efficacy, perceived security, prior usage experience, propensity of data/information sharing, and perceived health. According to the TAM, these predictors can align with the use of mHealth technology in general (eg, apps, smartphone, and internet) as well as to a specific mHealth technology (eg, a specific app such as the Iris app). In our study, we distinguished these TAM predictors. To examine the specific predictors of the Iris app, we provided participants with mock-ups of this app, explaining different elements of the potential coach, to provide participants with an idea about what the Iris app (ie, digital coach) would offer. A display with different screens of the Iris app was shown to the participants (Figure 1). We will first describe in detail below the assessment of the outcome variable; followed by the TAM predictors regarding the general use of apps, smartphone, and internet and the TAM predictors regarding the use of the Iris app; and finally the control variables. Unless otherwise specified, all questionnaire items were answered on a 5-point Likert scale ranging from 1 (strongly disagree) to 5 (strongly agree). The description of the items of the outcome variable and predictors (including Cronbach α) is depicted in Table 1. If the variable was measured with 2 or more items, the mean was used to compute the variable.

Figure 1. Screenshots of the Iris T2D app. (A) Introduction of the coach Iris. (B) Nutritional advice. (C) Setting daily dietary goals. (D) Daily reminder. (E) Feedback and compliments. (F) Tips and exercises.

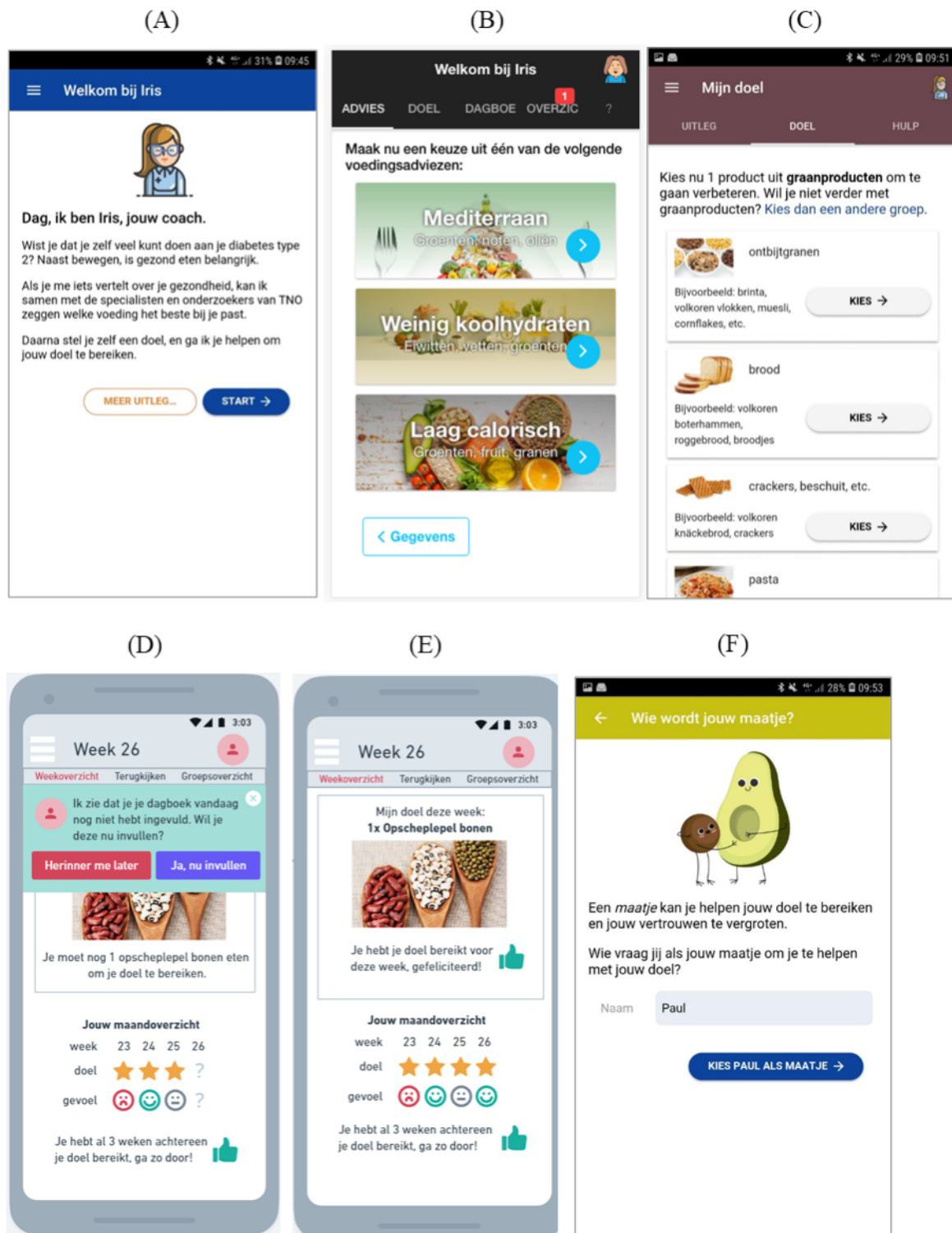


Table 1. Descriptive statistics of the outcome variable and TAM predictors.

Construct	Item	Cronbach α	Mean (SD)	n
Outcome variable				
Acceptance of the Iris app	<ul style="list-style-type: none"> I would like to use the Iris app, if this was presented to me. I intend to use the Iris app to improve my health. I would use the Iris app for managing type 2 diabetes. 	.936	3.67 (0.91)	N/A ^a
Predictors regarding the general use of apps/smartphone/internet				
Perceived usefulness/outcome expectancies	<ul style="list-style-type: none"> Health apps can help me improve my health. Health apps make it easier for me to cope with my diabetes. Health apps ensure that I am less dependent on others. By daily keeping track of my diet, I am better at coping with my diabetes. I appreciate it when I receive direct advice from an app to improve my lifestyle. An app needs to be fun, if I want to use it. I like to use my mobile phone. I find it annoying to receive daily reminders of an app {R}^b. I question whether an health app can support me quite effectively {R}. 	.787	3.64 (0.69)	91
Perceived ease of use	<ul style="list-style-type: none"> I find it easy to use health apps. I quickly learn how to operate new apps. 	$r=0.702$, $P<.001^c$	3.65 (1.06)	89
Social influence				
Subjective norm ^d	<ul style="list-style-type: none"> My doctor thinks that health apps could help me with my diabetes. 	N/A	3.30 (0.95)	61
Descriptive norm ^d	<ul style="list-style-type: none"> Most of the people I know already use health apps. 	N/A	2.81 (1.20)	62
Perceived security	<ul style="list-style-type: none"> I think it is important that information of health apps is reliable. It is important that the data I enter in the app are secure. I am confident that my data in health apps are secure. I only want to use an app if I know that my privacy is guaranteed. 	.836	4.12 (0.93)	92
Prior usage experience				
Behavior regarding internet use	<ul style="list-style-type: none"> I use the internet to search for information about my diabetes (problems). 	N/A	3.86 (1.27)	87
Frequency of smartphone use ^e	<ul style="list-style-type: none"> How often do you use your smartphone? 	N/A	N/A	92
Use of app for their diabetes ^e	<ul style="list-style-type: none"> Do you use apps for your diabetes and which one(s)? 	N/A	N/A	92
Perceived health				
Attitude regarding diabetes self-management	<ul style="list-style-type: none"> I am worried about my diabetes. I have my diabetes well in hand. I think that my treatment (medication/insulin) helps my diabetes. With eating healthy food, I can decrease the risk of diabetes problems. Exercising helps to reduce diabetes problems. My weight is of influence on my diabetes. My health is important for me. I would like to improve my overall health. 	.730	3.65 (0.67)	92

Construct	Item	Cronbach α	Mean (SD)	n
Self-efficacy regarding diabetes self-management	• I succeed in controlling my diabetes.	.822	4.19 (0.57)	92
	• I succeed in eating healthy daily.			
	• I succeed to sufficiently exercising weekly.			
	• I succeed to watch out for the number of meals and snacks.			
	• I succeed in checking my blood glucose regularly.			
Self-care regarding diabetes self-management	• I take my diet into account for a good blood glucose level.	.730	3.54 (0.71)	92
	• I take my diabetes medication as required.			
	• I have tried to lose weight because of my diabetes.			
	• Once in a while I eat too much sweetness and other food rich in carbohydrates {R}.			
	• I prefer not to go to doctor appointments for my diabetes {R}.			
	• Sometimes I eat more than I intended to {R}.			
	• I tend to skip exercise/sport {R}.			
	• I am bad taking care of myself with respect to diabetes {R}.			
Predictors regarding the use of the Iris app				
Perceived usefulness	• I like a digital coach that motivates me to eat healthier.	$r=0.863$, $P<.001^c$	3.53 (0.88)	92
	• I find it useful if a digital coach motivates me to eat healthier.			
Perceived ease of use	• I question whether a digital coach can support me quite effectively {R}.	.698	3.03 (0.71)	92
	• I find it unpleasant if I would receive daily messages of a digital coach {R}.			
	• I prefer to be supported by a real person {R}.			
	• It is easier for me to cope with my diabetes with a digital coach.			
Perceived social influence				
Subjective norm	• My health practitioner would find it important that I use the digital coach.	$r=0.568$, $P<.001^c$	3.14 (0.73)	92
	• People close to me (family, friends) would find it important that I use the digital coach.			
Perceived control	• I succeed in using a digital coach daily.	N/A	3.25 (1.04)	92
Willingness to share data	• My general practitioner would be allowed to view the data that I maintain in the app.	.835	3.86 (0.80)	92
	• My data that I gather in the app can be used for research.			
	• I would share my data if these help other patients with diabetes.			

^aN/A: not applicable.

^b{R} means reverse coded.

^cCronbach α could not be calculated for variables with 2 items, and therefore Pearson correlation (r) and P value were reported.

^dThese 2 predictors had a great number of missing information because participants responded that “they did not know” (30/92, 33% and 29/92, 32%, respectively).

^eThese 2 predictors were dichotomous; for more information about the percentage of these predictors, see [Table 2](#).

Overview

3 items. An additional response option to the 5-point Likert scale included “not applicable,” which was recoded as missing.

Outcome

The outcome variable was acceptance of the Iris app. Acceptance refers to the intended use of the Iris app. It was measured with

TAM Predictors Regarding the General Use of Apps, Smartphone, and Internet

Perceived usefulness was assessed by outcome expectancies that indicate the positive consequences of using health apps. It was measured with 9 items.

Perceived ease of use was assessed with 2 items.

Perceived social influence was assessed by the following 2 variables: subjective norm (also referred to as injunctive norm) regarding app use, and descriptive norm regarding app use. Subjective norm regarding app use was measured with 1 item on a 5-point Likert scale ranging from 1 (strongly agree) to 5 (strongly disagree). Answers were reverse coded. Descriptive norm regarding app use was measured with 1 item on a 5-point Likert scale ranging from 1 (strongly agree) to 5 (strongly disagree). Answers were reverse recorded.

Perceived security was assessed with 4 items.

Prior usage experience was assessed by the following 3 variables. Behavior regarding internet use was measured with 1 item. Frequency of smartphone use was measured with 1 item and response categories were recoded into 2 categories: “more than 1 time a day” and “daily to weekly.” Use of apps for their diabetes was measured with different responses (eg, Koolhydraatkenner; Mijn Eetmeter; MyFitnessPal), and computed into 2 response categories: “do not use any apps for diabetes management” and “yes, do use, 1 or more apps for diabetes management.”

Perceived health was assessed by the following 3 variables, obtained from the Diabetes Management Self-Efficacy Scale (DMSES; [43]) and the Diabetes Self-Management Questionnaire (DSMQ; [44]). *Self-efficacy regarding diabetes self-management* was measured with 5 items. *Attitudes regarding diabetes self-management* were measured with 8 items. For each item, participants could also answer “not applicable,” which was recoded as missing. *Self-care regarding diabetes self-management* was measured with 8 items. A high score represents positive self-care.

TAM Predictors Regarding the Use of the Iris App

Perceived usefulness was assessed with 2 items.

Perceived ease of use was assessed with 4 items.

Perceived social influence was assessed by the subjective norm regarding digital coach use with 2 items. Descriptive norm was not measured because the digital coach was not yet publicly available or in use.

Perceived control was measured with 1 item.

Willingness to share data was measured with 3 items.

Control Variables

Sociodemographic Factors

Gender was coded as “male” and “female.” Age was categorized into 2 based on the sample median: “<63 (=25-62) years” and “≥63 (63-84) years.” Education was assessed using 10 categories (ranging from primary education to university degree), and recoded into 3 categories, of which low-level education was

computed as the reference category and intermediate- and high-level education as the 2 dummies. Ethnicity was based on country of birth. This variable was recoded into 2 categories: “Dutch” and “other.” Household was recoded into 2 categories: “living alone” and “living together with partner and/or children.”

Health-Related Factors

BMI was measured by length (in centimeters but recoded into meters) and weight (kg). We calculated BMI (kg/m^2), and classified it into 3 categories: “normal” (≥ 20 and $< 25 \text{ kg}/\text{m}^2$), “overweight” (≥ 25 and $< 30 \text{ kg}/\text{m}^2$), and “obese” ($\geq 30 \text{ kg}/\text{m}^2$) [45]. We computed 2 dummies with “normal” BMI as the reference category.

Amount of years with diabetes was measured by asking how long (number of years) people were diagnosed with T2D. Diabetes-related complaints that participants could indicate included, for example, eye problems, nerve damage (neuropathy), kidney problems. Ticking more than 1 box was possible. This was computed into the following 2 categories: “no, having no complaints” and “yes, having 1 or more complaints.” Medication use was measured by asking which medicines do you use for your T2D, and was computed into the following 2 categories: “not using medication” and “using medication.”

Data Analyses

We first checked for multicollinearity ($r \geq 0.80$) between the predictors, but this was not the case. The full correlation table, including correlations between the predictors, can be requested from the first author. To examine the research question, we performed the analyses in 3 steps. First, we performed bivariate linear regression analyses with the (control) variables and the outcome (step 1). Second, we conducted a multiple linear regression analysis (step 2), including the significant (control) variables of step 1. We first analyzed, in step 2a, a multiple linear regression model including the significant TAM predictors regarding the general use of apps, smartphone, and internet as well as the use of the Iris app (eg, perceived usefulness, perceived ease of use, descriptive and subjective norms, perceived self-efficacy/behavioral control, perceived security, prior usage experience, perceived health, and willingness to share data). Subsequently, in step 2b, we added the significant control variables (eg, gender, age, education, ethnicity, household, BMI, amount of years with diabetes, diabetes-related complaints, and medication use) to the multiple linear regression model. Finally, we repeated the multiple linear regression analysis with only the significant (control) variables of step 2 (step 3). We used pairwise missing data and a P value $< .05$ was considered significant. Moreover, we computed the R^2 for steps 2 and 3. To provide more additional information about the model quality, we plotted the dependent variable against the predicted values, and performed bootstrapping. Overall, the scatterplot shows that the model gives a pretty good prediction for the outcome (see [Multimedia Appendix 1](#)). In addition, the bootstrapping analyses indicated that overall our model is quite robust.

Ethics Approval

The Institutional Review Board (IRB) of the Netherlands Organization for Applied Scientific Research (ie, TNO) approved the study (IRB registration number: 2018-029).

Results

Demographics and Descriptive Analysis

Of the 97 participants that filled out the survey, 2 participants never used a smartphone and 1 participant had missing values on the majority of the questions, and thus, were removed from the data set and analyses. In addition, 2 other participants were excluded from the analyses, as they indicated that they did not experience any diabetes-related complaints, did not use

medication, and had 0 years of diabetes, ergo they may not have had T2D. Thus, in total, 92 participants were included in the data analyses. The sample characteristics of the 92 participants are presented in [Table 2](#). The majority of the participants (57/92, 62%) did not use an app for diabetes management. The participants that did use health or lifestyle apps predominantly used the app “MyFitnessPal” (9/92, 10%), and 2 Dutch food-related apps, namely, “Koolhydraatkenner” (10/92, 11%) and “Mijn Eetmeter” (14/92, 15%).

Descriptive analyses (mean and SD) of the predictors and outcome are depicted in [Table 1](#). Except for descriptive norms regarding app use (mean 2.81, SD 1.20), average ratings were higher than 3 on all variables, implying a positive stand on these variables.

Table 2. Demographics of the study participants (n=92).

Variable	Values
Female gender, n (%)	48 (52)
Age (years)	
Range	25-80
Mean (SD)	62.76 (8.29)
≥63 ^a , n (%)	49 (53)
Missing, n (%)	1 (1)
BMI (kg/m²), n (%)	
<25 (normal)	15 (16)
25-<30 (overweight)	39 (42)
≥30 (obese)	35 (38)
Missing	3 (3)
Highest completed level of education, n (%)	
Low	40 (44)
Intermediate	28 (30)
High	24 (26)
Country of birth (the Netherlands), n (%)	86 (93)
Household (together with partner or children), n (%)	76 (83)
Frequency of phone use (>1 time/day), n (%)	74 (80)
Number of years with diabetes	
Range	0-34 ^b
Mean (SD)	11.41 (8.32)
Missing, n (%)	2 (2)
Diabetes-related complaints (yes), n (%)	80 (87)
Medication use (yes), n (%)	82 (89)
Practitioner, n (%)	
General practitioner/nurse practitioner	68 (74)
Hospital doctor	21 (23)
Other	3 (3)
Use of apps for diabetes management (yes), n (%)	35 (38)

^aThe median was used to divide age into 2 categories.

^bThere was 1 person indicating 0 years with diabetes, but also indicated medication use and complaints regarding diabetes and was included in the sample.

Predictors Associated With the Acceptance of the Iris App

We first identified with bivariate linear regression analyses the factors that were significantly (ie, $P < .05$) associated with the acceptance of the Iris app (Table 3, step 1). The findings indicated that beliefs of patients with T2D that general and specific use of technology is helpful/beneficial ($\beta = .42$, $P < .001$ and $\beta = .81$, $P < .001$, respectively) and easy to use ($\beta = .32$, $P = .003$ and $\beta = .55$, $P < .001$, respectively) increased the acceptance of the app. Besides, their belief that using (health) apps is reliable and secure was related to an increase in the acceptance of the app ($\beta = .29$, $P = .005$). Patients with T2D who used the internet

to search for information about their diabetes ($\beta = .29$, $P = .007$) or had a positive attitude toward diabetes self-management ($\beta = .34$, $P = .001$) showed a higher acceptance of the app. Except for behavior regarding internet use, prior usage (frequency of smartphone use, $\beta = .09$, $P = .40$; use of apps for their diabetes, $\beta = .02$, $P = .84$) was not significantly associated with acceptance of the app. Furthermore, perceived health (self-efficacy regarding diabetes self-management, $\beta = -.05$, $P = .62$; and self-care regarding diabetes self-management, $\beta = -.15$, $P = .15$), except for attitude regarding diabetes self-management, was not significantly associated with acceptance of the app. Beliefs of patients with T2D that others (health practitioner, family, friends) approved of using the app ($\beta = .61$, $P < .001$) and

perceiving a higher capability and personal control over using the app ($\beta=.58, P<.001$) increased the acceptance of the Iris app. Descriptive norms regarding the general use of apps, smartphone, and internet were not significantly associated with acceptance of the app ($\beta=.13, P=.32$). Patients with T2D who were willing to share their app data showed an increase in the acceptance of the app ($\beta=.52, P<.001$). Furthermore, being overweight ($\beta=.40, P=.008$) or experiencing more diabetes-related complaints ($\beta=.32, P=.002$) was significantly associated with a higher acceptance of the app. The sociodemographic factors (gender, age, education level, ethnicity, household) were not associated with a higher acceptance of the app.

Only the (control) variables that showed to be significant ($P<.05$) in the bivariate analyses were entered in the multiple linear regression analysis (Table 3, step 2b). The findings indicated that beliefs of patients with T2D that the use of app is helpful/beneficial ($\beta=.52, P<.001$), that others approved of using this app ($\beta=.18, P=.02$), and whether they were willing to share their app data ($\beta=.22, P=.002$) increased the acceptance of the Iris app. Furthermore, being overweight ($\beta=.22, P=.01$) or obese ($\beta=.20, P=.02$) was associated with an increase in the acceptance of the Iris app compared with having a “normal” weight. Moreover, the multiple regression analysis that we repeated with only the significant (control) variables (ie, for those where $P<.05$) of step 2 (Table 4, step 3) showed a similar pattern of results.

As perceived usefulness of the app showed to have a strong effect, we performed additional analyses to examine the predictors related to perceived usefulness of the app. We used the same statistical procedure as we did for acceptance of the app. The findings of the bivariate analyses for perceived usefulness of the app (Table 5, step 1) showed to be similar as the findings of the bivariate analyses for acceptance of the app, except for BMI, which was not significantly related to perceived usefulness of the app ($\beta=.24, P=.11$). The significant (control) variables (ie, $P<.05$) were entered in the multiple regression analysis (Table 5, Step 2b). The findings were partly in line with the findings of the acceptance of the app. Similar to the findings of the acceptance of the app, beliefs of patients with T2D that others (ie, health practitioner, family, friends) approved of using the app ($\beta=.26, P=.006$) and their willingness to share their app data ($\beta=.22, P=.01$) were related to an increase in perceived usefulness of the app. In contrast to the findings of the acceptance of the app, the findings also showed that beliefs of patients with T2D that the use of (health) apps is reliable and secure ($\beta=.24, P=.04$), that the use of the digital coach is easy to use ($\beta=.32, P=.003$), and that higher perceived capability and personal control with using the app ($\beta=.21, P=.03$) were related to an increase in the perceived usefulness of the app. Moreover, the multiple regression analysis, which we repeated with only the significant (control) variables (ie, $P<.05$) of step 2 (Table 6, Step 3), showed a similar pattern of results.

Table 3. Predictors associated with the acceptance of the Iris app by means of a linear regression analyses (method=Enter).

Variable	Acceptance of the Iris app ^a					
	Step 1		Step 2a ^b		Step 2b ^c	
	B (SE)	β (P value)	B (SE)	β (P value)	B (SE)	β (P value)
Control variables						
Gender (reference: male)	0.07 (0.19)	.04 (.74)	— ^d		N/A ^e	
Age (reference: <63 years)	-0.07 (0.19)	-.04 (.71)	—		N/A	
Education (reference: low level education)						
Middle/intermediate level of education	0.23 (0.22)	.12 (.31)	—		N/A	
High level of education	-0.19 (0.24)	-.09 (.42)	—		N/A	
Ethnicity (reference: Dutch)	-0.54 (0.38)	-.15 (.16)	—		N/A	
Household (reference: living alone)	0.43 (0.25)	.18 (.09)	—		N/A	
BMI (reference: normal)						
Overweight	0.72 (0.27)	.40 (.008)	—		0.40 (0.15)	.22 (.01)
Obese	0.35 (0.27)	.19 (.20)	—		0.36 (0.15)	.20 (.02)
Amount of years with diabetes	-0.01 (0.01)	-.06 (.60)	—		N/A	
Diabetes-related complaints (reference: having no complaints)	0.87 (0.27)	.32 (.002)	—		0.27 (0.17)	.10 (.11)
Medication use (reference: not using medication)	-0.37 (0.31)	-.13 (.23)	—		N/A	
Predictors regarding the general use of apps/smartphone/internet						
Perceived usefulness/outcome expectancies	0.55 (0.13)	.42 (<.001)	0.08 (0.14)	.06 (.57)	0.09 (0.13)	.07 (.49)
Perceived ease of use	0.27 (0.09)	.32 (.003)	-0.07 (0.07)	-.08 (.36)	-0.11 (0.07)	-.13 (.13)
Social influence						
Subjective norm	0.19 (0.12)	.20 (.13)	—		N/A	
Descriptive norm	0.10 (0.10)	.13 (.32)	—		N/A	
Perceived security	0.29 (0.10)	.29 (.005)	-0.03 (0.09)	-.04 (.70)	-0.002 (0.09)	-.002 (.98)
Prior usage experience						
Behavior regarding internet use	0.21 (0.08)	.29 (.007)	0.07 (0.06)	.09 (.28)	0.06 (0.06)	.09 (.30)
Frequency of smartphone use	0.20 (0.24)	.09 (.40)	—		N/A	
Use of apps for their diabetes	0.04 (0.20)	.02 (.84)	—		N/A	
Perceived health						
Attitude regarding diabetes self-management	0.54 (0.16)	.34 (.001)	0.12 (0.11)	.08 (.28)	0.13 (0.11)	.08 (.23)
Self-efficacy regarding diabetes self-management	-0.07 (0.14)	-.05 (.62)	—		N/A	
Self-care regarding diabetes self-management	-0.19 (0.13)	-.15 (.15)	—		N/A	
Predictors regarding the use of the Iris app						

Variable	Acceptance of the Iris app ^a					
	Step 1		Step 2a ^b		Step 2b ^c	
	B (SE)	β (P value)	B (SE)	β (P value)	B (SE)	β (P value)
Perceived usefulness	0.85 (0.06)	.81 (<.001)	0.56 (0.10)	.54 (<.001)	0.54 (0.09)	.52 (<.001)
Perceived ease of use	0.70 (0.11)	.55 (<.001)	0.003 (0.11)	.003 (.98)	-0.06 (0.11)	-.05 (.57)
Perceived social influence						
Subjective norm	0.76 (0.10)	.61 (<.001)	0.22 (0.10)	.17 (.03)	0.22 (0.09)	.18 (.02)
Perceived control	0.50 (0.08)	.58 (<.001)	0.09 (0.07)	.10 (.19)	0.08 (0.06)	.10 (.20)
Willingness to share data	0.59 (0.10)	.52 (<.001)	0.23 (0.08)	.20 (.007)	0.25 (0.08)	.22 (.002)

^aStep 1 includes bivariate linear regression analyses, step 2a multiple linear regression analysis with only the significant predictors of step1, and step 2b multiple linear regression analysis adding the control variables in Block 2.

^b $R^2=0.750$.

^c $R^2=0.782$.

^dNot available.

^eNot applicable (ie, variable was not significant in the previous step and thus not included in the analyses).

Table 4. Predictors associated with the acceptance of the Iris app by means of a linear regression analyses (method=Enter).

Variable	Acceptance of the Iris app	
	Step 3 ^a	
	B (SE)	β (P value)
Control variables		
Gender (reference: male)	N/A ^b	
Age (reference: <63 years)	N/A	
Education (reference: low level of education)		
Middle/intermediate level of education	N/A	
High level of education	N/A	
Ethnicity (reference: Dutch)	N/A	
Household (reference: living alone)	N/A	
BMI (reference: normal)		
Overweight	0.41 (0.14)	.23 (.01)
Obese	0.39 (0.15)	.21 (.01)
Amount of years with diabetes	N/A	
Diabetes related complaints (reference: having no complaints)	N/A	
Medication use (reference: not using medication)	N/A	
Predictors regarding the general use of apps/smartphone/internet		
Perceived usefulness/outcome expectancies	N/A	
Perceived ease of use	N/A	
Social influence		
Subjective norm	N/A	
Descriptive norm	N/A	
Perceived security	N/A	
Prior usage experience		
Behavior regarding internet use	N/A	
Frequency of smartphone use	N/A	
Use of app applications for their diabetes	N/A	
Perceived health		
Attitude regarding diabetes self-management	N/A	
Self-efficacy regarding diabetes self-management	N/A	
Self-care regarding diabetes self-management	N/A	
Predictors regarding the use of the Iris app		
Perceived usefulness	0.60 (0.08)	.57 (<.001)
Perceived ease of use	N/A	
Perceived social influence		
Subjective norm	0.25 (0.08)	.20 (.004)
Perceived control	N/A	
Willingness to share data	0.29 (0.07)	.25 (<.001)

^a $R^2=0.758$; step 3 is multivariate analysis with only the significant predictors of step 2.

^bNot applicable (ie, variable was not significant in the previous step and thus not included in the analyses).

Table 5. Predictors associated with perceived usefulness of the Iris app by means of a linear regression analyses (method=Enter).

Variable	Perceived usefulness of the Iris app					
	Step 1 ^a		Step 2a ^b		Step 2b ^c	
	B (SE)	β (P value)	B (SE)	β (P value)	B (SE)	β (P value)
Control variables						
Gender (reference: male)	0.03 (0.18)	.02 (.87)	— ^d		N/A ^e	
Age (reference: <63 years)	-0.14 (0.19)	-.08 (.47)	—		N/A	
Education (reference: low level of education)						
Middle/intermediate level of education	0.22 (0.22)	.12 (.31)	—		N/A	
High level of education	-0.06 (0.23)	-.03 (.80)	—		N/A	
Ethnicity (reference: Dutch)	-0.48 (0.37)	-.13 (.20)	—		N/A	
Household (reference: living alone)	0.30 (0.24)	.13 (.22)	—		N/A	
BMI (reference: normal)						
Overweight	0.43 (0.26)	.24 (.11)	—		N/A	
Obese	0.02 (0.27)	.01 (.96)	—		N/A	
Amount of years with diabetes	0.001 (0.01)	.01 (.91)	—		N/A	
Diabetes-related complaints (reference: having no complaints)	0.75 (0.26)	.29 (.005)	—		0.30 (0.21)	.11 (.16)
Medication use (reference: not using medication)	-0.42 (0.29)	-.15 (.16)	—		N/A	
Predictors regarding the general use of apps/smartphone/internet						
Perceived usefulness/outcome expectancies	0.52 (0.12)	.41 (<.001)	-0.11 (0.17)	-.09 (.53)	-0.09 (0.17)	-.07 (.58)
Perceived ease of use	0.26 (0.08)	.32 (.002)	0.003 (0.09)	.003 (.97)	-0.03 (0.09)	-.03 (.78)
Social influence						
Subjective norm	0.22 (0.12)	.24 (.06)	—		N/A	
Descriptive norm	0.05 (0.09)	.07 (.60)	—		N/A	
Perceived security	0.30 (0.10)	.31 (.003)	0.22 (0.11)	.23 (.05)	0.23 (0.11)	.24 (.04)
Prior usage experience						
Behavior regarding internet use	0.18 (0.07)	.25 (.02)	-0.02 (0.08)	-.03 (.76)	-0.03 (0.08)	-.04 (.71)
Frequency of smartphone use	0.001 (0.23)	.000 (>.99)	—		N/A	
Use of app applications for their diabetes	0.05 (0.19)	.03 (.80)	—		N/A	
Perceived health						
Attitude regarding diabetes self-management	0.38 (0.16)	.25 (.02)	-0.10 (0.14)	-.06 (.49)	-0.09 (0.14)	-.06 (.50)
Self-efficacy regarding diabetes self-management	-0.06 (0.14)	-.05 (.65)	—		N/A	
Self-care regarding diabetes self-management	-0.15 (0.13)	-.12 (.25)	—		N/A	
Predictors regarding the use of the Iris app						
Perceived ease of use	0.74 (0.10)	.60 (<.001)	0.44 (0.13)	.36 (.001)	0.40 (0.13)	.32 (.003)
Perceived social influence						
Subjective norm	0.70 (0.10)	.58 (<.001)	0.32 (0.11)	.27 (.005)	0.32 (0.11)	.26 (.006)

Variable	Perceived usefulness of the Iris app					
	Step 1 ^a		Step 2a ^b		Step 2b ^c	
	B (SE)	β (P value)	B (SE)	β (P value)	B (SE)	β (P value)
Perceived control	0.47 (0.07)	.56 (<.001)	0.16 (0.08)	.19 (.04)	0.18 (0.08)	.21 (.03)
Willingness to share data	0.45 (0.11)	.41 (<.001)	0.25 (0.10)	.23 (.01)	0.24 (0.10)	.22 (.01)

^aStep 1 is bivariate analyses, step 2a is multivariate analysis with only the significant predictors of step 1, and step 2b is multivariate analysis adding the control variables in block 2.

^b $R^2=0.588$.

^c $R^2=0.599$.

^dNot available.

^eNot applicable (ie, variable was not significant in the previous step and thus not included in the analyses).

Table 6. Predictors associated with the acceptance of the Iris app by means of a linear regression analyses.

Variable	Acceptance of the Iris app	
	Step 3 ^a	
	B (SE)	β (P value)
Control variables		
Gender (reference: male)	N/A ^b	
Age (reference: <63 years)	N/A	
Education (reference: low level of education)		
Middle/intermediate level of education	N/A	
High level of education	N/A	
Ethnicity (reference: Dutch)	N/A	
Household (reference: living alone)	N/A	
BMI (reference: normal)		
Overweight	N/A	
Obese	N/A	
Number of years with diabetes	N/A	
Diabetes-related complaints (reference: having no complaints)	N/A	
Medication use (reference: not using medication)	N/A	
Predictors regarding the general use of apps/smartphone/internet		
Perceived usefulness/outcome expectancies	N/A	
Perceived ease of use	N/A	
Social influence		
Subjective norm	N/A	
Descriptive norm	N/A	
Perceived security	0.15 (0.07)	.15 (.04)
Prior usage experience		
Behavior regarding internet use	N/A	
Frequency of smartphone use	N/A	
Use of app for their diabetes	N/A	
Perceived health		
Attitude regarding diabetes self-management	N/A	
Self-efficacy regarding diabetes self-management	N/A	
Self-care regarding diabetes self-management	N/A	
Predictors regarding the use of the Iris app		
Perceived ease of use	0.40 (0.11)	.32 (<.001)
Perceived social influence		
Subjective norm	0.31 (0.10)	.26 (.004)
Perceived control	0.16 (0.07)	.19 (.03)
Willingness to share data	0.22 (0.08)	.20 (.01)

^a $R^2=0.582$. Step 3 multivariate analysis was performed with only the significant predictors of step 2.

^bNot applicable (ie, variable was not significant in the previous step and thus not included in the analyses).

Discussion

Principal Findings

In this study we examined which factors could explain acceptance of a diabetes self-management eCoach (the Iris app). Acceptance of the app was mainly predicted by perceived usefulness, positive subjective norms, and willingness to share data. In addition, perceived usefulness was predicted by perceived security, positive subjective norms, willingness to share data, perceived ease of use, and perceived control. These predictors explained a high variance in acceptance and perceived usefulness of the Iris app (75.8% and 58.2%, respectively). Moreover, the TAM predictors regarding the use of the Iris app were more strongly associated with acceptance of this app than the predictors regarding the general usage of apps, smartphone, and internet. This can be explained by the compatibility principle, which indicates that the outcome variable will be better predicted if the specificity of the predictor matches the specificity of the outcome [46]. Furthermore, our study included elderly people (mean age of our sample was 63 years) and those with low educational level (40/92, 44%). Previous studies implied that elderly people and people with low SES may be more reluctant to use mHealth as they encounter more barriers while using innovative mHealth technologies [4,47]. Our findings showed that this was not the case regarding the Iris app, as there was no association between the sociodemographic factors (gender, age, education level, ethnicity, household) and the acceptance or perceived usefulness of the app.

Regarding the 2 core TAM predictors, perceived usefulness was strong and positively associated with acceptance of the Iris app, whereas perceived ease of use was not associated with acceptance of the app. However, perceived ease of use was moderately related to perceived usefulness of the app, which is in line with the TAM and a recent meta-analysis [48]. Moreover, perceived usefulness regarding the use of the (Iris) app showed to be a predictor but not perceived usefulness regarding the general use of apps, smartphone, and internet. Our findings imply that perceived usefulness is the most important predictor of acceptance of health technology, which is in line with previous studies (eg, [15,16,31,49]). Although our finding regarding perceived ease of use is in contrast to previous studies (eg, [31,49-51]), it was in line with the findings of Dou et al [16] and Zhang et al [15]. Their results did not show a significant association between perceived ease of use and patient's intention to use smartphone health technology [16] or diabetes management apps [15], but rather implied an indirect association through perceived usefulness. Thus, if people feel the technology is easy to use, they would be more likely to develop positive attitudes toward the use of the health technology and perceive it as beneficial and helpful.

Besides the 2 core elements, the TAM has been extended with a range of other predictors. Our findings showed support for social influence as a predictor, but only for subjective norms specifically regarding the Iris app but not for subjective norms regarding the general use of mHealth technology (ie, apps, smartphone, and internet) nor descriptive norms. Thus, patients with T2D tend to do what is socially approved by other people

regarding the use of the Iris app but not necessarily what is popular to do. A possible explanation as to why we did not find support for descriptive norms is that we did not measure this specifically regarding the app. Another possible explanation may be that, to assess descriptive norms, patients with T2D were only asked about the people they know. These people, however, are not necessarily the role models who patients with T2D acknowledge as important in their lives (eg, family, friends, health practitioner) or who they can identify with (eg, others who also have T2D). By contrast, to assess subjective norms, patients with T2D were explicitly asked about the people who are important in their lives (ie, family, friends, health practitioner).

Our findings showed that perceived behavioral control was not associated with acceptance of the Iris app by patients with T2D but was associated with perceived usefulness of the app. Individuals believing that they are capable of using the app are also more likely to perceive the app as beneficial and helpful. This finding is in line with extended models of the TAM [21,26] and with the findings of Dou et al [16]. They implied that perceived behavioral control was associated with perceived ease of use. In our study we did not examine this association, although we additionally calculated the correlation, which showed, in line with Dou et al [16], a significant, positive association ($r=0.484$, $P<.001$, $n=92$).

Our findings showed that willingness to share data predicted acceptance and perceived usefulness of the Iris app among patients with T2D. These findings imply that patients with T2D need to be convinced to share their app data. To do so, 2 issues might be important and need to be considered to increase the willingness of individuals to share their app data. First, some individuals (eg, older people, females, lower educated people, and people with a low propensity to trust others) are less willing to share information because they worry more about their privacy than others [37]. Our findings did not show a significant correlation between perceived security (including privacy) of health apps in general and sharing data of the Iris app ($r=0.174$, $P=.10$, $n=92$). Nevertheless, perceived security predicted perceived usefulness of the Iris app. However, more research is needed to examine which individuals are less likely to perceive security or share data on health technology use, and how these individuals can be convinced to share their data. Second, the data processing of the organization providing the mHealth tool can play an important role in convincing individuals to share information/data [37]. For example, the organization can consider the following aspects: (1) being transparent about the collection and storage of the data/information; (2) providing control to the individuals over whether or not their information/data are being collected, stored, and used; and (3) guaranteeing good security of the storage of the data/information [37].

Limitations

Some limitations of this study also need to be addressed. First, this study used cross-sectional data. Therefore, we are not able to determine or provide interpretations of causality or possible predictors. Thus, although we talk about predictors, this needs to be interpreted with caution. Second, calculations in sample

size software (Pass version 15) showed that our sample size achieves 80% power to detect a medium to large effect in the multiple regression analyses in step 2, with a significance level of .05. Furthermore, due to the sample size, we did not have sufficient power to test moderation effects of, for example, the sociodemographic factors (gender, age, education, ethnicity, household) or prior usage experience. Third, the majority of the measurements were self-constructed and based on the TAM, or empirical studies based on the TAM (eg, [16]), and the results of the 3 focus group interviews we conducted regarding the barriers and facilitators to use the Iris app among patients with diabetes. The reliability of the scales were good (Cronbach α ranged from .70 to .94). In addition, experts did check the face and content validity of the survey, but further validation of the survey is recommended. Fourth, although the explained variance was high in acceptance and perceived usefulness of the eCoach (75.8% and 58.2%, respectively), other important factors (eg, relationship to the doctor, resistance to change, enjoyment factor, technology anxiety, perceived value) might have contributed to an additional increase in the explained variance [16,52]. Moreover, for the final model (step 3), the scatterplots (see [Multimedia Appendices 1 and 2](#)) show that the model gives a pretty good prediction but that at the extremes there is a bit more dispersion in prediction. These other important factors might improve the model quality in future research. Finally, the participants that we recruited via online advertisement might also be the ones that often use mHealth technology, and thus, who perceive ease of use as less important. However, the descriptive statistics show this is probably not the case, as less than 40% (35/92, 38%) of the participants used an app for diabetes management.

Implications for Practice and Future Research

Our findings regarding subjective norms imply that (general) health practitioners, family, and friends might play an important role in facilitating the acceptance and perceived usefulness of the Iris app. To successfully develop and introduce this app for diabetes management among patients with T2D (including

elderly and lower educated people), it might be important to focus our efforts on blending the app with contact and communication with (general) health practitioners. For example, the health practitioner could play a role in discussing and encouraging the patient with T2D to share their app data, in explaining why the app could be beneficial/useful for managing their diabetes, and in communicating and guaranteeing the privacy when using the app. Moreover, family and friends increased the patients' acceptance and perceived usefulness of the app through their approval of using the app, and therefore they perhaps could also play a role in discussing and encouraging the patient with T2D to use the app.

Although our findings indicated that the explained variance was high in acceptance and perceived usefulness of the Iris app (75.8% and 58.2%, respectively), future research might also examine other additional predictors that might be essential for the acceptance of a diabetes self-management eCoach (eg, relationship to the doctor, social relationship, resistance to change, personal innovativeness, enjoyment factor, technology anxiety, perceived value) [16,52,53]. Furthermore, to develop and introduce an app for diabetes self-management, future research should need to identify which features of the app are effective for which type of individuals [11].

Conclusions

To stimulate the acceptance of a self-management eCoach for patients with T2D (including elderly people and lower educated people), we need to achieve that patients with T2D perceive the app as beneficial and helpful to use, and are willing to share their app data. In addition, we need to achieve that the people who are important in the life of patients with T2D (eg, family, friends, health practitioner) socially approve the use of this app. Furthermore, elderly and lower educated people were represented within our sample, but did not seem to score lower on acceptance of perceived usefulness of the app compared with younger people (<63 years old) or higher educated people (completing an intermediate or high level of education).

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Scatterplot of acceptance of the Iris app against the predicted values.

[\[PNG File, 28 KB - formative_v6i8e34737_app1.png\]](#)

Multimedia Appendix 2

Scatterplot of perceived usefulness of the Iris app against the predicted values.

[\[PNG File, 28 KB - formative_v6i8e34737_app2.png\]](#)

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Abbreviations

DMSES: Diabetes Management Self-Efficacy Scale

DSMQ: Diabetes Self-Management Questionnaire

eCoach: electronic coach

IRB: institutional review board

mHealth: mobile health

N/A: not applicable

SES: socioeconomic status

STAM: Senior Technology Acceptance Model

T2D: type 2 diabetes

TAM: Technology Acceptance Model

TNO: Netherlands Organization for Applied Scientific Research

UTAUT: Unified Theory of Acceptance and Use of Technology

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Original Paper

Determining the Influencing Factors on Acceptance of eHealth Pain Management Interventions Among Patients With Chronic Pain Using the Unified Theory of Acceptance and Use of Technology: Cross-sectional Study

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Abstract

Background: Chronic pain is a complex disease with high prevalence rates, and many individuals who are affected do not receive adequate treatment. As a complement to conventional therapies, eHealth interventions could provide many benefits to a multimodal treatment approach for patients with chronic pain, whereby future use is associated with the acceptance of these interventions.

Objective: This study aims to assess the acceptance of eHealth pain management interventions among patients with chronic pain and identify the influencing factors on acceptance. A further objective of the study is to evaluate the viability of the Unified Theory of Acceptance and Use of Technology (UTAUT) model and compare it with its extended version in terms of explained variance of acceptance.

Methods: We performed a cross-sectional web-based study. In total, 307 participants with chronic pain, as defined according to the International Association for the Study of Pain criteria, were recruited through flyers, posters, and web-based inquiries between December 2020 and July 2021. In addition to sociodemographic and medical data, the assessment included validated psychometric instruments and an extended version of the well-established UTAUT model. For statistical analyses, group comparisons and multiple hierarchical regression analyses were performed.

Results: The acceptance of eHealth pain management interventions among patients with chronic pain was overall moderate to high (mean 3.67, SD 0.89). There was significant difference in acceptance among age groups ($W=9674.0$; $r=0.156$; $P=.04$). *Effort expectancy* ($\beta=.37$; $P<.001$), *performance expectancy* ($\beta=.33$; $P<.001$), and *social influence* ($\beta=.34$; $P<.001$) proved to be the most important predictors of acceptance. The extended UTAUT (including the original UTAUT factors as well as sociodemographic, medical, and eHealth-related factors) model explained 66.4% of the variance in acceptance, thus supporting the viability of the model. Compared with the original UTAUT model (*performance expectancy*, *effort expectancy*, and *social influence*), the extended model explained significantly more variance ($F_{25,278}=1.74$; $P=.02$).

Conclusions: Given the association between acceptance and future use, the knowledge of the influencing factors on acceptance should be used in the development and promotion of eHealth pain management interventions. Overall, the acceptance of eHealth pain management interventions was moderate to high. In total, 8 predictors proved to be significant predictors of acceptance. The UTAUT model is a valuable instrument for determining acceptance as well as the factors that influence acceptance of eHealth

pain management interventions among patients with chronic pain. The extended UTAUT model provided the greatest predictive value for acceptance.

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KEYWORDS

eHealth; eHealth interventions; Unified Theory of Acceptance and Use of Technology; UTAUT; chronic pain; pain management; acceptance

Introduction

Background

According to the International Association for the Study of Pain, pain is defined as “an unpleasant sensory and emotional experience associated with, or resembling that associated with, actual or potential tissue damage” [1]. Pain is considered chronic when it persists or recurs for >3 months [2], whereby different time periods can be found in the literature. Keeping the definition in mind, chronic pain is not only a diagnosis in its own right but also occurs as a symptom in connection with numerous somatic and mental diseases. This in turn explains the high prevalence of chronic pain worldwide [3,4], with the number of diseases with chronic pain continuing to increase because of changing demographics [5,6].

Chronic pain negatively affects quality of life, is associated with sleep disorders and mental illness, and leads to increased mortality [4,7,8]. Chronic pain produces extraordinary costs stemming from absence from work, loss of productivity, hospital stays, physician consultations, diagnostics, and treatment [9,10]. Although chronic pain affects a large part of the population worldwide, the care provided for patients seems to be insufficient. The period between the appearance of the first symptoms of a chronic pain condition and the start of pain therapy averages 4 years in Germany [11]. Patients who have to wait for >6 months for treatment show a worsening of their quality of life and a higher risk of being diagnosed with comorbid depression [12]. It is important to come up with new solutions for adequate health care for patients with chronic pain to improve the imbalance between the increasing numbers of such patients and the need for treatment, which remains unmet because of the comparatively small number of licensed pain therapists [11].

In clinical medicine, eHealth approaches can offer a variety of different treatment options. eHealth is a broad term that includes the use of electronic options such as mobile phones and computers to expand medical care [13]. Although eHealth interventions offer many benefits in the management of patients with chronic pain, they also present difficulties. First, not all patients have the same technical requirements. Thus, the use of eHealth is dependent on the socioeconomic status of patients [14]. In addition, difficulties could arise because of the possible physical distance between physician and patient or a lack of trust in the technology and concerns about data security [15-18]. eHealth interventions can provide a cost-effective extension of chronic pain health care that is flexible in terms of time and location [19]. Another benefit is the reduced requirement for caregiver resources in comparison with conventional face-to-face treatment. The anonymity provided by eHealth

might be able to lower the threshold for seeking therapy and reduce stigmatization [20]. Especially during the COVID-19 pandemic, care for patients with chronic pain became severely limited with a significant decrease in face-to-face treatment options because of pandemic restrictions [21].

Across different patient groups, research has shown that eHealth interventions have outcomes that are comparable to those of face-to-face therapy [22-24], in particular in the treatment of chronic pain [24]. Especially eHealth interventions that focus on internet-delivered cognitive behavioral therapy [25] and internet-based psychoeducational and therapeutic programs have provided satisfactory improvements in various patient-relevant outcomes such as pain magnitude, disability, and comorbid depression [26].

The initial results of such interventions have been promising [27,28], and it is certain that the efficacy of, as well as adherence to, new eHealth interventions strongly depend on patients' intention and perseverance to use them [29].

Numerous offerings, including pain apps, are already available, and a review comparing pain apps between 2011 and 2016 shows an increase in the number of apps [30,31]; yet, among the large number of apps, just 8% were developed with the assistance of health care professionals, and almost none of the reviewed apps have been thoroughly tested for effectiveness with regard to pain-related health outcomes. None of the apps offered self-management options [32]. The quality of the offerings is therefore questionable, and need-oriented care cannot be guaranteed in the absence of evidence.

Considering that three-fourths of users discontinue using an app within 48 hours of downloading it [33], it is important for clinical practice to identify the factors that drive patients to use, and stay adherent to, web-based interventions such as mobile apps. For the successful use of eHealth interventions, it is important to measure the acceptance of potential users because acceptance represents the key predictor of actual use. Acceptance in this case can be understood as intention to use and can therefore be operationalized as behavioral intention (BI) [34]. One way to increase acceptance is to involve the target group in the development process of eHealth interventions [35].

Until now, knowledge on the acceptance of eHealth interventions has been inconsistent. Before the development of the Unified Theory of Acceptance and Use of Technology (UTAUT), there was no validated instrument to determine the influencing factors of acceptance [16,36]. The UTAUT now provides a validated and well-established instrument that can be used to identify predictors that influence the acceptance of eHealth interventions. Barriers to acceptance are also identified;

therefore, they can be avoided or adequately addressed in the development of eHealth interventions [34,36,37].

The UTAUT was developed as a combination of different models to estimate the intention to use technology as well as predict actual use behavior. It is suitable for assessing the likelihood of eHealth use in different groups [16,37,38]. The instrument consists of four core predictors as direct determinants of user acceptance and use behavior: performance expectancy (PE), effort expectancy (EE), social influence (SI), and facilitating conditions (FCs), where FCs influence actual use but not the intention to use, also called BI (acceptance); PE covers the extent to which a patient believes that they will benefit from using eHealth offerings; and EE represents the expected effort associated with the use of eHealth offerings. The factor SI describes the degree to which patients believe that persons of trust think they should use eHealth offerings. FCs define the patients' perception that an organizational and technical infrastructure exists to enable the use of eHealth offerings. The first three predictors PE, EE, and SI are direct determinants of acceptance; that is, the intention to use pain management apps. FCs are direct determinants of actual use behavior. To the best of our knowledge, the UTAUT has never been used among patients with chronic pain.

Objectives

To further develop urgently needed eHealth approaches in pain care, the lack of knowledge about the acceptance of eHealth pain management interventions must be remedied. Therefore, this study aimed to assess the acceptance of eHealth pain management interventions among patients with chronic pain and identify the factors that influence their acceptance of such interventions. The acceptance is influenced by sociodemographic factors such as age [16,38,39], education [16,39], and employment [38], as well as prior eHealth use [39] and depressive symptoms [16,38,39]. An additional objective of the study was to examine the viability of the UTAUT model with its three predictors of acceptance (PE, EE, and SI) and compare it with the extended UTAUT model used in this study. The hypotheses of the study are as follows:

1. Previous studies have indicated overall low [16,40] to moderate [38,41,42] acceptance of eHealth interventions in different target groups. We expected similar results regarding acceptance of eHealth pain management interventions in patients affected by chronic pain.
2. We hypothesized a positive relationship between the UTAUT model's three core predictors of acceptance (PE, EE, and SI) and acceptance, as demonstrated in previous research [34,38,42]. Therefore, we expected the results to confirm the viability of the UTAUT model.
3. Age [16,38,39], gender [39], education [16,39], occupational status [38], prior eHealth use [39], internet anxiety [41], and mental health variables [16,38,39] are considered to be influencing factors on acceptance. We expected divergent levels of acceptance in the different subgroups in accordance with sociodemographic and health-related factors.

4. Furthermore, we anticipated a significantly higher level of explained variance using the extended UTAUT model compared with the original UTAUT [42].

Methods

Study Design and Participants

A cross-sectional study was conducted to determine the predictors that influence the acceptance of pain management apps. Between December 2020 and July 2021, participants were recruited with flyers and posters distributed at hospitals and practices of physicians and physiotherapists, as well as through web-based inquiries in pain-related social media support groups. Patients who endorsed pain were regarded as eligible for the survey. To be included in the data analysis, fulfilling the diagnosis criteria of chronic pain (International Association for the Study of Pain and International Classification of Diseases, Eleventh Revision, criteria) [2,43] was mandatory. Additional criteria for patients wishing to take part in the study were age ≥ 18 years, sufficient German-language knowledge, internet access, and providing electronic informed consent. The study was anonymous and voluntary. The survey was designed to be completed in 15 to 20 minutes, and the average time to completion was approximately 20 (SD 7.07) minutes. Of the 525 participants who started the survey and provided informed consent, 342 (65.1%) completed the survey, resulting in a completion rate of 65.1%. Of these 342 participants, 2 (0.6%) reported a *pain duration of < 3 months* and were excluded for not meeting the aforementioned definition of chronic pain. We also excluded the fastest 5% (16/342) and slowest 5% (17/342) of the participants from the study to ensure data quality because slow or fast completion can be an indication of lack of attention and care [44,45]. By excluding extremely fast and slow responders, it was possible to ensure that the data analysis was based on an average sample. This minimized possible biases in response behavior. Thus, of the 525 participants who started the survey and provided informed consent, 307 (58.5%) were included in the data analysis.

Ethics Approval

The study was conducted in accordance with the Declaration of Helsinki and approved by the ethics committee of the medical faculty of the University of Duisburg-Essen (19-89-47-BO).

Assessment Instruments

Patient-related data were collected using self-generated items on sociodemographic characteristics, including gender, age, marital status, educational qualifications, employment, and place of residence. Medical data included chronic pain diagnosis criteria, prior treatment, and more detailed description of the symptoms.

Depressive symptoms were screened with the Patient Health Questionnaire depression scale (PHQ-8) [46], in which 8 items assess depressive symptoms on a 4-point Likert scale (from 0=not at all to 3=nearly every day). Scores above the cutoff of 10 indicate major depressive symptoms. The Cronbach α value for this instrument was .84 in this study, indicating high internal consistency. The level of eHealth literacy was assessed with the German version of the eHealth Literacy Scale (eHEALS)

[47]. The scale assumes that reading skills are required to use technical offerings, the so-called literacy level. The eHEALS consists of 8 items to measure the skills in this regard. The items are intended to determine knowledge, comfort, and skills in finding, evaluating, and using eHealth information [47]. Sum scores for the eHEALS range from 8 to 40, with higher scores indicating a higher level of eHealth literacy. The Cronbach α value for this instrument was .90 in this study, indicating excellent internal consistency. Using self-generated items, further information concerning the general use of the internet and eHealth was collected. Participants were asked about their private use of media, such as duration and frequency of private internet use and confidence in dealing with eHealth. Internet anxiety was assessed by 3 items regarding concerns about internet use, with answers ranging from 1=strongly disagree to 5=strongly agree. Values above 5 indicate very high internet anxiety. The Cronbach α value for this instrument was .80 in this study, indicating sufficient internal consistency. Data regarding prior eHealth use were also collected.

The UTAUT was used to determine the factors that influence the acceptance of eHealth pain management interventions in patients with chronic pain. The instrument consists of 12 items. Responses are provided using a 5-point Likert scale ranging from 1=totally disagree to 5=totally agree. The added items, including sociodemographic, psychometric, medical, and eHealth-related variables, operate as direct predictors of acceptance. The individual items can be assigned to the predictors PE, EE, and SI. BI, which was operationalized as acceptance, was measured with 3 additional items. In this study, the values for Cronbach α were .90 for PE, .77 for EE, .82 for SI, and .87 for BI (=acceptance), indicating adequate to high internal consistency. More factors were added, including other sociodemographic, medical, and eHealth-related data, as direct predictors of acceptance to the original UTAUT model. The questionnaire with the exact wording of the items is presented in [Multimedia Appendix 1 \[16,34,38,40,42,48\]](#).

Statistical Analyses

Data analysis was performed using SPSS software (version 26.0; IBM Corp) and R (version 4.0.3; The R Foundation for Statistical Computing). Sum scores for PHQ-8 and eHEALS and mean scores for self-generated items for internet anxiety and eHealth-related knowledge were computed. Furthermore, the UTAUT model with its four scales (PE, EE, SI, and BI) was calculated, and the acceptance (=BI) scores were divided into categories based on previous research [16,38,42]: low acceptance was indicated by scores between 1 and 2.34, moderate acceptance between 2.35 and 3.67, and high acceptance between 3.68 and 5. As Shapiro-Wilk tests revealed that the data were not normally distributed, Wilcoxon rank-sum tests and an ANOVA were used to compare acceptance among the groups (age, number of treatments, treatment effectiveness,

cutoff score for PHQ-8, and experience with eHealth). Bonferroni-adjusted α levels were applied. A median split was used to dichotomize age. Multiple hierarchical regression analysis was applied to examine possible predictors of acceptance. Predictors were included blockwise: (1) sociodemographic data, (2) psychometric and medical data, (3) eHealth-related variables, and (4) UTAUT predictors. The extended model was additionally tested against the restricted UTAUT model that only included the UTAUT predictors (PE, EE, and SI). Homoscedasticity was tested through Breusch-Pagan tests. The level of significance was set at $\alpha < .05$. Effect sizes are presented according to Cohen [49], with values around 0.2, 0.5, and 0.8 being considered small, medium, and large effects, respectively.

Results

Sociodemographic, Medical, and Psychometric Data

The vast majority, that is, 92.5% (284/307), of the participants were women, 7.2% (22/307) were men, and 1 (0.3%) self-identified as nonbinary. The mean age of the participants was 45.96 (SD 10.66) years. The participants ranged in age from 18 to 69 years.

Most (280/307, 91.2%) of the patients had endorsed pain for at least 12 months; for 83.1% (255/307), the pain lasted for >2 years. Pain frequency was most frequently reported as permanent (143/307, 46.6%) and daily (102/307, 33.2%). In total, 17.3% (53/307) of the participants had tried >6 different pain treatments. More than half (183/307, 59.6%) of the participants had already received 3 to 6 different pain treatments, and 23.1% (71/307) had tried <3 different pain treatments. More than half (184/307, 59.9%) considered prior treatment efficient. The reported treatments included surgery, medication, psychotherapy, and alternative healing methods. In the PHQ-8 questionnaire, 73.3% (225/307) of the participants achieved a score above the cutoff of 10, indicating depressive symptoms. For further details, refer to [Table 1](#).

Of the 307 participants, 208 (67.8%) had no experience with eHealth pain management interventions. However, regarding digital media use, only 7.8% (24/307) of the participants reported feeling very insecure or a little uncertain. This represents a high level of confidence in the use of digital media in the sample, with 81.4% (250/307) of the participants feeling secure about using digital media (mean 4.17, SD 1.01). The mean level of internet anxiety in this sample was 1.78 (SD 0.83), whereas values above 5 indicate a very high level of internet anxiety. Thus, internet anxiety was low in the sample. On average, the participants showed a high level of eHealth literacy (mean 30.40, SD 5.34) according to eHEALS [47]. For further details, refer to [Table 2](#).

Table 1. Sociodemographic, medical, and psychometric data (N=307).

Variable	Value
Gender, n (%)	
Woman	284 (92.5)
Man	22 (7.2)
Nonbinary	1 (0.3)
Age (years), mean (SD)	45.96 (10.66)
Education, n (%)	
University and qualification for university	146 (47.6)
Lower qualification	161 (52.4)
Occupational status, n (%)	
Retired	41 (13.4)
Employed	176 (57.3)
Unemployed	51 (16.6)
Other	39 (12.7)
Place of residence (population size), n (%)	
Large city (>100,000)	86 (28)
Medium-sized city (>20,000)	91 (29.6)
Small town (>5000)	60 (19.5)
Rural municipality (<5000)	70 (22.8)
Marital status, n (%)	
Single	57 (18.6)
Married	152 (49.5)
In a relationship	65 (21.2)
Divorced or separated	29 (9.4)
Widowed	4 (1.3)
Pain period, n (%)	
3 to 6 months	12 (3.9)
6 to 12 months	15 (4.9)
>12 months	280 (91.2)
1 to 2 years	25 (8.1)
>2 years	255 (83.1)
Pain frequency, n (%)	
Permanent	143 (46.6)
Daily	102 (33.2)
Several times a week	53 (17.3)
Once a week	9 (2.9)
Number of prior treatments, n (%)	
<3	71 (23.1)
3 to 6	183 (59.6)
>6	53 (17.3)
Considered prior treatment efficient, n (%)	184 (62.4)
PHQ-8 ^a (sum score), mean (SD)	13.20 (5.29)
PHQ-8 score <10, n (%)	82 (26.7)

^aPHQ-8: Patient Health Questionnaire depression scale.

Table 2. eHealth-related data (N=307).

Variable	Value
No eHealth experience, n (%)	208 (67.8)
Duration of daily private internet use (hours), mean (SD)	2.9 (1.22)
Duration of daily private internet use (hours), n (%)	
0 to 1	39 (12.7)
1 to 2	83 (27)
2 to 3	99 (32.2)
3 to 4	34 (13.7)
>4	44 (14.3)
Confidence in dealing with eHealth, mean (SD)	4.17 (1.01)
Confidence in dealing with eHealth, n (%)	
Very little confident	10 (3.3)
A little unconfident	14 (4.6)
Neutral	33 (10.7)
Rather confident	106 (34.5)
Very confident	144 (46.9)
Internet anxiety ^a , mean (SD)	1.78 (0.83)
eHealth literacy ^b , mean (SD)	30.40 (5.34)
UTAUT^c core predictors, mean (SD)	
Behavioral intention	3.67 (0.89)
Social influence	3.46 (0.77)
Performance expectancy	3.36 (0.84)
Effort expectancy	3.47 (0.79)

^aValues above 5 indicate a very high level of internet anxiety (range 1-5).

^bHigher scores indicate a higher level of eHealth literacy (range 8-40).

^cUTAUT: Unified Theory of Acceptance and Use of Technology.

Acceptance of eHealth Pain Management Interventions

General acceptance was moderate to high, with a mean of 3.67 (SD 0.89). In total, 9.1% (28/307) of the participants showed low level of acceptance, 47.2% (145/307) showed moderate level of acceptance, and 43.6% (134/307) showed high level of acceptance.

Of the 307 participants, 154 (50.2%) were below the median age of 47 years, and the mean acceptance score in this group was 3.80 (SD 0.87), whereas 153 (49.8%) had a median age of ≥ 47 years and had a mean acceptance score of 3.55 (SD 0.89). The Wilcoxon rank-sum test revealed a significantly higher acceptance in the younger age group ($W=9674.0$; $r=0.156$; $P=.04$). Acceptance did not differ significantly among the groups divided by occupational ($F_{3,303}=0.44$; $P=.99$) or educational status ($W=10,515.0$; $P=.76$). There were no significant differences in acceptance regarding number of treatments ($F_{2,304}=2.27$; $P=.74$), treatment effectiveness ($W=9037.5$; $P=.67$),

cutoff for PHQ-8 ($W=8487.0$; $P=.99$), and experience with eHealth ($W=10,288.0$; $P=.99$).

Predictors of Acceptance of eHealth Pain Management Interventions

Multiple hierarchical regression analysis revealed that the sociodemographic predictors included in the first step explained 4.1% of the variance of acceptance ($R^2=0.041$; $F_{7,299}=1.83$; $P=.08$). In the first step, *age* significantly predicted acceptance ($\beta=-.01$; $P=.004$). With the second step, which included the psychometric and medical predictors ($R^2=0.069$; $F_{13,293}=1.66$; $P=.07$), the explained variance increased significantly to 6.9% ($\Delta R^2=0.028$; $F_{6,293}=2.97$; $P=.001$), although none of the included variables were significant predictors on their own. The eHealth-related predictors included in the third step ($R^2=0.130$; $F_{25,281}=1.68$; $P=.03$) further increased the explained variance significantly to 13% ($\Delta R^2=0.061$; $F_{12,281}=4.22$; $P<.001$). In the third step, *place of residence: medium-sized city* ($\beta=-.27$;

$P=.048$), *confidence in dealing with eHealth: neutral* ($\beta=.69$; $P=.04$), *confidence in dealing with eHealth: rather confident* ($\beta=.66$; $P=.03$), and *confidence in dealing with eHealth: very confident* ($\beta=.71$; $P=.02$) were additional significant predictors.

The last step included the UTAUT predictors ($R^2=0.664$; $F_{28,278}=19.63$; $P<.001$) and explained 66.4% of the variance in acceptance. The additional predictors increased the explained variance significantly by 53.4% ($\Delta R^2=0.534$; $F_{3,278}=147.46$;

$P<.001$). As expected, *EE* ($\beta=.37$), *PE* ($\beta=.33$), and *SI* ($\beta=.34$) significantly predicted acceptance (all $P<.001$). In addition to the UTAUT predictors, the following variables were found to be significant predictors of acceptance in the overall model (step 4): *place of residence: small town* ($\beta=-.28$; $P=.004$), *private daily internet use: 2 to 3 hours* ($\beta=-.25$; $P=.02$), and *private daily internet use: >4 hours* ($\beta=-.29$; $P=.02$). Table 3 presents an overview of the parameters included in each step in the hierarchical regression model.

Table 3. Hierarchical regression model of acceptance (the extended Unified Theory of Acceptance and Use of Technology model; N=307).

Predictor	β^a	β^b	T	R^2^c	ΔR^2^d	P value
Step 1: sociodemographic variables				0.041	0.041	— ^e
Age (years)	-.01	-.11	-2.75	—	—	.006
Occupational status						
Employed	-.11	-.13	-1.10	—	—	.27
Unemployed	-.14	-.15	-1.15	—	—	.25
Other	.00	.00	0.09	—	—	.98
Place of residence						
Medium-sized city	-.26	-.30	-3.12	—	—	.002
Small town	-.28	-.31	-2.91	—	—	.004
Rural municipality	-.12	-.13	-1.35	—	—	.18
Step 2^f: psychometric and medical variables				0.069	0.028	.001
PHQ-8 ^g	.01	.04	1.08	—	—	.28
Pain duration (months)						
6 to 12	-.02	-.03	-0.11	—	—	.92
12 to 24	-.37	-.41	-1.81	—	—	.07
>24	-.18	-.20	-1.04	—	—	.30
Number of treatments tried						
>6	.05	.06	0.58	—	—	.57
<3	-.13	-.15	-1.64	—	—	.10
Step 3^f: eHealth-related factors				0.130	0.061	<.001
Private daily internet use (hours)						
1 to 2	-.17	-.19	-1.51	—	—	.13
2 to 3	-.25	-.28	-2.27	—	—	.02
3 to 4	-.17	-.19	-1.33	—	—	.19
>4	-.29	-.33	-2.27	—	—	.02
Confidence in dealing with eHealth						
A little unconfident	-.23	-.26	-0.96	—	—	.34
Neutral	.28	.31	1.35	—	—	.18
Rather confident	.20	.23	1.05	—	—	.29
Very confident	.08	.09	0.42	—	—	.68
Internet anxiety	-.03	-.03	-0.66	—	—	.51
eHealth knowledge	.03	.03	0.83	—	—	.41
No eHealth experience	.07	.08	0.92	—	—	.36
eHEALS ^h	.00	.02	0.39	—	—	.70
Step 4^f: UTAUTⁱ core predictors				0.664	0.534	<.001
Effort expectancy	.37	.33	6.74	—	—	<.001
Performance expectancy	.33	.31	6.30	—	—	<.001
Social influence	.34	.29	6.46	—	—	<.001

^aStandardized coefficient beta.^bUnstandardized coefficient beta.^cDetermination coefficient.

^dChanges in R^2 .

^eNot available.

^fIn steps 2, 3, and 4, only the newly included variables are presented.

^gPHQ-8: Patient Health Questionnaire depression scale.

^heHEALS: eHealth literacy scale.

ⁱUTAUT: Unified Theory of Acceptance and Use of Technology.

Restricted UTAUT Versus Extended UTAUT Model

In our study, the explained variance for the restricted UTAUT with the three core predictors PE, EE, and SI was 61.2% ($R^2=0.612$, $R^2_{adj}=0.608$). The explained variance for our extended UTAUT model with added sociodemographic, medical, and eHealth-related factors reached 66.4% ($R^2=0.664$, $R^2_{adj}=0.630$) of explained variance. The comparison of the 2 models revealed a significant difference in explained variance ($F_{25,278}=1.74$; $P=.02$). Thus, the extended UTAUT model explains more variance in the acceptance of eHealth pain management interventions among patients with chronic pain.

Discussion

Principal Findings

The main objective of the study was to determine the acceptance of eHealth pain management interventions among patients with chronic pain, as well as identify the factors that influence acceptance. Overall, the acceptance among patients with chronic pain in this study was moderate to high. In total, 43.6% (134/307) of the participants showed a high level of acceptance, 47.2% (145/307) showed a moderate level of acceptance, and only 9.1% (28/307) showed a low level of acceptance.

We were able to confirm the positive relationship between the three core predictors (PE, EE, and SI) of the UTAUT model and acceptance, as demonstrated previously; for example, in patients with diabetes or obesity [34,38,42]. The 3 core predictors of the restricted UTAUT explained 61.2% of the variance in this study. This result is comparable to that in the original study in which the UTAUT was evaluated [50]. This underlines the viability of the UTAUT to be used for eHealth pain management interventions among patients with chronic pain. A comparison of the restricted UTAUT model and the extended UTAUT model revealed a higher explained variance for the extended UTAUT that included the added predictors. The additional factors were included in the extended UTAUT model because additional factors beyond the core predictors can be assumed to influence acceptance.

Age was a significant predictor of acceptance in this study. Young age, defined here as age <47 years, the median age in our sample, was associated with greater acceptance. This is consistent with the results from previous studies [16,39,42]. To increase acceptance among older patients too, they can be especially reached out to when addressing the target group for an intervention. With regard to the influence of SI on acceptance, this could be achieved, for example, through a recommendation by the family physician. We did not include gender in the analysis because our sample was not representative in terms of gender distribution. The place of residence was found

to have an influence on acceptance. Patients living in a medium-sized city or small town showed an increased level of acceptance. It is possible that there are fewer face-to-face treatments available in small towns than in large cities. However, when it comes to rural municipalities, we did not observe an increased level of acceptance. This might be comparable to the finding that in rural areas internet-based media platforms are used less often than in cities [51], which might indicate a more reserved attitude and makes individuals from rural areas a relevant target group for interventions that aim to increase acceptance. Education was not significantly associated with acceptance in our study, in contrast to previous studies [16,39]. However, it should be mentioned that an above-average number of participants in the survey have a university degree, and this could at least have had an influence on the high eHealth literacy level in the survey. The lack of effect of education could simply be because people with low education and who might have rated their acceptance level as low are not adequately represented in the study. Of note, this overrepresentation is a common bias in psychological research: 96% of psychological studies are conducted on Western, educated, industrialized, rich, and democratic samples [52,53]. Occupational status was also not significantly associated with acceptance. We did not observe an increased level of acceptance in patients with a higher number of treatment attempts and lower treatment effectiveness. On the one hand, it can be assumed that patients who have already tried various treatments and have still not found an effective treatment may be more willing to try other options, such as web-based interventions. On the other hand, it is possible that patients for whom no treatment has been successful even after many attempts may be suspicious of new forms of treatment because the absence of treatment success has lowered their trust level and perceived self-efficacy. It is possible that these effects may cancel each other out. Internet anxiety was low in the sample, which is in line with overall frequent private internet use and the fact that a proportion of the participants were recruited through the internet. The high level of confidence in the use of digital media underlines the patients' confidence in using eHealth technologies. Internet anxiety did not have a significant influence on acceptance. However, confidence in dealing with eHealth had an influence on acceptance. Acceptance in participants who felt confident was significantly higher than in those who described their confidence level as neutral. This might provide an opportunity to increase acceptance in the future; for example, the confidence could be increased in advance through training or tutorials by providing comprehensive information and personal assistance during the use of eHealth pain management interventions. Furthermore, it is noteworthy that despite frequent private internet use, only 32.2% (99/307) of the participants had already had experience with eHealth. It is unclear whether this is due to a shortage of eHealth offerings in everyday clinical practice or previous skepticism about

eHealth. Nevertheless, prior experience with eHealth had no influence on acceptance in this study.

In contrast to previous studies [42], we observed no association between depressive symptoms and acceptance of eHealth pain management interventions. The reasons for the high proportion (225/307, 73.3%) of participants with depressive symptoms may be multifactorial. First, the proportion of patients with depressive symptoms is higher among patients with chronic pain than in the general population [54-58]. Second, the data collection took place during the COVID-19 pandemic when the prevalence of depression was elevated [59]. However, the fact that an excessively high proportion (225/307, 73.3%) of participants in our sample showed depressive symptoms underlines the comorbidity of chronic pain and mental health burden [54,55]. Interestingly, acceptance decreased with increasing duration of private daily internet use. An explanation for this finding could be that participants who already use the internet a lot in their daily lives do not want to further extend the hours of internet use and therefore do not want to seek therapy through the internet. To assess this more accurately, it would be useful to conduct future studies to determine how patients with chronic pain use the internet and whether internet use itself is associated with acceptance. It would be interesting to know whether they associate internet use with work or see it more as entertainment, which they would like to keep separate from serious topics such as the treatment of their illnesses. In this case, future studies could also include questions on the circumstances in which participants judge offerings as serious.

Although we did not find an influence on the acceptance of eHealth pain management interventions for several of the aforementioned factors, overall acceptance was higher than in previous studies [37,38,40-42]. Several explanations for this can be considered. First, patients were also recruited through social media, and social media users might generally be more accepting of web-based programs. The fact that mainly women participated in the survey should also be noted. In a previous study with patients with diabetes, acceptance of eHealth interventions was significantly higher among women than among men [38]. Understanding the reasons behind possible gender differences in eHealth acceptance would thus be necessary to improve eHealth acceptance among men. An alternative explanation could be that patients with chronic pain generally show higher acceptance than other groups. To further investigate this, patients with chronic pain would need to be compared with other patient populations. Another reason for the higher acceptance could be the timing of data collection. It is likely that acceptance of eHealth interventions changes with their increasing implementation in health care [60]. In addition, younger people are already showing increased acceptance, and as they will make up a large part of the population in the future because of demographic change, increased acceptance can also be expected as a result.

Even with the extended UTAUT, only selected factors were tested for their influence on the acceptance of eHealth pain management interventions. It is likely that there are additional factors that need to be investigated to further understand acceptance and implementation of eHealth pain management interventions. Further research should target these influences.

Limitations

The results of the study should be interpreted in the context of the limitations discussed herein. A proportion of participants were reached through inquiries in web-based support groups. Part of the reason for this may be the timing of data collection. Because of the COVID-19 pandemic, for example, time spent by patients waiting inside physicians' offices was reduced, and hand-distributed flyers were accepted reluctantly, which made offline recruitment more difficult. It is quite possible that by recruiting through the internet, mainly those who are already more willing to use the internet were reached. Thus, a selection bias cannot be ruled out. In future surveys, more emphasis should be placed on recruiting through in-person channels. Because of the predominance of female participants, the influence of gender could not be investigated. The excessive proportion (284/307, 92.5%) of women in the sample is not representative of the gender composition in the overall population of patients with chronic pain, which limits the generalizability of the results because of sampling bias. A reason for this could be that recruitment widely took place in social media groups, which largely consist of female members, including groups for people with endometriosis and fibromyalgia, where the majority of those affected are women [61,62]. Furthermore, the study provides only a theoretical account of whether patients with chronic pain would be willing to use eHealth pain management interventions. If one regards acceptance as BI to use such offerings, the extent of their actual use remains to be determined. However, considering the intention-behavior gap [63], that is, the phenomenon that the intention to do something does not lead to real behavior to the same extent, it remains unclear whether the observed intention will also lead to actual use. Future studies should thus compare survey results of acceptance with subsequent use of such interventions. Nevertheless, knowledge of the factors influencing acceptance should be used and specifically addressed in the development of eHealth pain management interventions.

Conclusions

This study was able to demonstrate overall moderate to high acceptance of eHealth pain management interventions among patients with chronic pain. This high rate of acceptance suggests that eHealth interventions can offer a viable alternative for situations in which face-to-face treatment is not possible. The factors PE, EE, and SI were core predictors of acceptance. The extended UTAUT proved to be a useful tool for determining acceptance as well as the factors that influence the acceptance of eHealth pain management interventions among patients with chronic pain. Understanding the factors that influence acceptance is important to provide tailored eHealth pain management interventions and promote their actual use. When access to face-to-face treatment is limited, eHealth interventions offer a good alternative. With all that, we emphasize that the aim is not to replace face-to-face treatment but to complement it; for example, eHealth interventions can help bridge the gap until face-to-face therapy is received or complement existing therapies. Finally, this study highlights the importance of taking patients' expectations, needs, and capabilities into account when developing new treatment approaches.

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Authors' Contributions

AB, MT, and E-MS initiated and conceptualized the study. LJ and PS performed the statistical analyses and interpretation of the data, and PS wrote the first draft of the manuscript. Data acquisition was performed by LJ and PS. AB, CR, MT, and E-MS contributed to the design of the study. UK and DM gave important input regarding the specifics of the target cohort. All authors contributed to the further writing of the manuscript and approved its final version.

Conflicts of Interest

None declared.

Multimedia Appendix 1

The used Unified Theory of Acceptance and Use of Technology.

[[DOCX File, 28 KB - formative_v6i8e37682_app1.docx](#)]

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Abbreviations

BI: behavioral intention
EE: effort expectancy
eHEALS: eHealth literacy scale
FC: facilitating condition
PE: performance expectancy
PHQ-8: Patient Health Questionnaire depression scale
SI: social influence
UTAUT: Unified Theory of Acceptance and Use of Technology

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Original Paper

Evaluation of a Text Messaging Intervention to Promote Preconception Micronutrient Supplement Use: Feasibility Study Nested in the Healthy Life Trajectories Initiative Study in South Africa

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Abstract

Background: Social messaging strategies such as SMS text messaging and radio are promising avenues for health promotion and behavior change in low- to middle-income settings. However, evidence of their acceptability, feasibility, and impact in the context of young women's health and micronutrient deficiencies is lacking.

Objective: This study aimed to evaluate the feasibility of an automated 2-way text messaging intervention nested in an ongoing preconception health trial, the Healthy Life Trajectories Initiative (HeLTI; HeLTI *Bukhali*) in Soweto, South Africa. Second, we aimed to evaluate the acceptability of a health promotion radio serial, which aired concurrently in the region.

Methods: In this feasibility study, 120 participants enrolled in HeLTI *Bukhali* between November 2020 and February 2021 received the 6-month 2-way text messaging intervention. Quantitative and qualitative data on intervention acceptability, usability, interaction, perceived benefit, and fidelity were collected during 5 focus group discussions (FGDs) and from study data logs. During the FGDs, data were collected on the acceptability of the radio serial. Following the text messaging intervention, capillary hemoglobin levels were assessed, and a participant questionnaire provided information on adherence and attitudes toward supplements. The text messaging control group comprised the first 120 women recruited from November 2019 to February 2020, who received the *Bukhali* intervention but not the text messages. Statistical significance testing and a linear mixed model were used for indicative effect comparisons between the text message-receiving and control groups.

Results: The text messaging intervention was found to be acceptable and to have perceived benefits, including being reminded to take supplements, gaining knowledge, and feeling supported by the study team. The use of the 2-way text messaging reply function was limited, with only a 10.8% (13/120) response rate by week 24. Barriers to replying included a lack of interest or phone credit and technical issues. Regarding the indicative effect, participants receiving the text messages had higher self-reported adherence at follow-up than the text messaging control group (42/63, 67% vs 33/85, 39% taking supplements every time; $P=.02$), and altitude-adjusted hemoglobin increased more between baseline and follow-up in the SMS text message-receiving group than

in the text messaging control group (1.03, 95% CI 0.49-1.57; $P < .001$). The radio serial content was acceptable, although few participants reported exposure before the FGD.

Conclusions: Women reported that the text messaging intervention was useful and described the benefits of receiving the messages. Examination of hemoglobin status indicated a promising beneficial effect of text messaging support on adherence to micronutrient supplementation, requiring further exploration through randomized controlled studies. Health promotion through radio and text messages were both found to be acceptable, although more research into the radio serial reach among young women is needed.

Trial Registration: Pan African Clinical Trials Registry (PACTR) PACTR201903750173871; <https://tinyurl.com/4x6n32ff>

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KEYWORDS

preconception health; micronutrient supplements; adherence; behavioral; SMS text messaging intervention; mobile health; mHealth; radio serial; mobile phone

Introduction

Background

Women's health and nutritional status before and during pregnancy are increasingly being identified as important determinants of their future health, pregnancy success, and the health of the next generation [1]. However, across high-, middle-, and low-income countries, both over- and undernutrition remain prevalent before and during pregnancy, and nonadherence to nutritional recommendations is a global issue [1-7]. Micronutrient deficiencies persist in South Africa, with anemia affecting 23% to 31% of women of reproductive age in urban settings [8,9]. In this context, preconception health and its consequences have also been identified as important knowledge gaps among young women [10].

Using digital spaces for health promotion and health behavior change is an increasing global phenomenon. In South Africa, radio is the most consumed form of media, with an estimated 37.8 million weekly listeners, of whom approximately 30% listen via mobile phones [11]. Although radio messaging has shown promise for improving health knowledge [12], health behavior changes may be more effectively achieved when messaging is targeted to specific population subgroups and tailored to the needs of the individual [13].

SMS text messaging interventions are a potential avenue for providing targeted and tailored behavior change support, reinforced by the high level of mobile phone penetration in many low- to middle-income settings. For example, approximately 96% of households in South Africa in 2018 had a mobile phone, and of the country's population, 82% were estimated to have a smartphone subscription (smartphone penetration) [14]. Increasing data support the use of various SMS text messaging interventions to improve appointment attendance, medication adherence, and risk-related behavior change, mostly in the context of chronic diseases [15-19]. However, systematic reviews from low- to middle-income countries have found mixed or inconclusive evidence of the impact of SMS text messaging interventions, which are often not explicitly designed using behavior change theory [20-22]. In South Africa, SMS text messaging interventions have shown highly promising results for HIV care adherence, support, and education [23-25], as well as for pregnant and postpartum

women, through the National MomConnect SMS text message health messaging program [26,27]. Data from high-income settings suggest that a 2-way SMS text messaging intervention can support nutritional behavior change, resulting in weight loss and maintenance in the postpartum period [28], and that a mobile app can effectively improve preconception nutrition [29]. However, to the best of our knowledge, the use of SMS text messaging to improve nutritional status during the preconception period has not been previously explored.

Objectives

The main aim of this study was to evaluate the feasibility of a tailored 6-month SMS text messaging intervention to support adherence to preconception micronutrient supplementation in women enrolled in the Healthy Life Trajectories Initiative (HeLTI) *Bukhali* trial, a complex preconception health trial in Soweto, South Africa. This included an evaluation of the acceptability, usability, perceived benefit, fidelity, cost, and indicative effects of the SMS text messaging intervention for promoting supplement adherence. The second objective was to evaluate the acceptability of a radio serial and accompanying Facebook page aimed at supporting health promotion in the trial setting, which was aired toward the end of the SMS text messaging intervention.

Methods

Setting and Population

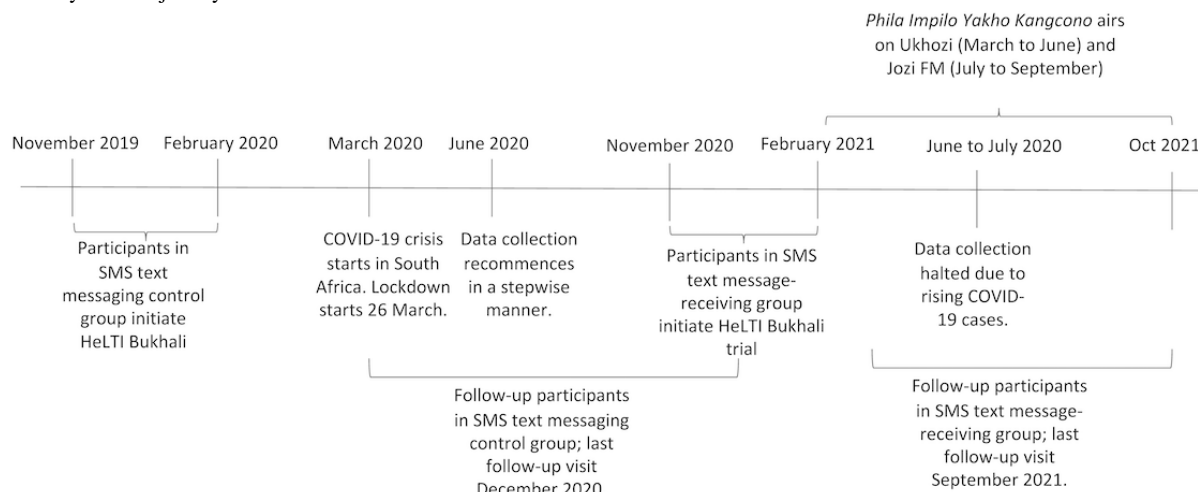
This study was nested in the intervention group of the South African site of the HeLTI *Bukhali* study, a randomized controlled trial that aimed to evaluate a multifaceted intervention for promoting the health of women of reproductive age (18-28 years) [30,31]. Similar trials are ongoing in Canada, India, and China in collaboration with the World Health Organization. HeLTI *Bukhali* is based in Soweto, a historically disadvantaged township bordering Johannesburg, with approximately 1.3 million residents, and recruitment started in 2018. The intervention was delivered by research staff trained in healthy conversation skills [32], who distributed educational resource material and provide health feedback in terms of BMI, hemoglobin, blood pressure, hemoglobin A_{1c} to assess hyperglycemia, HIV testing, and mental health and facilitated sessions to support improved health behaviors around nutrition, physical activity, sleep, health monitoring (eg, HIV testing),

and other goals identified by the participants. An aspect of the HeLTI *Bukhali* intervention is the provision of multimicronutrient supplements based on participants' anemia status. Women receive a supplement containing, among other micronutrients, 27 mg iron twice per week if they are nonanemic (capillary hemoglobin ≥ 12 g/dL) and daily if they are mildly anemic (hemoglobin < 12 g/dL), with women who are severely anemic (hemoglobin < 7 g/dL) receiving referrals to receive the current standard of care, comprising further assessment, supplementation, and additional management as required. The trial's control group was contacted once a month through telephone, SMS text message, or email to deliver information on *life skills* not directly related to health and had access to standard health services such as HIV and pregnancy testing. The intervention and control arms of the trial were included in the trial program for a total of 18 months and were followed throughout pregnancy and postpartum periods in case of pregnancy within the 18-month time frame [31].

The exclusion criteria for HeLTI *Bukhali* were a diagnosis of type 1 diabetes, cancer, or epilepsy; the presence of an intellectual disability that hinders informed consent; and being unwilling or unable to consent. For this feasibility study, only women recruited into the preconception intervention group of the trial were included. This study evaluated 2 distinct remote media approaches (SMS text messaging and radio combined with Facebook) in the same trial.

As indicated in the timeline in Figure 1, the first 120 women enrolled in HeLTI *Bukhali* between November 1, 2020, and February 2021, who consented to the SMS text messaging substudy, received the SMS text messaging intervention. This *SMS text message-receiving* group was asked to participate in this study's focus group discussions (FGDs), in which the acceptability of the health promotion radio serial was also evaluated.

Figure 1. Timeline of SMS text messaging feasibility study and airing of the radio serial in the context of the COVID-19 pandemic in South Africa. HeLTI: Healthy Life Trajectory Initiative.



In addition, for the preliminary evaluation of the indicative effect of the SMS text messaging intervention, a comparison group receiving the *Bukhali* intervention but not receiving the SMS text messages (*SMS text messaging control group* from here on) comprised the first 120 women who were recruited to the HeLTI *Bukhali* intervention arm from November 2019 onward until the target sample size was attained without any matching the SMS text message-receiving group. The time frame of the SMS text messaging control group recruitment was chosen to avoid seasonal variability in micronutrient status. This also avoided the major hiatus in data collection in response to the COVID-19 crisis that started in March 2020. Follow-ups for participants in the SMS text message-receiving and SMS text messaging control groups were conducted between May and October 2021 and May and December 2020, respectively. The delays in follow-up in both groups were largely attributable to the COVID-19 pandemic.

The HeLTI *Bukhali* Text Messaging Intervention

The HeLTI *Bukhali* SMS text messaging intervention and message bank were developed based on existing evidence and the behavior change theory. [Textbox 1](#) provides an overview of the SMS intervention according to the TIDieR (Template for Intervention Description and Replication) checklist. The Health Actions Process Approach (HAPA) [33] was the main guiding theoretical approach for developing the SMS text message library. The HAPA is a sociocognitive model encompassing 2 phases: the motivation phase, including outcome and risk perception and self-efficacy, and the volitional phase, including action-oriented processes such as action planning and maintenance of self-efficacy. HAPA has previously been shown to successfully inform medication adherence and UK-based SMS text messaging interventions [28,34,35]. The message bank was developed with input from young women in Soweto, including lessons from formative work for HeLTI *Bukhali* around barriers to supplement use [31], and was tested for any content or technical issues before this feasibility study.

Textbox 1. Reporting of the Template for Intervention Description and Replication checklist items for the Healthy Life Trajectories Initiative (HeLTI) Bukhali SMS text messaging intervention.

Template for Intervention Description and Replication checklist item and brief description

- Brief name
 - The brief name is HeLTI Bukhali SMS text messaging intervention.
- Why
 - A lack of adherence to micronutrient supplementation is a prevalent barrier to improving micronutrient deficiencies in the preconception period. SMS text messaging interventions are accessible and have shown potential as a cost-effective avenue to support behavior change in middle- and low-income settings. Therefore, this SMS text messaging intervention aims to improve adherence to and knowledge around micronutrient supplements in women of reproductive age. The intervention development is grounded in behavior change theory, specifically the Health Action Process Approach.
- What (materials)
 - The intervention consisted of comprised 48 SMS text messages delivered over the course of 24 weeks (2 per week). Messages were sent around midday on varying days of the week, as programmed from the day of initial HeLTI Bukhali enrollment. In addition to an introductory message, the 3 main types of SMS text messages were as follows: Health literacy messages: weekly educational messages on the contents and potential benefits of the micronutrient supplement, how they work, potential side effects, the importance of a balanced diet, tips on when to take the supplements, and how to remember them more easily Adherence messages: weekly 2-way messages querying whether participants had taken their supplements in the week (“did you take all your micronutrient pills this week?”); participants could reply “yes” or “no,” prompting a second message asking the main reason for not taking the supplement if the answer was “no” (“I forgot, I ran out of pills, the pills made me feel unwell, other”) Side effect–reporting messages: 2-way messages sent in weeks 2, 8, 13, and 20 instead of the health literacy message, asking participants if they had experienced any side effects from the supplements, to which participants could reply “yes” or “no,” and if they replied “yes,” a second message was sent asking which symptoms were present.
 - The message bank can be accessed from the corresponding author upon reasonable request. Participants were automatically supplied with ZAR 5 prepaid airtime weekly, which sufficiently covered the cost of responding to an SMS text message through any available provider.
- What (procedure)
 - SMS text messages were automatically sent twice a week to participant phone numbers, using Twilio Inc, and airtime was supplied automatically using FlickSwitch Control South Africa (Cape Town). The intervention evaluation was nested in the HeLTI South Africa Bukhali trial, which evaluates a complex intervention (education, social support, behavior change, and micronutrient supplement) [30,31]. Both the SMS text message–receiving and SMS text messaging control groups received the intervention arm of HeLTI Bukhali, although the control arm did not receive the SMS text messaging intervention in any form. As part of the trial, multimicronutrient supplements are provided based on the participants’ anemia status (see Setting and Population section for more details).
- Who provided
 - The SMS text messaging intervention was developed by the research team with input from young women in Soweto during the development phase. The delivery of the SMS text messaging intervention was automated.
- How
 - The mode of delivery was through SMS text messages. In the control group, no SMS text messages were delivered.
- Where
 - The intervention was delivered through SMS text messages. Participants were based in Soweto, a historically disadvantaged township bordering Johannesburg, with approximately 1.3 million residents.
- When and how much
 - The SMS text messaging intervention was delivered to 120 participants newly enrolled in HeLTI Bukhali between November 1, 2020, and February 2021 who additionally consented to the SMS text messaging substudy. The SMS text messaging intervention was delivered twice weekly for 6 months at midday on varying days of the week, as automatically scheduled based on the day of the participants’ initial enrollment in HeLTI Bukhali. For the feasibility study, the last participant received the last message in August 2021. The SMS text messaging control group comprised 120 HeLTI Bukhali participants who enrolled between November 2019 and February 2020, receiving the Bukhali intervention but no SMS text messages.
- Tailoring
 - The SMS text messaging intervention was not tailored to individual participants.
- Modification
 - The SMS text messaging intervention was not modified during the course of the feasibility study.

- How well (planned)
 - The fidelity of the planned intervention in terms of messages received, airtime received, and presence of any technical errors will be reviewed using a log of the automated SMS text messaging and airtime delivery systems.
- How well (actual)
 - See the Results section.

As described in [Textbox 1](#), participants received 2 messages every week for 24 weeks, with messages comprising health literacy, adherence, and side effect reporting. From the time participants were recruited to HeLTI *Bukhali*, SMS text messages were sent and received using an automated SMS text message delivery platform—Twilio Inc. To avoid nonparticipation in the 2-way SMS text messages because of a lack of funds, participants were automatically supplied with 5 South African Rand (ZAR 5, around US \$0.30) prepaid minutes of phone credit (“airtime”) weekly, which sufficiently covered the cost of responding to an SMS text message through any available provider, using FlickSwitch SIMControl South Africa (Cape Town). The successful delivery of the SMS text messages and airtime could be monitored through these respective platforms and was evaluated through qualitative data collection.

The Phila Impilo Yakho Kangcono Radio Serial

The *Phila Impilo Yakho Kangcono* (translating to “Live Your Best Life”) radio serial was designed as media support for the HeLTI trial, and an overview based on the TIDieR checklist is provided in [Textbox 2](#). The weekly radio serial targeted young people and aimed to promote well-being and health. It was aired in isiZulu and English between March and June 2021 on a Sunday youth show on Ukhozi FM, South Africa’s largest radio station, and on Jozi FM, a local radio station popular in Soweto, from July to September 2021. An associated Facebook page was created and referred to in the radio episodes [36]. The content of each episode was designed by an independent production team working with and guided by young adults (both men and women) from Soweto and the research team.

Textbox 2. Reporting of Template for Intervention Description and Replication checklist items for the Phila Impilo Yakho Kangcono radio serial intervention.

Template for Intervention Description and Replication checklist item and brief description

- Brief name
 - The brief name is the Phila Impilo Yakho Kangcono radio serial.
- Why
 - Preconception health and its significance are important knowledge gaps among young women, and radio is one of the most consumed forms of media in South Africa. Therefore, population-based health promotion through radio could be an accessible way of increasing health awareness and well-being among young people in South Africa.
- What (materials)
 - The intervention comprised 11 radio serial episodes of 15 to 20 minutes in English and isiZulu, designed to cover health and well-being topics identified as important by youth, such as mental health (eg, suicide and depression), diabetes, gender-based violence, hypertension, HIV, healthy food, and community gardens. In addition, an associated Facebook page was created to promote the radio serial and for listeners to comment and catch up on missed episodes. Each of the radio serial episodes can be accessed on the Facebook page, which is fully accessible to the public [36].
- What (procedure)
 - The radio serial was aired weekly on 2 radio stations—Ukhozi FM (South Africa’s largest radio station with a listener base of around 8 million people) and Jozi FM (a local radio station popular in Soweto)—with referral to the associated Facebook page.
- Who provided
 - The intervention was delivered over the radio and therefore not provided by individual care providers.
- How
 - The mode of delivery was radio (and Facebook), designed as a media campaign to be delivered on a population level rather than to individual participants.
- Where
 - The intervention was delivered through radio on Ukhozi FM and Jozi FM and through the associated Facebook page.
- When and how much
 - The radio serial aired once a week at 2:30 PM on Sundays from March to June 2021 on Ukhozi FM and at 10:30 AM from July to September 2021 on Jozi FM.
- Tailoring
 - The radio serial was not personalized or tailored.
- Modification
 - The intervention was not modified over the course of the study.
- How well (planned)
 - Not applicable.
- How well (actual)
 - Not applicable.

Ethics Approval

The human research ethics committee (Medical) at the University of Witwatersrand approved this study (M171137 and M1811111). Participants gave written informed consent before enrollment into the study and provided additional written informed consent before participating in the recorded FGDs.

Outcomes

This mixed methods study adopted a parallel-convergent approach, using a combination of quantitative and qualitative data sources to address feasibility outcomes [37]. The framework for evaluating young women’s perceptions of the HeLTI *Bukhali* SMS text messaging intervention and the radio serial and associated Facebook pages are outlined in Table 1 and are based on the existing literature on process evaluation [38,39]. The

main outcomes of interest for evaluating women's perceptions of the SMS text messaging intervention were acceptability, usability and level of interaction, perceived benefit, intervention cost and fidelity, and indicative effects. For the *Phila Impilo*

Yakho Kangcono radio serial and associated Facebook page, the main outcome was the acceptability of the radio serial and the associated Facebook page.

Table 1. Main outcomes and data sources for the study.

Objective	Main question addressed	Data source
Objective 1: feasibility of Healthy Life Trajectories Initiative Bukhali SMS text messaging intervention		
Acceptability	<ul style="list-style-type: none"> To what extent was the intervention delivery agreeable and acceptable to participants? 	Qualitative data from FGDs ^a with participants
Usability and interaction	<ul style="list-style-type: none"> To what extent could the intervention be used and was the intervention used adequately by the participants? 	Data log of the number of participants using the 2-way SMS text messaging system throughout the 6-month intervention; qualitative data from FGDs with participants
Perceived benefit	<ul style="list-style-type: none"> What were the perceived benefits of the intervention? Were there any unintended consequences of the intervention? 	Qualitative data from FGDs with participants
Fidelity of intervention delivery	<ul style="list-style-type: none"> To what extent was the intervention delivered as designed? 	Log of messages received, airtime received, and technical errors
Cost of intervention delivery	<ul style="list-style-type: none"> What costs were associated with intervention delivery? 	Log of cost of intervention
Indicative effect	<ul style="list-style-type: none"> What are the indicative effects of the intervention on self-reported adherence, attitudes toward micronutrient supplements, and hemoglobin level at follow-up? 	Quantitative baseline and follow-up hemoglobin values; quantitative surveys of attitudes to micronutrient supplements at follow-up
Objective 2: acceptability of the Phila Impilo Yakho Kangcono radio serial		
Acceptability	<ul style="list-style-type: none"> To what extent was the intervention delivery agreeable and acceptable to participants? To what extent had participants been exposed to the radio serial? 	Qualitative data from FGDs with participants

^aFGD: focus group discussion.

Data Collection

HeLTI Bukhali Text Messaging Intervention

Qualitative data on the acceptability, usability, interaction with, and perceived benefit of the SMS text messaging intervention were collected during 5 FGDs, including 2 to 9 participants. These were conducted by trained research staff from Soweto using a topic guide developed by the research team and were organized and attended by LMS. Participants were invited at random from those receiving SMS text message notifications 4 to 8 months after the initiation of the study. Refusals to participate in the FGDs were because of having moved away from Soweto, having other commitments, or being ill on the day of the FGD. Refreshments were provided at the FGD, which took 1 to 2 hours. The FGDs were conducted in English and in the participants' preferred language and were audio recorded (Philips Digital Voice Recorder DVT4110 and DVT1150). The recordings were transcribed verbatim but were anonymized and translated into English where necessary.

To evaluate the indicative effect of SMS text messaging intervention, data were captured and managed using REDCap (Research Electronic Data Capture; Vanderbilt University) [40]. Data were collected by trained research assistants at the research

unit in Soweto. At baseline, a validated questionnaire was used to gather information on participant age, attitudes toward and confidence in supplement use, parity, country in which the participant was born, their home language, education level, employment status, and food security [41]. Participants were categorized as *at risk of food insecurity* if they answered *yes* to one of the 3 questions in the food security questionnaire ("Does your household ever run out of money to buy food?"; "Do you ever cut the size of meals or skip meals because there is not enough money to buy food?"; "Do you go to bed hungry because there is not enough money to buy food?") and as *food insecure* if they answered *yes* to ≥ 2 of the questions, as previously described in our setting [42].

At a follow-up visit conducted approximately 6 months after initial recruitment for both the SMS text message-receiving and SMS text messaging control groups, a questionnaire was used to gather data on self-reported adherence to the micronutrient supplements (1=I never took them to 5=I took them every time), participants' perceived understanding of the condition of anemia, perceived health improvement because of the supplement, fears and side effects related to the supplement, and main reasons for not taking the supplement. At both baseline and follow-up, hemoglobin levels were measured using a Hemocue 201 device. As Soweto is situated >1700 m above

sea level, hemoglobin was altitude adjusted by -0.5 g/dL, according to the World Health Organization recommendation [43], as has previously been evaluated in our setting [44]. The difference in hemoglobin levels from baseline to follow-up (Δ hemoglobin) was calculated (hemoglobin follow-up – hemoglobin baseline).

Data obtained from the log of the automated SMS text messaging system also provided information on participant interaction with the intervention (rate of response to 2-way SMS text messaging features) and intervention fidelity (number of messages successfully received, technical failures, and airtime received by participants). The study records provided information on the total intervention costs per participant.

Phila Impilo Yakho Kangcono Radio Serial

During the 5 FGDs described in detail previously, all participants played 1 to 2 episodes of the *Phila Impilo Yakho Kangcono* radio serial and were shown the associated Facebook page to ensure exposure among all participants. Subsequently, data were collected on the acceptability of the radio serial. These data were recorded and transcribed as described previously.

Data Analysis

Qualitative data analysis was informed by the thematic analysis methods described by Braun and Clarke [45]. The analytic process and presentation of results followed the phases set out in the framework method, which is a codebook approach to thematic analysis [46]. The coding of transcripts combined a deductive approach based on the study objectives and the adapted process evaluation framework [38,39] outlined in [Table 1](#), with inductive analysis to allow for flexibility in incorporating unforeseen findings. LMS read the transcripts to familiarize herself with the data. The initial coding of the transcripts was completed by LMS using MAXQDA software (version 20.4.1; VERBI GmbH), and preliminary themes and framework matrices were reviewed by and discussed with LJW, SK, and MM to refine the analysis.

Quantitative data analysis was performed using STATA (version 13.0, StataCorp). Baseline characteristics and SMS text message response data were described as numbers and percentages for categorical variables and mean and SD or median and IQR for continuous variables. Outcomes at the 6-month visit, including change in hemoglobin from baseline (Δ hemoglobin) and change in anemia status, were compared between the participants receiving SMS text messages and the SMS text messaging control group using the Student *t* test (2-tailed) or Wilcoxon rank-sum test, depending on the normality of the data. The

baseline characteristics of participants lost to follow-up in the SMS text message–receiving and SMS text messaging control groups were described and compared with followed-up participants using statistical significance testing. Mixed linear modeling was used to explore the time point–adjusted association among altitude-adjusted hemoglobin, intervention exposure, time from baseline to follow-up, and the interaction between intervention exposure and time. A second, adjusted model was run adding variables that were statistically significantly different between the SMS text message–receiving and SMS text messaging control groups at baseline.

Results

The HeLTI Bukhali Text Messaging Intervention

Participant Baseline Characteristics

[Figure 2](#) shows the participants of this study. For the SMS text messaging intervention, 72.5% (87/120) of participants in the SMS text message–receiving group and 81.7% (98/120) of participants in the SMS text messaging control group had their data collected at the follow-up visit. Of these, 90.8% (79/87) in the SMS text message–receiving group and 90.8% (89/98) in the SMS text messaging control group had hemoglobin data available from their follow-up visits. Reasons for loss to follow-up included withdrawal from HeLTI *Bukhali* (not specifically from the SMS text messaging substudy; 17/240, 7.1%; 13/120, 10.8%, in the SMS text message–receiving, and 4/120, 3.3%, in the SMS text messaging control group) and relocation or an inability to trace (38/240, 15.8%). The main baseline characteristics in the followed-up versus lost to follow-up group are provided in [Table S1](#) in [Multimedia Appendix 1](#), and the only statistically significant difference between these 2 groups was the number of participants born in South Africa (185/185, 100%, in the followed group vs 53/55, 96%, in the lost to follow-up group).

[Table 2](#) shows the main baseline characteristics of the study participants. The median age was 21.5 (IQR 19–24) years, and 30.8% (74/240) of the participants had anemia (hemoglobin <11.9) at baseline. More SMS text message–receiving participants were unemployed and fewer had graduated from high school than the SMS text messaging control group participants. Moreover, the number of participants with mild or severe anemia at baseline was higher in the SMS text message–receiving group than in the SMS text messaging control group (50/120, 41.7% vs 24/120, 20%).

Figure 2. Overview of study participants during the feasibility study. HeLTI: Healthy Life Trajectory Initiative.

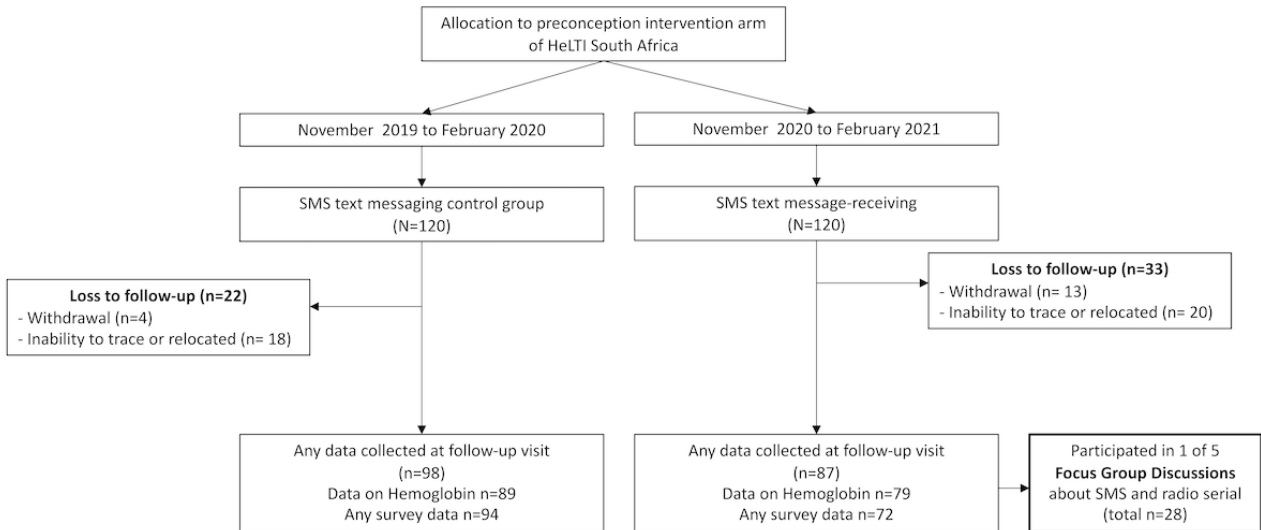


Table 2. Baseline characteristics of participants from Healthy Life Trajectories Initiative Bukhali assigned to the SMS text messaging or SMS text messaging control groups in the SMS text messaging intervention study (N=240).

Characteristics	All	Receiving SMS text messages (n=120)	SMS text messaging control (n=120)	P value
Age (years), median (IQR)	21.5 (19-24)	22 (20-25)	21 (19-24)	.07
Hemoglobin altitude adjusted (g/dL), median (IQR)	12.4 (11.7-13.6)	12.2 (11.5-13.2)	12.6 (12.1-13.8)	<.001 ^b
Anemia status, n (%)				
≥12	166 (69.2)	70 (58.3)	96 (80)	.001 ^b
7-11.9	72 (30)	48 (40)	24 (2)	.001 ^b
<7	2 (0.8)	2 (1.7)	0 (0)	.001 ^b
BMI, median (IQR)	23.7 (20.8-28.1)	24.4 (21.3-29.1)	22.6 (20.2-27.8)	.05
Weight status, n (%)				
Underweight	21 (8.8)	8 (6.7)	13 (10.8)	.18
Normal weight	124 (51.7)	58 (48.3)	66 (55.0)	.18
Overweight or obese	95 (39.6)	54 (45.0)	41 (34.2)	.18
Attitudes toward supplements at baseline, n (%)^a				
How sure are you that you will be able to take all or most of your supplements as directed?				
Not at all	1 (0.6)	0 (0)	1 (1.8)	.24
Somewhat sure	11 (6.4)	6 (5.3)	5 (8.8)	.24
Very or extremely sure	159 (93)	108 (94.7)	51 (89.5)	.24
How sure are you that the supplements will have a positive effect on your health?				
Not at all	4 (2.3)	2 (1.8)	2 (3.5)	.67
Somewhat sure	28 (16.4)	20 (17.5)	8 (14)	.67
Very or extremely sure	139 (81.3)	92 (80.7)	47 (82.5)	.67
Demographic characteristics, n (%)				
Previous live births				
0	132 (55.2)	59 (49.6)	73 (60.8)	.21
1	76 (31.8)	42 (35.3)	34 (28.3)	.21
≥2	31 (13.0)	18 (15.1)	13 (10.8)	.21
Born in South Africa	239 (99.6)	119 (99.2)	120 (100)	.32
Unemployed (and not studying)	184 (76.7)	99 (82.5)	85 (70.8)	.03 ^b
Graduated high school	145 (60.4)	64 (53.3)	81 (67.5)	.03 ^b
Food security^c				
At risk (1)	55 (22.9)	29 (24.2)	26 (21.7)	.71
Food insecure (≥2)	86 (35.8)	40 (33.3)	46 (38.3)	.71
Current frequent smoker	30 (12.5)	15 (12.5)	15 (12.5)	.49
Smoked in the past year	54 (22.5)	23 (19.2)	31 (25.8)	.22

^aTotal sample n=171; SMS text messaging group n=114; SMS text messaging control group n=57.

^bIndicates a statistically significant difference between the SMS text message-receiving and control groups at $P<.05$ using a Mann-Whitney U test for continuous outcomes and chi-square statistic or Fisher exact test (if cell count <5) for categorical outcomes.

^cTotal sample n=239; SMS text messaging group n=119; SMS text messaging control group n=120.

Objective 1: Feasibility of the Bukhali Text Messaging Intervention**Acceptability**

In terms of acceptability, participants liked receiving SMS text messages on their phones, which they expressed using frequently, and reported that the content was acceptable (Table 3).

The participants suggested changes that would make the SMS text messages more acceptable and useful. For example, participants suggested sending SMS text messages earlier in

the morning and on days when they had to take micronutrient supplements (such as Mondays). Participants taking a daily dose of micronutrient supplements expressed the potential added value of receiving reminder messages every day. However, some participants described adherence messages as repetitive, resulting in them not always being read. Although some participants expressed that the health literacy messages were too long, others liked them and described reading them in full. Participants gave suggestions unique to their personal preferences and needs, such as receiving messages at night or preferring phone calls.

Table 3. Qualitative evaluation of the acceptability of the Healthy Life Trajectories Initiative Bukhali SMS text messaging intervention^a.

Acceptability	Quotes
Timing	
In support (positive)	
The timing of receiving the messages was acceptable	<ul style="list-style-type: none"> • “I think it’s fine, there’s nothing wrong with the timing...It asks you questions about the supplements and then tell you what the supplements provide you with, so I think it doesn’t cause any harm” [FGD^b 1] • “Whatever time I get the notification I read it and see what it contains, then I’m fine, I don’t see anything wrong.” [FGD 1] • “I think it’s the perfect time because they usually send an SMS in the morning.” [FGD 2]
Against (negative)	
Receiving the SMS text message at midday or later in the day was too late	<ul style="list-style-type: none"> • “I think mornings are better because you know that when you wake up, after breakfast you take it [micronutrient supplements].” [FGD 5] • “[I receive the SMS] around 12 and you find that I am in class.”
Participants wanted to receive the message on Monday when they take their supplement	<ul style="list-style-type: none"> • “For me the one that I want for the morning is the Monday one because when I’m from the weekend, I don’t want to lie, I forget.” [FGD 3]
Other participants had personal timing preferences	<ul style="list-style-type: none"> • “I prefer night time because I just take it before bed time then sleep.” [FGD 5]
Suggested adaptations	
To receive the messages early in the morning and on Mondays	<ul style="list-style-type: none"> • “They should input it on time and not input it late, they should send it at around seven” [FGD 3] • “I think they should send them Mondays and Wednesdays around 9, if you forgot, that will be a reminder that ‘I was supposed to take my supplements’” [FGD 1]
Frequency	
In support (positive)	
Receiving messages twice a week was acceptable	<ul style="list-style-type: none"> • “I think it’s fine, because you have to take them twice a week. So yes, it’s OK.” [FGD 4] • “it was actually a good thing getting them twice a week.” [FGD 2] • “I think twice a week it’s perfect.” [FGD 2]
Against (negative)	
Receiving messages twice a week was not enough	<ul style="list-style-type: none"> • “I think it’s too little.” [FGD 3] • “I wish they would send those every day” [FGD 1]
Suggested adaptations	
To receive the messages every day, particularly for those taking their supplements daily	<ul style="list-style-type: none"> • “At least every day, for me.” [FGD 3] • “You should take them every day if your iron is low, so the SMS’s should also come every day. If your iron is OK; they should come in on your designated days to take the supplements.” [FGD 5]
However, some expressed that receiving the same messages every day would be too repetitive	<ul style="list-style-type: none"> • “Sometimes the SMS’s say the same thing; so do you think it’s right that we get those every day?” [FGD 5]
Content	
In support (positive)	
The content was found to be easy to understand	<ul style="list-style-type: none"> • “They are OK; even the explanation is straight forward.” [FGD 5] • “The English they use is simple, they don’t use bombastic...” [FGD 5] • “It is self-explanatory and not complicated English.” [FGD 4] • “The language is understandable” [FGD 2]
Against (negative)	
The repetitive nature of the adherence to SMS text messages was found boring	<ul style="list-style-type: none"> • “They sent the very same thing over and over so...no man!” [FGD 5] • “Sometimes it was boring me, to be honest it was boring me. You do the same thing all the time.” [FGD 3]

Acceptability	Quotes
Suggested adaptations	
To vary the phrasing of the adherence message from day to day (although some repetitiveness is inherent to the nature of these messages)	__ ^c
Length	
In support (positive)	
The length of the messages was acceptable	<ul style="list-style-type: none"> • “The length is not that much, like it’s very convenient, it doesn’t even take much of your time whereby you like now you have to sit down and read.” [FGD 2] • “I think the long information is better.” [FGD 2]
Against (negative)	
The information messages were too long	<ul style="list-style-type: none"> • “What I disliked is that they were lengthy.” [FGD 5] • “When you are tired from school and all the studying then you receive a long text...its draining.” [FGD 1] • “Sometimes they send lengthier ones and maybe you are busy so I didn’t like those.” [FGD 5]
Suggested adaptations	
To shorten the information messages or split them into multiple messages	<ul style="list-style-type: none"> • “They should keep it brief and straight forward.” [FGD 5] • “They should try and limit it and make sure they stick to the relevant key points and not add anything else.” [FGD 5] • “So instead of sending one long message, they could send two different messages, one immediately after the other.” [FGD 1]

^aMain conclusion: The intervention was found to be acceptable, easy to understand, and delivered through an acceptable medium; however, opinions differed according to personal preference and needs on frequency, timing, and length of the messages.

^bFGD: focus group discussion.

^cIndicates a suggested adaptation formulated by the study team inferred from the presented evidence from the FGD but without direct supporting evidence from the participants.

Interaction and Usability

On the basis of quantitative analysis of the data log of participants’ use of the 2-way SMS text messaging system, the participants’ interactions with the 2-way SMS text messaging intervention in terms of response rate were low, with only 59.2% (71/120) of participants replying to any 1 message (Figure 3). Use declined over the 6 months of the intervention, and 10.8% (13/120) of participants still receiving messages replied in week 24.

In the FGDs, participants described their main reasons for not using the reply function as being too busy, lack of interest, lack of airtime, not understanding whether they were required to reply, and a technical error (Table 4). Participants expressed that a fuller explanation of the reply function and the received weekly prepaid airtime was needed. Similarly, participants expressed that being too busy, a lack of interest, and technical issues were the main barriers to receiving and reading SMS text messages. In terms of technical issues, some participants received the message in 2 parts or only received half of the message, possibly because of the length of some of the health literacy messages.

Figure 3. Use of 2-way SMS text messaging system by the number of SMS text message respondents and response rate by week.

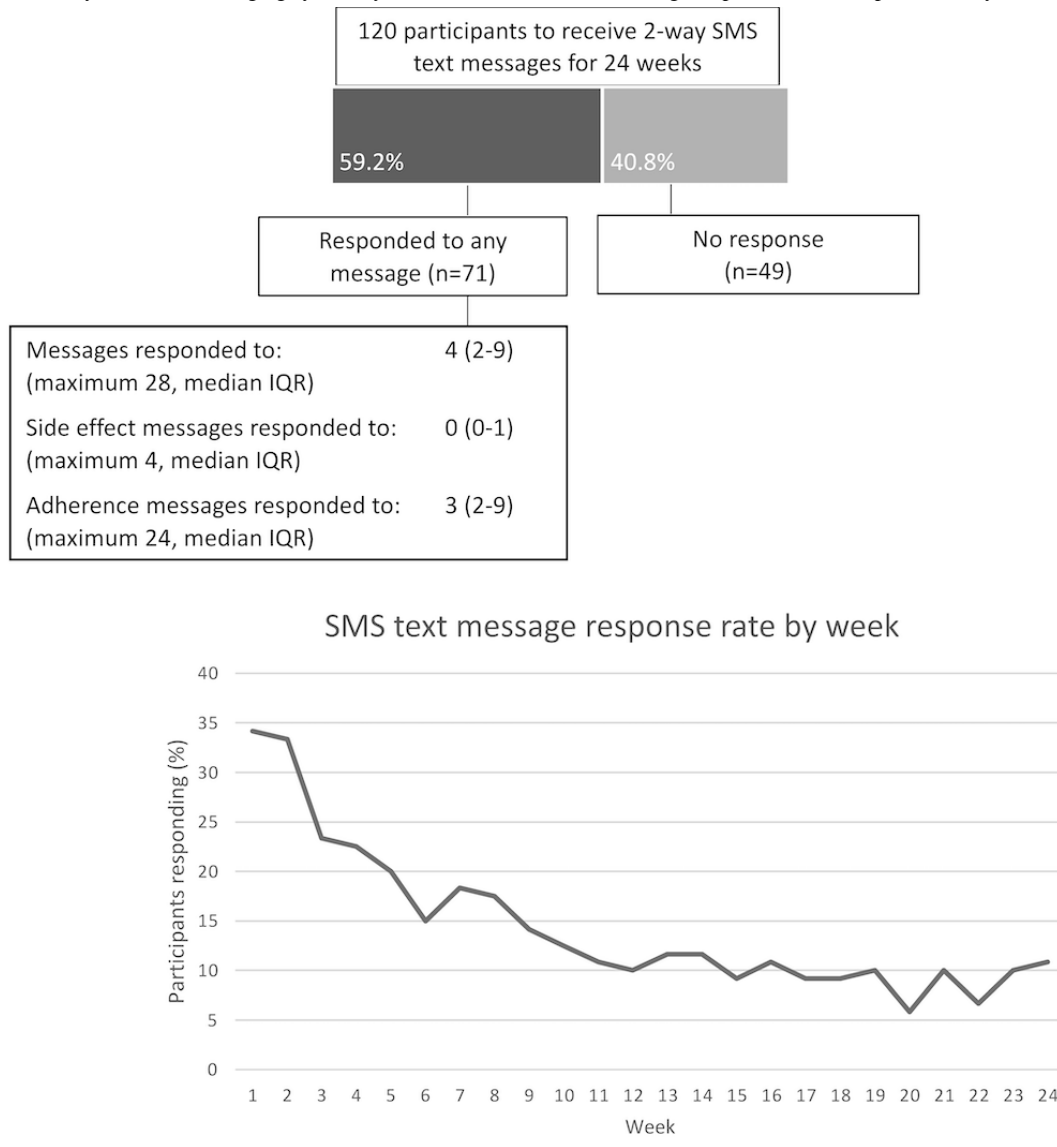


Table 4. Qualitative evaluation of the usability of and interaction with the Healthy Life Trajectories Initiative Bukhali SMS text messaging intervention^a.

Usability and interaction	Quotes
Receiving and reading	
In support of (positive)	
The SMS text message reached and was read by participants	<ul style="list-style-type: none"> • “I always read them.” [FGD^b 1] • “Yeah every time I got the message I read everything that is written on it.” [FGD 2] • “If I saw that it is a different message I’d read the message.” [FGD 2]
Against (negative)	
Reasons for not reading the SMS text messages included being too busy, loss of interest, and technical issues in receiving the SMS text messages	<ul style="list-style-type: none"> • “I won’t lie, when I am in class I just look at it and just put it back in my pocket.” [FGD 5] • “I read them in the first week. I had the energy to; I would even sit down for it. But after that, no.” [FGD 5] • “The phone I used to receive the SMS’s is broken, so...I no longer received the SMS’s” [FGD 1]
Suggested adaptations	
To send SMS text messages at a more convenient time (eg, earlier in the morning)	— ^c
To resolve technical problems and unearthing and solving individual participants’ technical problems by asking for regular feedback about this	—
Responding	
In support of (positive)	
The respond function was used by some participants	<ul style="list-style-type: none"> • “Even if I don’t have airtime I make a plan and respond because I know if I don’t respond and I have taken them it won’t be OK.” [FGD 4]
Against (negative)	
There was limited uptake for replying to the SMS text messages	<ul style="list-style-type: none"> • “I only replied twice; all the other times I would just use the airtime for my own good.” [FGD 5] • “I don’t look to check if I can reply or something. I don’t reply anyway.” [FGD 3]
The main reasons for not replying were being busy, lack of interest, lack of airtime ^d , a technical error, and not understanding whether it is necessary to reply	<ul style="list-style-type: none"> • “What prevented me from replying was that I would receive the SMS while I am in class and I can’t reply and by the time I get home; I have lost interest in the SMS.” [FGD 5] • “I didn’t have time. And sometimes it was boring me.” [FGD 3] • “Sometimes the airtime disappears to your airtime advances payments before you can reply” [FGD 5] • “I used to respond but I can’t anymore, it just says error.” [FGD 1] • “That is where I struggle to understand if they really want us to reply or you just leave it like that?” [FGD 1]
Suggested adaptations	
To justify and explain the reply function at the start of the intervention	<ul style="list-style-type: none"> • “I think that you should explain...what should we reply? We must understand, you must give us the explanation.” [FGD 3]
To improve participant knowledge and understanding of the reply function and the airtime received at the start of the intervention, possibly through a short training session	—
To encourage participants to reply later even if they are busy at the moment of receiving the SMS text messages	—
To evaluate the usefulness of the reply function in this setting	—

^aMain conclusion: Although participants reported reading the SMS text messages, technical issues, a lack of time, and missing information were barriers to intervention usability, and participants expressed their use of the reply function was limited.

^bFGD: focus group discussion.

^cIndicates a suggested adaptation formulated by the study team inferred from the presented evidence from the FGD but without direct supporting evidence from the participants.

^dPhone credit per minute.

Perceived Benefits Versus Unintended Consequences

Participants described experiencing benefits from the intervention, including feeling supported by the study team, being reminded to take the micronutrient supplements, and learning new concepts from the health literacy messages (Table 5). Unintended consequences associated with the health literacy messages that were described included feelings of fear about the information in the side effect messages and feeling patronized (made to feel “stupid”) by the messages. This may

be because the SMS text messages reinforce content from the HeLTI *Bukhali* resources, and for participants with limited health literacy, this may feel that it highlights their lack of knowledge and understanding.

In general, participants did not feel the need to respond to the messages, although positive feelings about communicating through the reply function were expressed by one participant. In addition, some participants expressed feeling guilty for not responding to the messages or feeling like they might have been judged if they replied that they had not taken their supplements.

Table 5. Qualitative evaluation of the perceived benefits and consequences of the HeLTI^a Bukhali SMS text messaging intervention^b.

Perceived benefits vs consequences	Quotes
Overall intervention	
In support of (positive)	
The intervention helped participants feel supported by the study team	<ul style="list-style-type: none"> • “They make me feel like they care.” [FGD^c 4] • “I liked it because it showed that you do follow up, you are not just giving us the supplements only.” [FGD 5] • “They show that they want to be a part of this so that they can help us so that we can be focused and remember” [FGD 3]
Suggested adaptations	
To expand the SMS text messaging service to facilitate additional communication to address questions, monitoring of side effects, and delivery of the supplements	<ul style="list-style-type: none"> • “If they can create a WhatsApp number where we can text them.” [FGD 5] • “They must send me an SMS that by this date, we are going to be able to bring you your supplements.” [FGD 3] • “To monitor [side effects] and...where it has boosted you so far” [FGD 3]
Receiving health literacy messages	
In support of (positive)	
The health literacy messages were found to be educational and filled a knowledge gap	<ul style="list-style-type: none"> • “I am happy about it. It teaches me how to balance my diet, supplements and things like that” [FGD 1] • “the SMS’s tell you exactly what they are for and what they do and help with” [FGD 4] • “I actually got to learn the names of vitamins...for me it was exciting” [FGD 4] • “At clinics or wherever they don’t give us that much information. Now you know that even the small things that you can be able to plant yourself you can be able to get iron and be sharp.” [FGD 3] “I think twice a week it’s perfect.” [FGD 2]
Against (negative)	
An unintended consequence of the health literacy messages was feelings of fear about side effects	<ul style="list-style-type: none"> • “I think they should cut out the side effects one because sometimes it’s scarier to know that the medication you are about to take, you might come across this situation and that situation...might stop people from taking the supplements” [FGD 1]
An overlap between the health literacy messages and HeLTI intervention resources was disadvantageous	<ul style="list-style-type: none"> • “Because we already have the pamphlets; you make us feel like we are stupid by repeating the same thing; so I don’t like reading the same thing repetitively.” [FGD 5]
Suggested adaptations	
To review the phrasing of side effect messages for fear-inducing language and adapt where necessary	— ^d
To ensure information messages complement and refer to HeLTI intervention resources	—
To additionally disseminate the health literacy messages through platforms such as social media, television, and word of mouth	<ul style="list-style-type: none"> • “Community health workers...with people, if someone knocks, you open for them and give them your attention, and then they educate.” [FGD 1] • “Everything that there is on Facebook, I look at it.” [FGD 1]
Receiving adherence messages	
In support of (positive)	
Participants expressed that the adherence messages were an effective reminder	<ul style="list-style-type: none"> • “They were helpful because sometimes you forget to take them but when you receive the message you remember.” [FGD 5] • “We don’t receive them anymore and it shows because I forget to take them, but yes, they were a reminder.” [FGD 4] • “And also, our lives are busy, a lot so the SMS sometimes reminds you that you have to wake up, do like this and like this and like this.” [FGD 3]
Against (negative)	
The repetitive nature of the adherence message was not found useful	<ul style="list-style-type: none"> • “The information one I read, but the other one I don’t see it as necessary...because it’s the same thing.” [FGD 3]

Perceived benefits vs consequences	Quotes
Suggested adaptations	
(Please see above for suggestions for improved acceptability for adherence messages)	<ul style="list-style-type: none"> (Please see above for suggestions for improved acceptability for adherence messages)
Responding to adherence messages	
In support of (positive)	
Being able to reply to the messages felt beneficial for some	<ul style="list-style-type: none"> “I also feel good letting them know that I am taking the supplements.” [FGD 4]
Against (negative)	
Other participants did not perceive a benefit to responding to the messages	<ul style="list-style-type: none"> “Why should I have to reply?” [FGD 3] “I felt no type of way.” [FGD 3]
An unintended consequence of the response option was feelings of guilt and judgment for not responding or taking supplements	<ul style="list-style-type: none"> “Because of that part that you cannot answer, you seem like a person who is not cooperative, but you do want to cooperate it’s just that you don’t have what they require [airtime].” [FGD 4] “I felt like they would judge me and say I’d ruin my body...When I didn’t take the supplements I felt a bit odd because I did not want to disappoint them.” [FGD 4]
Suggested adaptations	
To justify and explain the reply function at the start of the intervention	<ul style="list-style-type: none"> “I think that you should explain...what should we reply? We must understand, you must give us the explanation.” [FGD 3]
To assess the need for a reply function in this intervention	—
To thoroughly explain the nonjudgmental nature of the reply function, which is intended to help the participant.	—

^aHeLTI: Healthy Life Trajectories Initiative.

^bMain conclusion: Participants perceived practical, supportive, and educational benefits to receiving SMS text messages; however, there was little perceived benefit for the response option, and feelings of worry and fear were unintended consequences associated with the intervention.

^cFGD: focus group discussion.

^dIndicates a suggested adaptation formulated by the study team inferred from the presented evidence from the FGD but without direct supporting evidence from the participants.

Fidelity and Cost of Intervention Delivery

On the basis of the quantitative data log of received messages, airtime, and technical errors, there was only one participant to whom the SMS text messages were not delivered as intended because of a technical error, which was resolved at week 16 of the 24 weeks after updating the participant’s number and provider. As indicated in [Table 4](#), in the FGDs, participants sometimes reported receiving messages in 2 parts or only receiving half a message, particularly when using nonsmartphone models. Some also reported having technical problems when trying to reply to the message. However, the exact cause or number of cases in which this occurred could not be determined.

In terms of receiving weekly prepaid airtime, a few participants experienced technical problems, with 4.2% (5/120) of participants experiencing repeated technical errors. Of these, 3 were because of the initial recording and use of the wrong cell network by the research team. One was because of a change in the phone number. For these 4 participants, errors were resolved within 2 months of onset. For the fifth participant with a

repeated technical error, technical failure could not be resolved, likely because they had a nonchargeable SIM card.

On the basis of the cost log for the intervention, delivering the SMS text messaging intervention cost ZAR 71.65 (US \$4.65) per participant or, on average, ZAR 245.64 (US \$15.93) per week for the 35 weeks that SMS text messages were sent. When including the weekly prepaid airtime, the intervention cost per participant was ZAR 266.26 (US \$17.27) or ZAR 912.91 (US \$59.21) per week.

Indicative Effect of the Bukhali Text Messaging Intervention

This section reports the results of preliminary, nonrandomized comparisons between the SMS text message-receiving and SMS text messaging control groups. As shown in [Figure 4](#), at follow-up, self-reported adherence was higher in the SMS text message-receiving group (42/63, 67% reported taking supplements every time) than in the SMS text messaging control group (33/85, 39%; $P=.02$). In addition, a larger percentage of the SMS text message-receiving group (32/63, 51%) strongly agreed that the supplements had a positive impact on their health than the SMS text messaging control group (36/85, 42%; $P=.09$;

Figure 5). The main reasons for sometimes or often missing supplements in both groups were traveling (and therefore not having access to the supplement) and forgetting; however, fewer participants in the SMS text message–receiving group reported missing their supplements for these reasons. Moreover, a lower number of participants in the SMS text message–receiving group reported having fears about taking the supplements than in the SMS text messaging control group (4/63, 6% vs 16/77, 21%; $P=.02$), although the number of participants reporting a side

effect in the SMS text message–receiving group was nonstatistically significantly higher than in the SMS text messaging control group (13/64, 20% vs 9/84, 11%). In addition, statistically significantly more participants in the SMS text message–receiving group agreed or strongly agreed that the micronutrient supplements were explained to them well (59/64, 92% vs 66/87, 76% in the SMS text messaging control group; $P=.03$).

Figure 4. Bar graph comparing the SMS text message–receiving and SMS text messaging control group participants’ self-reported adherence at follow-up.

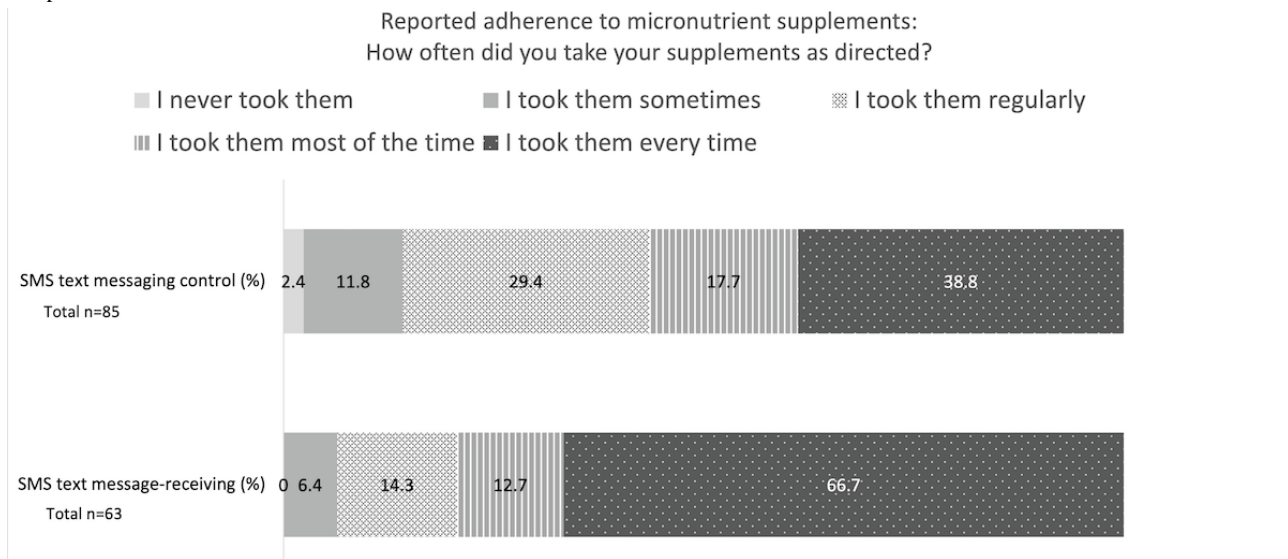
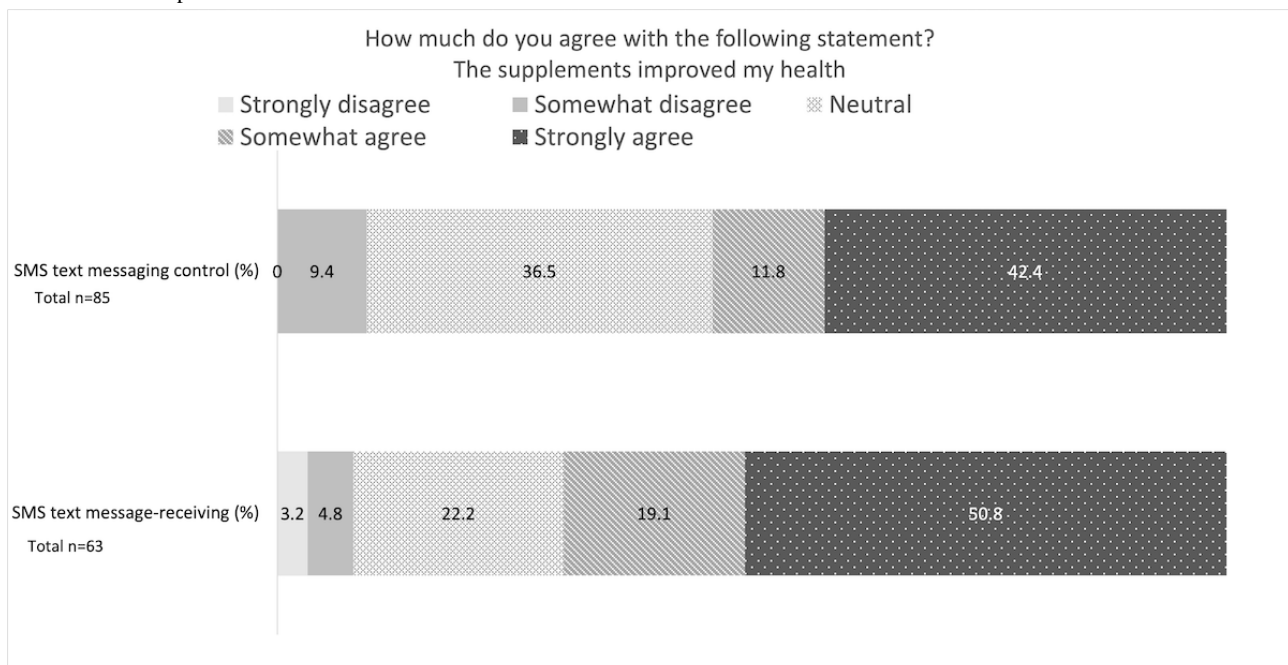


Figure 5. Bar graph comparing the SMS text message–receiving and SMS text messaging control group’s attitudes toward supplements improving their health at follow-up.



The mean difference in hemoglobin from baseline to follow-up (Δ hemoglobin) was negative in the SMS text messaging control group (mean -0.46 , SD 1.59), whereas in the SMS text message–receiving group, Δ hemoglobin was positive (mean 0.52 , SD 2.18 ; $P=.002$). This difference in hemoglobin levels between the 2 groups remained statistically significant when

the 2 participants with severe anemia at baseline were excluded from the SMS text message–receiving group ($P=.003$).

Exploring this finding further with a mixed linear model, we found that the altitude-adjusted hemoglobin increased more between baseline and follow-up in the SMS text

message-receiving group than in the SMS text messaging control group, as indicated by the interaction term in the model (1.03, 95% CI 0.49-1.57; $P < .001$; Table 6), although absolute the hemoglobin level was lower in the SMS text message-receiving group when adjusted for time (-0.70 , 95%

CI -1.13 to -0.28 ; $P = .001$). These results remained statistically significant and were not attenuated after correcting for differences present at baseline (employment status and level of education; Table S2, Multimedia Appendix 1).

Table 6. Linear mixed modeling for altitude-adjusted hemoglobin, adjusting for intervention exposure, time (baseline vs follow-up), and the interaction between time and intervention exposure^{a,b}.

Model	Coefficient (95% CI)	P value
SMS text message-receiving group	-0.70 (-1.13 to -0.28)	.001
Time (baseline to follow-up)	-0.51 (-0.88 to -0.14)	.007
SMS text message-receiving group \times time	1.03 (0.49 to 1.57)	$<.001$

^aNo other covariables other than those shown were included in the model. SMS text message-receiving group \times time indicates the interaction term between the SMS text messaging intervention exposure and time of measurement (baseline vs follow-up).

^bAverage observations per group 1.7; P value model = .001.

The Phila Impilo Yakho Kangcono Radio Serial Intervention

Objective 2: Acceptability of the Radio Serial and Facebook Page

Participants expressed that they found the content of the messages educational and relatable and that they enjoyed the

narrative aspect of the radio serial as a way of communicating health messages (Table 7). The participants reported not having previously heard the radio serial on the national radio station (Ukhozi FM) or on the local station (Jozi FM).

Table 7. Qualitative evaluation of the acceptability of the Phila Impilo Yakho Kangcono radio serial^a.

Acceptability radio serial	Quotes
Delivery	
In support (positive)	
Participants liked the delivery of health messages through a narrative radio serial	<ul style="list-style-type: none"> • “On radio you get to hear people’s voices and emotions and by hearing what they’re saying maybe you can change your diet, your ways.” [FGD^b 2]
Participants liked the associated Facebook page	<ul style="list-style-type: none"> • “It’s informative, it’s youthful.” [FGD 4] • “I find it really inspirational because we learnt about things we did not know about.” [FGD 5]
Participants reported listening to the radio occasionally and in specific situations	<ul style="list-style-type: none"> • “You find that people don’t know how you get diabetes,...so it’s educational.” [FGD 2] • “I personally think it [relationship between characters in serial] is realistic.” [FGD 1] • “she [character] is the one who educates others...She also wants to learn so that she helps her mother, she’s so supportive.” [FGD 1]
Against (negative)	
Participants reported not having previously heard the radio serial	<ul style="list-style-type: none"> • “I listen to radio but have never heard it before.” [FGD 3] • “I don’t listen to radio.” [FGD 1]
Suggested adaptations	
To increase awareness of the radio serial	<ul style="list-style-type: none"> • “And word of mouth will help, just to say there’s this show on the radio.” [FGD 2]
Content	
In support of (positive)	
The content and characters of the radio serial were found to be relatable and acceptable	<ul style="list-style-type: none"> • “You find that people don’t know how you get diabetes,...so it’s educational.” [FGD 2] • “I personally think it [relationship between characters in serial] is realistic.” [FGD 1] • “she [character] is the one who educates others...She also wants to learn so that she helps her mother, she’s so supportive.” [FGD 1]
Suggested adaptations	
To incorporate additional health literacy topics of interest, including exercise, hygiene, sexually transmitted illnesses, cancer, COVID-19, gender-based violence, and mental health	<ul style="list-style-type: none"> • “How to deal with your anxiety. Because with me when I walk the streets, I get scared...I overthink a lot especially with my schoolwork” [FGD 3] • “I think cancer as well because we think it’s only for older people and we also get cancer now.” [FGD 5] • “COVID-19 as well” [FGD 5]

^aMain conclusion: Participants found the delivery radio serial and associated Facebook page acceptable and the content likable and relatable.

^bFGD: focus group discussion.

Advantages and Disadvantages of SMS Text Messaging, Radio, and Facebook Page

An overview of the advantages and disadvantages of the different health messaging media based on the FGD data is provided in [Table 8](#). Although participants expressed concerns

about the accessibility of data-requiring messaging platforms such as Facebook and had not visited the Facebook page associated with the radio serial before the FGD, participants liked that it provided a community with whom they could interact.

Table 8. Qualitative results comparing the advantages and disadvantages of health messaging in the social messaging media, including SMS text messaging, radio, and a Facebook page.

Media	Quotes
Advantages	
SMS text messaging	
Participants frequently use their phones	<ul style="list-style-type: none"> • “The fact that I’m always on my phone and it’s easy to access” [FGD^a 4] • “I always have time [to read the message] because I am always on my phone” [FGD 1]
Does not require access to data	<ul style="list-style-type: none"> • “What if you don’t have data for social media? SMS doesn’t need data.” [FGD 1]
Radio	
Ability to listen to health messages through a story	<ul style="list-style-type: none"> • “On radio you get to hear people’s voices and emotions” [FGD 2] • “I think radio communicates better than the SMS’s because sometimes you are lazy to read SMS’s but listening is better.” [FGD 5]
Does not require access to data and can be accessed anywhere	<ul style="list-style-type: none"> • “On radio it’s an advantage...you can just switch on your radio, headsets and listen, whether you’re in a taxi, whether you’re doing something and you listen” [FGD 2]
Facebook page	
The community associated with the page	<ul style="list-style-type: none"> • “Some people go through a lot...it can actually help people open up about themselves.” [FGD 3] • “I think with this page we can, people can talk and express their feelings.” [FGD 2]
Ability to find past content (eg, past radio serial episodes)	<ul style="list-style-type: none"> • “[I prefer] social media. When you miss this show, nowadays there’s load shedding then when you miss the show they must repeat it so that you can listen to it again.” [FGD 2]
Disadvantages	
SMS text messaging	
Some participants indicated a preference for phone calls	<ul style="list-style-type: none"> • “I prefer that they call; these older models are very problematic...so I prefer them to call, the same way they call when they run sessions.” [FGD 5]
Radio	
Not all participants listen to the radio frequently	<ul style="list-style-type: none"> • “We don’t often listen to the radio so I prefer the SMS” [FGD 4]
Inability to find past content	<ul style="list-style-type: none"> • “Nowadays there’s load shedding [power cuts] then when you miss the show they must repeat it so that you can listen to it again.” [FGD 2]
Facebook page	
Data requiring	<ul style="list-style-type: none"> • “Social media, we always don’t have data.” [FGD 2] • “Not all of us can access the internet.” [FGD 4]
Participants need to proactively log in	<ul style="list-style-type: none"> • “When you get the notification you take your phone and check, but with Facebook, a week might go by without you logging in.” [FGD 1] • “I don’t have Facebook I just deleted it so I prefer to listen to radio.” [FGD 2]

^aFGD: focus group discussion.

Discussion

Principal Findings and Implications

In this nested feasibility study, the HeLTI *Bukhali* SMS text messaging intervention, aimed at improving preconception

adherence to micronutrient supplements, was found to be acceptable, beneficial, and usable by participants. Indicative effect results suggest a promising potential effect of the SMS text messaging intervention on self-reported supplement adherence and changes in hemoglobin from baseline to

follow-up, although these are not based on a randomized comparison. These findings are in line with evidence from high-income countries on the acceptability and potential of SMS text messaging interventions to support behavior change in various life stages and contribute to the existing evidence, although less conclusive, for SMS text messaging interventions from low- and middle-income countries [20,21,27,28]. Finally, the health-promoting radio serial was found to be acceptable for young women.

Although participants reported finding the SMS text messages easy to understand and helpful, we received several suggestions for adapting the SMS text messaging intervention. This included a preference for receiving messages in the early morning on days they were meant to take their supplement. Although personalizing the timing and frequency of SMS text message delivery could negatively affect the scalability of the intervention [47], it may be feasible to send more frequent messages to those participants taking supplements daily, as suggested in the FGDs. As the SMS text messaging intervention was automated, it required few resources and was not demanding on implementation staff, increasing its practicality in limited-resource settings such as ours. However, introducing a nonautomated aspect to the intervention, for example, through a *help desk*, which participants could reach by replying to a number, could help manage the technical challenges experienced by participants and facilitate communication with the study team. Existing evidence also suggests that a nonautomated, personalized element may increase interaction with and the effect size of the intervention, although this remains to be tested from a cost-effectiveness perspective [48]. It is important to establish the feasibility and affordability of such a service in low- and middle-income settings, given that automated systems could be more scalable and sustainable in resource-constrained environments. Furthermore, in the context of the HeLTI *Bukhali* trial, there are likely other intervention priorities that would take precedence over such a service, particularly in terms of the allocation of human resources. However, there could be less resource-intensive ways of integrating these learnings into the intervention implementation, such as reminding those delivering the intervention to follow up more intentionally about the delivery of SMS text messages with participants.

In our study, the 2-way reply function of the SMS text messaging intervention was underused, with only 10.8% (13/120) of participants using the reply function in the final week of the intervention. A study evaluating a 2-way SMS text messaging intervention for weight loss in postpartum women in a high-income setting found good engagement with a comparable *yes or no* SMS text message reply option, with most participants replying to over half of the messages and high engagement contributing to the outcome of interest [28]. In a low- to middle-income setting, some evidence suggests that a 2-way SMS text messaging intervention could be effective if engagement is high enough [49]; however, a study of a 2-way SMS text messaging intervention for improved HIV care in pregnant and postpartum women in Kenya found a similarly low response frequency [50]. Qualitative research from Uganda indicated similar barriers to responding to a 2-way SMS text messaging intervention, as expressed by our participants,

including a lack of airtime, being too busy, and phone-specific issues [51]. Whether these barriers can be minimized through more extensive instructions, explanations, participant encouragement at intervention initiation, or the use of alternative media such as unstructured supplementary service data would require further assessment before this aspect of the intervention can be recommended in our setting. Despite the low response rate, the SMS text messaging intervention was found to be acceptable and showed a potentially indicative effect. Therefore, a 2-way function may not be an essential component of an intervention aimed at improving supplement intake, as opposed to more complex behavior change targets.

In terms of population-level health promotion messaging, our participants indicated a preference for the narrative and accessible nature of the *Phila Impilo Yakho Kangcono* radio serial. Radio health messaging has been found to increase health knowledge and awareness in the context of, among others, maternal health, HIV prevention research, and child health in low- and middle-income settings, including Southern Africa [52-56]. However, we found that not all participants listened to the radio frequently, indicating the need for research on the reach of such a radio-based health promotion campaign among young women in our setting. By combining media, directed health messaging (such as SMS text messaging) could be used to increase young women's awareness of new radio and social media campaigns to improve their reach and effectiveness [57].

Strengths and Limitations

To the best of our knowledge, this is the first study in our setting to evaluate social messaging through individual-level SMS text messaging intervention and population-level radio serial for preconception health promotion. However, a limitation of this study is that more in-depth data on the acceptability, feasibility, and impact of the radio serial were not available as participants' exposure was limited to 1 or 2 episodes, which they heard for the first time during the FGDs. Another limitation is the high rate of loss to follow-up and the presence of missing data, which threatens the validity of the findings regarding the indicative effect of the SMS text messaging intervention. Moreover, the loss to follow-up may indicate that collecting data on these end points might be challenging in the context of a full randomized controlled trial. Although a portion of the loss to follow-up can likely be explained by the unique circumstances of the COVID-19 pandemic, additional methods to limit withdrawal, increase participant motivation for participation, and prevent loss of contact (eg, through community engagement) could be useful to explore. The withdrawal and loss-to-follow-up rates were higher in the SMS text message-receiving group than in the SMS text messaging control group, which could be because of the greater impact of COVID-19 later in the pandemic (with data collected in 2021 vs 2020). Although there was no indication from the participants that they were withdrawing in response to the SMS text messaging intervention, further (randomized) analysis could help confirm this. The evaluation of the indicative effect of the SMS text messaging intervention was not conducted between the 2 randomized groups, and the baseline difference in hemoglobin levels between the SMS text message-receiving and SMS text messaging control groups, although adjusted for in the linear mixed model, may have

affected our results. Therefore, a fully randomized controlled exploration of the effectiveness, as well as the cost-effectiveness, of the intervention is still needed.

The FGDs were moderated by trained research staff from Soweto who were not involved in the development of the intervention. The researcher performing the initial coding and qualitative analysis (LMS) was a cultural outsider as a White European woman, which may have affected nuanced aspects of data interpretation, although the outcomes were reviewed by other members of the research team [58]. LMS was also involved in the study implementation and management (although not the development of either intervention), which may have contributed to observer bias [59]. Nevertheless, this study contributes to the understanding of women's perceptions of preconception health messaging strategies in our setting.

Conclusions

In this feasibility study, young women found that an SMS text messaging intervention aimed at increasing adherence to

preconception micronutrient supplements was acceptable. In addition, mass media health promotion through a radio serial aimed at young people was found to be acceptable and relatable. Participants found the HeLTI *Bukhali* SMS text messaging intervention beneficial and useful. The intervention may also help improve self-reported adherence, attitudes toward supplements, and measured hemoglobin levels at follow-up, although these results are based on a limited, nonrandomized comparison. Although these findings suggest a previously unexplored potential for SMS text messaging interventions to support improvements in preconception micronutrient supplement adherence, further studies in the form of randomized trials are still needed. In addition, some refinements based on participant suggestions and reassessment of the 2-way SMS text messaging component are needed. Social messaging interventions for improving the health and nutrition of young women could consider how directed messaging (such as SMS text messaging) and mass messaging strategies (such as radio) may be used to complement each other to promote the health of young women in the preconception period.

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Authors' Contributions

LJW and MCM conceptualized this project, and LJW, MCM, and AP developed the intervention and focus group topic guides. LJW, CED, and SAN contributed to developing the research methods and implemented the overarching preconception trial. LMS managed the project, contributed to data collection, analyzed the data, and drafted the first version of the manuscript. SK contributed to the qualitative data analysis and interpretation. All authors contributed to writing and editing the manuscript. All the authors approved the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1

The main baseline characteristics in the followed-up versus lost to follow-up group and linear mixed modeling for altitude-adjusted hemoglobin, adjusting for intervention exposure, time (baseline vs follow-up), the interaction between time and intervention exposure, and employment status and level of education.

[[DOCX File, 20 KB - formative_v6i8e37309_app1.docx](#)]

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Abbreviations

- FGD:** focus group discussion
HAPA: Health Actions Process Approach
HeLTI: Healthy Life Trajectories Initiative
REDCap: Research Electronic Data Capture
TIDieR: Template for Intervention Description and Replication

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Original Paper

Social Media Use and Well-being With Bipolar Disorder During the COVID-19 Pandemic: Path Analysis

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Abstract

Background: Reliable and consistent social support is associated with the mental health and well-being of persons with severe mental illness, including bipolar disorder (BD). Yet the COVID-19 pandemic and associated social distancing measures (eg, shelter in place) reduced access to regular social contacts, while social media use (SMU) increased concomitantly. Little is currently known about associations between the well-being of adults with BD and different types of SMU (eg, passive and active).

Objective: For this study, we had two goals. First, we report descriptive information regarding SMU by persons with BD during COVID-19 (all platforms). Specific to Facebook, we next developed and tested a hypothesized model to identify direct and indirect associations between BD symptoms, social support, loneliness, life satisfaction, and SMU. Responses were collected during the global spread of the Delta variant and prior/concurrent with the Omicron variant, 20 months after the World Health Organization declared COVID-19 a global pandemic.

Methods: Over 8 weeks, we obtained responses from an international sample of 102 adults with BD using the Qualtrics online platform. Most had previously participated in the BADAS (Bipolar Affective Disorders and older Adults) Study (n=89, 87.3%); the remainder were recruited specifically for this research (n=13, 2.7%). The subsamples did not differ in age ($t_{100}=1.64$; $P=.10$), gender ($\chi^2_2=0.2$; $P=.90$), socioeconomic status ($\chi^2_6=9.9$; $P=.13$), or time since BD diagnosis ($t_{97}=1.27$; $P=.21$). Both were recruited using social media advertising micro-targeted to adults with BD. On average, participants were 53.96 (SD 13.22, range 20-77) years of age, they had completed 15.4 (SD 4.28) years of education, and were diagnosed with BD 19.6 (SD 10.31) years ago. Path analyses were performed to develop and test our hypothesized model.

Results: Almost all participants (n=95, 93.1%) reported having both Facebook and LinkedIn accounts; 91.2% (n=93) reported regular use of either or both. During the pandemic, most (n=62, 60.8%) reported accessing social media several times a day; 36.3% (n=37) reported using social media more often since the emergence of COVID-19. Specific to Facebook, the model we hypothesized differed somewhat from what emerged. The resulting model suggests that symptoms of depression predict loneliness and, inversely, social support and life satisfaction. Social support predicts social Facebook use, whereas passive Facebook use predicts life satisfaction. Symptoms of depression emerged as indirect predictors of SMU via social support.

Conclusions: Our findings suggest that the operational definition of passive-active SMU requires further analysis and refinement. In contrast to theory, passive Facebook use appears positively associated with well-being among certain populations. Longitudinal data collection over multiple points is required to identify associations between BD symptoms, SMU, and well-being over time.

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KEYWORDS

bipolar disorder; COVID-19; life satisfaction; loneliness; social media use; social media; Facebook; social support; mental health; mental illness; mental disorder; social media advertising; advertising; advertisement; mania; hypo/mania; manic; depressive; depression

Introduction

Social Support With Bipolar Disorder

Well-being with bipolar disorder (BD) has many facets; for most, this entails routine and consistency, including regular social contact and support [1]. The importance of social support for adults with BD is well documented. It has been shown, for instance, that greater contact with friends and family fosters well-being with BD [2], and those with less social support report more symptoms of mania [3]. The perceived absence of social support is associated with the recurrence of BD mood episodes [4] and slower time to recovery [5].

Isolation and disruption in routine caused by the COVID-19 pandemic have been especially difficult for those with mental health conditions. For instance, one Israeli study showed that those who reported being most lonely during the pandemic were 82% more likely to struggle with depression and anxiety [6]. A similar US study reported that greater loneliness was associated with increased symptoms of depression and suicidal ideation [7].

Initial research on the psychological effects of COVID-19 early in the pandemic reported no significant effects on persons with mental health conditions compared to prepandemic symptoms [8,9]. Some lifestyle changes caused by the COVID-19 pandemic restrictions (eg, lowered access to social support) were less pronounced for persons with BD than healthy controls [10]. This may be due to fewer social contacts at baseline for those with BD (ie, smaller social networks or family estrangement). However, reduced access to social support, along with disruptions to routine, lower income, and unemployment, have a longer-lasting impact on those with BD, leading to longer-term disruptions [11]. This is reflected in recent research [11-13]. In a study from Australia, those with mood disorders (depressive disorder or BD) reported elevated levels of psychological distress (ie, stress, anxiety, or depression) when compared to those free of psychopathology [12].

Social Media Use and Mood Disorders

In the absence of interpersonal contact, many turned to various social media [14]. With an estimated 4.6 billion global users [15], social media (eg, Facebook, Instagram, Twitter, or TikTok) have become platforms, and in some cases replacements, for in-person community building and support [16]. This has been particularly true during the global COVID-19 pandemic [17,18] when in-person social support ceased to be an option for many, particularly those living alone. Yet our understanding of the effects of social media use (SMU) on mental health remains incomplete despite the omnipresence of social media in modern life.

Excessive SMU may well cause or exacerbate symptoms of depression. Among adolescent and young adults, associations between depressive symptoms and SMU are well established

[19-21]. Research on persons with chronic depression suggests that an increase in SMU exacerbates symptoms [22]. Alternatively, depression may predict excessive SMU [23], as those with severe chronic depression are often socially isolated and rely on online interactions [24]. Different facets of SMU may play differing roles, as active versus passive use patterns appear to have opposing associations with social comparison and, in turn, depressive symptoms [25].

Most SMU and mental health research to date has focused on depression and anxiety [26]. The relationship between SMU and other mental health conditions is even less well understood. BD is an especially stigmatized mental health condition as reflected online; tweets relating to BD were found to be more stigmatizing than those pertaining to other mental health conditions [27]. This may create a complex online experience for those with BD. However, research also points to the potential for social media to confer peer support to those with BD, either as a supplement or alternative to in-person support. Qualitative research findings suggest that those with severe mental illness, including BD, seek out opportunities to connect with peers online [28] and that peer support occurs naturally among those who share their experiences online [29]. In intervention research, intentional weight loss was fostered by online support and interaction [30].

Passive and Active Social Media Use

Research conducted with general adult samples underscores that SMU is not a singular behavior [16]; instead, there are various ways in which social media are used, with differential effects on mental health and well-being [31]. Active SMU entails direct engagement with social media, such as posting comments or commenting on posts. Active use includes sharing pictures, opinions, or interests to communicate or connect with friends and family. In contrast, passive SMU entails consuming online information without posting or commenting (eg, scrolling news feeds and viewing posts). This behavior allows the user to observe other people while maintaining relative anonymity.

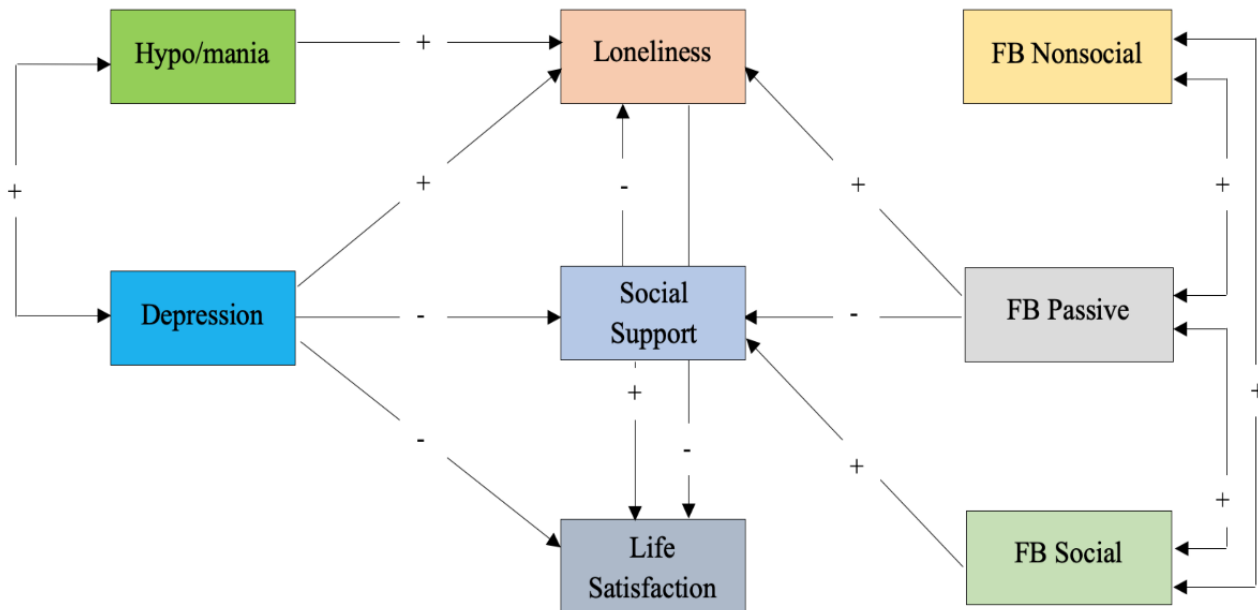
There is no consensus regarding associations between different patterns of SMU and well-being. Multiple studies suggest that active SMU is negatively associated with depressive symptoms [32] and perceived loneliness, and that this relationship is mediated by social support [33,34]. Yet other studies suggest that passive SMU is negatively associated with well-being because it encourages social comparison and feelings of envy [35], and is associated with a depressed mood [36,37]. However, the active-positive and passive-negative dichotomy is not universally accepted. One study performed during the COVID-19 pandemic initially found a positive association between active SMU and meaning in life, yet in a replication study, the opposite was found as well as an association between active SMU and emotional loneliness [38]. There is also evidence that passive SMU is associated with positive well-being such as life satisfaction [39].

This lack of consensus regarding the effects of active and passive SMU may be due in part to different definitions of terms and scales. A meta-analysis found that, of 40 studies of active and passive SMU and well-being, there were 36 different operational definitions of active and passive SMU [40]. Existing scales do not fully differentiate between different nuances of active and passive SMU (eg, public and private use or social and nonsocial use) and are not universally applicable to the range of social media platforms that exist today [35,40]. The effects of social media on the well-being of adults with severe

mental illness are unclear. Additionally, the role of social media in daily life may have become even more prominent as a result of the COVID-19 pandemic.

The aims of this study were twofold. First, we set out to describe general patterns of SMU by adults with BD during COVID-19 (all platforms). Specific to Facebook, we next tested a hypothesized model to identify direct and indirect associations between BD symptoms, social support, loneliness, life satisfaction, and SMU (passive, active social, and active nonsocial; see Figure 1).

Figure 1. Statistically significant associations depicted as paths (directional arrows) or correlated associations (double-headed arrows). Positive (+) and negative (-) directional associations hypothesized a priori. FB: Facebook.



In keeping with previously published research, we hypothesized that:

- Social Facebook use would predict social support
- Passive Facebook use would predict both loneliness and lower social support
- Depressive symptoms would predict lower life satisfaction
- Depressive symptoms would predict loneliness and lower social support
- Symptoms of hypo/mania would predict loneliness

Methods

Online Recruitment and Data Collection

Most (n=89, 87.3%) of the 102 participants previously took part in the Bipolar Affective Disorders and Older Adults (BADAS) study [41]; the remainder were recruited specifically for this study. Subsamples did not differ in age ($t_{100}=1.64$; $P=.10$), gender ($\chi^2_2=0.2$; $P=.90$), socioeconomic status ($\chi^2_6=9.9$; $P=.13$), or country of residence ($\chi^2_3=6.0$; $P=.11$). They also did not differ in symptoms of depression ($t_{100}=.93$; $P=.36$), hypo/mania ($t_{100}=0.95$; $P=.35$), or time since BD diagnosis ($t_{97}=1.27$; $P=.21$). Both subsamples were recruited using microtargeted Facebook advertising. This method has been used effectively to recruit

clinical samples from low prevalence populations, including BD [42].

BADAS participants who authorized future contact provided their email addresses [41,43]. They were sent up to three personalized notices requesting their participation in this study. A first email was sent in early November 2021, a reminder was sent 1 week later (if there was no response to the first), and 3 weeks thereafter (if there was no response to the first or second).

Concurrently, a Facebook page was established, and microtargeted advertisements were sent to prospective new participants using the A/B test method (ie, two versions of the same advertisement compared). The more successful was then used in the third round of advertising. Prospective participants were ≥ 18 years of age, could read and write English, and were members of ≥ 1 online BD advocacy or support group. Responses were obtained during the global spread of the Delta variant and prior/concurrent with the Omicron variant, 20 months after the World Health Organization declared COVID-19 a global pandemic.

Both BADAS and newly recruited participants were directed to an online questionnaire hosted on the Qualtrics platform. Participants were initially asked their age in years and, later, their date of birth in the demographics questionnaire to corroborate candid responding. To facilitate data collection,

participants could enter a lottery to win a single US \$500 prize (ie, an Amazon gift card).

Ethics Approval

Ethics approval was received from the Institutional Review Board at Ben-Gurion University of the Negev, Be'er Sheva, Israel (#2157-2). By clicking to proceed, respondents indicated consent to participate as stated on the study splash page. They were not required to provide identifying information aside from an email address if they wished to receive a study summary or participate in the lottery.

Instruments

The Bipolar Disorder Symptom Scale (BDS_x) was developed to measure symptoms of both depression and hypo/mania (hypomania + mania = hypo/mania: continuum where the point of transition is not immediately apparent) [43-45]. Respondents indicate the extent to which each of the 20 items describes how they feel at this moment, on a Likert scale ranging from *not at all* (0) to *a lot* (2). Internal consistency of BDS_x responses by BD outpatients was reported as $\alpha=.90$ for the depression subscale (cognitive + somatic symptoms) [46] but lower for the hypo/mania subscale at $\alpha=.76$ (affrontive + elation and loss of insight) [47]. This difference may be due to the low frequency of hypo/manic versus depressive symptoms [48].

Concurrent validity of BDS_x responses by BD outpatients has been demonstrated relative to the self-reported Hamilton Rating Scale for Depression and the Altman Self-Rating Mania Scale [47]. Similarly, sensitivity and specificity are high for the BDS_x depression subscale at 88% and 76%, respectively [46]. Sensitivity is lower at 57% for the BDS_x hypo/mania subscale (90% specificity), but sensitivity is higher than for the Altman scale (43%) [46].

The Satisfaction with Life Scale (SLS) [49] measures perceived quality of life based on person-specific criteria [50]. The SLS is composed of five questions (eg, "The conditions of my life are excellent") with response alternatives ranging from *strongly disagree* (1) to *strongly agree* (7). Higher totals are suggestive of greater life satisfaction [51]. Test-retest reliability over 1-month has been reported as $r=0.84$ [52]. Concurrent validity of SLS responses has been demonstrated relative to the Fordyce Global Scale ($r=0.82$) [34]. Among adults with BD, internal consistency has been reported as $\alpha=.89$ [53].

The eight-item UCLA Loneliness Scale (ULS-8) is a brief measure developed to study relationships between loneliness and health-related behavior [54]. Responses are reported along a Likert scale ranging from *I never feel this way* (0) to *I often feel this way* (3). Internal consistency of ULS-8 responses is high ($\alpha=.84$) [55].

The Multidimensional Scale of Perceived Social Support is a 12-item measure of subjective social support from partners, family, and friends [56]. Responses are reported on a Likert scale ranging from *very strongly disagree* (1) to *very strongly agree* (7). High internal consistency was reported in scale development ($\alpha=.88$ [56]) and subsequent research ($.83<\alpha<.93$ [57,58]).

The Passive and Active Facebook Use Measure (PAUM) was developed to distinguish different types of Facebook use [59]. Exploratory factor analyses suggest three distinct patterns: active social, active nonsocial, and passive. Active social use pertains to direct engagement (eg, chatting or commenting to Facebook posts), whereas active nonsocial use does not entail direct interaction with others (eg, post videos or tag photos), and passive use is limited to viewing photos and checking the status of others (ie, no engagement). Internal consistency across subscales ranges from adequate to good ($.70<\alpha<.81$ [59,60]).

We created a self-report questionnaire to collect demographic information. Participants indicated their country of residence (drop-down menu), number of years of education, work or occupation, employment status, and current relationship status. They were asked their gender, ethnicity, if they had been diagnosed with BD by a clinician (eg, psychiatrist), BD subtype if known, and date of BD diagnosis (month, year).

Statistical Methods

Path analysis was performed for this study as a three-step process [61]. A hypothesized model was first tested, nonsignificant paths were deleted, and statistically significant paths not initially hypothesized were added if supported by existing research or theory (see Figure 1).

Path analysis is an extension of multiple linear regression with three significant advantages. Path analysis allows us to simultaneously predict one or more dependent variables (touched by arrowheads in path models). Arrows pointing from independent to dependent variables represent significant prediction (ie, critical ratio values $>|1.96|$, $P<.05$). Path analysis is a multivariate statistical procedure meaning that all significant paths emerged concurrently (ie, over and above other statistically significant results).

Path models allow us to identify both direct and indirect predictors; indirect prediction occurs via other variables (ie, ≥ 2 pathways between variables). In complex or more nuanced models, variables can have both direct and indirect effects on dependent variables; indirect effects can be of equal or greater magnitude than direct effects (total effects = direct + indirect effects).

Computing path analyses with structural equation modeling software allows us to obtain goodness of fit information for the overall model. Good model fit is required to interpret individual results [62]. In accord with convention, we report three goodness of fit indexes to assess overall model fit: an incremental (comparative fit index [CFI]), an absolute (standardized root mean residual [SRMR]), and a parsimonious fit index (root mean square error of approximation [RMSEA]). Ideal SRMR and RMSEA values are less than 0.055, whereas ideal CFI values are greater than 0.95 [61]. Descriptive and comparative analyses were performed using SPSS v28 (IBM Corp), and path analyses were performed using AMOS v28 and maximum likelihood estimation [62].

Results

Descriptive Features

We recruited 102 participants over 8 weeks who were 53.96 (SD 13.22; range 20-77) years of age on average, had completed 15.4 (SD 9.88) years of education, and were diagnosed with BD 19.61 (SD 10.29; range 1-58) years ago. Most participants were women (n=69, 67.6%) and currently married, cohabitating, or partnered (n=56, 54.9%); 27 were single, 11 separated or

divorced, and 4 widowed. Most lived in North America (Canada: n=45, United States: n=15), Western Europe (eg, United Kingdom: n=18, Ireland: n=10), South Africa (n=4), and Australia (n=4) or New Zealand (n=3). [Table 1](#) reports descriptive statistics and the psychometric information for scale responses (eg, internal consistency). Responses are largely within normal limits (limited skewness and kurtosis) with adequate to ideal internal consistency for almost all study measures (see [Table 1](#)).

Table 1. Descriptive features and psychometric statistics for study variables (N=102).

	Mean (SD)	Range	Skewness	Kurtosis	Cronbach α^a
Age (years)	53.96 (13.22)	20-77	-0.40	-0.73	__ ^b
Education (years)	15.40 (4.28)	2-25	0.05	1.28	—
Duration BD D _x ^c (years)	19.60 (10.31)	1-58	1.17	1.57	—
BDS _x ^d : depression	9.94 (5.69)	0-22	-0.01	-0.91	.89
BDS _x : hypo/mania	3.72 (3.39)	0-13	0.93	-0.11	.78
Life satisfaction	16.69 (7.50)	5-35	0.49	-0.60	.89
Loneliness ^e	20.52 (5.52)	8-32	-0.15	-0.91	.83
Social support ^f	53.94 (18.53)	12-84	-0.44	-0.43	.93
Facebook ^g passive	6.84 (3.25)	0-13	-0.47	-0.13	.67
Facebook social	7.76 (4.39)	0-18	-0.03	-0.46	.83
Facebook nonsocial	2.22 (2.62)	0-12	1.47	2.12	.70

^aInternal consistency of scale responses as measured by Cronbach alpha.

^bNot applicable.

^cBD D_x: bipolar disorder diagnosis.

^dBDS_x: Bipolar Disorder Symptom Scale.

^eLoneliness: UCLA Loneliness Scale.

^fSocial support: Multidimensional Scale of Perceived Social Support.

^gFacebook: passive and active Facebook use.

Social Media Use During COVID-19

All participants reported living under government-regulated social distancing or shelter-in-place restrictions, either prior or concurrent to completing the study questionnaire. When asked, 60.8% (n=62) of the 102 participants reported using social media multiple times a day, with Facebook and LinkedIn the most commonly used platforms: 93.1% (n=95) reported accounts on either or both platforms and 91.2% (n=93) reported regular use of either or both. More than one-third (n=37, 36.3%) reported using social media more since the start of the COVID-19 pandemic.

BD Symptoms, Life Satisfaction, and Facebook Use During COVID-19

We performed path analyses to test our hypothesized model of Facebook use (see [Figure 1](#)). Symptoms of depression were assumed to predict loneliness, lower social support, and lower life satisfaction. Use of Facebook was assumed to indirectly predict life satisfaction via social support. Our sample of 102 participants is not large but sufficient to detect medium to large

effect sizes with 7 independent variables (where $\alpha=.05$, $d=0.80$) [[63](#)].

A somewhat different model emerged (see [Figure 2](#)). Goodness of fit for this path model was within optimal parameters for two of three statistics examined ($\chi^2_{17}=15.7$; $P=.55$). That is, the comparative fit index (CFI>.95; CFI=.99) and the root mean square error of approximation (RMSEA<0.055, RMSEA=0.001; 0<RMSEA 90% confidence limits<0.083) were both within ideal limits. The SRMR was within adequate parameters (SRMR<0.055; SRMR=0.06).

Consistent with previous research [[64](#)], symptoms of depression and hypo/mania are positively correlated; only the former, however, significantly predicts loneliness ($\beta=.46$; $P<.001$), social support ($\beta=-.30$; $P=.001$), and life satisfaction ($\beta=-.46$; $P<.001$). Passive Facebook use predicts life satisfaction ($\beta=.15$; $P=.048$), and social support predicts social Facebook use ($\beta=.13$; $P=.048$), not the reverse as originally predicted. Fully 45% of variance in life satisfaction with BD is explained by this model ($R^2=0.45$; $P<.001$; see [Table 2](#)).

Depressive symptoms appear to have a direct and indirect effect on both loneliness and life satisfaction via social support, and depressive symptoms have a small indirect effect on social Facebook use. We assumed that the various aspects of Facebook

use would predict social support and life satisfaction with BD; however, associations appear bidirectional. Facebook use is both a predictor of life satisfaction and predicted by social support.

Figure 2. Direct and indirect predictors of Facebook use and life satisfaction with bipolar disorder during COVID-19. Parameters are expressed as maximum likelihood estimates (standardized solution). Parenthetical numbers indicate significance levels (ie, Critical Ratio [CR] values >|1.96|, $P < .05$; $CR > |2.58|$, $P < .01$). FB: Facebook.

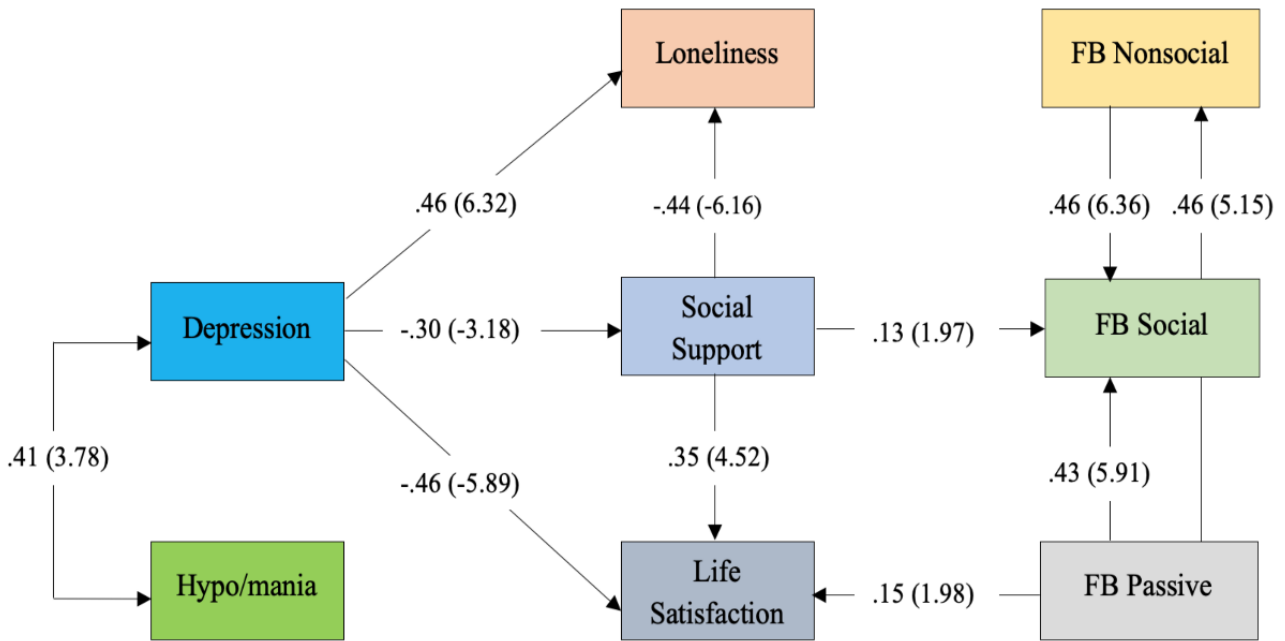


Table 2. Direct and indirect predictors of life satisfaction and Facebook use by adults with bipolar disorder.^a

	Depression	FB ^b passive	FB nonsocial	Support
FB nonsocial				
Direct	— ^c	0.46	—	—
Indirect	—	0.00	—	—
Total	—	0.46	—	—
Social support				
Direct	-0.30	—	—	—
Indirect	0.00	—	—	—
Total	-0.30	—	—	—
Loneliness				
Direct	0.46	—	—	-0.44
Indirect	0.13	—	—	0.00
Total	0.59	—	—	-0.44
Life satisfaction				
Direct	-0.46	0.15	—	0.35
Indirect	-0.11	0.00	—	0.00
Total	-0.56	0.15	—	0.35
FB social				
Direct	0.00	0.43	0.46	0.13
Indirect	-0.04	0.21	0.00	0.00
Total	-0.04	0.64	0.46	0.13

^aNumbers represent percentages of variance explained by each variable (direct variance=path in model).

^bFB: Facebook.

^cNot applicable.

Discussion

Study Hypotheses

As expected, a significant association emerged between social support and Facebook use; however, the direction of this association was opposite than expected, with social support predicting social Facebook use, not the reverse. Additionally, contrary to our hypothesized model, passive Facebook use predicted life satisfaction. These findings suggest bidirectional associations between different facets of SMU and well-being with BD during the COVID-19 pandemic.

As predicted, depressive symptoms were negatively associated with both social support and life satisfaction, and positively associated with loneliness. Though symptoms of hypo/mania and depression were correlated, no direct or indirect associations emerged between hypo/mania and measures of well-being or SMU.

Comparison With Previous Research

These results are consistent with prior research indicating a positive association between symptoms of depression and hypo/mania [65]. Consistent with existing research, our findings confirm that Facebook use is not a singular behavior but multifaceted [66], with differential effects upon social support

and well-being [25]. Our finding that social support predicts active social Facebook use, but not other forms of Facebook use, suggests that those with stronger feelings of in-person social support may be more inclined to use social media to maintain connections online. This positive association may be understood in terms of the outsize role that social media played in providing a substitute for in-person social support during the COVID-19 pandemic; this finding needs to be corroborated with other populations with and without mental illness.

Our result suggesting a positive association between passive Facebook use and life satisfaction is contrary to most prior research with general adult samples [60]. However, this finding is consistent with other research indicating a more complex relationship between SMU types and well-being [44]. The association between passive Facebook use and life satisfaction may indicate that for certain populations, such as older adults or persons with BD, passive behavior is not indicative of social comparison or lack of self-confidence but rather of neutral or positive character traits such as contemplativeness or sense of self. Note that passive and active SMU are defined differently by different scales, thus leading to ambiguity regarding how these facets of SMU are related to well-being. The role of active nonsocial Facebook use on well-being requires further research; no association with measures of well-being emerged for this

study. This may be due to the lower levels of active nonsocial Facebook use in our sample.

SMU has become central to daily life and functioning [67]; over the course of the COVID-19 pandemic, social media became even more deeply embedded in daily life, integral for social networking when opportunities for in-person social interaction were limited or nonexistent. It remains to be seen whether SMU receded once the pandemic began to wane or whether digital relationships continued to take precedence over in-person interactions. There exists a need for both more universal measurement across social media platforms and more comprehensive measurement of all facets of active and passive use.

These questions remain even more pressing for those with severe mental health conditions such as BD. The timing of this study allowed us to explore relationships between SMU and indexes of well-being during a time when in-person social interaction was limited for all, not only for adults with mental health conditions who tend to self-isolate. This provided an opportunity to begin to explore the role of isolation in SMU and well-being. The findings of this study provide preliminary support for the assertion that those with mental health conditions and limited in-person social networks may benefit from certain types of SMU. As indicated by our findings, even passive SMU is suggestive of life satisfaction in this sample of adults with BD.

Limitations and Future Research

This study had several limitations. Both BADAS participants and newly recruited participants were recruited using Facebook. As discussed elsewhere, persons with BD recruited via social media are more symptomatic than psychiatric outpatients [46] and may not be representative of the population of persons with BD. Additionally, persons recruited via social media are likely more regular users than the general population, and participants recruited via Facebook self-reported BD diagnoses (date and BD subtype); this information was not corroborated by chart review or structured clinical interview.

Existing instruments measuring SMU are currently limited [68]. Though developed for use with general adult samples, the psychometric properties of PAUM responses suggest good internal consistency and concurrent validity with adults with

BD. Especially with psychiatric samples, future research is needed examining problematic SMU (eg, addiction) [69]. Though the PAUM appears to be the most widely used measure of SMU, it measures active and passive Facebook use only. Future research is needed examining the effects of other social media platforms on mental health and well-being [35].

The results of this study need to be replicated with larger samples recruited by more traditional methods (eg, psychiatric outpatients). A sample of 102 participants was sufficient to compute a path model with up to seven independent variables; larger samples are required to identify small effect sizes. Longitudinal research in particular is necessary to understand variability in social support and SMU, especially in relation to change in BD symptoms over time.

Conclusions and Summary

The majority of existing research on SMU and well-being has examined young healthy adults. However, social media is today used by most of the world and pervades every population irrespective of age, socioeconomic status, and health. Due to the proliferation of platforms and social media options, different populations may use and relate to social media in distinct ways. To understand the effect of these distinct use patterns and their effects on well-being, it is necessary to study use patterns across diverse populations over time.

The aim of this study was to describe general patterns of SMU by adults with BD during COVID-19 across social media platforms and then to develop and test a hypothesized model specific to Facebook use to identify direct and indirect associations between BD symptoms, social support, loneliness, life satisfaction, and SMU. Contrary to our hypotheses that the patterns of association would conform with the research, indicating active-positive and passive-negative associations with well-being, we found distinct patterns of association.

Our results suggest that adults with BD may use and relate to social media differently than general adult samples. There is a need for further tool development to measure and compare different types of SMU [37] and for longitudinal research examining associations between SMU types and well-being of adults with BD and other forms of severe mental illness (eg, schizophrenia).

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Conflicts of Interest

None declared.

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Abbreviations

- BADAS:** Bipolar Affective Disorders and Older Adults
- BD:** bipolar disorder
- BDSx:** Bipolar Disorder Symptom Scale
- CFI:** comparative fit index
- PAUM:** Passive and Active Facebook Use Measure
- RMSEA:** root mean square error of approximation
- SLS:** Satisfaction with Life Scale
- SMU:** social media use
- SRMR:** standardized root mean residual

ULS-8: eight-item UCLA Loneliness Scale

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Original Paper

Examining the Relationship Between Pediatric Behavioral Health and Parent Productivity Through a Parent-Reported Survey in the Time of COVID-19: Exploratory Study

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Abstract

Background: Pediatric behavioral health needs skyrocketed during the COVID-19 pandemic. Parents and caregivers lacked access to well-established tools to identify risk and protective factors while also experiencing decreased access to treatment options to meet their families' behavioral health needs.

Objective: The aim of this study is to investigate the associations of known pediatric behavioral health risk factors and parents' reports of workplace productivity.

Methods: A clinical research team at Brightline—a virtual, pediatric behavioral health solution—drew on standardized instruments to create a survey designed to understand pediatric behavioral health conditions, child stress, and family resilience and connection during the COVID-19 pandemic. Multivariable linear regression was used to characterize the relationship between these variables and parents' reports of workplace productivity.

Results: Participants (N=361) completed the survey between October 2020 and November 2021. In the multivariable model, higher pediatric stress and time spent managing children's behavioral health needs were associated with greater productivity loss among working parents, whereas higher family connection was associated with lower productivity loss. COVID-19 diagnoses among parents and dependents, financial impact of COVID-19 on households, and family resilience were not associated with parents' workplace productivity.

Conclusions: This survey captured child stress, family connection, and productivity as reported by parents and caregivers during the COVID-19 pandemic. Exploratory studies are the first step in understanding the relationship between these variables. The results from this study can empower parents by providing insights to help manage their child's behavioral health concerns and identify pediatric behavioral health services to aid working parents who are caregivers.

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KEYWORDS

adolescent; child, family health; mental health; behavioral health; stress; protective factors; productivity; COVID-19

Introduction

In March 2020, the COVID-19 pandemic was declared in the United States, which set off a flurry of lockdowns, school

closures, and layoffs. The pandemic amplified the already increasing prevalence of mental health conditions for both adults and children, and exacerbated barriers to receiving behavioral health services [1-4]. While the risks for mental health disorders

associated with the pandemic have broadly risen, they have disproportionately affected children and adolescents who already experience even greater barriers to care than adults [5].

As a result, rates of depression and anxiety among children have doubled since the pandemic began. Currently, 1 in 4 children experience increased depression symptoms, and 1 in 5 experience increased anxiety symptoms [6]. Adolescent girls, in particular, have visited emergency departments during the pandemic for eating disorders and tic behaviors at alarming rates [7,8]. Not surprisingly, the decline in children's mental health and well-being during the pandemic is now identified as a major cause of parents' increased stress, job turnover, decreased productivity, and lost income [9].

The prolonged and far-reaching impact of pandemics such as COVID-19 on well-being requires not only increased surveillance of pediatric mental health disorders but also identification of child- and household-level risk and protective factors that may affect pediatric health outcomes [10,11]. For instance, studies have identified risk factors for disaster-related mental health problems among children and adolescents [12-14]. Such factors include both nonmodifiable and modifiable factors, including gender (female), age (younger), ethnic minority, preexisting disabilities, predisaster emotional status, previous trauma history, postdisaster levels of psychological distress, and family resilience [12]. Knowing risk and protective factors can help to predict who may be vulnerable to future disaster-related mental health conditions.

However, because childhood is a time of change and development, it can be challenging for parents to gauge how they and their children are doing with respect to these known risk factors [15]. As such, parents and caregivers often rely on input from schools, day cares, and other caregivers to help them notice potentially problematic shifts and changes in their child's behavior. During calamities such as the COVID-19 pandemic, parents may be cut off from these community resources and support. The lack of access to these support systems and mental health services during the recent pandemic-related closures led to decreased mental health screenings, diminished ability to identify learning disabilities, and less child-protective and mental health referrals [16].

Delays in addressing modifiable risk factors for pediatric behavioral health problems over the past 2 years of COVID-19-related shutdowns have resulted in higher rates of emergency department visits attributed to mental health concerns among children and adolescents [17]. The emergency medical services system, though, is not the optimal point of access for effective treatment due to (1) a shortage of on-site mental health professionals to accurately diagnose or treat conditions, (2) long waits to receive care, and (3) patients failing to continue treatment postdischarge [18]. What follows is a cycle of crisis care, which is ultimately costly, ineffective, and more time intensive than early prevention and intervention. This cycle of crisis care for youth in distress arguably leads to increased parental stress as their children remain undiagnosed or ineffectively treated.

For employed parents, balancing the demands of raising children with behavioral health needs against work commitments can

lead to higher levels of stress and burnout, making it difficult to be a present parent and productive employee—which were amplified when our country overwhelmingly pivoted to work from home [19,20]. During lockdowns and school closures, parents and caregivers lacked access to easy-to-use tools to help identify their children's risk for mental and behavioral health conditions as well as resources to help them manage their children's behavioral health outside of the emergency department. Our clinical research team at Brightline—a virtual behavioral health solution designed for children (aged 18 months up to 18 years) and their families—recognized this gap in support and saw an immediate need to help parents and caregivers who were struggling to understand and meet the mental and behavioral needs of their children.

As a response, we developed a web-based 30-item survey to assess 4 key areas linked to increased risk of behavioral health conditions among children and adolescents: preexisting behavioral health conditions, psychological stress, family resilience, and family connection. As a mental and behavioral digital health company that provides services to children and their families, we were interested in understanding the broad impact that child behavioral health conditions have on other aspects of a parent's life. Therefore, we added questions to ascertain how parents perceived their child's behavioral health impacted their productivity at work. Given the context of the global pandemic, we also included standardized questions about direct household impacts of COVID-19 as they relate to finances and COVID-19 diagnoses of household members.

This exploratory study of survey responses investigated the associations of pediatric behavioral health risk factors and parents' workplace productivity. While the survey was developed during the COVID-19 pandemic, we were not researching the direct impacts of COVID-19 on psychological stress, children's behavioral health conditions, or time spent managing behavioral health. Instead, our aim in creating the survey was to provide parents with feedback on their child's mental and behavioral health based on their survey responses, and to guide them to relevant resources.

Methods

Recruitment

Brightline is a company that offers a technology-enabled behavioral health solution designed for children (aged 18 months up to 18 years) and their families [21]. Brightline delivers self-guided content, coaching services, and virtual care through multidisciplinary care teams, family-focused support, and evidence-based care delivery geared toward helping children and their families across developmental stages. Commonly reported behavioral health needs by Brightline users include anxiety, depression, and disruptive behavior disorders.

The web-based survey was available on a landing page on the Brightline company website between October 2020 and November 2021 and provided an overview of the survey to participants ([Multimedia Appendix 1](#)). A link to the survey was shared on Brightline's social media platforms, such as LinkedIn and Twitter, throughout the survey window. Other than being

shared on social media and through the other avenues, participants were not actively recruited to participate in the survey. Moreover, Brightline membership was not required to access and complete the survey.

Participants

Anyone who visited the Brightline website during the study period could complete the survey. Participants were not compensated for completing the survey. There were no other eligibility criteria or exclusion criteria for participation. While this allowed our survey to be accessible to any interested participant, it also meant that a nonparent could complete the survey.

Procedures

Participants voluntarily completed the anonymous, web-based survey. The survey took approximately 10 minutes to complete. Once participants submitted the survey, they received a summary of each of the 4 survey components ([Multimedia Appendix 2](#)). The participant could then choose to follow a link to resources and a guide to help facilitate a conversation with a pediatric behavioral health care provider ([Multimedia Appendices 3 and 4](#)).

Measures

The survey was designed from 3 standardized clinical instruments, focusing on psychological stress, family resilience, family connection, and preexisting behavioral health conditions. The survey was augmented by a set of questions about parental productivity and time spent managing children's behavioral health, as well as questions related to the direct impacts of the COVID-19 pandemic and participant demographics ([Multimedia Appendix 5](#)). These instruments were selected because they aligned with previous research that identified both nonmodifiable and modifiable risk factors for children's postdisaster mental health outcomes and well-being, such as mass disasters (eg, 9/11 attacks), natural disasters (eg, hurricanes), and previous epidemics [11-14]. Further, these instruments were selected because they do not evaluate for any clinical domains that would require Brightline to intervene in the case of high acuity needs.

Preexisting Behavioral Health Conditions

Preexisting behavioral health conditions were assessed with children with special health care needs (CSHCN) screener [19]. The CSHCN screener is a set of 5 yes or no question sequences used to identify children with special health care needs ([Multimedia Appendix 5](#)). The purpose of including the CSHCN screener was not to evaluate whether COVID-19 was a catalyst for behavioral health conditions in the participants' children but rather to assess for already existing behavioral health conditions.

Psychological Stress

Pediatric stress was measured during the pandemic, specifically at the time of the survey, using the PROMIS (Patient-Reported Outcome Measurement Information System) Pediatric Parent Proxy Psychological Stress Experiences Measure ([Multimedia Appendix 5](#)) [22]. PROMIS has been used in research to study children's stress levels associated with cancer treatment, sickle

cell disease, as well as other chronic illnesses [23-27]. Participants rated the frequency of their child's stress experience on a 5-point Likert scale. Scores were grouped into 4 categories based on general interpretation guidelines: scores less than 50 indicate pediatric stress was within normal limits; scores between 50 and 55 indicate mild pediatric stress; scores between 55 and 65 indicate moderate pediatric stress; and scores greater than 65 indicate severe pediatric stress [22].

Family Resilience and Connection Index

The family resilience and connection index (FRCI) was used to measure family resilience and connection, a 6-item index that comprises 4 family resilience items and 2 additional items that measure parent-child connection and parent coping ([Multimedia Appendix 5](#)) [28]. The FRCI has been used in research to evaluate the connection between family resilience and parenting stress with children's mental health and attention deficit hyperactivity disorder as well as their ability to flourish and engage at school [29-31]. The 4-item family resilience index (FRI) asked parents about their approach to problem-solving and hopefulness. Additionally, the 2-item family connection index (FCI) asked parents about their connectedness with children and perception of how well they are managing the day-to-day demands of child raising. One point was assigned for each time a participant answered "all of the time" to 1 of the 4 FRI items. Moreover, one point was assigned for each time a parent responded "very well" to 1 of the 2 FCI items. Scores were grouped into three categories based on general interpretation guidelines: scores between 0 and 1 indicate low family resilience or connection; scores between 2 and 3 indicate moderate family resilience or connection; and scores between 4 and 6 indicate strong family resilience or connection.

Productivity

Two additional questions written by the research team were added about time spent by parents managing their children's behavioral health concerns, and about its impact on productivity ([Multimedia Appendix 5](#)).

COVID-19 Impact

To determine the potentially adverse effects COVID-19 may have had on participants, a set of 3 yes or no questions from the Coronavirus Aid, Relief, and Economic Security Act was included in the survey ([Multimedia Appendix 5](#)) [32]. These questions asked whether the respondent experienced a COVID-19 adverse event, which includes being diagnosed with COVID-19, a spouse or dependent being diagnosed, or the presence of an adverse financial consequence from COVID-19. The questions about the pandemic were included to ascertain COVID-19 exposure experiences as a facet of participant demographics.

Background and Demographics

The following demographics information was collected: marital status of the parent answering the survey, household income, race or ethnicity, highest educational level achieved, gender, and state of residence ([Multimedia Appendix 5](#)).

Analyses

This retrospective, cross-sectional study analyzed survey responses collected from participants (N=361) between October 2020 and November 2021. All statistical analyses were performed in R version 4.1.2 (R Foundation for Statistical Computing). Prior to analysis, all predictor variables underwent min-max normalization. Multivariable linear regression was used to characterize the associations among productivity interruptions, family stress, family connection, family resilience, and COVID-19–related exposure experiences. This linear regression was adjusted for household income and parental education level. Goodness of fit was performed for linear regressions.

Ethics Approval

This study protocol was approved by the Western Institutional Review Board and the Copernicus Group Institutional Review Board.

Results

Participants

Participant demographics are presented in [Table 1](#). The participants primarily had a White racial background, were married women who were highly educated, and reported high incomes.

Table 1. Participant demographics (N=361).

Variable	Value, n (%)
Gender	
Female	257 (71.1)
Male	62 (17.2)
Nonbinary	10 (2.8)
Prefer not to say	32 (8.9)
Marital status	
Divorced	22 (6.1)
Married	278 (77.0)
Prefer not to say	9 (2.5)
Separated	21 (5.8)
Single, never married	19 (5.3)
Widowed	12 (3.3)
Education level	
Completed some high school	7 (1.9)
High school graduate	19 (5.3)
Associate degree	18 (5.0)
Completed some college	32 (8.9)
Bachelor's degree	87 (24.1)
Completed some postgraduate	21 (5.8)
Master's degree	123 (34.1)
PhD, law, or medical degree	33 (9.8)
Prefer not to say	21 (5.8)
Household income (US \$)	
<25,000	19 (5.3)
25,000 to 35,000	13 (3.6)
35,001 to 50,000	20 (5.5)
50,001 to 75,000	36 (10.0)
75,001 to 100,000	37 (10.2)
100,01 to 150,000	50 (13.9)
>150,000	147 (40.7)
Prefer not to say	39 (10.8)
Race or ethnicity	
American Indian or Alaska Native	7 (1.9)
Asian	45 (12.5)
Black or African American	24 (6.6)
Hispanic or Latino	31 (8.6)
Native Hawaiian or Other Pacific Islander	2 (0.5)
Other or multi-ethnic	15 (4.2)
Prefer not to say	40 (11.1)
White	197 (54.6)

COVID-19 Exposure-Related Experiences

The direct impact of COVID-19 on participants are presented in [Table 2](#). Over 90% (341/361) of the participants reported neither they nor their spouse had been diagnosed with

COVID-19. The responses to the question “I have experienced adverse financial consequences due to COVID-19” are also summarized in [Table 2](#). A majority of participants (233/361, 65%) said they had not experienced financial consequences as a result of COVID-19.

Table 2. COVID-19 exposure-related experiences (N=361).

Question	“Yes,” n (%)	“No,” n (%)
I was diagnosed with COVID-19.	20 (6)	341 (94)
My spouse or my dependent was diagnosed with COVID-19.	26 (7)	335 (93)
I have experienced adverse financial consequences because (1) I or a member of my household was quarantined, laid off, or had work hours reduced due to COVID-19; (2) I or a member of my household was unable to work as a result of a lack of childcare due to COVID-19; (3) a business owned or operated by me or a member of my household closed or reduced hours due to COVID-19; or (4) I or a member of my household had a reduction in pay (or self-employment income) due to COVID-19 or had a job offer rescinded or start date for a job delayed due to COVID-19.	128 (35)	233 (65)

Survey Results: CSHCN Screener Results

The preexisting behavioral health needs of the participants’ children from the CSHCN screener, which is commonly used to evaluate whether a child already has behavioral health needs prior to evaluation, are presented in [Table 3](#). Approximately

28% (102/361) were described as having an emotional, developmental, or behavioral problem for which he or she needs or gets treatment or counseling, and 21% (76/361) reported their child needing more medical care, mental health, or educational services than is usual for most children.

Table 3. CSHCN^a screener results.

Question	“Yes,” n (%)	“No,” n (%)
Does your child currently need or use medicine prescribed by a doctor (other than vitamins)?	51 (14)	309 (86)
Does your child need or use more medical care, mental health, or educational services than is usual for most children of the same age?	76 (21)	285 (79)
Is your child limited or prevented in any way in his or her ability to do the things most children of the same age can do?	57 (16)	303 (84)
Does your child need or get special therapy, such as physical, occupational, or speech therapy?	56 (16)	304 (84)
Does your child have any kind of emotional, developmental, or behavioral problem for which he or she needs or gets treatment or counseling?	102 (28)	258 (72)

^aCSHCN: children with special health care needs.

The responses for the item “Since Covid began, how much time (on average) are you spending managing your child or children’s behavioral health concerns (including their stress, anxiety, disruptive behaviors)?” are summarized in [Table 4](#). Nearly 50% (155/361) of the participants reported spending between 2 and 4 hours per week managing their children’s behavioral health. The responses to the question “How much is your child’s behavioral health and well-being affecting your productivity and ability to work if you are currently employed?” are also summarized in [Table 4](#). The majority of the participants (307/361, 85%) reported some impact on their productivity and ability to work.

The responses for the PROMIS measure are summarized in [Table 5](#). The mean summed PROMIS raw score was 23.05. The scaled score is approximately 64.4, which indicates moderate pediatric stress reported at the time of the survey among the participants in our study.

The responses for the FRCI measures are summarized in [Table 6](#). The mean summed FRI score was 1.03, indicating low family resilience among participants in our study. The mean summed FCI score was 2.3, indicating moderate family connection among the participants in our study.

Table 4. The impact of child's behavioral health on parents' time and productivity.

Variable	Value, n (%)
Time managing child behavioral health concerns results (hours/week)	
0-1	78 (22)
2-4	155 (43)
5-8	77 (21)
>8	51 (14)
Child's behavioral health affecting your productivity results	
Large impact	34 (9)
Definite impact	144 (40)
Slight impact	130 (36)
No impact	53 (15)

Table 5. PROMIS^a results.

Variable	Mean (SD)
PROMIS pediatric physical stress raw summed score	23.05 (6.15)
In the past 7 days, my child felt overwhelmed.	3.05 (0.87)
In the past 7 days, my child felt that his or her problems kept piling up.	2.76 (1.05)
In the past 7 days, my child felt that he or she had too much going on.	2.66 (1.06)
In the past 7 days, my child felt unable to manage things in his or her life.	2.68 (1.01)
In the past 7 days, my child felt under pressure.	2.80 (0.99)
In the past 7 days, my child had trouble concentrating.	3.14 (1.05)
In the past 7 days, everything bothered my child.	2.72 (1.03)
In the past 7 days, my child felt stressed.	3.23 (0.83)

^aPROMIS: Patient-Reported Outcome Measurement Information System.

Table 6. FRCI^a results.

Variable	Mean (SD)
Family resilience index score	1.03 (0.52)
When your family faces problems, how often are you likely to talk together about what to do?	0.56 (0.36)
When your family faces problems, how often are you likely to know we have strengths to draw on?	0.57 (0.35)
When your family faces problems, how often are you likely to work together to solve our problems?	0.60 (0.29)
When your family faces problems, how often are you likely to stay hopeful even in difficult times?	0.56 (0.31)
Family connection index score	2.30 (1.00)
How well can or do you think you are managing the day-to-day demands of raising children?	0.48 (0.28)
How well can or do you share ideas and talk about things that really matter with your child?	0.55 (0.32)

^aFCRI: family resilience and connection index.

Factors Associated With Productivity Loss

In the multivariable model, there was a strong association between productivity loss and the time spent managing children's behavioral health needs ($\beta=.365$; $P<.001$) as well as Stress Index scores ($\beta=.213$; $P<.001$) (Table 7). There was a

weaker association between productivity loss and FCI scores ($\beta=-.125$; $P=.053$) (Table 7). COVID-19 diagnoses among parents and dependents, financial impact of COVID-19 on households, and family resilience were not associated with parents' workplace productivity (Table 7).

Table 7. Multivariable linear regression of survey items associated with productivity loss ($F^9_{351}=14.97$; $P<.001$; adjusted $R^2=0.2588$).

Independent variables	β	SE β	P value
Time spent managing child behavioral health concerns	.365	.043	<.001
PROMIS ^a pediatric physical stress raw summed score	.213	.075	<.001
Family connection score	-.125	.064	.053
Family resilience score	-.019	.067	.78
COVID-19 diagnosis (self)	-.099	.068	.14
COVID-19 diagnosis (partner or dependent)	.036	.060	.54
Adverse COVID-19 financial impact	.025	.029	.34
Caregiver education	-.015	.056	.79
Household income	.032	.024	.18

^aPROMIS: Patient-Reported Outcome Measurement Information System.

Discussion

Principal Findings

Our findings show that parents spend a considerable amount of time managing their children's behavioral health needs. Although we did not find that having a COVID-19 diagnosis among a household member or having a significant financial impact on the household from COVID-19 impacted productivity, this may have been due to the fact that our participants had low rates of COVID-19 infection and were relatively high-income earners. An important extension of this work would be to assess the association of COVID-19 diagnoses and financial consequences of the pandemic on workplace productivity among lower-income earners and those with significant COVID-19-associated illness.

In addition, we found that high pediatric stress and more time spent managing children's behavioral health problems were associated with increased productivity losses for parents regardless of COVID-19-related experiences. While COVID-19 variables were used as predictors in our multivariable regression model, we discovered that COVID-19 exposure-related experiences did not have a significant effect on our outcome. Despite the lack of representation of families affected by COVID-19, we felt it was important to incorporate this variable in our model.

Our findings also showed that enhanced parent-child connection is inversely associated with the parents' productivity loss, even amid adversity [33-35]. This finding is significant because there are known behavioral health interventions that can be mobilized to enhance parent-child connection where parents are trained to support the management of children's behavioral health problems. Our results further support those of previous studies, which show that pediatric stress and family connection are good predictors of pediatric behavioral health outcomes [36-38].

Limitations and Future Studies

As with all survey research, there are limits inherent to this research method. As the survey was completed anonymously and was internet-based, we were unable to control for the chance that a nonparent completed the survey. Moreover, the tool

produced some basic pediatric behavioral health insights that were tailored to the users' answers after completing the survey; therefore, the participants may have been encouraged to take the survey more than once in order to receive different answers. This means that the same participant could have taken the survey multiple times without us knowing. However, allowing for anonymity likely increased the response rate and participation.

In this exploratory study, the majority of respondents represented a well-educated, high-income, female population. Further, participants were only recruited using digital channels (eg, search engines, email, and social media), all of which can potentially limit the generalizability to other populations. The participants may have included parents searching on the web for information related to child behavioral health; therefore, their responses related to perceived child stress and family resilience might not reflect the general parent population. Future studies will share the survey through alternate venues to recruit more diverse participants.

In designing the survey, we did not include questions on the number, age, and gender of children, potentially limiting the ability to draw insights on the differences between children and adolescents across behavioral health needs and impact on stress, family resilience, and family connection. However, research has shown that having a higher number of children is positively associated with a higher level of psychological distress in families [39]. Additionally, the survey did not include questions from the Sickness Index Profile, which evaluates the effect of disease on physical and emotional functioning [40]. There is opportunity to further explore the impact of COVID-19 and other illnesses or stressors on children's behavioral health needs.

Building on our preliminary findings, in future studies, we aim to learn more about the time spent and its impacts on the larger family unit. In this iteration of the survey, we asked parents about their time spent managing their child's behavioral health concerns. What we received is an estimated snapshot. We are interested in developing questions and methods to ascertain changes in time spent to learn whether this is associated with differing productivity and stress levels. Further, this survey includes responses from parents and caregivers on their individual time spent managing their children's behavioral

health (independent of their partner). Collecting data on time spend on the household level would give us greater insight into the impact a child's mental and behavioral health has on the family and measures of productivity more broadly. Lastly, when completing the survey, the participants received recommendations and tools to help support their children's mental and behavioral health needs. In future studies, we aim to collect data on the use of these resources.

Conclusion

Our preliminary findings confirm that measures of increased psychological stress in children and lower family connection are associated with productivity loss regardless of COVID-19 diagnosis, financial consequences of COVID-19, education

level, and income level. These results suggest a continued need for research on family-focused behavioral health benefits that address pediatric stress levels and that offer support to manage children's behavioral health problems and improve parent-child connections. Surveys that integrate standardized and validated measures of known risk and protective factors for children's postdisaster well-being and outcomes can be useful mental and behavioral health points of entry for parents. The feedback that participants receive after completing a survey, for example, can make parents or caregivers more aware of these factors and help them to facilitate conversations with health care professionals about their concerns. This is especially important during crises such as COVID-19, when families have limited access to face-to-face community indicators of well-being.

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Conflicts of Interest

This work was conducted using research expenditures from Brightline, Inc. DG, JB, and TL are employees of Brightline, Inc. DB is on the advisory board of Brightline, Inc.

Multimedia Appendix 1

Survey landing page.

[\[DOCX File, 452 KB - formative_v6i8e37285_app1.docx\]](#)

Multimedia Appendix 2

Sample survey results summary.

[\[DOCX File, 129 KB - formative_v6i8e37285_app2.docx\]](#)

Multimedia Appendix 3

Resources from survey results.

[\[DOCX File, 65 KB - formative_v6i8e37285_app3.docx\]](#)

Multimedia Appendix 4

Guide for finding behavioral health care.

[\[DOCX File, 87 KB - formative_v6i8e37285_app4.docx\]](#)

Multimedia Appendix 5

Survey items.

[\[DOCX File, 20 KB - formative_v6i8e37285_app5.docx\]](#)

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Abbreviations

COBI: COVID-19 behavioral health instrument

CSHCN: children with special health care needs

FCI: family connection index

FRCI: family resilience and connection index

FRI: family resilience index

PROMIS: Patient-Reported Outcome Measurement Information System

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Original Paper

mHealth Physical Activity Intervention for Individuals With Spinal Cord Injury: Planning and Development Processes

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Abstract

Background: Interventions to support physical activity participation among individuals with spinal cord injury (SCI) are required given this population's low levels of physical activity and extensive barriers to quality physical activity experiences.

Objective: This study aimed to develop a mobile health intervention, called *SCI Step Together*, to improve the quantity and quality of physical activity among individuals with SCI who walk.

Methods: Our overarching methodological framework was the Person-Based approach. This included the following 4 steps: conduct primary and secondary research (step 1); design intervention objectives and features (step 2a); conduct behavioral analysis and theory (step 2b); create a logic model (step 3); and complete the SCI Step Together program content and integrated knowledge translation (IKT; step 4), which occurred throughout development. The partnership approach was informed by the SCI IKT Guiding Principles. Three end users pilot-tested the app and participated in the interviews.

Results: Step 1 identified issues to be addressed when designing intervention objectives and features (step 2a) and features were mapped onto the Behavior Change Wheel (step 2b) to determine the behavior change techniques (eg, action planning) to be included in the app. The logic model linked the mechanisms of action to self-determination theory (steps 2/3). Interviews with end users generated recommendations for the technology (eg, comparing physical activity levels with guidelines), trial (eg, emailing participants' worksheets), and intervention content (eg, removing *graded tasks*; step 4).

Conclusions: Using the SCI IKT Guiding Principles to guide partner engagement and involvement ensured that design partners had shared decision-making power in intervention development. Equal decision-making power maximizes the meaningfulness of the app for end users. Future research will include testing the acceptability, feasibility, and engagement of the program. Partners will be involved throughout the research process.

Trial Registration: ClinicalTrials.gov: NCT05063617; <https://clinicaltrials.gov/ct2/show/NCT05063617>

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KEYWORDS

exercise; stakeholder participation; spinal cord injuries; telemedicine; mobile apps; mobile phone

Introduction

Approximately 3 million individuals live with a spinal cord injury (SCI) worldwide, with 180,000 new cases of SCI reported each year [1]. Although most individuals who sustain a SCI use a wheelchair for mobility, a small but growing number of individuals retain the ability to walk after their injury [2]. More than half of individuals living with a SCI have an incomplete injury, meaning that motor function and ambulation recovery are possible [3]. A recent study showed that 207 out of 460 individuals with SCI sustained incomplete injuries, of which 47% ambulated some or all the time [4]. However, there is little epidemiological data on the number of individuals who ambulate for their primary mode of mobility, as there is often no follow-up after the acute injury. Individuals with SCI who walk still live with SCI-related impairments that have profound impacts on their physical, psychological, and social health. For instance, individuals with SCI who ambulate have reduced bowel function [5] and experience pain and fatigue during walking due to greater metabolic energy demands [6].

Physical activity is one behavior that can help individuals manage and overcome challenges associated with SCI-related implications. A recent review identified the following benefits of physical activity participation for individuals with SCI who walk: increased cardiovascular fitness, reduced pain and fatigue, improved cognition, and decreased depressive symptoms [7]. Although increasing the amount of physical activity is important, quality physical activity experiences are another valuable aspect of participation. Quality physical activity reflects the subjective perceptions and experiences of individuals [8]. Positive quality physical activity experiences can lead to benefits such as improved well-being, health [9], and sustained participation [10]. Although individuals with SCI who walk participate in less physical activity than those with SCI who use wheelchairs [11], there have been few attempts to help improve the quantity or quality of leisure-time physical activity for this group. Thus, interventions are required to facilitate quality physical activity behavior change among individuals with SCI who walk.

According to a meta-analysis, physical activity behavioral interventions for individuals with physical disabilities have a small to medium effect size on physical activity behavior (mean $g=0.35$, SE 0.07) [12]. Interestingly, most physical activity behavioral interventions for individuals with physical disabilities have been delivered in person or over the telephone, with few using digital platforms (eg, email, texting, and video) [12]. Although apps have been used to deliver other types of health interventions for individuals with SCI (eg, transitional care) [13], to the best of our knowledge, no physical activity interventions have been provided to individuals with SCI through a mobile health (mHealth) format.

mHealth interventions offer a convenient way to deliver physical activity support to individuals with SCI, especially because of the sparse and geographically distant number of individuals with SCI who walk, which makes in-person interventions nearly impossible. In addition, delivering an intervention through an app can alleviate transportation and built environment barriers to access, which are substantial for the SCI population [14].

mHealth interventions are cost-effective, available, accessible, and give users the option of flexible and convenient access to individualized programming (eg, [15]). Among able-bodied adults, a meta-analysis of smartphone-based physical activity interventions demonstrated a significant overall moderate effect size ($g=0.54$ for increased physical activity) [16]. Together, these data indicate the potential value of using mHealth formats (ie, smartphone apps) to deliver physical activity interventions to individuals with SCI who walk.

However, very few physical activity smartphone apps are theory based [17]. Although most existing physical activity apps use the behavior change techniques (BCTs) of goal setting, self-monitoring, and feedback, other valuable theory-based strategies are missing, such as social support, self-talk, and coping planning [18]. Indeed, the more theory-based strategies an app contains, the greater the use rates of physical activity apps [19] and the more effective they are at increasing physical activity in general [20]. In physical activity interventions for people with physical disabilities, the largest effects occurred for interventions guided by the behavior change theory [12]. Accordingly, the development of mHealth interventions to increase physical activity behavior should be explicitly informed by the behavior change theory.

Furthermore, engaging with partners throughout the development process (ie, integrated knowledge translation [IKT]) [21] is important for intervention design. For example, a physical activity counseling intervention for individuals with SCI was developed using an IKT approach and produced the largest effects reported for a behavioral intervention in this population (self-reported physical activity, Cohen $d=1.04$; peak oxygen uptake [$\dot{V}O_2$ peak], Cohen $d=0.54$) [22]. The authors attribute the success largely to the co-development process of intervention development [23]. Indeed, the authors of a recent landmark paper argued that physical activity policies, recommendations, and resources must use an IKT approach to drive greater quantity and quality of physical activity participation experiences for persons with disabilities [24].

Similarly, the Person-Based approach for intervention development provides the groundwork for developing interventions, which account for the context, perspectives, and experiences of end users through mixed methods research [25]. This approach has been used to guide the development of many digital health interventions as a primary goal of this method is to increase the feasibility, acceptability, and engagement of interventions [26]. Notably, the Person-Based approach is used complementarily with theory- and evidence-based approaches [15,26]. However, a limitation is that it does not provide guidance on when and how to include partners in the intervention development process. Greater clarification on how to implement partner engagement using IKT in combination with Person-, theory-, and evidence-based approaches is needed.

Recently, 8 IKT guiding principles for SCI research (refer to Gainforth et al [27] for more details) were developed to address the gap in guidance on partner engagement. These principles help researchers to engage meaningfully in partnered research that is relevant and usable [27]. Using these principles to guide IKT has the potential to reduce experiences of tokenism,

increase the coproduction of knowledge, and create meaningful SCI research partnerships [27].

The purpose of this paper is to describe the 4-step intervention planning and development processes of an mHealth intervention to increase the quantity and quality of physical activity participation among individuals with SCI who walk. This paper provides an illustration of how the Person-Based approach can be used alongside IKT, theory, and evidence to plan and develop an mHealth intervention. Of note, this paper reports on the processes of steps 2 to 4, whereas step 1 is summarized because these details are reported elsewhere [7,28,29].

Methods

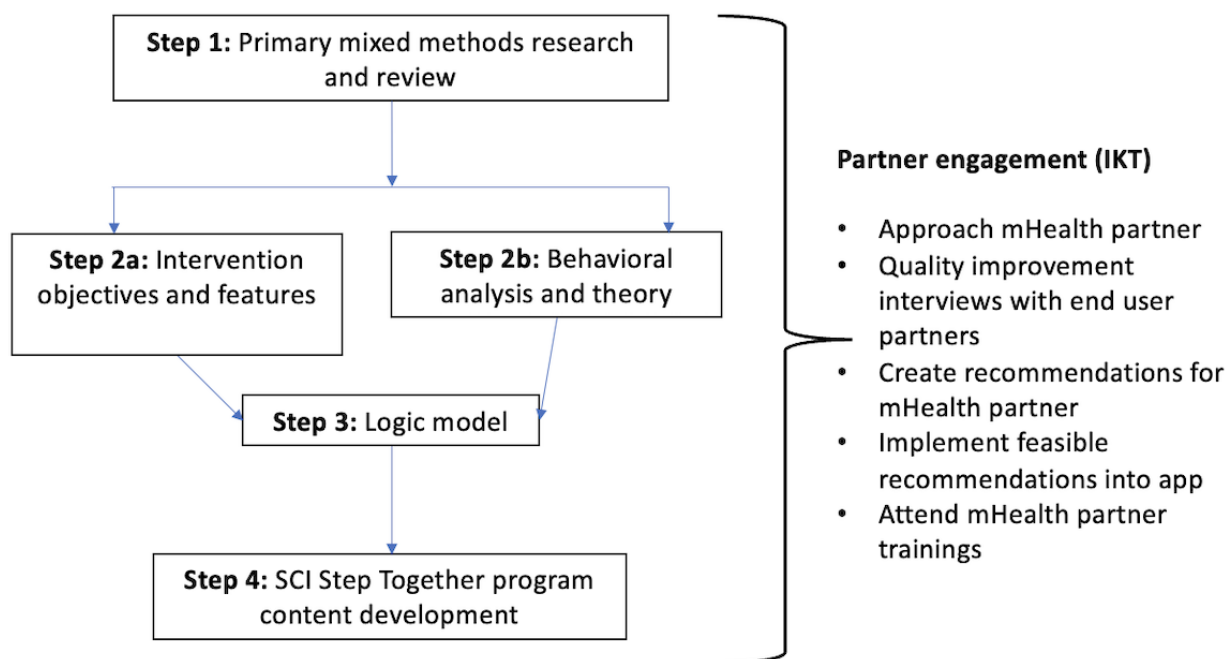
Context

Our intervention, SCI Step Together, was developed as a program within an existing app called *Stronger Together*. The Stronger Together app was created through partnership with Curatio Networks Inc and the University of British Columbia to create communities of peer support for self-management of various chronic conditions (eg, patients who have undergone knee replacement surgery, adults with physical disabilities, and COVID-19 long-haulers). The platform takes a differentiated approach to behavioral change by embedding social connections

into health literacy and management interventions. The platform is privacy and regulatory compliant to meet the requirements of life sciences policy and protocols. The Stronger Together platform has already undergone usability and acceptability testing privately through Curatio Networks Inc. Overall, the app provides users access to educational modules, health tracking, peer support, and individual behavioral support from a live community coach.

In the following sections, we describe the methods for planning, adapting, and developing the SCI Step Together intervention. Adapted from the study by Band et al [15], Figure 1 shows each step in the intervention planning and development process, including partner engagement activities to demonstrate the IKT approach. Importantly, evidence from primary studies and systematic reviews was incorporated throughout the intervention development process, with the intervention development steps being updated and carried out iteratively. This included four steps: (1) conduct primary mixed methods research and review, (2a) design intervention objectives and features, (2b) conduct behavioral analysis and theory, (3) create a logic model, and (4) complete the SCI Step Together program content development. In addition, partner engagement occurred throughout the intervention planning and development process and will be described in step 4.

Figure 1. Steps in intervention planning and development process for the SCI Step Together program. Adapted from Band et al [15]. IKT: integrated knowledge translation; mHealth: mobile health; SCI: spinal cord injury.



Step 1: Primary Mixed Methods Research and Review

Step 1 involved conducting three studies: a scoping review, a quantitative cross-sectional study, and a qualitative study. The purpose of step 1 was to gain an understanding of the background and context of physical activity participation for people living with SCI who walk. The goal was to identify factors to target in the intervention along with recognizing the

context of lived experience for end users. The methods for step 1 are not novel and are only described briefly. Importantly, IKT was incorporated into all 3 studies and is described in detail elsewhere (along with the methods and results) [7,28,29].

Scoping Review

The purpose of the scoping review was to understand the amounts, types, correlates, and outcomes of physical activity

participation for individuals with SCI who ambulate as their primary mode of mobility. IKT was used by consulting individuals with SCI who walk and a provincial SCI organization to determine research questions and search strategies. Using a published method for scoping reviews [30], a systematic search was conducted among academic (MEDLINE, PsycINFO, Embase, CINAHL, Web of Science, and Sport Discus) and gray literature (Open Access Theses and Dissertations and ProQuest Dissertations and Theses) databases, yielding 3257 articles. After a 2-phase screening process by 2 independent coders, 17 articles were selected for inclusion, and the data were charted and summarized, and correlates were coded using the Capability, Opportunity, Motivation-Behavior (COM-B) model [31]. The COM-B model identifies the source of the behavior, which is the first step in the Behavior Change Wheel (BCW; see below in Step 2b for more detail) [31], a theoretically aligned approach to developing interventions.

Primary Mixed Methods Research

Two studies were conducted with a sample of adults with SCI who self-reported that they walked for daily mobility more often than not (ethics board approval time: 52 days). IKT was used by partnering with individuals with SCI, a behavior change theory expert, and a provincial SCI organization to determine measure selection and adaptation, recruitment, and data analysis. The first study (n=43) used a cross-sectional design and required 1.5 hours of time from participants. This study used the Theoretical Domains Framework [32] to identify behavioral change factors related to physical activity participation among ambulators with SCI. The Theoretical Domains Framework is embedded in the COM-B model. The Theoretical Domains Framework domains are used to assess capability-, opportunity-, and motivation-related barriers and facilitators to engage in a behavior [33]. A modified version of the validated Determinants of Physical Activity Questionnaire [34] was used to assess behavioral change factors. We also measured the duration, type, and intensity of physical activity performed during the previous week using the Physical Activity Recall Assessment for individuals with SCI [35,36]. This measure has demonstrated adequate test-retest reliability and evidence of criterion and construct validity [35-37].

The second study used a qualitative approach to explore the conditions and elements involved in quality physical activity experiences. Semistructured interviews were conducted with 22 participants in the cross-sectional study. The interviews lasted for approximately 60 minutes and were transcribed verbatim. Using a philosophically pragmatic approach [38], the data were reflexively thematically analyzed [39] with the goal of informing the SCI Step Together intervention. The data were first inductively coded by 2 independent coders, with feedback from critical friends. Then, the data were deductively coded using the Quality Passport Participation Framework [40] to identify conditions and the Quality Participation Framework [41] to identify elements of quality participation.

Step 2a: Intervention Objectives and Features

An essential component of the Person-Based Approach [25], the purpose of this step was to develop key intervention

objectives and design needs, along with associated intervention features that address these objectives.

First, we stated the objectives of the intervention with respect to behaviors and outcomes and described the relevant aspects of users and their context, as informed by step 1 [25]. In addition, we identified the key behavioral issues, needs, and challenges that the intervention must address. Second, we formulated the intervention design objectives according to the evidence generated in step 1. Third, we generated the design features intended to achieve each objective based on the intervention planning, evidence from step 1, behavioral analysis from step 2b, and logic model from step 3. These objectives and features have been refined throughout the intervention planning and development process based on partner engagement and evidence (eg, inclusion of theory).

Step 2b: Behavioral Analysis and Theory

The purpose of step 2b was to use behavior change theory to identify BCTs to be included in the intervention content as well as to choose a specific theory to inform intervention content.

Behavioral Analysis

The behavioral analysis was conducted using BCW [31], which is a theoretical framework that guides researchers to identify the source of behavior (ie, capabilities, opportunities, and motivations) and then links these to the selection of intervention functions, policy categories, and BCTs. The results from the quantitative study examining the Theoretical Domains Framework behavior change factors (step 1) were used to inform the behavioral analysis. First, the Theoretical Domains Framework domains (predictors of, and barriers to, physical activity) were linked to intervention functions. The most common and feasible intervention functions were identified, and these were linked to common and feasible policy categories. The intervention functions and Theoretical Domains Framework domains were then linked to BCTs, noting the most frequently used BCTs [42]. Finally, 2 reviews of the effectiveness of BCTs in physical activity and self-management interventions among individuals with SCI and physical disabilities generally were consulted [12,43]. These reviews allowed us to decide which BCTs should be included or excluded based on their effectiveness in similar interventions.

Theory

In addition to conducting a behavioral analysis and identifying BCTs for inclusion in the intervention, we selected a theory to inform the intervention. Using theory helps to outline the critical assumptions that underlie the intervention protocol, the primary constructs that are effective, and the causal processes tested by mediators [44]. The first author (SL) reviewed theories on changes in physical activity behavior [45]. In addition, discussions occurred among the first and senior authors (experts in exercise psychology) regarding theory fit and choice. We considered the evidence identified in primary mixed methods studies (step 1; ie, Theoretical Domains Framework domains to target and context from qualitative interviews) in addition to the intervention objectives identified in step 2a.

Step 3: Logic Model

The purpose of developing the logic model was to clarify the hypothesized causal relationships and mechanisms of action that mediate intervention outcomes [46]. The logic model was created in accordance with the Medical Research Council evaluation guidance [46] and process evaluation methods [47]. The logic model included the intervention inputs, processes or actions, outputs, and outcomes. Having clear intervention objectives and features enabled us to understand the problems that needed to be addressed and to select appropriate intervention components. The BCTs identified in the behavioral analysis in step 2 were included as intervention inputs in the logic model, whereas the theory selected in step 2 informed all aspects of the logic model's causal assumptions. The logic model underwent several iterations as the development process continued to include feedback from all partners involved.

Step 4: SCI Step Together Program Content Development and IKT

The partners involved in the development of the SCI Step Together program included 2 SCI physical activity behavior change scientists (SL and KMG); an external project manager at Curatio, Inc, the company that hosts the technology platform (LC); the CEO of Curatio, Inc (LBG); and potential end users of the program (ie, ambulators with SCI; JS, MM, and CJ). The partners included both women (n=5) and men (n=2) and were both over (n=2) and under (n=5) the age of 50 years.

The SCI Step Together program is hosted on Curatio's Stronger Together platform, which was developed and tested among other users with physical disabilities. Six months after the launch of Stronger Together (January 2021), the senior author (KMG) approached Curatio, Inc (LBG), and the 2 partners agreed to create a community for ambulators with SCI using an evidence- and theory-based approach.

One of the original (January 2021) Stronger Together communities is for adults with physical disabilities who want to increase their physical activity. The first author (SL) reviewed the content modules for this community. SL then revised the modules for SCI Step Together, based on the information collected from steps 1 to 3 and content from other physical activity interventions for individuals with SCI, including the ProActive SCI Toolkit [23], Active Homes [48], the Blueprint for Quality Participation [49], and the SCI Physical Activity Guidelines [50].

The first author (SL) and senior author (KMG) wanted to engage end users to receive feedback on the preliminary intervention content and delivery. Accordingly, the first author (SL) developed an interview guide to conduct partnered quality improvement of the program content. Three potential end users (ambulators with SCI) were interviewed, all with different levels of physical activity participation. The purpose of the interviews

was to produce recommendations for the format and general content of this intervention. Before the interviews, the end users were asked to review the original Stronger Together program (physical activity for people with physical disabilities) to understand how the app works and its various components. In addition, end users were sent lay summaries of the (step 1) studies informing intervention development. Finally, we sent the end users the 8 IKT guiding principles for conducting quality and ethical SCI research (Multimedia Appendix 1) [27]. These principles are intended to be used by all partners early and throughout the research process [27]. The IKT guiding principles were discussed with the end users at the beginning of the interview to ensure that all partners were aligned with how the intervention development process would occur. The interviewer (SL) took notes throughout the interview to record recommendations.

Following the interviews, the first author (SL) met the project manager from Curatio. During the meeting, they discussed the project and timelines, and they reviewed the IKT guiding principles. The first author (SL) brought forward technology-related recommendations of the end users on how the original Stronger Together program could be adapted and improved for SCI Step Together. Recommendations were sent to the project manager and software developers who returned a list of what could and could not be changed. Ultimately, the recommendations from end users were incorporated as best as possible for both content and delivery, with the decisions reported in the Results section. These decisions were then communicated back to the SCI end users. Importantly, both the technology and SCI end user partners have been included as authors of this manuscript.

In addition, Curatio invited the first author (SL) to attend trainings on how to engage with participants, technology information, and how to record and manage time in addition to privacy concerns.

Ethics Approval

Ethical approval was not applied for to develop program content as it was completed for quality improvement. Under Article 2.5 of the Tri Council Policy Statement, quality assurance or quality improvement activities are not subject to institutional ethical review.

Results

Step 1: Primary Mixed Methods Research and Review

The results of the step 1 studies have been published elsewhere [7,28,29]. Key issues identified from the primary mixed methods research and scoping review are summarized in Table 1. The implemented intervention features addressing each issue are also reported in Table 1.

Table 1. Key issues from primary mixed methods research and scoping review and associated intervention features.

Issue identified by research	Intervention features addressing the issue
<ul style="list-style-type: none"> Ambulators with SCI^a participate in low levels of leisure-time physical activity, and no interventions exist for this group [7]. 	<ul style="list-style-type: none"> Intervention should be developed to improve physical activity participation.
<ul style="list-style-type: none"> Exercise intervention studies lacking measurement of psychosocial outcomes [7]. 	<ul style="list-style-type: none"> Intervention must address and measure psychosocial constructs related to physical activity participation.
<ul style="list-style-type: none"> Correlates related to physical activity include physical and psychological capability (eg, pain and lack of knowledge), environmental and social opportunity (eg, time and underestimated disability), and reflective and automatic motivation (eg, intentions and boredom) [7] Barriers to physical activity include lack of knowledge, weak beliefs about capabilities, lack of coping planning, and high goal conflict [28]. Coping planning, action planning, goal conflict, and skills significantly predict physical activity [28]. 	<ul style="list-style-type: none"> Intervention must target the following constructs through educational modules, behavioral support, and peer support: <ul style="list-style-type: none"> Physical activity guidelines and benefits (knowledge) Self-monitoring and goal setting (goal conflict) Action planning Coping planning Confidence (beliefs about capabilities) Skills
<ul style="list-style-type: none"> A total of 35 types of physical activity recorded and organized into 10 higher-order categories (eg, walking, resistance training, and rock climbing) [28]. 	<ul style="list-style-type: none"> Intervention content must include educational modules that refer to these types of physical activity when examples are used. A list of these types of physical activity as ideas for participants should also be included.
<ul style="list-style-type: none"> Ambulators with SCI have physical activity experiences, which are shaped by feelings of ableism, feeling sidelined, and the effects of their SCI [29]. 	<ul style="list-style-type: none"> Behavioral support in the intervention must be provided by a person who understands this context for physical activity participation.
<ul style="list-style-type: none"> Conditions and elements of quality physical activity experiences map onto the Quality Participation Framework [41] and Quality Parasport Participation Framework [29,40]. 	<ul style="list-style-type: none"> Conditions and elements of quality physical activity experiences must be included as a separate module for intervention. Quality of physical activity experiences must be referred to throughout the intervention.
<ul style="list-style-type: none"> Ambulators with SCI lack sense of community, especially in physical activity settings [29]. 	<ul style="list-style-type: none"> Peer support must be included and prioritized in intervention delivery.

^aSCI: spinal cord injury.

Step 2a: Intervention Objectives and Features

The objective of the SCI Step Together program, in terms of outcomes, is to increase the quantity and quality of leisure-time

physical activity participation among persons with SCI who ambulate. The implemented intervention objectives and features based on our understanding of the key behavioral issues can be found in [Table 2](#).

Table 2. Intervention objectives and features for the SCI^a Step Together program.

Intervention design objectives	Key features
To increase the quantity of physical activity among individuals with SCI who ambulate	<ul style="list-style-type: none"> Digital intervention to build autonomous motivation through teaching self-regulation skills (eg, action and coping planning) and increasing autonomy, competence, and relatedness Provide educational information on physical activity and self-regulatory behaviors Behavioral coach provides support to individuals through BCTs^b such as feedback on behavior and verbal persuasion.
To enhance the quality of physical activity among individuals with SCI who ambulate	<ul style="list-style-type: none"> Increase intrinsic motivation to participate in activities that align with their desires, needs, and lifestyles through building autonomy, competence, and relatedness Provide resources and support to individuals with SCI who ambulate through behavioral coaching and peer support to offer additional options that may be relevant for their context Provide education on quality participation elements and factors to increase opportunities for experiencing quality in physical activity
To build community among individuals with SCI who ambulate	<ul style="list-style-type: none"> Allow individuals to communicate in the app to offer support to each other and gain an awareness of others in their situation

^aSCI: spinal cord injury.

^bBCT: behavior change technique.

Step 2b: Behavioral Analysis and Theory

The theory chosen to inform the SCI Step Together program was the self-determination theory (refer to the study by Ryan and Deci [51] for a review), which is a theory of human motivation and personality that posits that three basic psychological needs must be met for a person to sustain a behavior (eg, physical activity): autonomy, competence, and relatedness [51]. Self-determined or autonomous motivation occurs when these 3 needs are met and individuals are intrinsically motivated [51]. This theory was chosen to inform the intervention content because the self-determination theory aligns well with not only increasing the quantity but also the quality of physical activity participation. We hypothesized that there is a positive correlation between intrinsic motivation for physical activity and quality physical activity participation.

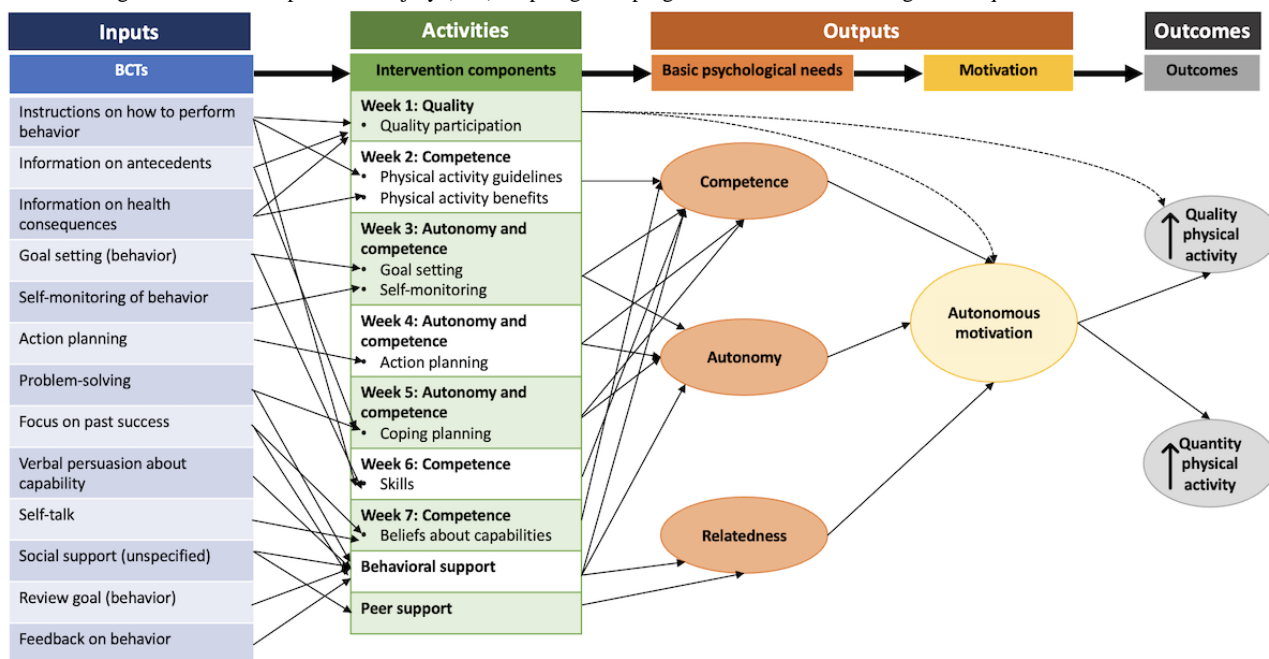
Importantly, all barriers and facilitators (ie, Theoretical Domains Framework domains) identified in step 1 can be targeted through self-determination theory constructs. For example, beliefs about capabilities and skills are two domains encompassed in the basic psychological need of competence. Furthermore, a recent review of health interventions maps BCTs onto basic psychological needs [52], making it possible to further align the work

completed in step 1 with self-determination theory. Basic psychological needs are incorporated as part of the intervention objectives and features in step 2b. In addition, the included BCTs and the associated Theoretical Domains Framework domains and intervention functions can be found in [Multimedia Appendix 2](#) [31,42,53]. The BCTs, their support for inclusion (or exclusion), and the associated basic psychological needs can be found in [Multimedia Appendix 3](#) [12,43,52,54]. [Multimedia Appendix 4](#) provides the BCTs, related intervention components, and rationale for how they are included in the intervention.

Step 3: Logic Model

The logic model for the intervention is illustrated in [Figure 2](#). The intervention inputs are the BCTs, the processes or actions are the intervention components, the outputs are the fulfillment of the basic psychological needs and motivation, and the outcomes are the quality and quantity of physical activity participation. The logic model presents the causal assumptions and theory of change within the intervention based on self-determination theory constructs and includes BCTs and intervention components identified from steps 1 to 2.

Figure 2. The logic model for the spinal cord injury (SCI) Step Together program. BCT: behavior change technique.



Step 4: SCI Step Together Program Content Development and IKT

No training sessions were provided to end users, as they felt comfortable navigating the app on their own. End users spent 1 to 2 hours using the Stronger Together program to become familiar with app use and engagement required. The initial interview with end users resulted in several recommendations for the final SCI Step Together program ([Table 3](#)). In general, end users (pilot participants) enjoyed the app, found it easy to

use, and experienced no technical issues. They appreciated how the community coaches are real, live people who can provide individualized feedback rather than standardized technological support. End users also liked the inclusion of peer support, noting its importance for participating in physical activity. All end users agreed that asking participants to engage with the program once per week was preferred, rather than daily or biweekly. They thought that the images used in the app were appropriate and the general content included in the educational modules was well done.

Table 3. End user recommendations and changes for the SCI^a Step Together program.

Partner	Recommendation	Curatio feedback	Implemented (yes or no)	How
Technology				
SL	Allow worksheets to be completed inter-actively within the app rather than as a PDF image	Not possible	No	— ^b
SL	Track only exercise (no other behaviors such as smoking)	Not possible	No	—
SL	Include physical activity planners or goal setting in the app instead of tracking medications	Possible to remove medication tracking but not possible to include planner or goal setting	Yes	Removed medication tracking. Participants can set and track physical activity goals in the “Notes” section of the app under “My Info.”
MM	Add the type of physical activity when tracking exercise	Unable to do	No	—
MM	See how your weekly physical activity compares with the guidelines every week	Unable to do within the app platform, but coach can compare	Yes	Coach will note comparisons with SCI physical activity guidelines when providing feedback on their behavior.
JS and CJ	Allow exercise tracking in the SCI Step Together app to sync with your smartphone activity or other fitness apps (eg, Strava)	Not possible from software standpoint	No	—
JS	Create a calendar to plan physical activity that syncs with iCal or Google Calendar	Not possible from software standpoint	No	—
SL	Change intensity from “Low” and “High” to “Mild,” “Moderate,” and “Vigorous” to align with the SCI physical activity guidelines	Not possible	No	—
SL	Allow participants to self-select minutes of exercise rather than choosing “0-10,” “11-20” etc	Not possible	No	—
Trial				
MM	Email participants the worksheets in addition to having them accessible in the app	Possible to do by researchers	Yes	Researcher will ask participants if they would like their weekly worksheet emailed.
MM and CJ	Give people choice in the modules they complete	Possible from research standpoint	Yes	Participants will be encouraged to complete all the modules, but they do not have to complete them all.
MM, JS, and CJ	Allow people to choose how often they would like to be notified by the community coach	Possible	Yes	Community coach will ask participants how often they would like to be reminded of completing the modules
Intervention content				
MM	Provide examples of strategies to be physically active at home	Possible to include in educational content (researchers)	Yes	Educational content uses examples throughout based on physical activity at home
MM, JS, and CJ	Include supportive, motivational, and individualized messages from the community coach	Possible	Yes	Community coach will use autonomy-supportive messages that are individualized to each user’s profile.
JS and CJ	Remove <i>graded tasks</i> BCT ^c —can be overwhelming for individuals new to physical activity	Possible	Yes	<i>Graded tasks</i> BCT removed from educational modules and community coach content

^aSCI: spinal cord injury.

^bNot available.

^cBCT: behavior change technique.

As seen in [Table 3](#), Curatio, Inc could not implement several technology-related recommendations. This is because the platform is already commercially available and hosts several communities in addition to SCI Step Together. Changing this technology would require substantial time, money, and human resources, which are not feasible for the academic or technology partners. As such, these recommendations will be considered in future iterations of Stronger Together communities.

Ultimately, SCI Step Together was designed as an 8-week program that consists of educational modules, peer support, and in-app behavioral support with a live community coach. For SCI Step Together, the first author serves as the community coach. The coach checks in weekly with participants using an autonomy-supportive approach to align with the self-determination theory [51], delivers appropriate BCTs (see the logic model in [Figure 2](#)), and provides support with the educational modules and app technology as needed. The educational modules incorporate BCTs and include links to local resources and worksheets so that participants can put their work into practice. Participants can provide and receive peer support by talking to each other in the app.

Discussion

Principal Findings

This paper provides the stepwise methodology used to develop the SCI Step Together intervention using a Person-, evidence-, and theory-based approach. Importantly, the approach transparently describes how various partners were involved throughout the intervention planning and development process using IKT. The intervention was systematically created with evidence generated from primary mixed methods and review research (step 1), which informed the behavioral analysis and theoretical modeling (step 2) to produce a logic model (step 3). Steps 1 to 3 along with partnership discussions using IKT helped to develop and optimize the Stronger Together program content and delivery (step 4). Overall, this intervention was developed in partnership to provide more meaningful, better-informed, and more relevant resources and support for physical activity participation to individuals with SCI who walk.

This study offers important contributions to the mHealth literature by outlining how programs can be planned and developed in partnership with partners, while using evidence, a Person-Based approach, and theoretical modeling. Although a growing number of physical activity interventions have been developed for individuals with SCI, this is the first intervention delivered in an mHealth format. Furthermore, considering that more than 50% of mHealth interventions do not incorporate theory or BCTs [18,55], this intervention development paper provides guidance on how to incorporate these important elements. The SCI Step Together program not only includes BCTs according to a behavioral analysis using the BCW [31] but is also directly guided by the self-determination theory [51] to inform causal assumptions. BCTs were also included and excluded based on previous reviews of effectiveness [12,43], thus adding confidence in the potential utility of the intervention. BCTs can be delivered and enacted appropriately using mobile technologies [56]. For example, the BCT of self-monitoring

may be easier to implement through mHealth formats because users' phones are ready and accessible immediately after exercising [57]. As such, self-reported physical activity measures may have increased precision [58], allowing participants to set more appropriate goals and coaches to provide better feedback and physical activity behavioral support [59].

This study also contributes to the mHealth literature by outlining an mHealth intervention development method that may be useful in promoting app engagement. Engagement with apps can be defined as "(1) the extent (eg, amount, frequency, duration, and depth) of use and (2) a subjective experience characterized by attention, interest, and affect" [60]. Engagement with mHealth programs is typically poor, which leads to insufficient behavior change (eg, [61]). Factors that increase engagement in mHealth interventions include using BCTs (eg, self-monitoring and action planning) and providing health care practitioner support [60,61]. By conducting a behavioral analysis and working with a technology partner who endorses social support from a health coach, the SCI Step Together program is more likely to support participant engagement. Other factors that influence app engagement include "safety netting" (ie, having the ability to re-engage with the app after disengaging) and tailored content [60,61]. Using IKT allowed us to work with end users to create tailored physical activity content that could be individualized in the app through the health coach. Furthermore, working in partnership with Curatio Inc means that the SCI Step Together program can be sustained after the intervention is tested, providing a "safety net" by allowing individuals to disengage and re-engage with the program whenever they please. As such, by including behavioral analysis and IKT in the intervention development process, participants are more likely to engage positively with the program.

In addition, this is one of the first mHealth interventions to explicitly report IKT activities conducted during intervention development. Similarly, this is the first study to use the IKT guiding principles for SCI research [27] to guide our research partnership. Partners were involved throughout steps 1 to 4 to provide feedback on program content and delivery. The involvement of partners best predicts the translation of research into practice [27,62], and it is becoming increasingly important in physical activity intervention development practices. This study outlines how IKT can add to the Person-Based approach by using principles to guide partnership [27], ensuring partners have shared decision-making power in intervention development, describing who and when partners were involved, and involving partners early and throughout the research process.

Future Directions

This paper describes the formative work of planning and developing an mHealth intervention to increase the quantity and quality of physical activity among persons with SCI who ambulate. As such, the next step, according to the Medical Research Council guidance on developing complex interventions [63], is to pilot-test the acceptability, feasibility, and engagement of the SCI Step Together program among a sample of users. This pilot study is currently underway, and the trial is registered at [ClinicalTrials.gov](https://clinicaltrials.gov) (NCT05063617) [64]. The goal of the pilot study was to gain an understanding of how individuals used the

program, whether they were satisfied with the components, and any areas for improvement before running a larger trial. In addition, we hope to estimate the effects of the intervention on key outcomes to determine a sample size for a future trial. If these feasibility and subsequent effectiveness trials are successful, the next step is implementation, whereby the program will be disseminated among the larger community and long-term outcomes will be monitored [63]. Finally, future research is needed to understand if and how BCTs are enacted by participants in an mHealth format and whether BCT enactment relates to intervention outcomes [56].

Importantly, as we move forward, the Person-Based [25] and IKT approaches [21] will continue to be used to ensure that partners are involved throughout the intervention evaluation process. For example, community and provincial SCI organizations will be involved in participant recruitment for the pilot trial and will be involved in the long-term implementation of the program. In addition, the program will be iteratively updated as mixed methods research continues to be used for program evaluation [25].

Limitations

Some limitations of the intervention planning and development processes should be recognized. First, the studies in step 1 were conducted before the COVID-19 pandemic, and the intervention was released in July 2021. As such, some factors related to the quantity and quality of physical activity participation may differ due to social distancing, facility closures, and other public health measures. We have included several examples of at-home physical activity strategies in the SCI Step Together program, considering pandemic-related restrictions. Second, a relatively

small sample of participants was used in step 1 and for partner interviews in step 4, and their preferences for programming may be limited to this sample. However, we included evidence from larger systematic reviews to inform theoretical content (eg, [43]) and build from previous interventions for individuals with SCI (eg, [23]); thus, we expect the program to be beneficial for a broader sample of individuals with SCI who walk. Third, no studies have been conducted to understand whether and how self-determination theory and quality participation are related. We do not know whether these hypothetical causal assumptions will work as expected, and larger-scale studies are required to test the relationship between self-determination theory and quality participation. Fourth, we acknowledge that many of the cocreated ideas and recommendations developed using the IKT process were not incorporated into the intervention because of the limited capacity of the technology and thus lacked feasibility for implementation. Finally, our partners were limited in racial and ethnic representation, and future partners should include a more diverse sample of individuals with SCI who walk.

Conclusions

This is the first physical activity mHealth intervention for persons with SCI and the first physical activity intervention designed specifically for people with SCI who walk. This study provides an innovative methodology for intervention planning and development that integrates Person-Based approach, evidence, theory, and IKT. The SCI Step Together program was developed in partnership with partners to optimize intervention content and delivery. Accordingly, it is anticipated that the SCI Step Together program will be acceptable, feasible, and have appropriate engagement when pilot testing is underway.

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Conflicts of Interest

LBG is the Chief Executive Officer of Curatio Networks Inc, and LC is a project coordinator at Curatio Networks Inc. Curatio Networks Inc provided in-kind support to back the Stronger Together platform.

Multimedia Appendix 1

Integrated knowledge translation guiding principles [27].
[DOCX File, 14 KB - [formative_v6i8e34303_app1.docx](#)]

Multimedia Appendix 2

How behavior change techniques target Theoretical Domains Framework domains and intervention functions.
[DOCX File, 22 KB - [formative_v6i8e34303_app2.docx](#)]

Multimedia Appendix 3

How behavior change techniques may target basic psychological needs and evidence for use in interventions.
[DOCX File, 61 KB - [formative_v6i8e34303_app3.docx](#)]

Multimedia Appendix 4

Outlining how behavior change techniques are incorporated into the intervention content.

[[DOCX File , 14 KB - formative_v6i8e34303_app4.docx](#)]

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Abbreviations

BCT: behavior change technique

BCW: behavior change wheel

COM-B: Capability, Opportunity, Motivation-Behavior

IKT: integrated knowledge translation

mHealth: mobile health

SCI: spinal cord injury

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Original Paper

Modification and Validation of an mHealth App Quality Assessment Methodology for International Use: Cross-sectional and eDelphi Studies

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Abstract

Background: Over 325,000 mobile health (mHealth) apps are available to download across various app stores. However, quality assurance in this field of medicine remains relatively undefined. Globally, around 84% of the population have access to mobile broadband networks. Given the potential for mHealth app use in health promotion and disease prevention, their role in patient care worldwide is ever apparent. Quality assurance regulations both nationally and internationally will take time to develop. Frameworks such as the Mobile App Rating Scale and Enlight Suite have demonstrated potential for use in the interim. However, these frameworks require adaptation to be suitable for international use.

Objective: This study aims to modify the Enlight Suite, a comprehensive app quality assessment methodology, to improve its applicability internationally and to assess the preliminary validity and reliability of this modified tool in practice.

Methods: A two-round Delphi study involving 7 international mHealth experts with varied backgrounds in health, technology, and clinical psychology was conducted to modify the Enlight Suite for international use and to improve its content validity. The Modified Enlight Suite (MES) was then used by 800 health care professionals and health care students in Ireland to assess a COVID-19 tracker app in an online survey. The reliability of the MES was assessed using Cronbach alpha, while the construct validity was evaluated using confirmatory factor analysis.

Results: The final version of the MES has 7 sections with 32 evaluating items. Of these items, 5 were novel and based on consensus for inclusion by Delphi panel members. The MES has satisfactory reliability with a Cronbach alpha score of .925. The subscales also demonstrated acceptable internal consistency. Similarly, the confirmatory factor analysis demonstrated a positive and significant factor loading for all 32 items in the MES with a modestly acceptable model fit, thus indicating the construct validity of the MES.

Conclusions: The Enlight Suite was modified to improve its international relevance to app quality assessment by introducing new items relating to cultural appropriateness, accessibility, and readability of mHealth app content. This study indicates both the reliability and validity of the MES for assessing the quality of mHealth apps in a high-income country, with further studies being planned to extrapolate these findings to low- and middle-income countries.

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KEYWORDS

evaluation tool; mobile health; mHealth; smartphone app; app; international mHealth

Introduction

Use and access to mobile phones and the internet is ubiquitous in many countries [1]. In 2020, there were 4 billion mobile internet users, and this figure is expected to grow to 5 billion by 2025 [2]. In 2017, over 325,000 mobile health (mHealth) apps were available to download across various app stores with the number of app publishers rising by 45% in the same year [3]. This market proliferation has created a challenging task for health care professionals to identify high-quality apps, as many have been created without expert medical involvement, appropriate testing, and validation [4]. A review published in 2020 indicated that most safety concerns about apps related to the quality of their content [5]. Examples of inappropriate app content include a recommendation for people with bipolar disorder to “take a shot of hard liquor an hour before bed” and a suggestion that bipolar disorder is “contagious” [6].

Given the rapid proliferation of mHealth apps, regulation of this sector is challenging for policy makers [7]. Various strategies are being used to tackle shortcomings of mHealth apps especially in high-income countries (HICs). For example, the Food and Drug Administration applies regulatory oversight to a subgroup of mHealth apps regarded as medical devices or that pose patient safety risks [8]. For low- and middle-income countries (LMIC), there is a growing demand to develop and apply assessment frameworks that meet contextual aspects relevant to one’s specific country. While comprehensive, timely, and effective national regulation is awaited, various mHealth app quality assessment methodologies have been proposed for use in the interim. Examples include the Enlight Suite [9], the Mobile App Rating Scale [10], and the App Chronic Disease Checklist (ACDC) [11].

A review of mHealth app quality assessment methodologies indicated the scope for improvement of such methodologies to enhance their comprehensiveness and relevance across resource-diverse settings [12]. The review found that none of the existing generic app assessment methodologies [9-11,13,14] explicitly considered cultural appropriateness. Only two methodologies addressed privacy and security of information [9,13]. Similarly, readability was considered by only two methodologies [11,13]. Only the ACDC [11] addressed the availability of mHealth apps in offline mode. The ability of the apps to facilitate behavior change was only addressed by three methodologies [9-11]. In addition, most existing generic app assessment methodologies only offered some form of face and content validity based on expert opinions [9-11,13] with the reliability of only 2 methodologies reported [9,10]. The construct

validity of all the app assessment methodologies was not evaluated [12].

Although the Enlight Suite was adjudged as thorough and comprehensive, it has limited international applicability because it does not consider attributes that are relevant to the successful uptake of mHealth apps in low-, middle-, and HICs, including cultural appropriateness, readability, and access [12,15]. It is important to consider cultural appropriateness when developing content and designing user interfaces of apps for international and country-specific audiences [16]. If the content or user interface of an mHealth app is not culturally appropriate for a particular audience, acceptability and uptake may be low [16]. Similarly, poor readability may affect the acceptability and uptake of apps among prospective users [17,18]. Previous research revealed that many mHealth apps were written at excessively high reading grade levels, which may not be suitable for users with low levels of literacy especially in LMIC [17-19]. In addition, access to the internet may affect mHealth use especially in LMIC and among deprived communities of HICs [20]. Although the mobile broadband penetration rate has doubled in LMIC over the last decades [21], users continue to experience challenges with the cost and speed of internet services.

The purpose of this study is therefore to modify the Enlight Suite [9] to be more considerate and effective for use internationally. Additionally, this paper serves to provide an initial reliability and validity assessment of the Modified Enlight Suite (MES) in practice.

Methods

Verifying the Content Validity of the Modified Enlight Suite

To formulate the MES and confirm content validity, a two-round iterative Delphi process was undertaken. Delphi techniques are widely used for this type of research with its validity for questionnaire formulation and modification confirmed in past literature [22,23].

Participant Characteristics and Recruitment

Previous research recommends having between 3 and 10 professionals to verify content validity [24]. Therefore, a total of 7 digital health researchers with backgrounds in clinical medicine (n=4), nursing (n=1), clinical psychology (n=1), and information technology (n=1) were recruited in this phase of the study. Of the participants, 3 were affiliated universities in Ireland, 1 was affiliated to a university in Malawi, and 3 were affiliated to universities in the United Kingdom. Although most

of these experts currently reside in HICs, they have varied hands-on clinical (n=2) or research (n=5) experience in LMIC.

Experts were identified based on the following inclusion criteria: hold a professional title in the areas of technology, medicine, health, or clinical psychology; have a minimum of 2 years professional experience in their respective field; be willing to engage in all Delphi phases of this study digitally; and have suitable internet access.

Delphi Process

The panel of experts analyzed the questions in the pre-existing Enlight Suite as well as those proposed by the facilitators (FW and JOD). Version 1 (V1) of the MES contained 7 sections with a total of 33 questions. Of these questions, the facilitators proposed 5 questions based on considerations of a past review of app assessment methodologies indicating potential weaknesses in the Enlight Suite for international mHealth app evaluation practices [12]. Each panelist was asked to examine the suitability of questions within V1 of the MES for mHealth app evaluation practices internationally, both individually and collectively. Participants were asked to consider each of the questions (and proposed questions) with respect to its appropriateness and relevance across all resource-level settings (ie, HICs and LMIC).

During round 1 of the Delphi process, both quantitative and qualitative feedback were gathered. For quantitative evaluation of the content validity, a 3-point scale was used (1="exclude question," 2="include question but modify," and 3="include question as is") to rate each question. Whenever a panelist indicated that a question should be modified, qualitative feedback was requested. Additionally, panelists were asked at the end of each section of the MES if further adaptations to that section were necessary.

Standard methods to determine consensus in Delphi studies are not available [25]. However, for the purposes of this study, consensus was measured via the percentage who agreed with amendments after round 1 ($\geq 4/7$). Following round 1 of the Delphi process, the facilitators (FW and JOD) discussed suggested amendments and reflected on both qualitative and quantitative feedback before formulating Version 2 (V2) of the MES. Results were summarized and panelist feedback was anonymized before round 2 of the Delphi process commenced.

In round 2, panelists were provided with V2 of the MES. During this round, panelists were asked if they accepted or rejected the changes that the facilitators made to V1 of the MES to create V2. Additionally, panelists could review comments and suggestions made by fellow participants, albeit anonymously. The Delphi process would be terminated should the outcome of a round yield "minor" or "out of scope" amendments only. In this case, the facilitators would discuss the feedback and make changes accordingly without another round occurring.

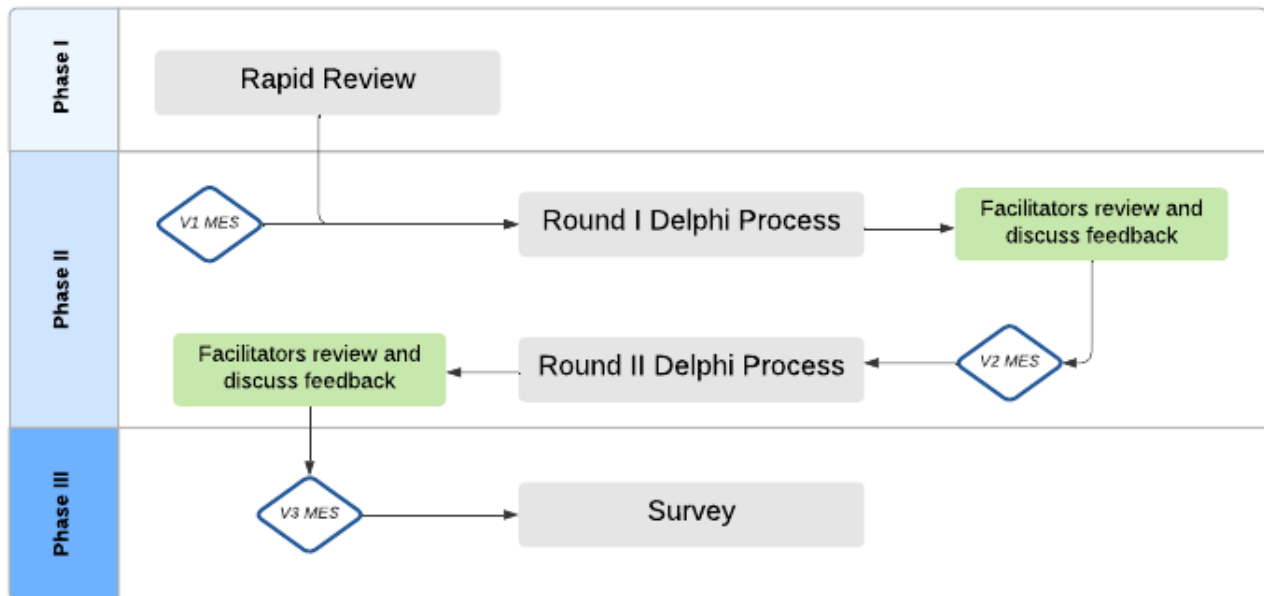
Verification of the Validity and Reliability of the Modified Enlight Suite

To assess the reliability of the MES, the construct was distributed in digitized form to participants who were asked to use it to evaluate the Irish COVID-19 app, a popular freely available mHealth app in Ireland [26]. The MES was tested in Ireland to serve two purposes: (1) to avoid language acting as a confounding variable falsely affecting reliability results and (2) for convenience purposes to promptly identify reliability issues prior to international testing.

The following were inclusion criteria to participate: be a health care professional or health care student with a minimum of 2 years clinical exposure, own a smartphone device, and be familiar with the Irish COVID-19 app.

Convenience sampling was used to recruit participants via targeted social media platforms and through the university emailing list. When validating a questionnaire, there are no fixed rules for an ideal sample size [27]. Some have suggested that a sample size of 50 is considered very poor, 200 as fair, and >1000 being excellent [28]. Larger sample sizes are always more reflective of the population; ergo, the investigators sought as many participants as possible.

The reliability of the MES was assessed using SPSS version 28 software (IBM Corp). The Cronbach α for the overall Enlight scale and each of the seven subscales (usability, visual design, user engagement, content, therapeutic persuasiveness, therapeutic alliance, and general subjective evaluation of the app's purpose) was calculated. A Cronbach α of .7 or above is traditionally regarded as an indication of reliability [29]. The construct validity was assessed using Amos version 26 (IBM Corp) for confirmatory factor analysis. The model for the confirmatory factor analysis was based on the seven pre-existing categories listed above. A flowchart indicating each stage of this research can be viewed in [Figure 1](#).

Figure 1. Flow Chart Indicating Each Phase of the Research Process. MES: Modified Enlight Suite.

Ethical Considerations

The Social Research Ethics Committee of University College Cork Ireland granted ethical approval for this stage of the project (SREC/SOM/19062020/1/25112020/). Prior to engagement, participants were given an information leaflet with details of the study and asked to sign a consent form. All data collected during the study was kept secure on a password-encrypted computer. This research was partly funded by an Irish Health Research Board Scholarship (scholarship SS-2020-089).

Results

Developing the Finalized Version of the Modified Enlight Suite

Round 1

Round 1 of the Delphi study was conducted in July 2020. During this round, the facilitators proposed five questions to be included in the MES. Of these questions, three served to improve the relevance of the MES for quality assessment purposes internationally. These questions were based on the following topics: (1) culture appropriateness, (2) accessibility, and (3) readability. The facilitators also proposed 2 questions that affect a user's ongoing use of an app. These questions were concerned with the following topics: (1) errors and (2) timeliness. Following round 1 of the Delphi process, consensus was reached that each of these questions should be included within the final version of the MES.

Furthermore, the panelists made 47 suggestions/comments. These were categorized by the facilitators into "minor amendments" (n=33), "significant amendments" (n=9), and "other comments" (n=5). Following this round and discussion by the facilitators, 26 of these amendments were accepted and incorporated to create V2 of the MES. An extraction table with categorized feedback from round 1 can be viewed in [Multimedia Appendix 1](#).

Round 2

V2 of the MES contained 7 sections with 32 questions. All amendments made by the facilitators based on feedback from round 1 were accepted by participants in round 2. During this round, participants provided 25 additional comments/amendments that were subcategorized into "minor" (n=18) and "other" (n=7). Of these, 12 were incorporated into the final version (ie, Version 3 [V3]) of the MES ([Multimedia Appendix 2](#)). An extraction table with feedback from round 2 can be viewed in [Multimedia Appendix 3](#).

This multi-round iterative process was terminated after round 2, as modifications in V2 of the MES were accepted by panelists. Given the nature of feedback suggested by panelists during round 2, the facilitators made additional minor amendments as necessary. The comprehensibility of the original Enlight Suite facilitated this short Delphi process. Given the interdisciplinary nature of the professional panel, the Delphi process served to confirm the content validity of the MES for international use.

Reliability of the MES

A total of 800 responses were gathered during this phase to assess the reliability and construct validity of the MES. Of the 800 participants, 91% (n=728) fell within the 18 to 34 years of age category. Health care professionals represented 20% (n=160) of the participants, while the remaining 80% (n=640) were health care students with a minimum of 2 years clinical work experience. The majority (n=712, 89%) of participants identified as being of White/Caucasian ethnicity. Less than half (n=376, 47%) of the responses were complete.

The reliability analysis showed satisfactory internal consistency of the overall scale (Cronbach $\alpha=.93$). Similarly, the subscales demonstrated high reliability except for the user engagement scale (Cronbach $\alpha=.65$), which is slightly lower than the traditionally regarded reliability level (Cronbach $\alpha=.7$) [29]. Deletion of items under user engagement did not improve the reliability of the subscale. The Cronbach α for the scale and the subscales are presented in [Table 1](#).

Table 1. Reliability statistics.

Section	Items, n	Cronbach α
Usability	7	.82
Visual design	3	.77
User engagement	5	.65
Content	5	.80
Therapeutic persuasiveness	6	.78
Therapeutic alliance	3	.73
General subjective evaluation of the app's purpose	3	.76
Overall scale	32	.93

Construct Validity of the MES

The concept of fitness in confirmatory factor analysis refers to the extent to which the empirical data (eg, our survey findings) supports the construct validity of the theoretical model being tested (which is the MES in our study) [30]. The chi-square goodness-of-fit test ($\chi^2_{443}=1045.9$; $P<.001$; $\chi^2 / df = 2.36$) indicates that our model fits modestly with the data [28]. Although a significant P value as in our study indicates a poor fit, this is not unexpected due to our large sample size [30]. For studies with large sample sizes, it is recommended to consider the model as highly fit with data when the χ^2 / df is less than 2 [30]. Although the value in our model is not less than 2, this is still an acceptable value. Similarly, the comparative fit index

(0.89) and Tucker-Lewis index (0.87) show that our model modestly fits with the data, as a value of at least 0.9 is required for the model fit to be deemed acceptable [31]. However, the root-mean-square error of approximation (0.041, 95% CI 0.038-0.043) indicates that our model is a close-fitting model, as it is below the 0.05 cutoff point [32] and all factor loadings are positive and statistically significant (Table 2). In other words, the data from the survey provides support, albeit modestly, for the validity of the constructs (ie, 32 items and 7 categories) of the MES. It is worth noting that the first item in each category does not include significance tests (SE, critical ratio, and P value) because the unstandardized estimate for each first item was fixed at 1 rather than estimated as part of the adopted methodology, hence the empty cells in Table 2.

Table 2. Construct validity.

Variable	Standardized estimate	Unstandardized estimates	SE	Critical ratio	P value
Usability					
Navigation	0.779	1	N/A ^a	N/A	N/A
Access	0.446	0.850	0.090	9.442	<.001
Understandability	0.653	0.827	0.058	14.256	<.001
Errors	0.557	0.941	0.079	11.956	<.001
Timeliness	0.670	0.976	0.067	14.663	<.001
Learnability	0.689	0.864	0.057	15.135	<.001
Ease of use	0.728	1.014	0.063	16.048	<.001
Design					
Aesthetics	0.701	1	N/A	N/A	N/A
Layout	0.789	1.133	0.079	14.263	<.001
Size	0.689	0.914	0.071	12.888	<.001
Engagement					
Content presentation	0.655	1	N/A	N/A	N/A
Interactive	0.567	1.271	0.121	10.513	<.001
Not irritating	0.459	0.941	0.108	8.705	<.001
Targeted tailored personalized	0.455	0.966	0.112	8.629	<.001
Captivating	0.574	1.037	0.098	10.627	<.001
Content					
Evidence-based content	0.642	1	N/A	N/A	N/A
Cultural appropriateness	0.673	1.114	0.096	11.599	<.001
Quality of information provision	0.715	1.095	0.090	12.128	<.001
Clarity about the app purpose	0.608	0.939	0.088	10.693	<.001
Complete and concise	0.701	1.076	0.090	11.948	<.001
Therapeutic persuasiveness					
Call to action	0.674	1	N/A	N/A	N/A
Rewards	0.600	1.055	0.098	10.754	<.001
Real data-driven adaptive content	0.639	0.958	0.085	11.337	<.001
Therapeutic rationale and pathway	0.645	0.903	0.079	11.453	<.001
Ongoing feedback	0.629	0.969	0.087	11.168	<.001
Expectations and relevance	0.480	0.773	0.088	8.788	<.001
Therapeutic alliance					
Acceptance and support	0.710	1	N/A	N/A	N/A
Positive therapeutic expectations	0.669	0.843	0.074	11.413	<.001
Relatability	0.676	0.972	0.084	11.502	<.001
General subjective evaluation					
Appropriate features to meet the clinical aim	0.702	1	N/A	N/A	N/A
Right mix of ability and motivation	0.674	1.002	0.083	12.086	<.001
I like the app	0.766	1.138	0.084	13.500	<.001

^aN/A: not applicable.

Discussion

Principal Findings

The objectives of this study were to modify the Enlight Suite and test the reliability and validity of the MES. The Delphi process resulted in a comprehensive MES, which contains 32 questions over 7 sections including additional dimensions not in the original Enlight Suite, including access, cultural appropriateness, readability, errors, and timeliness.

The subsequent survey demonstrated an overall reliability of the MES and its subscales. The confirmatory factor analysis demonstrated a positive and significant factor loading for all 32 items in the MES with a modestly acceptable model fit that is indicative of the construct validity of the MES.

Comparison With Prior Work

The inclusion of cultural appropriateness, readability, and access criteria differentiates the MES from existing methodologies [9-11,13,14], which either considered only one or none of these important criteria. Questions on cultural appropriateness, readability, and access acknowledge the multi-demographic nature of the mHealth market [1]. For instance, there may be a need to present the content of an mHealth app in a local language to enhance its utility in a particular locality [1,33]. Similarly, the consideration of access in offline mode in the MES recognizes that internet access may not be continuous for many users [34]. These newly introduced dimensions (access, cultural appropriateness, and readability) have been identified by previous studies as important aspects of apps that ought to be considered for successful uptake across both HICs and LMIC [12,15]. Thus, the introduction of these dimensions has improved the applicability of the MES internationally.

The overall reliability of the MES was quite high in our study as well as the reliability of the subscales except for the user engagement subscale. However, the original Enlight Suite demonstrated adequate reliability across all domains including user engagement [9]. Interestingly, the major modifications to the Enlight Suite in this study were not in the user engagement category. The difference in the reliability results could be attributed to the variation in the approach used by the two studies. While the reliability of the original Enlight Suite was based on ratings by 2 trained researchers [9], the reliability testing in our study was based on the ratings by 800 health care professionals and students who would be the end users of the MES. Thus, the original Enlight Suite [9] was validated to be used with prior training, while the MES is validated to be used by any health care professional.

The demonstration of construct validity in this study with a modestly acceptable model fit supports the position of the authors of the original tool who regarded it as a suite consisting of multiple scales rather than a single scale whose result could be aggregated [9]. These results should be interpreted with caution due to the possible impact of the missing data in our study on the model fit. Due to missing data, we were only able to use the maximum likelihood estimation approach, which assumes that the variables are normally distributed [35].

Strength and Limitations

This paper builds upon a rapid review that identified shortcomings of mHealth app quality assessment methodologies [12]. The MES was developed with input by international experts in mHealth. Given their diverse background and expertise, the content of this tool could be considered applicable internationally. To the best of our knowledge, the MES is the first mHealth app quality assessment methodology that considers factors known to affect the fundamental usability of mHealth technologies in LMIC.

The reliability and validity assessment of the MES in this study was undertaken in Ireland, an HIC. Of the participants who engaged in the survey, 89% (712/800) identified as either White or Caucasian. This highlights a need for similar studies to test the reliability and validity of the MES in LMIC. For the MES to be reliably effective for all, participants from more diverse backgrounds and ethnicities are needed in the future to extrapolate these findings. The modest construct validity of the MES is also a limitation, and improved modeling could possibly be achieved with less missing data.

Future Work

While this study demonstrates the content validity via an international panel of mHealth stakeholders, health care professionals with no technological background may have been underrepresented in the Delphi process. This is currently being investigated with focus groups in Malawi and South Africa. Additional modifications may be made to V3 of the MES based on feedback from these focus groups. The reliability of the updated Enlight Suite will then be assessed with participants recruited internationally.

The original Enlight Suite provided a comprehensive quality and therapeutic potential tool for both mobile and web-based eHealth interventions. While the focus of this study was to adapt the suite to improve its international relevance for mHealth app evaluation, future works could expand on its web-based potential. This study introduced additional dimensions (access, cultural appropriateness, and readability) that are relevant to international applicability of the Enlight Suite. Future works could look into developing a framework for the international applicability of scales.

Conclusion

The need for quality assessment in mHealth is clear. This study is a key primary step in improving the scope, content, and relevance of mHealth quality assessment methodologies across diverse settings. It is of the authors opinion that the MES is the first quality assessment methodology to also consider factors known to hinder the uptake and continued use of mHealth apps in resource-poor settings. Furthermore, the authors believe that this research improves the validity of the construct while taking measures to enhance its fundamental usability. There is scope that the MES may be adopted by health care professionals internationally to assess the quality and suitability of mHealth apps available to their patients before recommending them. This would help ensure patient safety.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Data extraction from round 1 of the Delphi process.

[[DOCX File, 27 KB - formative_v6i8e36912_app1.docx](#)]

Multimedia Appendix 2

Version 3 of the Modified Enlight Suite.

[[DOCX File, 38 KB - formative_v6i8e36912_app2.docx](#)]

Multimedia Appendix 3

Data extraction from round 2 of the Delphi process.

[[DOCX File, 20 KB - formative_v6i8e36912_app3.docx](#)]

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Abbreviations

- ACDC:** App Chronic Disease Checklist
- HIC:** high-income country
- LMIC:** low- and middle-income countries
- MES:** Modified Enlight Suite
- mHealth:** mobile health
- NIHR:** National Institute for Health and Care Research
- V1:** Version 1
- V2:** Version 2

V3: Version 3

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Original Paper

Cell Phone Availability and Usage for mHealth and Intervention Delivery to Persons Living With HIV in a Low-Resource Setting: Cross-sectional Study

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Abstract

Background: HIV/AIDS is now a manageable chronic illness owing to effective antiretroviral therapy (ART), which involves routine follow-up care, including regular physical visits to the clinic. In the recent past, and in wake of the COVID-19 pandemic, there has been increased need for virtual care and intervention delivery, a modality known as mobile health (mHealth), which includes cell phone-delivered services for medical and public health practice.

Objective: Here we describe cell phone use and its relationship with alcohol use in a cohort of persons living with HIV and latent tuberculosis (TB).

Methods: We performed a cross-sectional analysis of baseline data from a cohort of persons living with HIV and latent TB in HIV care in southwestern Uganda. We estimated proportions of cell phone and text message use and evaluated their associations with alcohol use—a common modifiable behavior among persons living with HIV. Cell phone use (primary outcome) was defined as owning a cell phone that is turned on at least half of the day. Any alcohol use was defined as any self-reported alcohol use in the prior 3 months or a phosphatidylethanol (an alcohol biomarker) level of ≥ 8 ng/mL.

Results: A total of 300 participants (median age 40 years; $n=146$, 48.7% male) were included in the analysis. Most ($n=267$, 89.0%) participants had access to a phone and of them, 26 (9.7%) shared the phone with someone else. In total, 262/300 (87.3%) of participants owned a cell phone that is turned on at least half of the time; the majority ($n=269$, 89.7%) rarely or never sent text messages, and over two-thirds ($n=200$, 66.9%) rarely or never received text messages. Most ($n=214$, 71.3%) had any alcohol use in the prior 3 months. In adjusted analyses, any alcohol use was not significantly associated with cell phone use (adjusted odds ratio [aOR] 0.48, 95% CI 0.18-1.25; $P=.13$) or sending (aOR 0.82, 95% CI 0.28-2.37; $P=.71$) or receiving (aOR 1.31, 95% CI 0.70-2.47; $P=.40$) text messages.

Conclusions: There is hope that mHealth interventions in this population can be carried out using cell phones owing to their popularity; however, the interventions may need to employ methods that do not rely on the sending and receiving of text messages only.

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KEYWORDS

cell phone use; phone usage; cell phone; mHealth; HIV; low resource setting; low resource; mobile health; antiretroviral; Uganda; Africa; alcohol; text message; text messaging; cellphone; mobile health; low income; LMIC; TB; tuberculosis; viral infection; infectious disease; sexually transmitted; STD

Introduction

HIV/AIDS is now a manageable chronic illness owing to the widespread rollout of antiretroviral therapy (ART) [1]. Treatment and prevention of HIV/AIDS involves routine lifelong follow-up care and ongoing interventions to mitigate disease spread and improve treatment outcomes. Follow-up care involves scheduled visits for clinical reviews, medication receipt, laboratory testing, and psychosocial services including counseling and peer support groups. These visits normally involve a physical presence; however, the recent COVID-19 pandemic has made apparent the need for using mobile devices to assist in health and intervention delivery, known as mobile health (mHealth) [2]. mHealth has been studied as both an alternative to and a way to augment physical visits in the chronic care of people living with HIV/AIDS. Recent mHealth interventions for persons living with HIV include cell phone-delivered reminders to promote treatment adherence, motivational messages to encourage clinic attendance and ART adherence, delivery of laboratory tests, and behavior modification messages [3-5]. mHealth interventions may also bridge the service delivery gap during periods of interruptions in valuable HIV/AIDS services including lack of resources for transportation, or more recently, lockdown measures instituted to curb the spread of COVID-19, political unrest, or other epidemic outbreaks including Ebola.

In sub-Saharan Africa where two-thirds of persons living with HIV reside, cell phone access and use has greatly increased over the last decade from an ownership prevalence of 10% in the early 2000s to over 75% in 2019 [6]. In East Africa, cell phone use ranges from approximately 60% in Uganda to over 90% in Kenya [7,8]. Cell phone use gained popularity owing to the widespread coverage quality and ability to reach “everywhere” including resource limited remote areas and the low operational cost. This widespread usage and low cost have been tapped into for mHealth [9]. However, while there has been high enthusiasm for mHealth to improve HIV and other health outcomes, the results of cell phone-delivered interventions among persons living with HIV have been mixed [10,11]. Barriers to the implementation of mHealth interventions may include lack of infrastructure, concerns over privacy and confidentiality, usability issues [12], low level of literacy, low phone ownership, and cost of data to patients [13]. In order to determine the potential for cell phone-delivered interventions for persons living with HIV in low-resource settings, full understanding of cell phone ownership, active use (ie, duration for which a cell phone is kept on and used), and SMS (or texting) use of the targeted intervention population is important as persons living with HIV may differ from the general population in terms of their socioeconomic status and level of literacy [14].

In this analysis, we describe cell phone ownership and use in a cohort of persons living with HIV, who are coinfecting with latent tuberculosis (TB) in southwestern Uganda. We also

describe the association between alcohol use and cell phone use. Alcohol use and HIV are prevalent in sub-Saharan Africa. Alcohol use affects several HIV treatment outcomes, including ART adherence, viral suppression, and the development of opportunistic infections such as the activation of latent TB, all of which may fuel onward transmission of HIV [15-17]. Alcohol use is, however, a modifiable behavior that could potentially be positively impacted using mHealth interventions [18].

Methods

Setting and Population

This was a cross-sectional analysis of baseline data from a study of persons living with HIV who were recruited from a large HIV clinic in southwestern Uganda, entitled the Alcohol Drinkers' Exposure to Preventative Therapy for Tuberculosis (ADEPTT) study (registered under NCT03302299 in the ClinicalTrials.gov registry). The study was a single-arm prospective trial examining the safety, tolerability, and adherence to a 6-month daily isoniazid (INH) regimen among persons living with HIV who were coinfecting with latent TB, who recently consumed alcohol (two-thirds of the sample) or abstained from alcohol consumption (one-third of the sample).

Study Design

We conducted screening for the ADEPTT study using a multistep process. Eligibility criteria at the initial screening step included being an adult (≥ 18 years old) living with HIV, being fluent in Runyankole (the local language) or English, having been prescribed ART for at least 6 months, living within 2 hours' driving distance of or 60 km from the study site, having no plans to relocate from the catchment area, and having no history of active TB or taking TB preventive medications. Alcohol use eligibility additionally included self-reporting current (prior 3 months) alcohol use, or alcohol abstinence (no use in the prior year), with a target of enrolling 200 persons in the former and 100 persons in the latter category. Exclusion criteria are currently taking or having taken nevirapine in the prior 2 weeks, or taking anticonvulsant medications (both contraindications to INH). Further eligibility criteria included alanine transaminase (ALT) and aspartate transaminase (AST) levels being $< 2 \times$ their normal upper limits, being cleared of active TB (for those reporting TB symptoms), and not being pregnant. Finally, participants were screened for evidence of latent TB by research assistants trained in administration and interpretation of the tuberculin skin test (TST), latent TB was defined as a positive TST finding with an induration of ≥ 5 mm read 48-72 hours after injection with purified protein derivative (PPD). Those with positive TST results were invited to participate in the study. Data included in this analysis are baseline data.

All study participants were reimbursed for transport costs following completion of study procedures at each study visit.

Ethics Approval

The study was approved by the University of California, San Francisco Institutional Review Board (16-19093), the Mbarara University of Science and Technology Research Ethics Committee (11/10-16), and the Ugandan National Council for Science and Technology (HS2183). Participants provided written consent prior to study participation.

Measures

Data were collected using an interviewer-administered laptop-based survey using the Computer Assisted Survey Information Collection system. The surveys were conducted in private spaces, for confidentiality reasons, in Runyankole or English, depending on the participants' preference. Baseline blood draws were conducted for testing for a biomarker of alcohol use—phosphatidylethanol [19]. Phosphatidylethanol is a sensitive and specific marker of prior 3 weeks' alcohol consumption.

Outcome Variables

Overview

The primary outcome variable was cell phone use, a self-reported binary outcome defined as owning a cell phone and reporting that it was turned on for at least half of each day. Two secondary outcomes were frequent sending and receiving of text messages. Participants were asked 2 separate questions about how frequently they send and receive SMS text messages: several times per day, several times per week, rarely, or never. These were binary outcomes defined as “yes” if the participant self-reported sending and receiving text messages several times a week or more.

We categorized them as above because for mHealth interventions to be effective, participants need to have a working phone that is turned on most of the time and text messaging several times a week for SMS interventions to be useful.

Main Independent Variable

Alcohol use was assessed on the basis of self-report and Phosphatidylethanol levels. Participants were administered the Alcohol Use Disorders Identification Test—alcohol consumption questions [20], which was modified to ask about drinking in the prior 3 months. A score of ≥ 3 was considered indicative of an Alcohol Use Disorders Identification Test – Consumption positive status for women and ≥ 4 was considered positive for men [21]. For the main analyses, we defined alcohol use as any self-reported alcohol use in the last 3 months or a Phosphatidylethanol level of ≥ 8 ng/mL [22]. In exploratory analyses, we examined the level of alcohol use as a 3-level variable, defined as follows: “none” implying no self-reported alcohol use in the prior 3 months and a Phosphatidylethanol level of < 8 ng/mL, “moderate” implying any self-reported alcohol use in the prior 3 months but an Alcohol Use Disorders Identification Test – Consumption negative status and a Phosphatidylethanol level of ≥ 8 to < 50 ng/mL, and “heavy” implying an Alcohol Use Disorders Identification Test – Consumption positive status or a Phosphatidylethanol level of ≥ 50 ng/mL.

Covariates

We controlled for participant characteristics such as age, sex, literacy, level of education, household asset index, and organized religious activity because of their prior [23–26] or suspected associations with alcohol use and cell phone use. Level of literacy was assessed by asking the participants to read a sentence in the language they are most comfortable with; we considered those who were able to read all or part of the sentence to be literate. The household asset index (HHI) was created using principal component analysis (PCA) [27] and was based on durable goods, housing quality, and available energy sources. Cell phones were excluded from the list of durable goods included in the PCA. We dichotomized this measure as low (bottom 40%) and medium or high (top 60%) because of concern about small cell sizes in multivariable analyses.

We assessed organized religious activity by asking about the frequency of attending religious activities using the Duke University Religion Index [28], and categorized it as weekly or more versus less than weekly attendance of religious activity.

Statistical Analyses

We described sample characteristics using proportions for categorical variables and median (IQR) values for continuous variables. We used unadjusted and adjusted logistic regression models to examine associations with cell phone use (primary outcome), and sending and receiving text messages (secondary outcomes). The multivariable models controlled for the following potential confounders selected a priori: age, sex, literacy, HHI, and organized religious activity. In the multivariable model for frequent sending of text messages, we included education instead of literacy owing to a zero cell (ie, no one in the nonliterate group reported sending text messages frequently). Finally, we conducted exploratory analyses using the 3-level alcohol use variable rather than any alcohol use as the main independent variable of interest.

Results

Results Overview

A total of 1434 people were screened for the ADEPTT study. Main reasons for ineligibility included a history of active TB ($n=26$) or TB medications ($n=42$), elevated AST or ALT ($n=79$), and testing negative on the TST ($n=848$). Of the screened participants, 308 people were found to be eligible for enrollment. Six people declined enrollment, one was later found to be ineligible and was excluded, and one was missing cell phone use data; 300 participants were included in this analysis.

Of the 300 participants included, approximately half of them ($n=146$, 48.7%) were male and their median age was 40 (IQR 33–47) years (Table 1). The majority of the participants ($n=219$, 73.0%) had no more than primary school (6 years) education. Two-thirds ($n=199$, 66.6%) of the participants were either married or cohabiting. Approximately half ($n=158$, 52.7%) of the participants reported attending organized religious services at least once a week. The majority of the participants ($n=263$, 87.7%) were literate. By design, over two-thirds ($n=214$, 71.3%) of participants had consumed alcohol in the past 3 months.

Table 1. Baseline characteristics of study participants with data on cell phone use in Mbarara, Uganda (N=300).

Variables	Values
Age (years), median (IQR)	40 (33-47)
Sex, n (%)	
Female	154 (51.3)
Male	146 (48.7)
Marital status, n (%)	
No	100 (33.4)
Yes	199 (66.6)
Education, n (%)	
Primary or less	219 (73.0)
More than primary	81 (27.0)
Literate, n (%)	
No	37 (12.3)
Yes	263 (87.7)
Employment status, n (%)	
Unemployed	12 (4.0)
Employed	288 (96.0)
Household asset index, n (%)	
Low	120 (40.1)
Middle or high	179 (59.9)
Organized religiosity: frequency of attending religious services, n (%)	
Less than weekly	142 (47.3)
Weekly or more	158 (52.7)
Any alcohol use, prior 3 months^a, n (%)	
No	85 (28.4)
Yes	214 (71.3)
Level of alcohol use, prior 3 months^b, n (%)	
None	85 (28.4)
Moderate	66 (22.1)
Heavy	148 (49.5)
Risky sexual behavior^c, n (%)	
No	297 (99.3)
Yes	2 (0.7)
Cell phone use, n (%)	
Has access to use a cell phone	
No	33 (11.0)
Yes	267 (89.0)
Shared a cell phone (n=267 persons with cell phone access)	
No	241 (90.3)
Yes	26 (9.7)
Owens a cell phone (n=267)	
No	5 (1.9)

Variables	Values
Yes	262 (98.1)
For how much of the time is the phone on (n=267)	
Most of the time	259 (97.0)
Approximately half of the time	7 (2.6)
Less than half of the time	1 (0.4)
Cell phone use: summary	
Does not own a phone, or phone is on less than half of the time	38 (12.7)
Owns a phone and it is on half of the time or more	262 (87.3)
Frequency of text message (SMS) receipt	
Rarely or never	200 (66.9)
Several times a week or more	99 (33.1)
Frequency of sending text messages (SMS)	
Rarely or never	269 (89.7)
Several times a week or more	31 (10.3)

^aAny alcohol use in the prior 3 months was defined as any alcohol use self-reported in the prior 3 months or a phosphatidylethanol level of ≥ 8 ng/mL.

^bLevel of alcohol use in the prior 3 months defined as follows: “none” implies no self-reported alcohol use in the prior 3 months and a Phosphatidylethanol level of < 8 ng/mL; “moderate” implies any self-reported alcohol use in the prior 3 months but an Alcohol Use Disorders Identification Test–alcohol consumption questions (AUDIT-C) negative status and a Phosphatidylethanol level of ≥ 8 to < 50 ng/mL; “heavy” implies an AUDIT-C positive status or a Phosphatidylethanol level of ≥ 50 ng/mL.

^cRisky sexual behavior implies having had unprotected sex with someone who was not a husband, wife, or steady partner during the participant’s most recent sexual encounter.

Cell Phone Use

The majority (n=267, 89.0%) of participants reported they had access to a cell phone; of them, 262 (98.1%) owned the phone and 26 (9.7%) shared the phone. The majority (n=262, 87.3%) of participants used a cell phone (owned a cell phone and had it on for more than half of the day; [Table 1](#)). In unadjusted analysis, any alcohol use was not significantly associated with cell phone use (odds ratio [OR] 0.76, 95% CI 0.34-1.67; $P=.49$)

([Table 2](#)). Adjusted analyses showed lower odds of cell phone use among those who consumed alcohol than among those who did not, although this did not reach statistical significance (adjusted OR [aOR] 0.48, 95% CI 0.18-1.25; $P=.13$).

We observed associations between literacy and cell phone use (aOR 4.15, 95% CI 1.74-9.89; $P<.01$) and also between middle or high HHI and cell phone use (aOR 8.03, 95% CI 3.26-19.79; $P<.01$).

Table 2. Unadjusted and adjusted associations with cell phone use.

Variable	Participants who do not own a phone or whose phone is on for less than half the time (n=38)	Participants who own a phone that is on for greater than or equal to half of the time (n=262)	Unadjusted odds ratio (95% CI)	P value	Adjusted odds ratio ^a (95% CI)	P value
Any alcohol use, prior 3 months^b, n (%)				0.49		.13
No	9 (10.6)	76 (89.4)	1.00 (reference)		1.00 (reference)	
Yes	29 (13.6)	185 (86.5)	0.76 (0.34-1.67)		0.48 (0.18-1.25)	
Age (years), median (IQR)	42 (35-47)	40 (33-47)	0.99 (0.95-1.02)	.46	1.00 (0.96-1.04)	>.99
Sex, n (%)				.39		.28
Female	22 (14.3)	132 (85.7)	1.00 (reference)		1.00 (reference)	
Male	16 (11.0)	130 (89.0)	1.35 (0.68-2.69)		1.61 (0.68-3.78)	
Literate, n (%)				<.001		.001
No	14 (37.8)	23 (62.2)	1.00 (reference)		1.00 (reference)	
Yes	24 (9.1)	239 (90.9)	6.06 (2.76-13.30)		4.15 (1.74-9.89)	
Household asset index, n (%)				<.001		<.001
Low	31 (25.8)	89 (74.2)	1.00 (reference)		1.00 (reference)	
Middle or high	7 (3.9)	172 (96.1)	8.56 (3.62-20.21)		8.03 (3.26-19.79)	
Organized religiosity: frequency of attending religious services, n (%)				.73		.79
Less than weekly	19 (13.4)	123 (86.6)	1.00 (reference)		1.00 (reference)	
Weekly or more	19 (12.0)	139 (88.0)	1.13 (0.57-2.23)		1.11 (0.50-2.46)	

^aCalculated with 298 participants.

^bAny alcohol use in the prior 3 months was defined as any alcohol use self-reported in the prior 3 months or a phosphatidylethanol level of ≥ 8 ng/mL.

Exploratory Analysis

We performed exploratory analyses to assess the impact of level of drinking on cell phone use but did not find an association

between level of alcohol use (moderate and heavy vs no use) and cell phone use (moderate use: aOR 0.62, 95% CI 0.19-2.04; heavy use: aOR 0.42, 95% CI 0.15-1.17; $P=.25$; [Table 3](#)).

Table 3. Adjusted odds ratios (aORs) and 95% CIs for cell phone use.

Parameters	aOR (95% CI)	P value
Level of alcohol use, prior 3 months^a		.25
None	1.00 (reference)	
Moderate	0.62 (0.19-2.04)	
Heavy	0.42 (0.15-1.17)	
Age (per 1 year)	1.00 (0.96-1.04)	.94
Sex		.21
Female	1.00 (reference)	
Male	1.78 (0.72-4.38)	
Literate		.001
No	1.00 (reference)	
Yes	4.08 (1.71-9.69)	
Household asset index		<.001
Low	1.00 (reference)	
Middle/High	7.98 (3.23-19.70)	
Organized religiosity: frequency of attending religious services		.76
Less than weekly	1.00 (reference)	
Weekly or more	1.13 (0.51-2.50)	

^aLevel of alcohol use in the prior 3 months defined as follows: “none” implies no self-reported alcohol use in the prior 3 months and a phosphatidylethanol level of <8 ng/mL; “moderate” implies any self-reported alcohol use in the prior 3 months but an Alcohol Use Disorders Identification Test–alcohol consumption questions (AUDIT-C) negative status and a Phosphatidylethanol level of ≥8 to <50 ng/mL; and “heavy” implies an AUDIT-C positive status or a Phosphatidylethanol level of ≥50 ng/mL.

Text Message (SMS) Use

Over two-thirds (n=200, 66.9%) of the total participants reported rarely or never receiving text messages and the majority (n=269, 89.7%) reported rarely or never sending text messages (Table 1). Of those who had access to a cell phone (n=267), only one-third (99/267, 37.1%) reported frequently receiving text messages, while only (31/267, 11.6%) reported frequently sending text messages.

In adjusted analyses, any alcohol use was not significantly associated with frequent sending (aOR 0.82, 95% CI 0.28-2.37; $P=.71$) or receiving (aOR 1.31, 95% CI 0.70-2.47; $P=.40$) text messages (Tables 4 and 5).

Age was significantly associated with frequent sending of text messages (aOR 0.93, 95% CI 0.88-0.98; $P<.01$) but not with frequent receiving of text messages (aOR 0.98, 95% CI 0.95-1.00; $P=.09$) (Tables 4 and 5).

Table 4. Unadjusted and adjusted associations with receiving text messages (SMS) several times a week or more.

Variables	Frequency of receiving text messages		Unadjusted odds ratio (95% CI)	P value	Adjusted odds ratio ^a (95% CI)	P value
	Rarely or never (n=200)	Several times a week or more (n=99)				
Any alcohol use, prior 3 months^b, n (%)				.21		.40
No	61 (72.6)	23 (27.4)	1.00 (reference)		1.00 (reference)	
Yes	139 (65.0)	75 (35.1)	1.43 (0.82-2.49)		1.31 (0.70-2.47)	
Age (years), median (IQR)	40 (35-48)	37 (31-45)	0.98 (0.95-1.00)	.06	0.98 (0.95-1.00)	.09
Sex, n (%)				.51		.47
Female	105 (68.6)	48 (31.4)	1.00 (reference)		1.00 (reference)	
Male	95 (65.1)	51 (34.9)	1.17 (0.73-1.90)		1.24 (0.69-2.22)	
Education, n (%)				<.001		
Primary or less	164 (75.2)	54 (24.8)	1.00 (reference)		— ^c	
More than primary	36 (44.4)	45 (55.6)	3.80 (2.22-6.48)		—	
Literate, n (%)				.006		.03
No	32 (88.9)	4 (11.1)	1.00 (reference)		1.00 (reference)	
Yes	168 (63.9)	95 (36.1)	4.52 (1.55-13.18)		3.41 (1.13-10.36)	
Household asset index, n (%)				<.001		.001
Low	96 (80.7)	23 (19.3)	1.00 (reference)		1.00 (reference)	
Middle or high	103 (57.5)	76 (42.5)	3.08 (1.79-5.30)		2.62 (1.50-4.58)	
Organized religiosity: frequency of attending religious services, n (%)				.62		.33
Less than weekly	97 (68.3)	45 (31.7)	1.00 (reference)		1.00 (reference)	
Weekly or more	103 (65.6)	54 (34.4)	1.13 (0.70-1.83)		1.31 (0.76-2.26)	

^aCalculated with 297 participants.

^bAny alcohol use in the prior 3 months was defined as any alcohol use self-reported in the prior 3 months or a phosphatidylethanol level of ≥ 8 ng/mL.

^cNot determined.

Table 5. Unadjusted and adjusted associations with frequency of sending text messages (SMS) several times a week or more.

Variable	Frequency of sending text messages		Unadjusted odds ratio (95% CI)	P value	Adjusted odds ratio ^a (95% CI)	P value
	Rarely or never (n=269)	Several times a week or more (n=31)				
Any alcohol use, prior 3 months^b, n (%)				.73		.71
No	77 (90.6)	8 (9.4)	1.00 (reference)		1.00 (reference)	
Yes	191 (89.3)	23 (10.8)	1.16 (0.50-2.70)		0.82 (0.28-2.37)	
Age (years), median (IQR)	40 (34-48)	34 (29-40)	0.93 (0.89-0.98)	<.001	0.93 (0.88-0.98)	.005
Sex, n (%)				.68		.46
Female	137 (89.0)	17 (11.0)	1.00 (reference)		1.00 (reference)	
Male	132 (90.4)	14 (9.6)	0.85 (0.41-1.80)		0.69 (0.26-1.83)	
Education, n (%)				<.001		<.001
Primary or less	211 (96.4)	8 (3.7)	1.00 (reference)		1.00 (reference)	
More than primary	58 (71.6)	23 (28.4)	10.46 (4.45-24.60)		10.35 (4.02-26.60)	
Literate, n (%)						
No	37 (100)	0 (0.0)	— ^c		—	
Yes	232 (88.2)	31 (11.8)	—		—	
Household asset index, n (%)				0.007		.40
Low	115 (95.8)	5 (4.2)	1.00 (reference)		1.00 (reference)	
Middle/High	153 (85.5)	26 (14.5)	3.91 (1.46-10.49)		1.60 (0.53-4.80)	
Organized religiosity: frequency of attending religious services				.05		.08
Less than weekly	122 (85.9)	20 (14.1)	1.00 (reference)		1.00 (reference)	
Weekly or more	147 (93.0)	11 (7.0)	0.46 (0.21-0.99)		0.43 (0.17-1.09)	

^aCalculated with 298 participants.

^bAny alcohol use in the prior 3 months was defined as any alcohol use self-reported in the prior 3 months or a phosphatidylethanol level of ≥ 8 ng/mL.

^cNot determined.

Exploratory Analysis

We performed exploratory analyses to assess the impact of level of drinking on frequent sending and receiving of text messages and found an association between level of alcohol use and frequent receipt of text messages (aORs for moderate and heavy

alcohol use, respectively: 0.76, 95% CI 0.35-1.65 and 1.84, 95% CI 0.93-3.66; $P=.03$), but not with frequent sending of text messages (aORs for moderate and heavy alcohol use, respectively: 0.64, 95% CI 0.17-2.31 and 0.96, 95% CI 0.30-3.05; $P=.73$; Table 6).

Table 6. Adjusted odds ratios (aORs) and 95% CIs for sending and receiving text messages (SMS) frequently.

Variables	Frequent receipt of text messages (n=297)		Frequent sending of text messages (n=298)	
	aOR (95% CI)	P value	aOR (95% CI)	P value
Level of alcohol use, prior 3 months^a		.03		.73
None	1.00 (reference)		1.00 (reference)	
Moderate	0.76 (0.35-1.65)		0.64 (0.17-2.31)	
Heavy	1.84 (0.93-3.66)		0.96 (0.30-3.05)	
Age (per 1 year)	0.98 (0.95-1.01)	.12	0.93 (0.88-0.98)	.007
Sex		.91		.37
Female	1.00 (reference)		1.00 (reference)	
Male	1.04 (0.56-1.90)		0.63 (0.23-1.73)	
Literate		.02		
No	1.00 (reference)		— ^b	
Yes	4.04 (1.30-12.57)		—	
Education				<.001
Primary or less	—		1.00 (reference)	
More than primary	—		10.28 (3.99-26.51)	
Household asset index		<.001		.37
Low	1.00 (reference)		1.00 (reference)	
Middle or high	2.85 (1.62-5.03)		1.65 (0.55-4.99)	
Organized religiosity: frequency of attending religious services		.34		.07
Less than weekly	1.00 (reference)		1.00 (reference)	
Weekly or more	1.31 (0.75-2.27)		0.43 (0.17-1.08)	

^aLevel of alcohol use in the prior 3 months defined as follows: “none” implies no self-reported alcohol use in the prior 3 months and a phosphatidylethanol level of <8 ng/mL; “moderate” implies any self-reported alcohol use in the prior 3 months but an Alcohol Use Disorders Identification Test–alcohol consumption questions (AUDIT-C) negative status and a Phosphatidylethanol level of ≥8 to <50 ng/mL; “heavy” implies a AUDIT-C positive status or a Phosphatidylethanol level of ≥50 ng/mL.

^bNot determined.

Discussion

Principal Findings

We evaluated cell phone ownership and use (frequency of sending and receiving text messages) in a cohort of persons living with HIV in HIV care, who were coinfecting with latent TB in Uganda. We also evaluated the association between alcohol use and cell phone use. The results showed a high prevalence of both cell phone ownership and use in this population. This is consistent with many other studies and surveys of cell phone access and use in Uganda [3,29] and in Africa [30]. This high prevalence of cell phone ownership may be largely attributed to the ease of use and relatively low cost of cell phones [11,31]. Persons living with HIV have been shown to find cell phones convenient as an mHealth tool [32] and have reported that it helps reduce transportation costs and still provides access to much needed health information [3]. We found high levels of cell phone use, indicating the potential utility of cell phone ownership in providing care and treatment for persons living with HIV, and as a tool that can be leveraged for mHealth and interventions.

In this analysis, alcohol use was not significantly associated with cell phone use. This finding held up in exploratory analyses examining the level of drinking. Our findings were different from a study conducted in Uganda among persons living with HIV in a fishing community that found that cell phone use was associated with alcohol use before sexual intercourse, although this was only among young females aged 14-24 years [26]. Other studies, conducted in high-resource settings, in the general population (ie, not focused on persons living with HIV) and among young persons, have found positive associations between alcohol use and cell phone use [33,34]. The differences observed may be due to the fact that in these other studies, the population was much younger than that in our study. In our study, the median age was 40 years while many of these studies were among younger persons. Younger persons may use cell phones for social reasons, including making plans for drinking and entertainment [35] with peers, while older persons may use cell phones more for economic reasons, as they have to provide for families and have more responsibilities; hence, we observed a lack of association with alcohol and instead observed an association with HHI and literacy. These findings suggest the

need to carefully evaluate the target population for cell phone-based interventions, and that these interventions should take into consideration the level of literacy and economic status of the population.

We also found that participants rarely sent or received text messages (approximately 30%). This was different from other studies, especially those conducted in middle- and high-resource countries where sending and receiving of text messages was high (60%) [36], but similar to a study among youths with HIV in Uganda (27%) [5]. A suggested explanation for the low text message use is the loss of novelty of sending or receiving text messages on a mobile phone in Africa [5] and therefore decreased use of the function. A great majority of the participants were literate; literacy was associated with frequent receiving of texts, and none of the persons who frequently sent text messages were nonliterate. While we could not include literacy in the model because no nonliterate person reported sending text messages; there was a strong effect of education with sending of text messages, which is consistent with prior reports [37,38]. We did not observe an association between any alcohol use and frequent sending and receiving of text messages; however, the exploratory analysis suggests that level of alcohol use may be associated with odds of frequent receipt of text messages. While cell phone use was high, using text messages alone as an mHealth intervention may not be effective, especially with interventions that require responses.

Limitations of the Study

This study was limited in the fact that the sample was selected for the main study enrollment purposes (ie, having latent TB); this may limit the generalizability of the study. However, we

did not observe any major differences between patients enrolled and those not enrolled when we analyzed major factors associated with one of the selection criteria (PPD+ skin test) [39]. Another limitation is that this study may have been underpowered to detect associations, as it was not designed to evaluate the relationships being examined. In a post hoc power calculation, we found the study would have approximately 80% power to detect an odds ratio of 0.34 or lower for the relationship between any alcohol use and any cell phone use, assuming 89% cell phone use among those without alcohol use as observed in our sample. The study was, therefore, likely underpowered to detect the magnitude of the association observed in this cohort.

Strengths of the Study

The strength of this study was that alcohol use was measured both by self-report and objectively by use of a biomarker to confirm actual alcohol use.

Conclusions

Many persons living with HIV own cell phones that are turned on for more than half of the day. There is, however, very little use of text messaging among persons living with HIV in this low-income setting.

There is hope that mHealth interventions in this population can be carried out using cell phones owing to their popularity; however, the interventions may need to employ methods that do not rely exclusively on the sending and receiving of text messages. Future mixed methods studies with large sample sizes should be conducted to further evaluate preferred alternatives to text messages such as interactive voice response and the relationship between alcohol use and cell phone use.

Conflicts of Interest

JH received consulting fees from Pear Therapeutics.

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Abbreviations

ADEPTT: Alcohol Drinkers' Exposure to Preventative Therapy for Tuberculosis

ALT: alanine transaminase

ART: antiretroviral therapy

AST: aspartate transaminase

AUDIT-C: Alcohol Use Disorders Identification Test—alcohol consumption questions

HHI: household asset index

INH: isoniazid

PCA: principal component analysis

PPD: purified protein derivative

TB: tuberculosis

TST: tuberculin skin test

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Original Paper

Reliability and Validity of Electronic Patient-Reported Outcomes Using the Smartphone App AllerSearch for Hay Fever: Prospective Observational Study

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Abstract

Background: Hay fever is a highly prevalent, heterogenous, and multifactorial disease. Patients may benefit from longitudinal assessments using mobile health (mHealth) principles. We have previously attempted to establish an effective mHealth platform for patients with hay fever through AllerSearch, our in-house smartphone app that assesses electronic patient-reported outcomes through a questionnaire on hay fever and provides evidence-based advice. To be used by the public, an investigation on its reliability and validity is necessary.

Objective: The aim of this paper is to assess the reliability and validity of subjective symptom data on hay fever collected through our app, AllerSearch.

Methods: This study used a prospective observational design. The participants were patients aged ≥ 20 years recruited from a single university hospital between June 2, 2021, and January 26, 2022. We excluded patients who could not use smartphones as well as those with incomplete data records and outlier data. All participants answered the Japanese Allergic Conjunctival Disease Standard Quality of Life Questionnaire (JACQLQ), first in the paper-and-pencil format and subsequently on AllerSearch on the same day. The JACQLQ comprises the following three domains: Domain I, with 9 items on ocular or nasal symptoms; Domain II, with 17 items on daily activity and psychological well-being; and Domain III, with 3 items on overall condition by face score. The concordance rate of each domain between the 2 platforms was calculated. The internal consistency of Domains I and II of the 2 platforms was assessed using Cronbach alpha coefficients, the concurrent validity of Domains I and II was assessed by calculating Pearson correlation coefficients, and the mean differences between the 2 platforms were assessed using Bland-Altman analysis.

Results: In total, 22 participants were recruited; the data of 20 (91%) participants were analyzed. The average age was 65.4 (SD 12.8) years, and 80% (16/20) of the participants were women. The concordance rate of Domains I, II, and III between the paper-based and app-based JACQLQ was 0.78, 0.85, and 0.90, respectively. The internal consistency of Domains I and II between the 2 platforms was satisfactory (Cronbach alpha of .964 and .919, respectively). Pearson correlation analysis yielded a significant

positive correlation between Domains I and II across the 2 platforms ($r=0.920$ and $r=0.968$, respectively). The mean difference in Domains I and II between the 2 platforms was 3.35 units (95% limits of agreement: -6.51 to 13.2).

Conclusions: Our findings indicate that AllerSearch is a valid and reliable tool for the collection of electronic patient-reported outcomes to assess hay fever, contributing to the advantages of the mHealth platform.

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KEYWORDS

hay fever; AllerSearch; smartphone app; mobile health; mHealth; patient-reported outcome; reliability; validity; Japanese Allergic Conjunctival Disease Standard Quality of Life Questionnaire; JACQLQ; questionnaire; allergic conjunctivitis

Introduction

Hay fever is currently believed to be the most common immunologic and allergic disease worldwide, with reports of nearly 30 million cases in the United States and Japan [1-3]. Hay fever symptoms can be chronic and therefore life altering, leading to a decrease in individuals' quality of life and work productivity [3]. This systemic illness targets multiple organs, most commonly manifesting as allergic rhinitis, conjunctivitis, and dermatitis [4,5]. The disease appears to evolve, changing its presentation with varying onsets, levels of severity, and responses to treatment based on the individual [3,4]. Therefore, a deeper understanding of the underlying pathophysiology and establishing an effective strategy to comprehensively assess changing symptoms become imperative to provide tailored, longitudinal care and to improve patients' quality of life [4-7].

Recent findings have increasingly confirmed the advantages of adopting patient-reported outcomes (PROs), which are clinical data grounded in patients' own subjective experiences that are not readily captured by routine medical evaluations [8,9]. With the recent advancements in mobile health (mHealth), a medical discipline centered around health care and support through advanced mobile devices such as smartphones, the electronic adaptation of PROs (ePROs) has been garnering attention as a novel data accrual option for clinical researchers [4,5,10-12].

We have previously taken advantage of the novel mHealth platform and conducted studies through our in-house hay fever smartphone app, AllerSearch, released in February 2018 [4,5]. The app successfully gathered comprehensive medical data related to hay fever without interrupting users' daily lives. By using data collected through AllerSearch, we were able to elucidate various risk factors that could exacerbate the disease, and we stratified the disease into subgroups based on collective symptoms and individual factors [4,5]. In our efforts to implement ePROs via AllerSearch, the app was equipped with features to administer hay fever symptom-related questionnaires, such as the Japanese Allergic Conjunctival Disease Standard Quality of Life Questionnaire (JACQLQ) [4,5,13,14]. Given the ongoing pandemic and the anticipated postpandemic era, the demand for longitudinal, nonintrusive health care continues to increase, and mHealth appears to hold the key to addressing this need. To realize such nonintrusive care that can also engage the principles of participatory medicine through mHealth, a robust validation of mHealth-accrued clinical data on subjective symptoms and their quantification strategies is required.

Hence, we evaluated the reliability and validity of the subjective symptom data collected through our mHealth app by conducting a comparative study between paper-based and app-based versions of the JACQLQ to evaluate the applicability of AllerSearch as a novel clinical tool for assessing hay fever.

Methods

AllerSearch Smartphone App

AllerSearch was initially developed in Japan using Apple Inc's open-source framework, ResearchKit [4,5], and released on Apple's App Store on February 1, 2018, under a consignment contract with Juntendo University Graduate School of Medicine and InnoJin, Inc, both based in Tokyo, Japan. The Android version was released on August 26, 2020. The AllerSearch is freely available on the App Store and Google play.

Design

This study employed a prospective observational design based on previously published validation studies of medical instruments [15,16].

Ethical Considerations

Written informed consent was obtained from all participants prior to the commencement of the study. The study was approved by the Independent Ethics Committee of Juntendo University Graduate School of Medicine (approval number H20-0242-H01, November 6, 2020) and adheres to the tenets of the Declaration of Helsinki.

Enrollment and Participants

The participants were patients aged ≥ 20 years, recruited between June 2, 2021, and January 26, 2022, from the Department of Ophthalmology, Juntendo University Hospital, Tokyo, Japan. We excluded patients who could not use smartphones as well as those with incomplete data records and outlier data.

All participants answered the paper-based JACQLQ at the outpatient service in the Department of Ophthalmology, Juntendo University Hospital. They subsequently answered the same questionnaire on an iOS version of AllerSearch (app-based JACQLQ) on the same day. AllerSearch had been preinstalled on the mobile phones provided for the purpose of this study. Our previous study contained the description of survey items in AllerSearch [4]. Briefly, participants provided electronic consent and basic information on demographics, medical history, lifestyle, hay fever status, and preventive behavior for hay fever. Subsequently, participants performed daily assessments of their conjunctiva and responded to a questionnaire on hay fever that

included the JACQLQ and assessments of nasal symptoms, nonnasal symptoms, daily subjective symptoms, and work productivity.

JACQLQ

The JACQLQ is a well-established metric that enables clinicians to comprehensively assess QOL among patients in the Japanese-speaking population who are affected by allergic conjunctival diseases [13]. The JACQLQ comprises the following three domains: Domain I with 9 items on ocular or nasal symptoms; Domain II with 17 items on daily activity and psychological well-being; and Domain III with 3 items on overall condition by face score. The questionnaire requires participants to rate each symptom on a 5-point Likert scale according to its severity, from “None” (0 points) to “Severe” (4 points). The total score (Domains I and II) for the scale and the total score of each domain was calculated as the sum of Domains I and II and the sum of items in each domain, respectively. Of note is that the default settings of the scale bar in AllerSearch, used to represent the 5-point scale, and the face score were both set to the lowest score, but users were able to adjust their ratings to higher scores as they deemed fit.

Statistical Analysis

The sample size for the Cronbach alpha test was predetermined based on the formula by Bonett [17]. Using these settings—power=90%, significance level=5%, number of items (k)=26, value of Cronbach alpha at null hypothesis=.0, and expected value of Cronbach alpha=.7—the required sample size was calculated to be 17.08 (rounded up to 18) cases. Accounting for 20% dropouts owing to missing data or withdrawal of consent, the final sample size was 22 cases.

Table 1. Participants’ characteristics (N=20).

Characteristics	Values
Age (year), mean (SD)	65.4 (12.8)
Gender, n (%)	
Female	16 (80)
Male	4 (20)
BCVA ^a , logMAR (SD)	-0.04 (0.07)
IOP ^b , mmHg (SD)	13.9 (2.6)

^aBCVA: best-corrected visual acuity.

^bIOP: intraocular pressure.

Scores and Concordance Rate of Paper-Based and App-Based JACQLQ

The median total score for Domains I and II was 6.5 (range: 1.75–13.25) for the paper-based JACQLQ and 4.5 (range: 1–8) for the app-based JACQLQ ($P=.003$). Table 2 shows each item’s

The median scores for the paper-based and app-based JACQLQ were compared using Wilcoxon matched-pairs signed-rank tests [18,19]. The concordance rate of each item and domain between the 2 platforms was calculated. The internal consistency of the app-based JACQLQ was assessed using Cronbach alpha coefficient, with an alpha score of $>.70$ considered acceptable [20]. Concurrent validity was assessed by calculating the correlations (Pearson coefficient) and mean differences (Bland-Altman analysis) [15,21].

Statistical analyses were performed using Stata/MP version 16.1 (Stata Corp) and GraphPad Prism version 9.1.2 (GraphPad Software). Statistical significance was set at $P<.05$.

Patient and Public Involvement

Input on the AllerSearch survey questionnaire was obtained to produce a version that was agreed upon by a committee comprising allergy specialists, ophthalmologists, otolaryngologists, epidemiologists, and the patient and public involvement members [4,5].

Results

Participant Characteristics

In total, 22 participants were recruited for this study. Following the exclusion of an individual with incomplete data records and another with outlier data, the data of 20 (91%) participants were analyzed. Table 1 shows the participants’ characteristics. The average age was 65.4 (SD 12.8) years, and 80% (16/20) were female participants. The mean best-corrected visual acuity value for both eyes was -0.06 (SD 0.05). The mean intraocular pressure was 13.9 (SD 2.6) mmHg.

median score and concordance rate for the paper-based and app-based JACQLQ. The individual total score of Domains I and II was significantly higher in the paper-based JACQLQ compared with the app-based JACQLQ. The concordance rates of each item, subscale, and domain were more than 70%.

Table 2. JACQLQ^a item scores and concordance rate between paper-based and app-based JACQLQ.

JACQLQ items	Paper-based JACQLQ, median (IQR)	App-based JACQLQ, median (IQR)	P value	Concordance rate (%)
Domain I, 0-36	3.5 (1.75-6)	2 (1-4.25)	.004	78
Eye symptoms, 0-20	2 (1-4.25)	1.5 (0-3)	.01	82
1. Itchy eyes	1 (0-1)	1 (0-1)	>.99	95
2. Foreign body sensation	1 (0-1)	0 (0-1)	.12	65
3. Red eyes	0 (0-1)	0 (0-0.25)	.13	80
4. Watery eyes	0 (0-0)	0 (0-0)	.50	90
5. Eye discharge	0 (0-1)	0 (0-0.25)	.13	80
Nasal symptoms, 0-16	1 (0-2.25)	0.5 (0-1)	.01	74
6. Runny nose	0 (0-1)	0 (0-0.25)	.06	75
7. Sneezing	0.5 (0-1)	0 (0-0.25)	.03	70
8. Stuffy nose	0 (0-1)	0 (0-0)	.38	75
9. Itchy nose	0 (0-0.25)	0 (0-0)	.06	75
Domain II, 0-68	2 (0-5.5)	1.5 (0-5.5)	.04	85
Daily activity, 0-44	2 (0-4.25)	0.5 (0-2)	.002	85
1. Obstacles to studying, working, and housework	0 (0-1)	0 (0-0)	.13	80
2. Poor mental concentration	0 (0-1)	0 (0-0)	.50	90
3. Decreased thinking ability	0 (0-0)	0 (0-0)	>.99	85
4. Impaired reading newspapers and other materials	0 (0-1)	0 (0-1)	.13	80
5. Poor memory	0 (0-1)	0 (0-0)	.50	90
6. Limitation of outdoor life such as sports and picnics	0 (0-0)	0 (0-0)	>.99	85
7. Limitation of going out	0 (0-0)	0 (0-0)	.38	80
8. Obstacles to socializing with people	0 (0-0)	0 (0-0)	.50	90
9. Interfering with conversations and telephone calls with others	0 (0-0)	0 (0-0)	>.99	90
10. Anxiety about people around you	0 (0-0)	0 (0-0)	>.99	95
11. Sleeping disorder	0.5 (0-1)	0 (0-1)	.03	70
Psychological well-being, 0-24	0 (0-1.25)	0 (0-2)	>.99	86
12. Dullness	0 (0-0.25)	0 (0-0.25)	>.99	80
13. Fatigue	0 (0-0)	0 (0-1)	.75	85
14. Frustrated	0 (0-0)	0 (0-0)	.25	85
15. Irritable	0 (0-0)	0 (0-0)	>.99	95
16. Depressed	0 (0-0.25)	0 (0-0)	.63	80
17. Dissatisfaction with life	0 (0-0)	0 (0-0)	>.99	90
Domain III, 0-4	1 (1-2)	1 (1-2)	>.99	90

^aJACQLQ: Japanese Allergic Conjunctival Disease Standard Quality of Life Questionnaire.

Reliability Between App-Based and Paper-Based JACQLQ

The internal consistency of the total, subscale, and domain scores between the paper-based and app-based JACQLQ is

indicated in [Table 3](#). Our results show satisfactory internal consistency for most questionnaire items (Cronbach alpha>.70), except for nasal symptoms in the app-based version (Cronbach alpha=.331).

Table 3. Reliability between the paper-based and app-based JACQLQ^a.

JACQLQ	No. of items	Cronbach alpha	
		Paper-based	App-based
Domains I and II	26	.964	.919
Domain I	9	.897	.746
Eye symptoms	5	.856	.788
Nasal symptoms	4	.776	.331
Domain II	17	.953	.896
Daily activity	11	.914	.915
Psychological well-being	6	.937	.731

^aJACQLQ: Japanese Allergic Conjunctival Disease Standard Quality of Life Questionnaire.

Correlation Between App-Based and Paper-Based JACQLQ

Figure 1 shows the correlation between the paper-based and app-based JACQLQ. There were significant positive correlations between the 2 measurements (Domains I and II: $r=0.971$, $P<.001$; Domain I: $r=0.920$, $P<.001$; and Domain II: $r=0.968$, $P<.001$). The x-axis indicates the total score for the paper-based

JACQLQ, and the y-axis the total score for the app-based JACQLQ.

Figure 2 shows the Bland-Altman analysis for the clinical agreement between the paper-based and app-based JACQLQ, revealing a difference (bias) with 95% limits of agreement of 3.35 (–6.51 to 13.2) units for Domains I and II, 1.85 (–3.05 to 6.75) units for Domain I, and 1.50 (–4.28 to 7.28) units for Domain II.

Figure 1. Correlation between the app-based and paper-based Japanese Allergic Conjunctival Disease Standard Quality of Life Questionnaires (JACQLQs). The correlation between the paper-based and app-based JACQLQs of Domains I and II, Domain I, and Domain II.

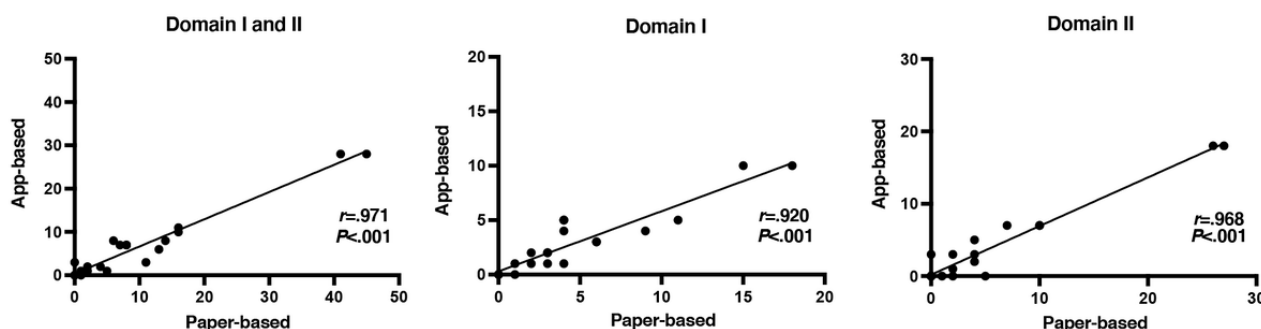
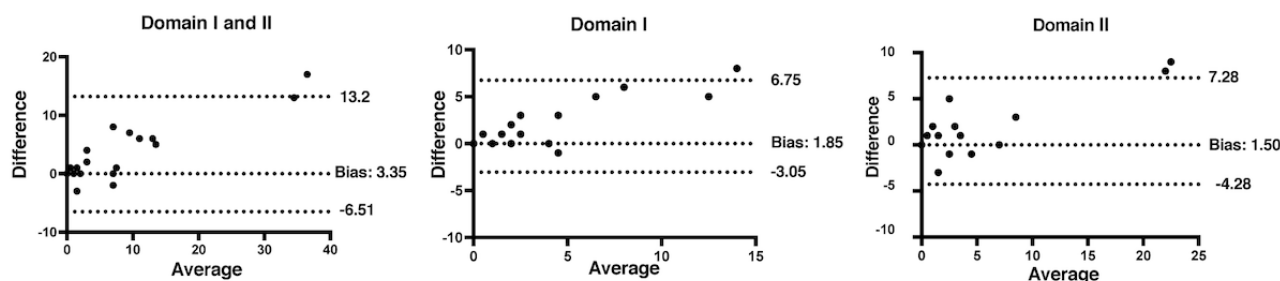


Figure 2. Bland-Altman plot for the paper-based and app-based Japanese Allergic Conjunctival Disease Standard Quality of Life Questionnaires (JACQLQs). The x-axis indicates the average of the 2 methods' scores, and the y-axis indicates the difference between the 2 methods' scores. The central line indicates the mean difference (bias) between the scores from the 2 methods, whereas the superior and inferior lines depict the intervals, which include the 95% limits of agreement. Differences between the JACQLQ of Domains I and II, Domain I, and Domain II.



Discussion

Principal Results

Hay fever, a highly heterogeneous and multifactorial disease, requires personalized assessments to develop effective preventive measures and management strategies. In this study,

we examined the reliability and validity of our smartphone app, AllerSearch, regarding collecting data on hay fever symptoms. Our results indicate that the digital administration of the JACQLQ through AllerSearch shows satisfactory reliability and validity metrics; AllerSearch may therefore be an accessible tool for hay fever management. Its accessibility may prove

advantageous for screening the undiagnosed population and promoting early, personalized interventions. The COVID-19 pandemic accelerated the breakthrough and subsequent growth of telemedicine and effective self-management. AllerSearch's ability to assist in the self-management of hay fever, with its extensive reach, aligns well with the aforementioned changing medical paradigm.

Our results show satisfactory internal consistency for most questionnaire items (Cronbach alpha > .70), except for nasal symptoms in the app-based version (Cronbach alpha = .331). Further, there were significant positive correlations between the 2 measurements (Domains I and II: $r=0.971$, $P<.001$; Domain I: $r=0.920$, $P<.001$; and Domain II: $r=0.968$, $P<.001$). These analyses yielded satisfactory results regarding the reliability and validity metrics of the app-based JACQLQ compared to the paper-based version, suggesting the role of ePROs in the future implementation of mHealth.

Our results also indicate that the app-based collection of nasal symptoms showed low internal consistency, which may lead to a discrepancy between nasal and nonnasal symptom assessments. However, nonnasal symptoms, as well as overall symptoms, maintained a high internal consistency, and the low internal consistency observed for nasal symptoms may be attributed to the small sample size in this study. Future efforts to increase power should be pursued to verify or improve on the observed low internal consistency for nasal symptoms.

Traditionally, in-person assessments have not proved very effective in comprehensive evaluations, mostly owing to the low frequency and time constraints of typical outpatient visits [22]. However, as hay fever presents itself as a heterogeneous, systemic disease with possible long-term detrimental effects, a holistic evaluation through established questionnaires, such as the JACQLQ, becomes crucial in selecting appropriate treatment regimens. Our findings revealed satisfactory internal consistency and a statistically significant correlation between the paper-based and app-based JACQLQ. It is noteworthy that the Bland-Altman plot analysis on the agreement between the paper-based and app-based JACQLQ resulted in a higher mean (bias) of 3.35 units (95% limits of agreement: -6.51 to 13.2) of the latter compared with the former. We believe that this is owing to a carryover effect stemming from the study design, in which a procedure of the study flow affects another downstream result [23]. We administered the app-based JACQLQ after the paper-based version, and future studies should address the discrepancy through a crossover trial with mixed cohorts on the questionnaire administration order.

Another explanation for the 3-point mean difference between the 2 platforms could be the length and order of the questionnaire items in the app-based version. Demographic and medical history questions preceded the JACQLQ, which might

have led to response fatigue [24], a frequently observed phenomenon with survey-type research methodologies. The app-based JACQLQ, by default, positions the scale bar for responses at 0, which may have predisposed fatigued users to quickly answer the JACQLQ items with a low score [25]. This could partially explain the higher score in the paper-based version, as it does not have a "default" score. For further validation of mHealth-driven ePROs and to minimize response fatigue, trials to reduce the number of questionnaire items and reorganize their sequence may be required. Although response fatigue can be addressed, it is practically inevitable; hence, we suggest that the psychological aspects and the resultant discrepancy based on the temporality of the answered items that may have affected the study's results should be considered. Future studies should also address the interface-led bias and discrepancies between the digital and paper questionnaires, one of which may call for a distinct cutoff score in the digital version for diagnoses and severity assessments. The 3-point mean difference, which does not appear highly relevant from a clinical perspective at this stage, and the consistent correlation between the 2 platforms suggest that ePROs collected through AllerSearch may be valid and feasible for assessing hay fever symptoms and advising on self-management.

Limitations

This study has several limitations. First, there may be a degree of selection bias stemming from the participants' demographics, including age and gender. This was also a single-center study, making the selection process prone to selection bias. Further, while there has not been a study, to the best of our knowledge, comparing paper-based and app-based questionnaires, this study had a smaller sample size in comparison to previous studies that investigated discrepancies between digital and paper questionnaires [18,24,26]. Therefore, greater sample sizes are needed for generalization. Lastly, this study did not involve any in-person clinical evaluations on allergic conjunctivitis and did not investigate the correlation of clinical findings with the JACQLQ results obtained through AllerSearch. Therefore, any capability of AllerSearch regarding allergic conjunctivitis diagnosis and screening should not be inferred from our results.

Conclusions

Our findings indicate that the data collected through the AllerSearch app had good internal consistency, with a Cronbach alpha of > .70 and significant positive correlations between the paper-based and app-based JACQLQ (Domains I and II: $r=0.971$; Domain I: $r=0.920$; and Domain II: $r=0.968$), as an instrument for hay fever symptom management. The mHealth-based PRO enables tailored, longitudinal data-based hay fever management and helps improve patients' quality of life.

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Data Availability

All data generated or analyzed during this study are included in this published article.

Authors' Contributions

Conceptualization was implemented by, T Inomata; methodology by YA and T Inomata; software by YA; validation by YA and T Inomata; formal analysis by YA; investigation by YA, T Inomata, YO, KF, MM, and KH; resources by T Inomata; data curation by YA; writing—original draft preparation by YA, T Inomata, and JS; writing—review and editing by YO, KF, MM, KH, MI, MM, NE, MN, T Ide, KN, and AM; visualization by YA; supervision by AM; project administration by T Inomata; and funding acquisition by T Inomata. All authors have read and agreed to the published version of the manuscript.

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Conflicts of Interest

AllerSearch was created using Apple's ResearchKit. T Inomata and YO are the owners of InnoJin, Inc, which developed AllerSearch. YA, JS, KF, MM, KH, MI, NM, NE, MN, T Ide, KN, and AM declare no conflicts of interest.

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Abbreviations

e-PRO: electronic patient-related outcome

JACQLQ: Japanese Allergic Conjunctival Disease Standard Quality of Life Questionnaire

mHealth: mobile health

PRO: patient-reported outcome

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Original Paper

Passively Captured Interpersonal Social Interactions and Motion From Smartphones for Predicting Decompensation in Heart Failure: Observational Cohort Study

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Abstract

Background: Heart failure (HF) is a major cause of frequent hospitalization and death. Early detection of HF symptoms using smartphone-based monitoring may reduce adverse events in a low-cost, scalable way.

Objective: We examined the relationship of HF decompensation events with smartphone-based features derived from passively and actively acquired data.

Methods: This was a prospective cohort study in which we monitored HF participants' social and movement activities using a smartphone app and followed them for clinical events via phone and chart review and classified the encounters as compensated or decompensated by reviewing the provider notes in detail. We extracted motion, location, and social interaction passive features and self-reported quality of life weekly (active) with the short Kansas City Cardiomyopathy Questionnaire (KCCQ-12) survey. We developed and validated an algorithm for classifying decompensated versus compensated clinical encounters (hospitalizations or clinic visits). We evaluated models based on single modality as well as early and late fusion approaches combining patient-reported outcomes and passive smartphone data. We used Shapley additive explanation values to quantify the contribution and impact of each feature to the model.

Results: We evaluated 28 participants with a mean age of 67 years (SD 8), among whom 11% (3/28) were female and 46% (13/28) were Black. We identified 62 compensated and 48 decompensated clinical events from 24 and 22 participants, respectively. The highest area under the precision-recall curve (AUCPr) for classifying decompensation was with a late fusion approach combining KCCQ-12, motion, and social contact features using leave-one-subject-out cross-validation for a 2-day prediction window. It had an AUCPr of 0.80, with an area under the receiver operator curve (AUC) of 0.83, a positive predictive value (PPV) of 0.73, a sensitivity of 0.77, and a specificity of 0.88 for a 2-day prediction window. Similarly, the 4-day window model had an AUC of 0.82, an AUCPr of 0.69, a PPV of 0.62, a sensitivity of 0.68, and a specificity of 0.87. Passive social data provided some of the most informative features, with fewer calls of longer duration associating with a higher probability of future HF decompensation.

Conclusions: Smartphone-based data that includes both passive monitoring and actively collected surveys may provide important behavioral and functional health information on HF status in advance of clinical visits. This proof-of-concept study, although small, offers important insight into the social and behavioral determinants of health and the feasibility of using smartphone-based monitoring in this population. Our strong results are comparable to those of more active and expensive monitoring approaches, and underscore the need for larger studies to understand the clinical significance of this monitoring method.

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KEYWORDS

heart failure; mobile device; social interaction; heart disease; mobile health; hospitalization

Introduction

Although there are numerous attempts to monitor heart failure (HF) in an outpatient setting using wearables and other point-of-care devices, compliance is often an issue and prevents monitoring for extended periods [1,2]. One key sensor system many of us carry with us on a day-to-day basis is the smartphone, and this has been shown to lead to longer patient engagement times than has wearables [3]. In this pilot study, we hypothesized that we could leverage the data recorded on the personal smartphones used by a population with HF to predict decompensation.

We defined HF decompensation status based on worsened functional symptoms or physical examination findings suggestive of lower cardiac output or increased intracardiac pressures. This includes but is not limited to fatigue, dyspnea, hypotension, and lower extremity edema [4]. Treatment includes diuretics and vasodilators intended to improve volume status and cardiac function. Unfortunately, even following successful treatment and return to the euvolemic (normal volume status) state, decompensation episodes can continue to occur with increasing frequency [4,5]. Patil et al [6] reported that about 20% of the patient cohort were readmitted within 30 days of initial hospitalization due to HF, with a median readmission time of 12 days. Furthermore, patients with a lower income had a higher readmission rate, indicating that socioeconomic factors could also contribute to the disease's progression. If low-cost monitoring methods identify decompensation episodes developing outside the clinic, medical interventions could be administered proactively to prevent hospitalization or other adverse outcomes.

Various studies have investigated techniques for noninvasively monitoring patients with HF. Packer et al [7] showed that using a combination of clinical variables and impedance cardiography features could be a predictor of a decompensation event in the following 14 days. Previous studies have also investigated the use of wearable devices adhered to the chest. In the "Multisensor Monitoring in Congestive Heart Failure" study [8], the authors propose an algorithm that uses physiological signals, reporting a sensitivity of 63% and a specificity of 92%. However, the authors provide few details and claim it is "proprietary." Inan et al [9] recorded seismocardiogram signals with a noninvasive wearable patch before and after a 6-minute walk test to analyze the cardiac response to exercise. The authors used graph similarity scores between the rest and recovery phases and found a significant difference between compensated and decompensated groups. In another example, similarity-based

modeling was used with physiological signals from a patch on the chest to detect changes from the baseline. This algorithm had a sensitivity of 76% to 88% and a specificity of 85% [10]. Using ballistocardiogram data recorded at home was also investigated [11], and authors demonstrated that collecting high-quality ballistocardiogram data at home is feasible, and an area under the curve of the receiver operator curve (AUC) of 0.78 could be achieved for classifying clinical status.

Other noninvasive approaches include patient-reported outcomes, which could be collected using clinically validated questionnaires such as the Kansas City Cardiomyopathy Questionnaire (KCCQ). The KCCQ assesses the quality of life and predicts readmissions and mortality in patients with HF [12]. In a previous study, Flynn et al [13] reported that KCCQ has modest correlations with exercise capacity measured by the 6-minute walk test in a population with HF.

With the advancement of technology, smartphones have become a ubiquitous part of our daily life. For long-term monitoring, using a smartphone could be advantageous to a solution requiring an additional device by reducing the disruption to patients' normal daily routine. Our research team and collaborators have previously developed the Automated Monitoring of Symptom Severity (AMoSS) app, which is a custom and scalable smartphone-based framework for remote monitoring [14]. Subsequently, we used the passive data from the first 10 participants of this study to estimate the KCCQ surveys collected through the app [15]. The model estimated the KCCQ score with a mean absolute error of 5.7%, providing an entirely passive method of monitoring HF-related quality of life. (The method was passive in the sense that it does not require any active participation by either the patient or clinical staff beyond the everyday use of a mobile phone to monitor activity and behavioral patterns in the background using software.). In subsequent work, motion data were then used to classify decompensation or compensation events [16]. By using a hold-out test randomly sampled from 30% of the events (N=32), the AUC of the classifier was found to be 0.76.

In this study, HF decompensation events were predicted from features derived from passive and active data collected by the smartphone-based framework. Features were extracted from 3 passive data modalities (motion, location, and social interactions) and 1 active (clinical survey data: short KCCQ [KCCQ-12]). Algorithms based on using a single modality and 2 sensor fusion approaches were developed. An analysis of the feature importance in the model is also presented. Finally, a novel late-fusion model that combines the KCCQ-12, motion, and social contact data is proposed.

Methods

Data Collection and Ethical Considerations

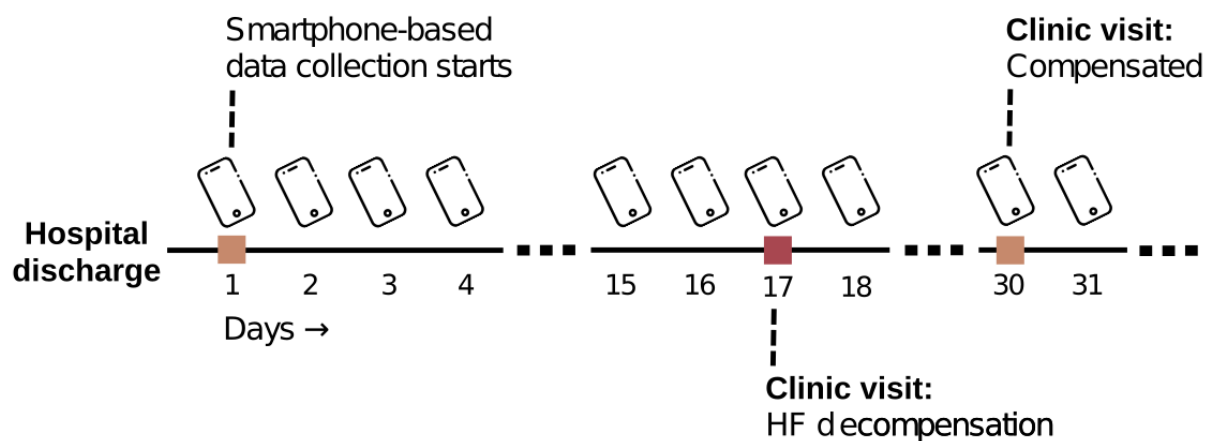
Earlier research with the AMoSS app [14] was augmented for use in this study. The app passively collected 3D accelerometer data at a 5-Hz sampling frequency on location, clinical surveys, and digital social contact.

Ethical Considerations

All data were deidentified at the source (on the participants' phones) with hashed identifiers, and random geographic offsets were added to the location data to protect the participants' privacy. The data were stored in HIPAA (Health Insurance Portability and Accountability Act)-compliant Amazon Web

Services data buckets, and the phone app uploaded data periodically (based on connectivity) every few hours. Participants with HF enrolled in the ongoing study at the Veterans Affairs Medical Center and Emory University Hospital in Atlanta, GA, USA, signed a consent form prior to the beginning of the study. The study protocol was approved by the institutional review board (#00075867) at Emory University. The clinical team provided participants with an Android-based smartphone with the app installed during the enrollment. The participant could opt to stop sharing any data type during the study, using switches provided in the app. Figure 1 illustrates the study timeline after the participant is enrolled. The app passively collected data while the clinical team recorded the clinical events, which consisted of hospital visits with compensated or decompensated status during the enrollment.

Figure 1. Illustration of the study timeline. Passive data collection started after the hospital discharge, and the clinical team recorded the clinical events after the enrollment. HF: heart failure.



Data Collection

The data from 28 participants (25 males) who contributed at least 1 clinical event were used in this research. The inclusion criteria for participants in the study were the following: a diagnosis consistent with congestive HF as noted in the electronic medical records within the Emory Health Network, an age over 18 years, the ability to consent to a clinical study,

and English as their primary language. Exclusion criteria were the following: diagnosis with a terminal illness with a life expectancy of fewer than 6 months, enrollment in a hospice program, or enrollment in a clinical study that precluded them from participating in another clinical study. Finally, participants had to be willing and able to comply with the use of their smartphones as indicated in the study. Table 1 shows the detailed information about the participants included in the study.

Table 1. Data set description: if the metric is not available, the participant is excluded from that row.

Participant characteristics	Values (N=28)
Sociodemographics	
Age (years), mean (SD)	67 (8)
Male, n (%)	25 (89)
BMI, mean (SD)	31 (6)
Mean ejection fraction (%), mean (SD)	35 (17)
Employed, n (%)	3 (11)
Race/ethnicity, n (%)	
Black	13 (46)
White	15 (54)
Health factors, n (%)	
History of diabetes	18 (64)
Previous myocardial Infarction	2 (7)
History of hypertension	19 (68)
Previous stroke	4 (14)
Peripheral vascular disease	2 (7)
History of atrial fibrillation	8(29)
Other non-atrial fibrillation arrhythmia	3 (1)
Events	
Compensated, n	62
Decompensated, n	48
Compensated per person, mean (SD)	2 (1.8)
Decompensated per person, mean (SD)	2 (1.7)

Clinical Events

Clinical events consisted of decompensated and compensated events and were collected by the clinical team when the participants visited the hospitals. In the compensated events, the participants visited the hospital for any reason, and their fluid levels were determined to be normal based on the clinician assessment, which includes a history and physical examination. For the decompensated events, the clinical team determined the participant to have functional limitations related to HF. Decompensated and compensated events were assigned to positive and negative classes, respectively.

Passive Data Sources

The raw 3D accelerometer data were converted to activity counts using the Actigraphy Toolbox to reduce the required memory for storing [17]. In the first step, the z-axis of the accelerometer data was filtered using a band-pass Butterworth filter with a 0.25 to 11-Hz passband to eliminate extremely slow or fast movements [18]. The maximum values inside 1-second windows were then summed for each 30-second epoch to obtain the activity counts, following a previously described approach [19]. If the participant shared data for less than 0.1% of the analysis window, that window was considered missing. A common way for visualizing motion data in sleep studies to emphasize shifts

in sleep rhythms is using a “double plot” format (Figure 2). This figure illustrates the motion data for 1 participant over a recording period of 300 days, and the darker colors indicate lower-intensity movement. Each column consists of 2 consecutive days of data stacked together. The first column shows motion intensity levels on days 1-2, and the second column shows days 2-3, and so on. White regions indicate missing data, which could be due to the participant turning off the data sharing or the smartphone running out of battery.

Social contact data included the contact identifier (ID), directionality, and the duration of each call. Each contact was anonymized and assigned a unique ID at the source (on the phone by the app). The age demographics of our population were such that social media was not uniformly used across the population [20], and therefore, we chose not to capture it to avoid bias. We found that phone calls more so than SMS text messaging were used in our population for digital social interactions. Some participants did not use SMS text messaging at all. We therefore chose to focus on call log data. The phone call log is particularly appealing in an older demographic because it reflects the interactions of close and trusted entities, particularly those that may offer advice on health [21]. Moreover, call logs can be generalized beyond phone calls to any communication medium that is the primary social digital interaction point for close and critical contacts.

Figure 2. Double plot representation of actigraphy data illustrating daily motion intensity levels for 1 participant. Darker colors indicate lower intensity movement, and the white color indicates missing data. On the top of the plot, decompensated and compensated clinical events are shown with red and orange squares, respectively. Comp: compensated; Decomp: decompensated.

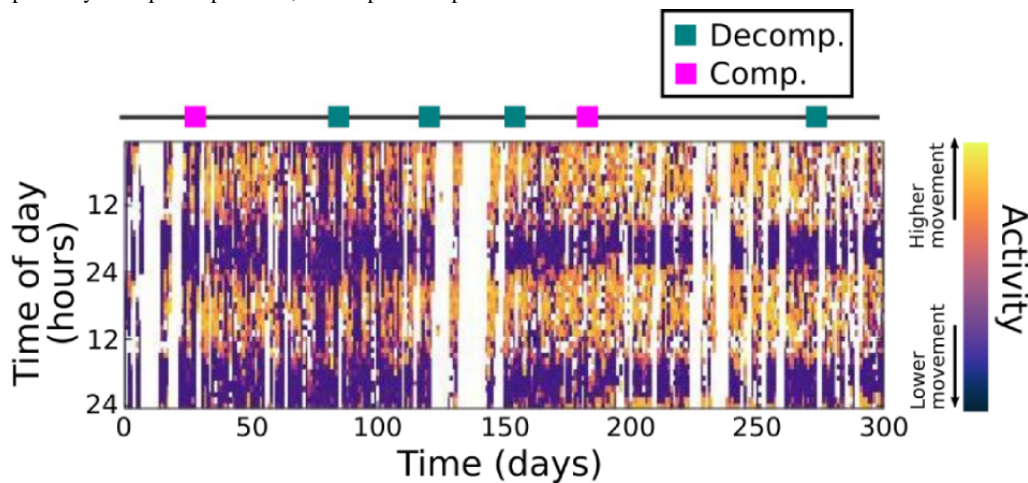


Figure 3 illustrates 1 participant’s social contact over 300 days for the 10 most frequently contacted IDs. Lastly, location data were collected using the Android location services app program interface, which generally used cellphone tower or Wi-Fi and not GPS for geolocation. Figure 4 shows the location data of a participant, collected from compensated and decompensated windows. High spatial resolution was not required since the aim was to identify the general environment in which a user

was located (eg, home, work, shops). If the smartphone moved at least 100 meters and at least 5 minutes had passed since the last location data update, a new relative location was recorded. These parameters were defined while designing the app to preserve battery life while still providing sufficient temporal and spatial resolution in comparison to the phone’s ability to geolocate without GPS. Figure 5 shows the kernel density estimate of 1 participant’s all-location data updates.

Figure 3. Participants' social contact intensity over 300 days. Each unique contact is assigned a number as shown in the y-axis, and the circle radius is proportional to the call duration to each ID. On the top of the plot, decompensated and compensated clinical events are shown with red and orange squares, respectively. Comp: compensated; Decomp: decompensated.

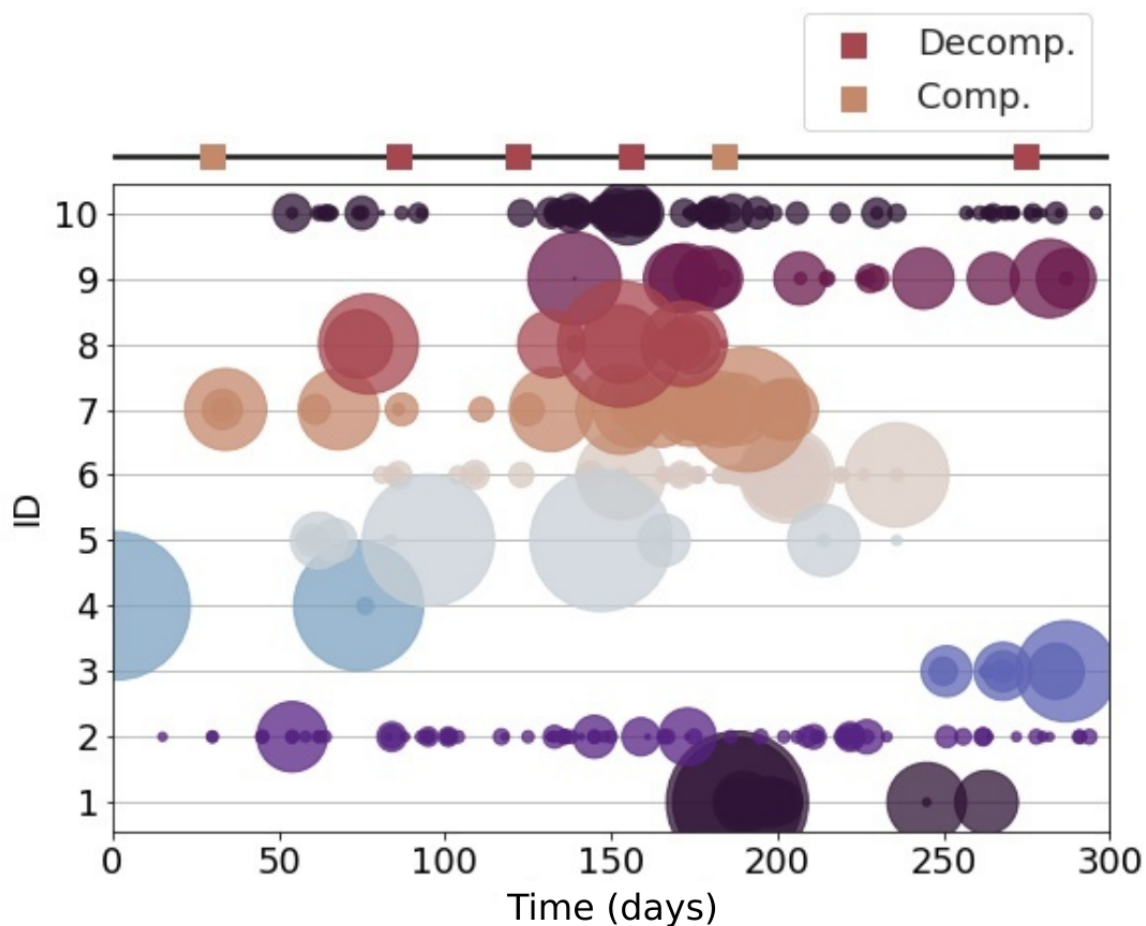


Figure 4. Location data collected in compensated (comp.) and decompensated (decomp.) windows for a participant shown on the same map with 50 km × 50 km dimensions.

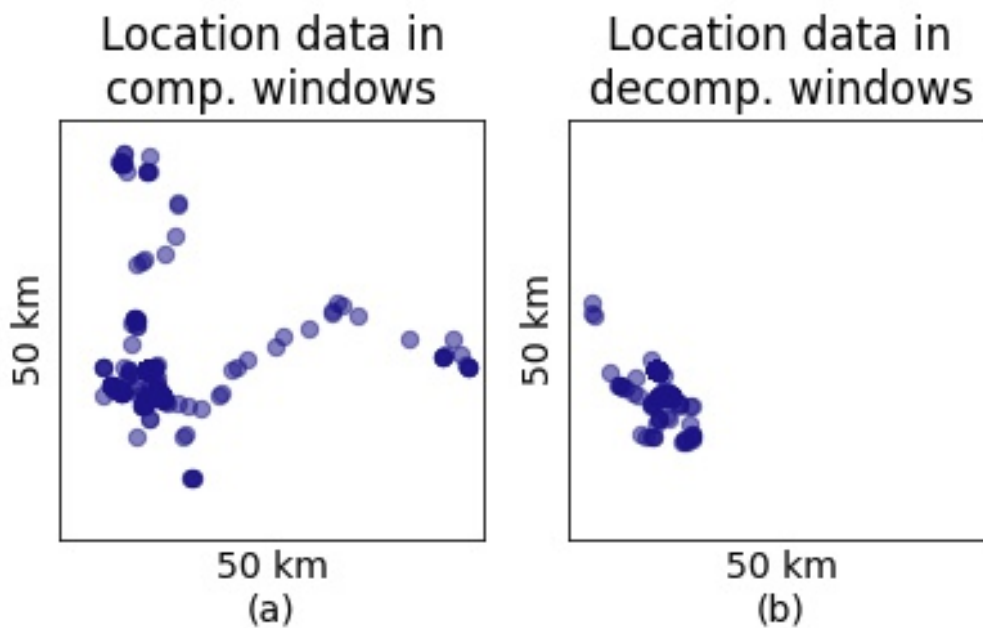
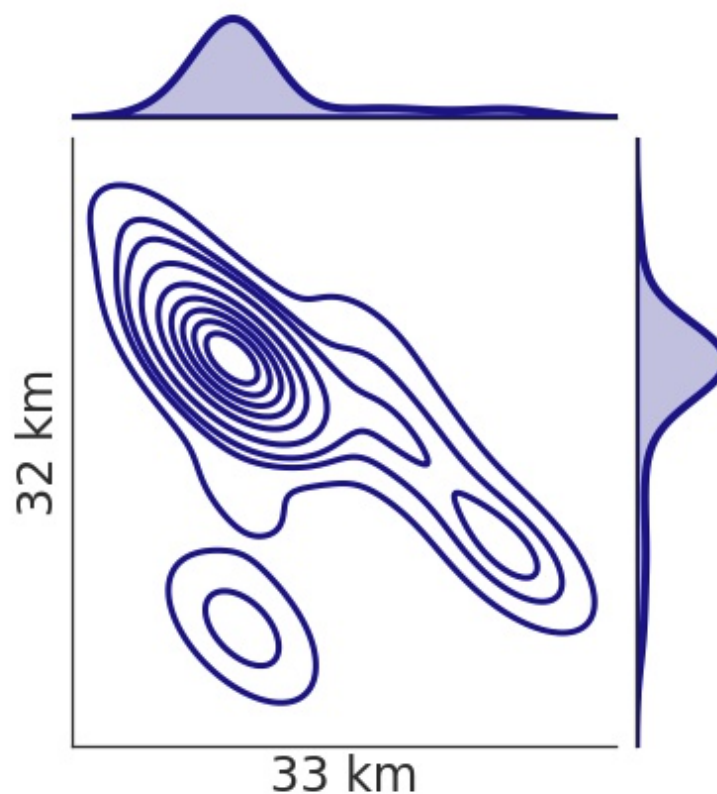


Figure 5. Kernel density estimate for the location data of 1 participant.

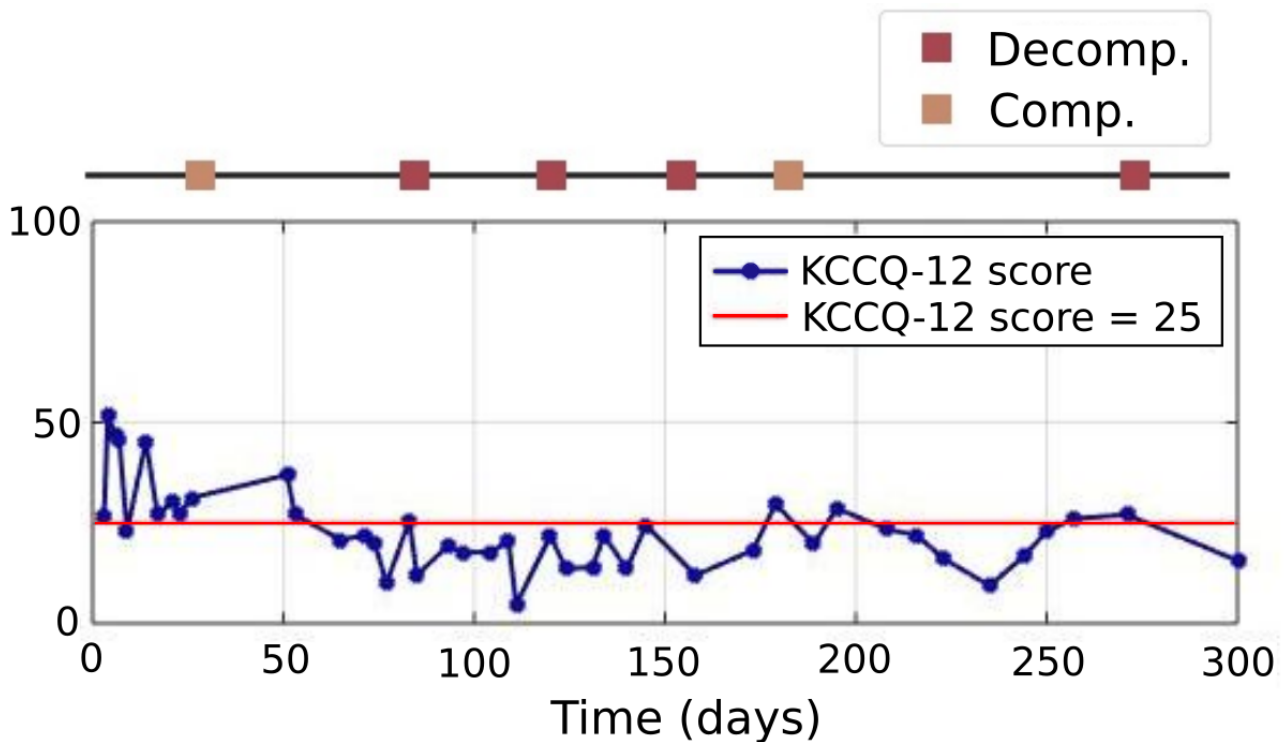


Active Data Sources

The active data type, which required user input, was the KCCQ administered through the smartphone app. The scores are lower for severe HF symptoms, and KCCQ scores ≤ 25 correspond to New York Heart Association class IV. In this study, we used the shorter version of the questionnaire, referred to as the

KCCQ-12 [22]. The KCCQ-12 survey had physical limitation, symptom frequency, quality of life, and social limitation domains, and the summary score (ranging from 0 to 100) was the average of all available domains. Figure 6 shows the KCCQ-12 scores administered through the app for a particular participant.

Figure 6. KCCQ-12 summary score over days for a particular participant. A KCCQ-12 score ≤ 25 indicates a transition to severe HF. Decompensated and compensated clinical events are shown with red and orange squares above the plot, respectively. Comp: compensated; Decomp: decompensated; HF: heart failure; KCCQ-12: short Kansas City Cardiomyopathy Questionnaire.



Feature Extraction and Temporal Windows

Several features were extracted for a particular time window from the data collected through the app to construct the motion feature set. A time window of data was the N day period before a clinical event, and the feature extraction was performed for each time window. The window size N was chosen to be 14 days initially since it was also selected by the developers of KCCQ-12 to represent the participant's recent functioning [12]. First, from preprocessed smartphone activity counts, descriptive statistics were extracted. These included mean (act_{mean}), SD (act_{std}), mode (act_{mode}), skewness (act_{skew}), and kurtosis (act_{kurt}). The completeness percentage (act_{comp}) was calculated by dividing the epochs with data by the total number of epochs in the time window. For each time window, the total number of calls ($numCalls$), the sum of the duration of calls ($durCalls$), the SD of the duration of calls ($durCalls_{std}$), the sum of time without any calls ($durNoCalls$), and the SD of time without any calls ($durNoCalls_{std}$) were calculated to be used as social contact features. For these 2 active data feature sets, the performance of using the mean of all surveys inside the window or using the most recent survey was also tested.

Using the participant's location data, the most frequently visited location was determined and defined as the "home" location. The number of times the participant was at the home location was calculated and used as a feature ($atHome$). For the second location feature, Haversine distances [23] between all locations to the home location were summed ($distToHome$). Finally, the area within a 2-km radius from home was defined as zone 1. The area outside of this radius was defined as zone 2. The

number of times the participant contributed from these 2 zones was calculated ($zone 1$ and $zone 2$, respectively).

From the KCCQ-12 data, 2 different sets of features were investigated. First, the summation score ($KCCQ-12_{sum}$) described in the Active Data Sources section was used as a feature. For the second set of features, each domain (physical limitation, symptom frequency, quality of life, and social limitation) of the KCCQ-12 survey was used separately ($KCCQ-12_{all}$).

Machine Learning Models

Logistic regression classifiers were trained to map the feature vector to the compensated or decompensated outcome. All the models were written in Python 3 language (The Python Software Foundation), and the programming code was based on scikit-learn [24]. Since each participant could contribute to more than 1 event, we used leave-one-subject-out cross-validation. The model was trained on the data from all participants except 1 hold-out participant, and this participant's data were used as the test set. This process was repeated for each participant in the data set.

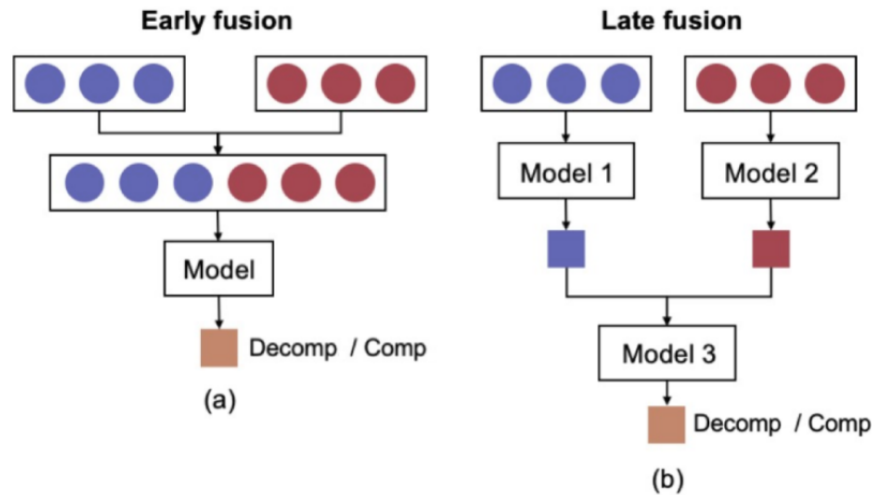
Since the number of compensated and decompensated events were highly imbalanced (Table 1), a majority undersampling was performed on the training set before training the classifiers. During the majority undersampling, all participants from the minority class were used, and the same number of participants from the majority class were randomly selected. Sequential forward feature selection was used to select the 3 most informative features from each modality.

Both early and late fusion approaches combined passive and active modalities (Figure 7). In the early fusion approach,

extracted features were combined at the input level of the classifier to create a single feature vector. For the late fusion approach, all single modality models' output probabilities were concatenated and used as input to another classifier. In all fusion

models, the participants who contributed with all data types were included in the analysis. Each analysis was repeated 50 times with different seeds. The mean and SD of the repeats were then presented as results.

Figure 7. Modality fusion techniques. Purple and red colors indicate 2 different modalities. The left side (a) shows the early fusion approach, and the right side (b) shows the late fusion of the modalities. comp: compensated; decomp: decompensated.



To examine and interpret the features further, Shapley additive explanation (SHAP) values for the early fusion model were calculated [25]. This framework is model agnostic, and SHAP values quantify the contribution and impact of each feature to the model.

Finally, we investigated how early the models can predict an outcome by implementing a time-to-event analysis and a window size analysis. The time-to-event methodology consisted of analyzing the performance of a model using data from only 1 day prior to the event but shifting which day is included in the analysis. The window size methodology consisted of analyzing different intervals of days prior to the event and evaluating the model performance on each window.

Results

Single Modality Model Results

The cross-validation performance for each single-modality model (motion, location, and social contact) is shown in Table 2. For these experiments, the time window was set to 14 days before each clinical event. The number of unique participants and the number of clinical events changed according to the modality since the participants could stop contributing data. For the motion model, 23 participants contributed with 28 decompensated events and 44 compensated events. For the social contact model, there were 21 participants with 27 decompensated events and 45 compensated events. Finally, there were 18 participants with 13 decompensated events and 33 compensated events for the location model.

Table 2. Passive data model performance results presented as the mean and SD of the external folds of each experiment.

Modality	Accuracy, mean (SD)	AUC ^a , mean (SD)	AUCPr ^b , mean (SD)	PPV ^c , mean (SD)	TPR ^d , mean (SD)
Motion	0.66 (0.03)	0.66 (0.03)	0.60 (0.06)	0.55 (0.04)	0.61 (0.06)
Location	0.59 (0.07)	0.56 (0.10)	0.39 (0.11)	0.34 (0.10)	0.49 (0.17)
Social	0.58 (0.05)	0.65 (0.05)	0.56 (0.06)	0.46 (0.06)	0.60 (0.07)

^aAUC: area under the curve of the receiver operator curve.

^bAUCPr: area under the precision-recall curve.

^cPPV: positive predictive value.

^dTPR: true positive rate.

Table 3 provides the single modality results for the active data type, the KCCQ-12 survey. The table shows the performance metrics when the mean of all the questionnaires within the 14-day window was used and when the most recent questionnaire was used for the 2 different active feature sets

(KCCQ-12_{sum} and KCCQ-12_{all}). For this active data type, 20 unique IDs contributed with 23 decompensated events and 32 compensated events. Using the summary KCCQ-12 score and taking the most recent questionnaire resulted in the highest area under the precision-recall curve (AUCPr) score of 0.69.

Table 3. Active data single modality model performance reported as the mean and SD of the external folds of each experiment.

Modality	Accuracy, mean (SD)	AUC ^a , mean (SD)	AUCPr ^b , mean (SD)	PPV ^c , mean (SD)	TPR ^d , mean (SD)
Mean of window					
KCCQ-12 _{sum} ^e	0.64 (0.01)	0.75 (0.01)	0.61 (0.02)	0.55 (0.01)	0.66 (0.03)
KCCQ-12 _{all} ^f	0.65 (0.02)	0.67 (0.02)	0.54 (0.04)	0.57 (0.02)	0.69 (0.04)
Most recent					
KCCQ-12 _{sum}	0.69 (0.01)	0.77 (0.01)	0.69 (0.02)	0.61 (0.02)	0.71 (0.03)
KCCQ-12 _{all}	0.69 (0.03)	0.70 (0.01)	0.61 (0.04)	0.60 (0.02)	0.74 (0.04)

^aAUC: area under the curve of the receiver operator curve.

^bAUCPr: area under the precision-recall curve.

^cPPV: positive predictive value.

^dTPR: true positive rate.

^eKCCQ-12_{all}: set of features for each short Kansas City Cardiomyopathy Questionnaire survey domain separately.

^fKCCQ-12_{sum}: summation scores for all short Kansas City Cardiomyopathy Questionnaire survey domains.

Fusion Modality Model Results

For the fusion model which combines KCCQ-12 and motion data, 17 participants contributed data for both modalities, with 21 decompensated events and 26 compensated events. When 3 modalities were used (KCCQ-12, motion, and social contact), 16 participants contributed with 18 decompensated events and 21 compensated events. Finally, when all data types were merged (KCCQ-12, motion, social contact, and location), there

were data available for 12 participants, with 10 decompensated events and 18 compensated events.

The results for the early fusion models are shown in [Table 4](#). For the late fusion models, the results are shown in [Table 5](#). The highest AUCPr of 0.77 was achieved when KCCQ-12, motion, and social contact modalities were combined with late fusion. For the early fusion models, using the same modalities resulted in an AUCPr of 0.69. The corresponding SHAP summary plot for the early fusion model is shown in [Figure 8](#).

Table 4. Results of early fusion models reported as the mean and SD of the external folds of each experiment.

Modality	Accuracy, mean (SD)	AUC ^a , mean (SD)	AUCPr ^b , mean (SD)	PPV ^c , mean (SD)	TPR ^d , mean (SD)
Motion + social	0.62 (0.04)	0.58 (0.03)	0.54 (0.04)	0.53 (0.05)	0.53 (0.06)
KCCQ-12 ^e + motion	0.73 (0.02)	0.81 (0.01)	0.75 (0.03)	0.69 (0.02)	0.73 (0.05)
KCCQ-12 + motion + social	0.71 (0.04)	0.72 (0.05)	0.69 (0.06)	0.70 (0.04)	0.66 (0.09)
KCCQ-12 + motion + social + location	0.67 (0.05)	0.64 (0.07)	0.57 (0.11)	0.55 (0.07)	0.56 (0.09)

^aAUC: area under the curve of the receiver operator curve.

^bAUCPr: area under the precision-recall curve.

^cPPV: positive predictive value.

^dTPR: true positive rate

^eKCCQ-12: the short Kansas City Cardiomyopathy Questionnaire survey.

Table 5. Results of late fusion models reported as the mean and SD of the external folds of each experiment.

Modality	Accuracy, mean (SD)	AUC ^a , mean (SD)	AUCPr ^b , mean (SD)	PPV ^c , mean (SD)	TPR ^d , mean (SD)
Motion + social	0.64 (0.03)	0.63 (0.04)	0.52 (0.05)	0.54 (0.04)	0.56 (0.07)
KCCQ-12 ^e + motion	0.67 (0.03)	0.75 (0.02)	0.67 (0.04)	0.61 (0.03)	0.72 (0.07)
KCCQ-12 + motion + social	0.71 (0.04)	0.79 (0.03)	0.77 (0.04)	0.68 (0.04)	0.70 (0.05)
KCCQ-12 + motion + social + location	0.62 (0.07)	0.72 (0.07)	0.60 (0.11)	0.49 (0.07)	0.68 (0.10)

^aAUC: area under the curve of the receiver operator curve.

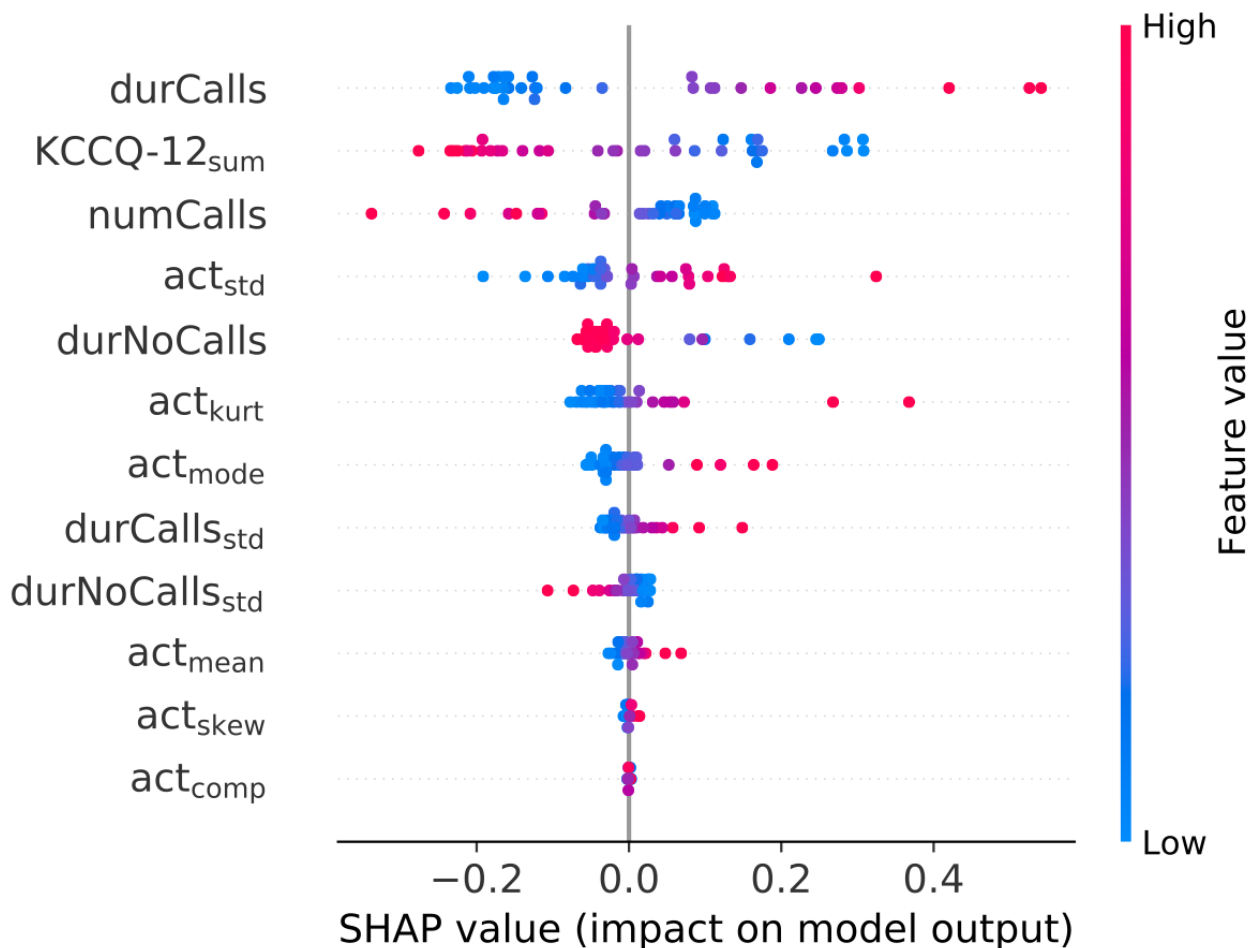
^bAUCPr: area under the precision-recall curve.

^cPPV: positive predictive value.

^dTPR: true positive rate.

^eKCCQ-12: the short Kansas City Cardiomyopathy Questionnaire survey.

Figure 8. SHAP summary plot for the early fusion model. Features are sorted by their impact on the y-axis. Each point on the plot shows the Shapley value for 1 instance. The horizontal location shows the feature’s effect for predicting positive class (decompensated) or negative class (compensated), and color indicates the feature value. SHAP: Shapley additive explanation.



Time-to-Event and Window Size Analysis

We investigated how early the algorithms can predict an outcome by shifting the days to the event and using different window sizes in days for each model in each category.

Figure 9 illustrates the AUC and AUCPr change of each model as the time in days to the event is increased. Only participants who contributed data during the time-to-event intervals and event type were included (n=13; with 13 decompensated events

and 18 compensated events). We observed a decrease in performance on the social contact modality when the time to event was 4 days. However, the motion model performance peaked at 4 days to the event. The best model was the late fusion model with a prediction window of 2 days prior to the event (Figure 9). This best model had an AUC of 0.83, an AUCPr of 0.80, a positive predictive value (PPV) of 0.73, a sensitivity of 0.77, and a specificity of 0.88. The 4-days-ahead model had a similar but lower performance with an AUC of 0.82, a AUCPr

of 0.69, a PPV of 0.62, a sensitivity of 0.68, and a specificity of 0.87.

Figure 9. Performance changes as the days to events are shifted. The x-axis indicates the time to event in days, and the y-axis indicates the AUC and AUCPr performance. Early fusion and late fusion models combine KCCQ-12, motion, and social contact modalities. AUC: area under the curve of the receiver operator curve; AUCPr: area under the precision-recall curve; fus: fusion; KCCQ-12: the shot Kansas City Cardiomyopathy Questionnaire.

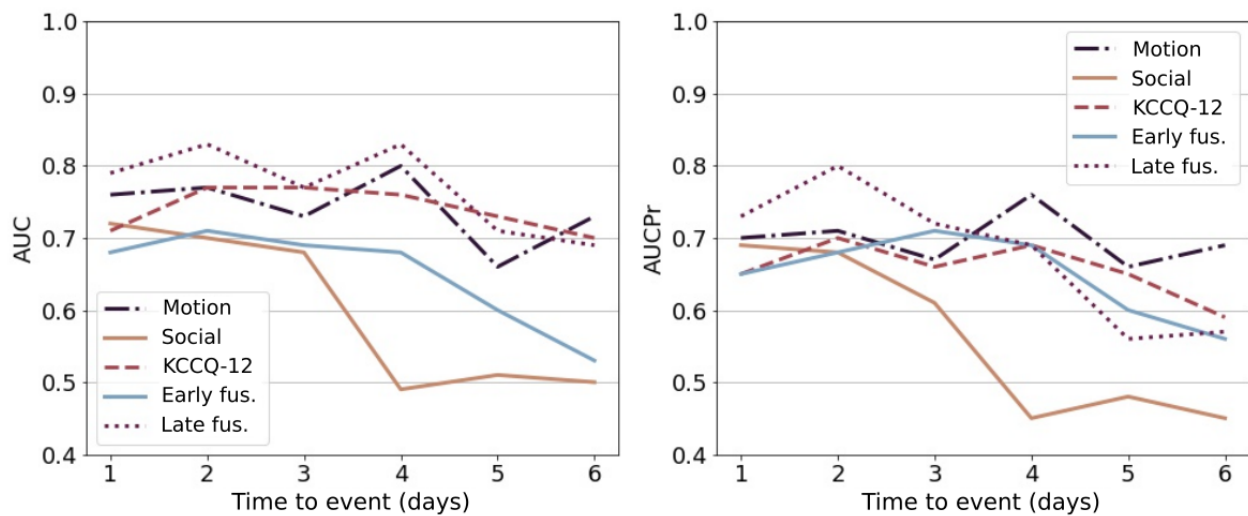
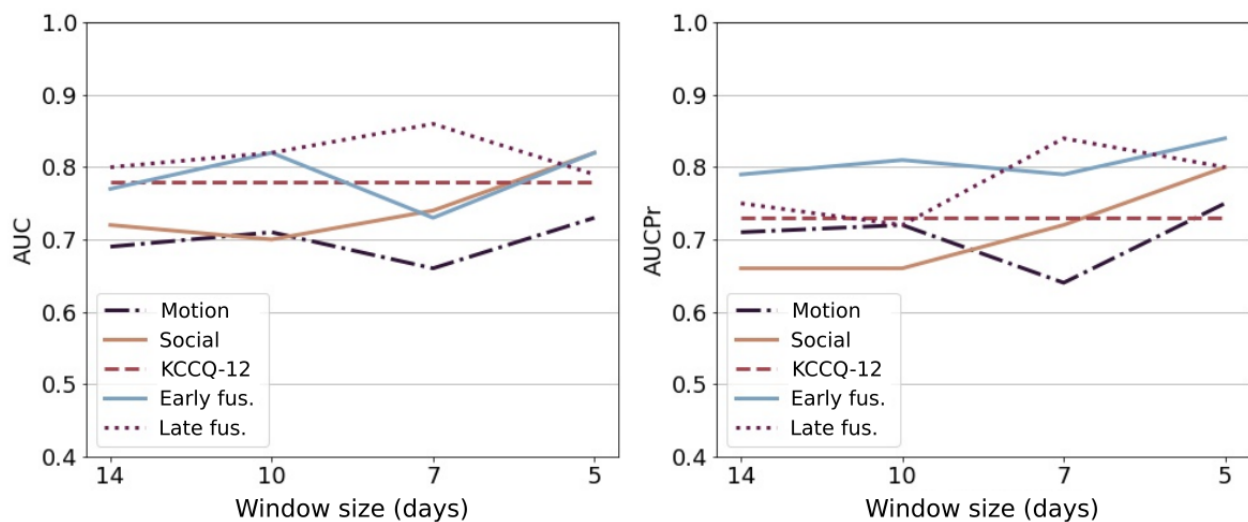


Figure 10 illustrates the performance of the models when the window size is increased. Participants with all the window size data and event type were included (n=11; 12 decompensation events and 15 compensation events). We observed that the

performance of the KCCQ-12 model was similar across all window sizes. However, the performance of the social contact model improved as the window size decreased.

Figure 10. Performance changes as the window size is reduced. The x-axis indicates the time to event in days and the y-axis indicates the AUC and AUCPr performance. Early and late fusion models use KCCQ-12, motion, and social contact modalities. AUC: area under the curve of the receiver operator curve; AUCPr: area under the precision-recall curve; fus: fusion; KCCQ-12: the shot Kansas City Cardiomyopathy Questionnaire; win: window.



Discussion

Overview

In this proof-of-concept study that involved tracking HF status with smartphone technologies, we showed that it is feasible to collect information from self-reported surveys and passive monitoring that are clinically relevant in classifying compensated versus decompensated status. This study is a first of its kind to evaluate 3 passive data modalities (motion, location, and social interactions) and 1 active data modality, the KCCQ-12 survey. We tested both individual and combined

active and passive metrics, and showed that each of them individually and in combination may be potentially useful in helping predict HF decompensation up to 6 days in advance of the clinical encounter.

Principal Findings

Next-day prediction algorithms were built using each modality separately. From the passive data sources, the motion data-based model achieved the highest AUCPr of 0.60. For a model based only on the responses of the KCCQ-12, using the summary of all domains and using the most recent score resulted in the best performance with an AUCPr of 0.74 (Table 3). Combining both

passive and active data modalities achieved a superior performance compared to models based on passive or actively collected data alone (see [Tables 4 and 5](#)). The highest performing model combined KCCQ-12, motion, and social contact data. Using the late fusion approach achieved a 6% higher AUCPr compared to early fusion when 3 modalities were used. Late fusion summarizes each modality and presents a lower-dimensional vector to the final classifier [26]. Therefore, this method could reduce the chances of overfitting and addresses the curse of dimensionality when the sample size is small. An AUC of 0.83, an AUCPr of 0.80, a PPV of 0.73, a sensitivity of 0.77, and a specificity of 0.88 for this model may indicate that the approach could potentially add clinical interventions into the framework and result in a low number of false alarms.

[Figure 8](#) illustrates the feature importance using the SHAP method. Duration and number of calls were among the most informative features, indicating that the dynamics of social interactions could be affected by the disease status. The SHAP summary plot also indicates that a higher duration but fewer calls results in a higher probability of HF decompensation for the model. Another important feature was the KCCQ-12 summary value, and a lower value of this parameter gave rise to higher SHAP values. The SHAP plot also indicated that higher mean smartphone motion intensity resulted in a higher probability of HF, which was unexpected since HF limits daily physical activity and is often associated with fatigue.

When different time-to-event horizons were tested, a general trend of lower performance for longer future predictions was observed. This was expected since symptoms are likely to become more pronounced closer to the event. However, predictions 2 days ahead were actually better than those 1 day ahead, and the performance 4 days ahead was almost as good as that 1 day before the event. This indicates that 1-day, 2-day, and 4-day models could be run simultaneously to identify short- and medium-term risks and result in different levels of intervention. Changes in performance will be affected by the levels of missingness as the event approaches, as well as the intrinsic behaviors, which may explain the performance of the 2-day window.

Comparison With Other Work

Our proof-of-concept study suggests that low-burden, smartphone-based methods of monitoring in HF may offer modest incremental predictive value. The accuracy of our models was similar to earlier work that used mobile health sensors [10] although the lead time was less. We obtained similar results with a late fusion model with a sensitivity of 77% and a specificity of 88% two days prior to the event. However, only a modest reduction in performance was seen for a 4-day prediction window, particularly using motion only, suggesting that running multiple models for different prediction windows may be appropriate. Similarly, the Link-HF study reports a sensitivity of 76% to 88% and a specificity of 85% in a median time of 6.5 (IQR 4.2-13.7) days prior to HF readmission [10]. Although the lead time is lower in our study (2 vs 6.5 days), the costs and burden are lower as well. Two-day advanced alerts may still accelerate care and trigger earlier treatments than may

usual care although more research is needed. Any reduction in delays of care with proactive monitoring and intervention may reduce the overall HF burden; nonetheless, the impact on costs and mortality remain to be explored. Because this is the first study of its kind, our primary focus was on the discovery of novel social and behavioral metrics that help to understand the biopsychosocial mechanisms underlying HF. As such, it underscores the need for larger studies aimed at training and testing models with larger lead times and the potential to reduce HF readmissions with sufficient statistical power.

Limitations

There are several key limitations to this study. First, when the data were missing, the app did not indicate whether this resulted from the participant closing the app voluntarily or if it resulted from the smartphone battery running out. These behaviors have different etiologies, which may be related to impending decompensation in different ways. For example, closing the app may indicate being tired, whereas a battery running out of charge may indicate apathy connected with depression. If an additional label is collected for missing sections, it could be used to learn other behavioral patterns. Second, text messages and social media can provide a more complete picture on social contact. However, due to the age demographics of our population, social contact was quantified using only phone call information [20]. Despite the limited data, our results showed a strong association with decompensated HF status and phone call information. Third, even though each participant contributed many days, the study's sample size was relatively small (N=28 participants), and, therefore, the methods should be further validated in a larger cohort. Finally, the reliance on hospital records rather than on independent examination of participants might have led to misclassification. We cannot rule out the possibility of unmeasured confounders in those who did and did not experience decompensation events, and our limited sample size restricted our ability to examine this as well. The small sample size also restricted our ability to examine differences by age and HF severity. Nevertheless, we were able to show the feasibility of combining passive and active features extracted from a mobile device to predict HF events. Our findings provide good evidence that we should perform a larger confirmatory study.

Conclusions

Our proposed novel smartphone-based approach for noninvasively monitoring patients with HF may help monitor health status changes through changes in movement, location, social interactions, or a combination of these. Many of these features are new discoveries and suggest important mechanisms of disease that have previously been less explored. Due to the ubiquity of smartphones and the ease of scalability of the framework, our method has the potential to facilitate low-cost monitoring of large populations. However, we note that this is a preliminary study on a relatively small population, and before it can be validated, a larger study is required. In addition, other passive monitoring devices (such as movement sensors in the house, electricity usage monitors, and home alarm systems) may provide additional useful information on the changes in behavior leading up to an intervenable event. Moreover, in

future work, the feasibility of combining the proposed method with clinical interventions (such as teleconsultations and drug dose modification) will need to be investigated to measure the potential impact of the framework described in this paper.

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Conflicts of Interest

None declared.

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Abbreviations

- act_{comp}**: completeness percentage activity counts
act_{mean}: mean of activity counts
act_{mode}: mode of activity counts
act_{kurt}: kurtosis activity counts
act_{skew}: skewness activity counts
act_{std}: SD of activity counts
AMoSS: Automated Monitoring of Symptom Severity
atHome: number of times the participant was at the home location
AUC: area under the curve of the receiver operator curve
AUCPr: area under the precision-recall curve
distToHome: sum of Haversine distances between all locations to the home location.
durCalls: sum of the duration of calls
durCalls_{std}: SD of the duration of calls
durNoCalls: sum of time without any calls
durNoCalls_{std}: SD of the time without any calls
HF: heart failure
HIPAA: Health Insurance Portability and Accountability Act
KCCQ: Kansas City Cardiomyopathy Questionnaire
KCCQ-12: short Kansas City Cardiomyopathy Questionnaire
KCCQ-12_{all}: set of features for each KCCQ-12 survey domains separately
KCCQ-12_{sum}: summation scores for all KCCQ-12 survey domains
NHLBI: National Heart, Lung, and Blood Institute
NIH: National Institutes of Health
numCalls: total number of calls
PPV: positive predictive value
SHAP: Shapley additive explanation
TPR: true positive rate

zone 1: number of times the participant was within a 2-km radius from home

zone 2: number of time the participant was outside the 2-km radius from home

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Original Paper

Willingness to Use Internet-Based Versus Bibliotherapy Interventions in a Representative US Sample: Cross-sectional Survey Study

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Abstract

Background: Self-help interventions have the potential to increase access to evidence-based mental health care. Self-help can be delivered via different formats, including print media or digital mental health interventions (DMHIs). However, we do not know which delivery format is more likely to result in higher engagement.

Objective: The aims of this study were to identify if there is a preference for engaging in print media versus DMHIs and whether there are individual differences in relative preferences.

Methods: Participants were 423 adults between the ages of 18 and 82 years (201/423, 47.5% female) recruited on *Prolific* as a nationally representative sample of the US population, including non-Hispanic White (293/423, 69.2%), non-Hispanic Black (52/423, 12%), Asian (31/423, 7%), Hispanic (25/423, 6%), and other individuals (22/423, 5%). We provided individuals with psychoeducation in different self-help formats and measured their willingness to use print media versus DMHIs. We also assessed participants' demographics, personality, and perception of each format's availability and helpfulness and used these to predict individual differences in the relative preferences.

Results: Participants reported being more willing to engage with print media than with DMHIs ($B=0.41$, $SE\ 0.08$; $t_{422}=4.91$; $P<.001$; $d=0.24$, 95% CI 0.05-0.43). This preference appeared to be influenced by education level ($B=0.22$, $SE\ 0.09$; $t_{413}=2.41$; $P=.02$; $d=0.13$, 95% CI -0.06 to 0.32), perceived helpfulness ($B=0.78$, $SE\ 0.06$; $t_{411}=13.66$; $P<.001$; $d=0.46$, 95% CI 0.27 - 0.66), and perceived availability ($B=0.20$, $SE\ 0.58$; $t_{411}=3.25$; $P=.001$; $d=0.12$, 95% CI 0.07 - 0.30) of the self-help format.

Conclusions: This study suggests an overall preference for print media over DMHIs. Future work should investigate whether receiving mental health treatment via participants' preferred delivery format can lead to higher engagement.

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KEYWORDS

psychotherapy; digital mental health; digital health; eHealth; adoption; preference; self-help; bibliotherapy; iCBT; CBT; internet-based intervention; self-guided intervention; mental health; print media; cognitive behavioral therapy; digital health intervention; patient education; psychoeducation; health resource; health information; health education; education material

Introduction

Background

Mental health disorders are the leading cause of disability worldwide [1]. However, the demand for mental health services has consistently exceeded the supply, and in recent times, this demand has continued to increase [2,3]. Therefore, innovative delivery of interventions that do not require the presence of a mental health professional may be one way of addressing the supply-demand gap. Cognitive behavioral therapy (CBT), for example, has shown efficacy across a variety of self-help formats [4].

Self-help Interventions

Self-help can be guided (ie, a self-help intervention with support by a trained professional or paraprofessional) or unguided (ie, self-guided, with no support). Guided self-help has been found to be more effective than unguided self-help [4]. However, unguided self-help has a greater potential for large-scale dissemination [5,6], and it is more effective than control conditions including care as usual or being allocated to a waiting list [5]. Self-help CBT can be delivered in many formats, including digital mental health interventions (DMHIs) that use smartphone apps, web pages, or other web-based formats to deliver the intervention. DMHIs can be highly accessible, with a wide range of resources publicly available on the internet [6]. While DMHIs are a promising way to reduce the public health burden of untreated depression and anxiety, users are currently being inundated with information and options for web-based self-help, most of which are not evidence-based [7]. Additionally, internet access and technical difficulties can be barriers to engaging with DMHIs [8,9].

Self-help interventions can also be delivered through written and print media, which is usually known as bibliotherapy. Meta-analytic reviews suggest that self-help delivered via print media is an effective delivery format [10]. Bibliotherapy is a promising model for disseminating CBT and other empirically supported treatments because it is effective, reasonably cheap, and circumvents the technological barriers associated with internet-based self-help interventions.

Although previous studies have established the efficacy of print media self-help and DMHIs when compared to treatment as usual and other controls for reducing depression [11,12], few studies have explored individuals' preferences for different delivery formats. Furthermore, even fewer studies have investigated how individuals might differ in their preference to use one format over the other. Individual differences may be especially relevant for understanding engagement with self-help since these interventions tend to suffer from low engagement rates [4]. Thus, it is essential to understand which factors could increase the likelihood of individuals engaging in self-help interventions.

Treatment Preferences

According to the Theory of Planned Behavior (TPB) [13], attitudes, norms, and perceptions can be used to predict behaviors such as treatment-seeking and engagement. Different studies have tested this theory, confirming a strong relationship

among attitudes, intention, and behavior [14]. In psychotherapy, for example, willingness to engage in treatment has been hypothesized to be a proxy for treatment-seeking [15]. Thus, attitudes toward the use of one format over the other could potentially be used to test which type of self-help format users would be more likely to engage with.

Furthermore, it is possible that certain sociodemographic traits could influence the preference for one treatment format over another. For example, younger individuals might be more strongly influenced by attitudes to engage with newer technologies than older individuals, who are influenced more by perceived behavioral control and subjective social norms [16]. In addition, other variables such as education and race could potentially impact the preference for print media versus DMHIs. For example, prior research has suggested that racial and ethnic minorities are less likely than non-Hispanic White individuals to seek and receive treatment owing to barriers such as stigma, health care engagement, and policies [17]. Thus, self-help might potentially be an alternative for individuals who are less likely to engage in traditional care, though it is unclear whether one self-help format would be preferred to the other. The broader literature on treatment engagement points to the role of variables including the presence of distress, maladaptive emotion regulation strategies, and personality as being predictors of engagement in treatment.

This Study

Our first objective was to explore the relative attitudes of individuals toward the use of self-help in print media (ie, bibliotherapy) versus an internet-based format (ie, DMHIs). We explored this question by providing individuals with psychoeducation on self-help and measuring their willingness to use bibliotherapy versus internet-based self-help, the perceived availability of the format, and its perceived helpfulness. Our second objective was to identify whether demographic and attitudinal variables predicted willingness to use one intervention over the other. We included variables related to treatment outcomes and engagement such as psychological distress, personality, and self-efficacy. We also added a COVID-19–related question to assess whether the pandemic influenced the outcomes.

Methods

Recruitment

Participants were adults over 18 years of age recruited via *Prolific* (N=423)—a web-based participant panel shown to be an effective way of collecting high-quality data from diverse participants for research purposes [18]. The sample was stratified by *Prolific* to be representative of the US population in terms of age, sex assigned at birth, and race/ethnicity according to the US Census Bureau. The study was advertised as being about “preferences for mental health treatments” and hosted on the Qualtrics website.

Ethical Considerations

The study was approved by the internal review board of the University of Pennsylvania (843424). All participants had to consent to the study by reading the informed consent form and

clicking that they consented to participate before commencing the survey. The informed consent form included information on the purpose of the study, future use of the data, possible risks, and researchers' contact information. Participants were compensated with US \$5 for their time.

Measures

Treatment Attitudes

Participants were presented with basic information regarding different treatment alternatives, including print media and internet-based self-help. Print media was described as "self-help books designed by psychologists and mental health professionals that include information and exercises designed to help people learn skills that improve their mental health or well-being." DMHIs were described as "websites, computer programs, or smartphone apps designed by psychologists and mental health professionals. These tools include information and exercises designed to help people learn skills that improve their mental health or well-being. In unguided online self-help programs and smartphone apps, individuals learn content from a website or an app on their own."

After reading about each treatment option, the survey asked about their willingness to try the intervention (ie, "If I were seeking support for my mental health or well-being, I would be willing to try this option"), perceived efficacy (ie, "I believe this option could be helpful for people looking to improve their mental health or well-being"), and perceived availability of the intervention (ie, "I believe this option is available and accessible for people looking to improve their mental health or well-being"). Responses to the questions about willingness, efficacy, and availability were rated on a 7-point Likert scale (1=strongly disagree, 7=strongly agree) [19].

Psychological Distress

We measured psychological distress using the Kessler Psychological Distress Scale (K6) [20]. The K6 is a 6-item scale assessing internalizing distress (ie, nervousness and depression) by asking participants to rate on a 4-point scale how often they have experienced negative affect symptoms over the past month (0=none of the time, 4=all of the time). Scores ranged from 0 to 24, with higher scores indicating higher distress. Specifically, scores of 6 may indicate mild distress, and scores of 13 may indicate more severe distress. The K6 has been validated and demonstrated to have criterion validity [21] and was an internally consistent measure of internalizing distress in a nationally representative sample ($\alpha=.89$) [20,22].

Expressive Suppression

We measured expressive suppression using the suppression subscale of the Emotion Regulation Questionnaire (ERQ-SUP) [23]. This is a 6-item subscale assessing participants' habitual use of expressive suppression by asking participants how much they agree with specific statements (eg, "I keep my emotions to myself") on a 7-point scale (1=strongly disagree, 7=strongly agree). Scores ranged from 4 to 28, with higher scores representing higher habitual use of suppression. The ERQ-SUP has been validated and shown to have criterion validity [24] and internal consistency ($\alpha=.76-.96$) [25].

Personality

We assessed the Big-Five personality traits (ie, neuroticism, extraversion, agreeableness, conscientiousness, and openness) using the Ten Item Personality Inventory (TIPI) [26]. This is a 10-item scale assessing personality traits with 5 bipolar factors representing extraversion, agreeableness, conscientiousness, emotional stability, and openness to experience. The measure contains 2 descriptors for each pole of all 5 personality dimensions. Each of these is rated using a 7-point scale (1=disagree strongly, 7=agree strongly). After reverse coding, the mean for each of the 5 personality dimensions were used as subscales. The TIPI has been validated and demonstrated to have adequate factor structure, convergent validity [27], and internal validity ($\alpha=.40-.73$) [26].

Self-efficacy

We also measured self-efficacy using the General Self-Efficacy Scale (GSF) [28]. This is a 10-item scale assessing participants' general sense of perceived self-efficacy by asking participants how much each specific statement feels true (eg, "I can usually handle whatever comes my way") on a 4-point scale (1=not at all true, 7=exactly true). Scores ranged from 10 to 40, with higher scores representing higher perceived self-efficacy. The GSF has been validated and shown to have criterion and internal validity ($\alpha=.75-.91$) [29].

Effect of the COVID-19 Pandemic

The survey also asked participants how the COVID-19 pandemic has affected their willingness to consider mental health treatment options that are not delivered in person. Participants could choose between "more likely," "less likely," and "no change" regarding their willingness to engage in other forms of treatment.

Statistical Analyses

All analyses were conducted using R [30] with the RStudio graphical user interface [31]. First, we present descriptive statistics to characterize the sample, including mean (SD) values for continuous variables and n (%) values for categorical variables. Our first objective was to determine whether participants, on average, were more willing to use print media or DMHIs. To explore this question, we conducted a paired sample *t* test, which tests if the within-person difference in preferences was significantly different from 0. With a sample size of 423 participants, the study was powered at 80% to detect minor differences (ie, $d=0.14$) at $P<.05$. We also report differences in the perceived efficacy and availability of print media and DMHIs. Our second objective was to determine whether baseline demographic and clinical variables affected the willingness to use print media versus internet-based self-help. Because there is very little theoretical or empirical work on preferences for print media versus DMHIs, we used a machine learning algorithm to select variables that could serve as individual differences in willingness to use print media versus DMHIs. Specifically, we used a model-based recursive partitioning with random forests to help us identify subgroups of observation with different parameters to the basic model, which describes the overall within-person difference in preference for print media versus internet-based self-help. In other words, this procedure allowed us to identify potential

predictors of the difference in willingness to use print media versus DMHIs [32]. A significant moderator of this relationship would imply that different subgroups of individuals differ in the extent to which they prefer print media versus DMHIs. Model-based recursive partitioning using random forests explores potential moderators by bootstrapping to identify the most influential moderators. We tested 1000 bootstrap samples. We used model-based recursive partitioning for variable selection because it has been successfully used in studies of individual differences in psychological interventions. The method is able to assess a large number of variables, test nonlinear relationships, and ultimately corresponds well with our research question (ie, whether the overall difference in preference is moderated by third variables).

The variables that were selected as candidate moderators were then entered into a linear regression predicting differences in willingness. To assess whether other attitudinal variables contributed to differences in willingness, we added differences in perceived availability and perceived helpfulness to the regression model with demographics, personality, and clinical variables.

Results

Demographics

Participants were 423 adults between the ages of 18 and 82 years (201/423, 47.5% female). The sample was representative of the US population, except that we undersampled American Indian or Alaskan Native and Pacific Islander individuals, who were not present in the sample (Table 1).

Table 1. Demographic characteristics of a nationally representative sample of 423 Prolific users.

Variables	Values
Age (years), mean (SD)	45 (16)
Gender identity, n (%)	
Male	213 (50.4)
Female	201 (47.5)
Gender-queer or gender non-conforming	9 (2.1)
Sexual orientation, n (%)	
Heterosexual	361 (85.3)
Not heterosexual+	62 (14.6)
Race, n (%)	
Non-Hispanic White	293 (69.3)
Non-Hispanic Black	52 (12.3)
Asian	31 (7.3)
Hispanic	25 (5.9)
Other	22 (5.2)
Education, n (%)	
Postgraduate	96 (22.7)
Bachelor's degree	163 (38.5)
High school or less	164 (38.8)
Yearly income (US \$), mean (SD)	71,000 (49,000)
Expressive suppression (Emotion Regulation Questionnaire)	2.85 (1.41)
Psychological distress (Kessler Psychological Distress Scale score), mean (SD)	6.77 (5.77)
Self-efficacy (General Self-Efficacy Scale score), mean (SD)	2.13 (.56)
Agreeableness (Ten Item Personality Inventory [TIPI] score), mean (SD)	5.30 (1.28)
Conscientiousness (TIPI score), mean (SD)	5.26 (1.40)
Extraversion (TIPI score), mean (SD)	3.38 (1.64)
Neuroticism (TIPI score), mean (SD)	4.68 (1.70)
Openness (TIPI score), mean (SD)	5.13 (1.27)
Perceived helpfulness of digital mental health interventions, mean (SD)	4.73 (1.33)
Perceived availability of digital mental health interventions, mean (SD)	5.67 (1.27)
Perceived helpfulness of print media, mean (SD)	5.11 (1.21)
Perceived availability of print media, mean (SD)	6.03 (1.07)

Overall Preference

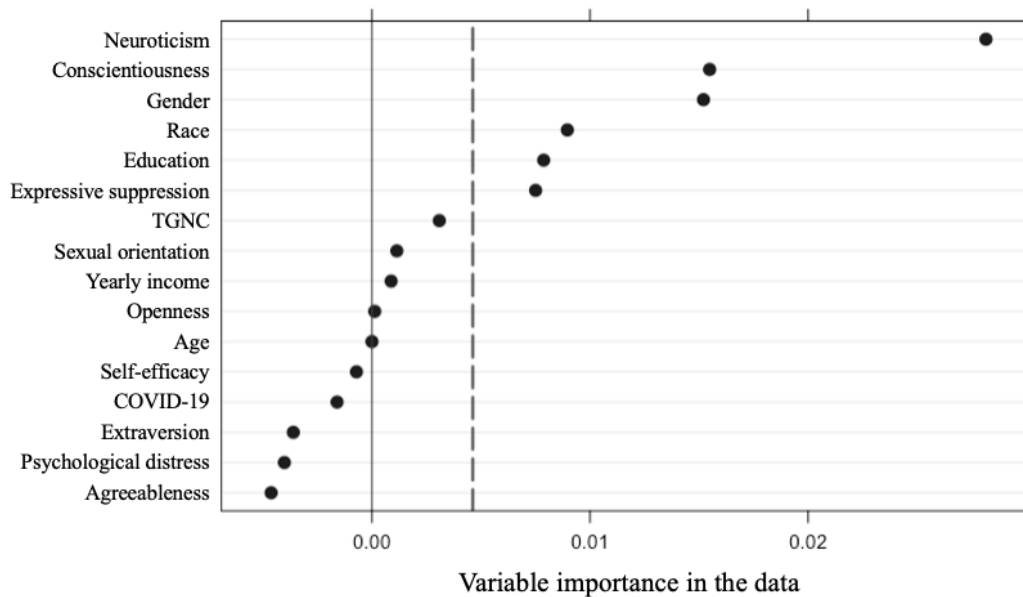
On average, participants reported higher willingness to use print media (mean 4.77, SD 1.82) rather than DMHIs (mean 4.37, SD 1.81). Comparing the within-person difference in willingness to use print media versus internet-based self-help revealed a significant but small preference for print media ($B=0.41$, SE 0.08; $t_{422}=4.91$; $P<.001$; $d=0.24$, 95% CI 0.05-0.43). Most participants reported being more willing to use print media (178/423, 42.1%) than DMHIs or no preference (159/423,

37.5%). Few preferred to use DMHIs than print media (86/423, 20%).

Predictors of Willingness

We explored whether baseline variables moderated the preference for print media over DMHIs using model-based recursive partitioning via random forests. The variable importance plot ranked neuroticism, conscientiousness, expressive suppression, and participants' gender, race, and education as the top predictive variables (Figure 1).

Figure 1. Variable importance plot for variables predicting willingness to engage in print media rather than internet-based self-help, representing mean decreases in accuracy when removing each variable. TGNC: transgender or gender non-conforming.



The variables identified by the MobForest algorithm were then included in a multiple regression as predictors of willingness to use print media over DMHIs. Including these variables yielded a significant overall regression model ($R^2=0.43$, $P=.03$). This model suggested that greater education is associated with a higher willingness to use print media over DMHIs ($B=0.22$, $SE\ 0.09$; $t_{413}=2.41$; $P=.02$; $d=0.13$, 95% CI -0.06 to 0.32). Across all but the lowest education levels (ie, high school or less), participants preferred print media DMHIs, and this preference was strongest among the most educated participants. Furthermore, identifying as Black (vs Non-Hispanic White) suggested a greater preference for print media to internet-based self-help ($B=0.49$, $SE\ 0.25$; $t_{413}=1.92$; $P=.06$; $d=0.29$, 95% CI 0.09 - 0.48).

Attitudes as Predictors of Willingness

We added attitudinal variables, namely differences in the perception of the helpfulness and availability of print media versus DMHIs to the linear model. When adding these variables to the regression model, race and education were no longer significantly associated with willingness to use print media versus internet-based self-help ($R^2=0.40$, $P<.001$). Perceived differences in helpfulness were strongly associated with the willingness to use print media versus DMHIs ($B=0.78$, $SE\ 0.06$; $t_{411}=13.66$; $P<.001$; $d=0.46$, 95% CI 0.27 - 0.66). The perceived availability of print media versus DMHIs also affected willingness to use, though these effects were smaller ($B=0.20$, $SE\ 0.58$; $t_{411}=3.25$; $P=.001$; $d=0.12$, 95% CI 0.07 - 0.30).

Discussion

Principal Findings

Our main findings indicate that most participants were more willing to use print media rather than DMHIs. This preference appeared to be influenced by education level, perceived availability, and perceived helpfulness of the DMHI. Specifically, higher perceived helpfulness had the most

substantial effect on participants' willingness to use print media rather than DMHIs. Furthermore, a higher education level was associated with a stronger preference for print media than for DMHIs.

Sociodemographic Predictors of Willingness to Engage

Previous research has suggested an association between lower education and a higher risk of symptom deterioration when engaging in DMHIs [33]. Thus, regardless of the format, making materials more understandable and engaging for individuals with lower education might be an important avenue for research. It is also important to note that age was not associated with the preference for print media over internet-based self-help. Previous research has suggested that younger individuals may be more likely to engage in newer technologies based on attitudes [16], such as perceived helpfulness or availability. Race was also associated with preferences. Specifically, Black individuals reported a stronger preference for print media than for DMHIs. However, this association was weak and requires further research.

Attitudes

The perceived helpfulness and availability of the self-help intervention format seem to be useful for understanding a participant's willingness to engage in self-help. Our finding alludes to a stronger preference toward print media because participants perceive it as potentially more helpful. These data could be used to improve efforts to engage individuals in treatment and personalize treatment allocation on the basis of individual preferences. In other words, willingness to use internet-based self-help could be optimized by using the information on the efficacy of internet-based self-help versus that of print media. According to the TPB, willingness to engage in treatment can be used as a proxy for treatment-seeking [34,35]. Thus, the relationship between attitudes and willingness to engage in self-help interventions could have potential implications for future efforts to increase use and engagement in evidence-based self-help interventions. Additionally, it is

possible that engagement with DMHIs could be improved if individuals had print media to support their use of DMHIs.

Limitations, Strengths, and Future Directions

Before interpreting the results of this study, several limitations are worth noting. First, although *Prolific* data appear to be of higher quality than those obtained from college student samples and from other web-based panels, the possibility of a selection bias affecting our results cannot be ruled out. Indeed, existing data suggest that individuals in web-based panels tend to be more depressed than the average adult in the United States. It must be noted that while this means that our sample is different from a representative US sample, it is not clear whether this would bias our findings. Our primary question is with regard to the differences between print media and DMHIs. We may nonetheless expect that people in a web-based panel may have stronger preferences for DMHIs than for print media given that they are already engaged with online tools such as *Prolific*.

Additionally, we measured self-reported willingness to use different self-help formats and not actual engagement with the content. Although willingness has been found to predict engagement, it is not a perfect predictor of actual behavior. Furthermore, we did not measure other aspects of the TPB including subjective norms and perceived behavioral control. Finally, although the sample was broadly representative of the US population, it undersampled American Indian or Alaskan Native and Pacific Islander individuals. Nevertheless, several strengths are worth considering. First, the study was powered to detect minor differences that may have practical implications, for example, for large-scale dissemination of self-help resources. Additionally, we measured a variety of individual differences

and used machine learning to identify factors that could be germane to treatment engagement.

One logical future direction is to test whether willingness to engage in treatment can predict actual engagement in treatment and how perceived helpfulness influences this relationship. Therefore, future studies could test whether providing education on the efficacy of interventions could increase participants' willingness to use them. Another alternative would be to test whether allocating patients to their preferred format could lower dropout rates, as our study suggested individual differences in preferences for the different interventions [36]. While DMHIs have received attention over the past couple of years, our results suggest that individuals may be more interested in print media. The combination of DMHIs with print media could be a potential avenue to explore to increase engagement with self-help materials.

Conclusions

Self-help interventions have the potential to improve access to mental health resources. Although there is great excitement for DMHIs, it is essential to remember that this is not the only available format. This study revealed an overall preference for print media over internet-based self-help, which seems to be related to the perceived helpfulness of the format. These findings indicate possible future targets for interventions to increase treatment-seeking and reduce dropout rates. These findings are especially important for self-help interventions that suffer from a high dropout rate [5]. Therefore, to optimize the usability of self-help interventions, we need more studies to confirm the association among self-help delivery formats, attitudes, and engagement in the interventions.

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Conflicts of Interest

LLL has received consulting fees from Happify Health, Inc., who had no role in the current research.

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Abbreviations

CBT: cognitive behavioral therapy
DMHIs: digital mental health interventions
ERQ-SUP: Emotion Regulation Questionnaire
GSF: General Self-Efficacy Scale
K6: Kessler Psychological Distress Scale
TIPI: Ten Item Personality Inventory
TPB: Theory of Planned Behavior

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Original Paper

Effects and Processes of an mHealth Intervention for the Management of Chronic Diseases: Prospective Observational Study

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Abstract

Background: Mobile health (mHealth) interventions for self-management are a promising way to meet the needs of patients with chronic diseases in primary care practices. Therefore, an mHealth intervention, TelePraCMan, was developed and evaluated for patients with type 2 diabetes mellitus, chronic obstructive pulmonary disease, high blood pressure, or heart failure in a German primary care setting. TelePraCMan entails a symptom diary, an appointment manager, a manager to document goals, and a warning system. The app should foster the self-management of participating patients.

Objective: We aimed to examine the effects of TelePraCMan on patient activation and quality of life and explored the underlying contextual factors, impacts, and degree of implementation.

Methods: In a prospective observational study design, we collected data by using interviews and written questionnaires from participating patients (intervention and control groups) and primary care workers (physicians and practice assistants). The primary outcomes of interest were patient-reported quality of life (12-Item Short Form Survey) and patient activation (patient activation measure). The quantitative analysis focused on differences between patients in the intervention and control groups, as well as before (T0) and after (T1) the intervention. Interviews were analyzed by using qualitative content analysis via MAXQDA (VERBI GmbH).

Results: At baseline, 25 patients and 24 primary care workers completed the questionnaire, and 18 patients and 21 primary care workers completed the follow-up survey. The patients were predominantly male and, on average, aged 64 (SD 11) years (T0). The primary care workers were mostly female (62%) and, on average, aged 47 (SD 10) years (T0). No differences were observed in the outcomes before and after the intervention or between the intervention and control groups. In the additional interviews, 4 patients and 11 primary care workers were included. The interviewees perceived that the intervention was useful for some patients. However, contextual factors and problems with implementation activities negatively affected the use of the app with patients. The main reasons for the low participation were the COVID-19 pandemic and the target group, which seemed to have less interest in mHealth; the interviewees attributed this to the older age of patients. However, the respondents felt that the app would be better accepted in 5 or 10 years.

Conclusions: Although the TelePraCMan app was rated as very good and important by the participants, few patients used it. The digital intervention was hardly implemented and had limited impact in the current setting of German primary care.

Trial Registration: German Clinical Trials Register DRKS00017320; <https://tinyurl.com/4uwrzu85>

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KEYWORDS

telemedicine; multimorbidity; primary health care; symptom assessment; chronic disease; mobile phone

Introduction

Background

An increasing number of people have ≥ 2 chronic conditions (multimorbidity) [1]. Meeting the needs of patients with multimorbidity poses a challenge for health care systems, especially for primary care [2]. Policy makers and health care workers have shown interest in telehealth's potential for the diagnosis, treatment, and prevention of health problems [3] as well as self-management support [4]. Self-management and self-management support for patients with multimorbidity is complex because of the effects of various diseases and emotional distress. Therefore, innovative care delivery models are required. Mobile health (mHealth) interventions are expected to provide self-management support interventions, which can be tailored to individual needs [5].

Previous research in various patient populations has shown mixed effects of mHealth tools for self-management support [4,5]. A review concluded that through enhanced symptom control, the use of mHealth apps has the potential to improve health outcomes in patients with multimorbidity [5]. A metareview concluded that telehealth is seen as a safe option for the delivery of self-management support, especially for the management of heart failure and type 2 diabetes, but the evidence was inconsistent for other conditions. However, they showed that findings of successful components in the interventions were limited and inconclusive [4]. Another review concerning the combination of mHealth and health coaching for improving self-management in chronic care showed that mHealth and health coaching interventions benefit from each other as well as patients still tend to prioritize human contact. The authors thereby concluded that it is desirable to personalize health technology [6]. A systematic review of reviews also showed that most effective technology-based interventions in improving diabetes self-management combined a feedback loop that connected patients and their health care team using 2-way communication, analyzed patient-generated health data, tailored education, and individualized feedback [7]. The results show that although telehealth interventions enhance self-management, communication and interactions with health care professionals are crucial for patients with chronic diseases, and a combination of both is important.

Furthermore, few studies explored the acceptance and actual use of mHealth interventions by older adults in Germany and the effects of their use on patient-reported outcomes such as patient activation and health-related quality of life. Previous studies on older multimorbid patients have shown that further research is needed for a successful integration of the interventions in patients' everyday life and in the workflow of primary care practices [8-10].

Objectives

Therefore, we developed and evaluated the TelePraCMan intervention, which aimed to support the self-management of patients with multimorbidity and enhance their quality of life. We examined the effects of TelePraCMan on patient activation and quality of life and explored the perceptions of practitioners on TelePraCMan. Concomitantly, a process evaluation was

undertaken to understand and explore the context, impacts, and implementation process.

Methods

Study Design

The developed mHealth app TelePraCMan was tested for 12 months (October 2019 to September 2020) as part of a multicenter randomized controlled study in 10 primary care practices in Baden-Württemberg. Patients, physicians, and practice assistants received a questionnaire at baseline and follow-up. As we did not reach the recruitment targets, we report on the outcome evaluation descriptively. In addition, we conducted a process evaluation in the form of a qualitative interview study and further questions in the questionnaire with these three groups alongside the randomized controlled trial, which is the primary focus of this study. For these reasons, we report the results of the randomized controlled study as well as the process evaluation and refer to the study design as a prospective observational study.

Recruitment and Sampling

Only practices using the case management program PraCMan [11] for at least 6 months were invited to participate in the study. Approximately 130 practices were contacted via letter, fax, email, or telephone. These practices were selected based on their geographic location and their practice size as well as on the consisting contacts of the research team. First, they were sent a reply form. After the expression of interest, the practices received an information leaflet, a consultation on the phone, and further information documents on the study implementation. After signing a consent form to participate in the study, an appointment was made for a brief training session lasting approximately 90 minutes, during which the study procedure, patient recruitment, and use of the app in the context of care were explained in detail.

The target group of the study was patients enrolled in the case management program PraCMan. These patients had type 2 diabetes mellitus, chronic obstructive pulmonary disease, high blood pressure, or heart failure. Other inclusion criteria were understanding German, being able to give consent, aged >18 years, and having a smartphone or tablet in the household. Eligible patients in the participating practices were addressed by the practice assistants, informed about the study, and asked for their interest.

If the patients were interested in participation, they were informed about the study verbally and in written form and were asked to sign an informed consent form. Patients were randomly assigned to either the intervention or control group. The patients were then given recruitment envelopes that had been prepared for the practices by the study center in Heidelberg. The envelopes included either the documents for use of the app in the intervention group or documents for study participation in the control group. The randomization was performed by lottery within the study center. The envelopes were constructed to look similar in both groups. The practice staff members were not informed about the order. Both envelopes included information leaflets, bank forms for the expense allowance, an initial

questionnaire (T0) for the baseline survey, as well as a short information on the next steps for patients and the practice team to simplify study conduction.

The process of patient recruitment was documented by the practice staff in screening lists. The day, the number of patients, and the respective outcome of the recruitment (whether the patient participates) were recorded in these lists. If patients did not wish to participate, the reason for nonparticipation was also recorded.

Of the 130 invited practices, a total of 10 practices with 24 physicians and practice assistants in T0 and 21 in T1 took part in the quantitative study. Of the 141 patients who were asked to participate, 25 completed the quantitative survey in T0 and 18 completed the follow-up survey in T1.

Intervention

TelePraCMan Development

TelePraCMan was developed and programmed by the Department of General Practice and Health Services Research at the Heidelberg University Hospital. In addition to PraCMan, an established model for structured management of chronic diseases in primary care [11,12], TelePraCMan was developed to foster self-management and can be used by practices that regularly use PraCMan and their patients who are subscribed within the PraCMan program. Primary care physicians, medical practice assistants with further training (VERAH [Versorgungsassistent/in in der Hausarztpraxis]), and patients were involved in the development of TelePraCMan via focus groups, interviews, and questionnaires. To adapt the app to the demands of the target group, one survey covered smartphone use and technology affinity to gain knowledge of user requirements before and during the app development process [13]. After evaluating the results, the app was adapted and now contains an appointment manager, a manager for target agreements, and the possibility for general practices to access the symptom data via remote access to TelePraCMan, in addition to the initial basic symptom diaries. TelePraCMan is a web-based app. This means that the app is not installed locally on a user's smartphone or tablet. Instead, data processing takes place on independent web servers (of University Hospital Heidelberg) and access is realized via a web browser on the user's smartphone or tablet, which means that an internet connection is required to use the app.

TelePraCMan Features

The main features of this app includes symptom diaries for 4 chronic diseases (type 2 diabetes mellitus, chronic obstructive pulmonary disease, high blood pressure, or heart failure). Patients can record values of blood pressure, blood sugar, weight, or mental health conditions in the symptom diaries. Further features of the app included a decent warning system (including what to do and who to contact in an emergency) whenever one of these symptoms or values exceeded the specified thresholds, an appointment manager, a manager for target agreements, and the possibility for primary care practices to access the symptom data via remote access. Within the home page of the app, a daily overview was provided including shortcuts to quickly get to upcoming tasks. The completed tasks were then automatically ticked off within the daily overview. The app was programmed as a browser-based app, so that it did not have to be downloaded and fulfilled the data protection regulations. Some figures of the main features of the app are included in [Multimedia Appendix 1](#).

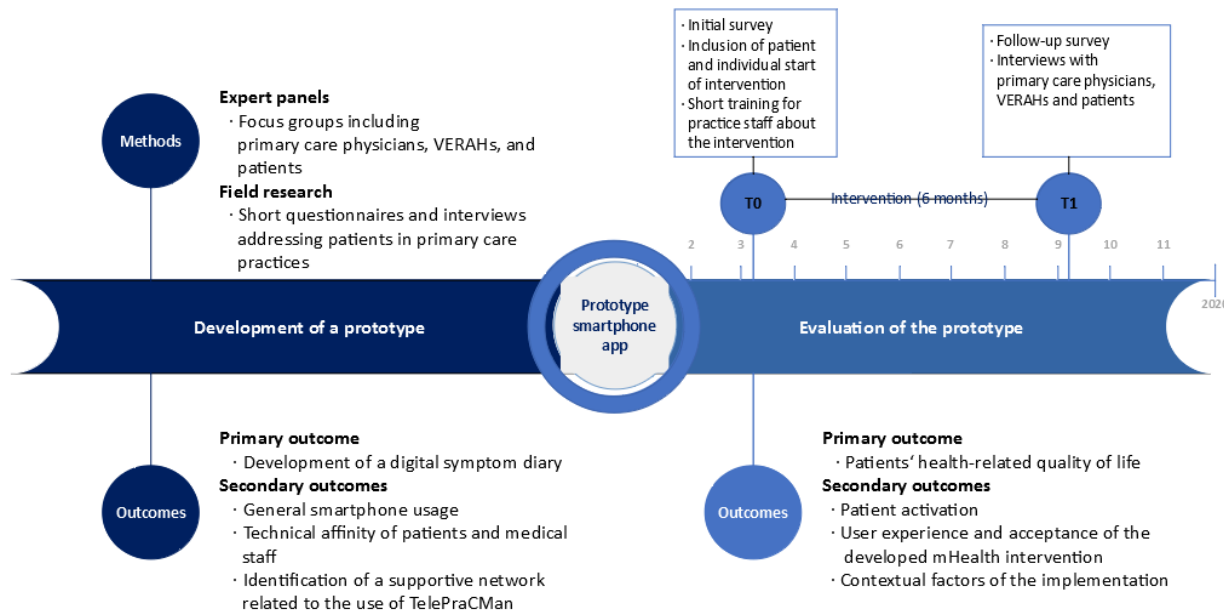
Study Intervention

Patients who were assigned to the intervention group received access to data for using the app in addition to the general study documents. Using a checklist in advance, practice staff and patients determined the frequency and time points at which the patients should document their symptoms or values. Furthermore, the primary care physicians specified thresholds for individualized values (such as the highest or lowest tolerable blood pressure) and documented these in the named checklist. For the first use of the app, the checklist provided guidance on how to individualize the app for themselves.

After the initial setup of the app, patients could use it for 6 months. Patients also continued to receive their usual treatment according to the PraCMan standard guidelines [11]. Before the monitoring appointments, patients could voluntarily transfer the recorded symptoms and values to the practice so that they could be included in the appointments for further treatment planning.

Patients assigned to the control group continued to receive treatment according to the PraCMan standard care guidelines. In addition to regular monitoring appointments, this also included the use of paper-based symptom diaries to document values and symptoms, which is one key element in PraCMan [11]. Patients in the control group were also included in the study for 6 months. [Figure 1](#) presents an overview of the study.

Figure 1. Study overview. VERAH: Versorgungsassistent/in in der Hausarztpraxis. T0: before the intervention; T1: after the intervention.



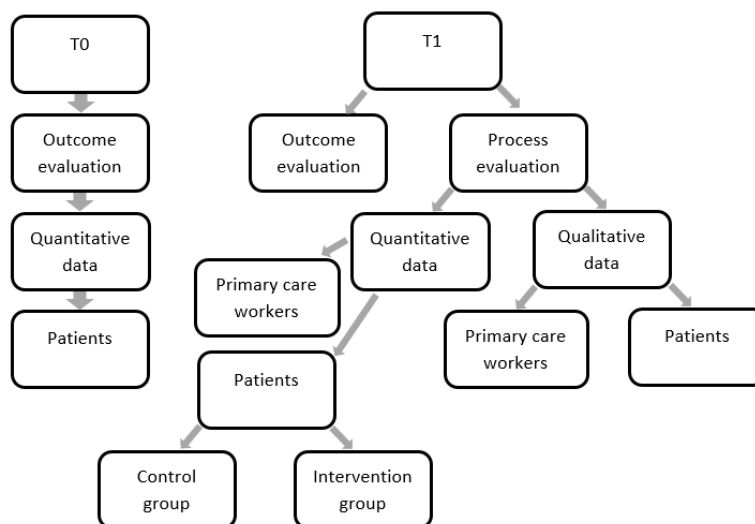
Data Collection and Measures

Overview

Quantitative data were collected before and after the intervention was applied. Data collection at T0 (baseline) took place at the start of the individual intervention for the practices after they had agreed to participate in the study. After the training session, practices received a written survey. Patients also received a

written survey at the start of the intervention together with the study documents. Data collection at T1 (follow-up) was performed at the end of the intervention; that is, after 6 months. For practice staff, the T1 survey was administered at the end of the study in September 2020 or after the end of the intervention when the last patient was included. Patients again received a written survey, which was distributed via the practice at the end of the intervention. Figure 2 visualizes the data collection structure.

Figure 2. Data collection structure. T0: before the intervention; T1: after the intervention.



Outcome Evaluation

For the outcome evaluation, we collected data via a written survey in the patient sample at baseline T0 and T1 (follow-up). We measured health-related quality of life using the 12-Item Short Form Survey (SF-12 [14,15]) and patient activation using the patient activation measure (PAM) [16].

The SF-12 consists of 8 subscales that were transformed to a scale from 0 to 100, and the mean value was calculated in each

case. In a sample [17], which is representative for Germany, the mean value of each scale is 50 points with an SD of 10 points. To improve comparability of data, the scales were standardized by a z-transformation and then transformed linearly (mean 50, SD 10). Using exploratory factor analysis, the 8 subscales were condensed into two superordinate scales: physical health (physical component summary [PCS]) and mental health (mental component summary [MCS]). The two scales were linearly transformed to a mean of 50 and an SD of 10 [15].

Patient activation was measured using the PAM-13D. Each statement is rated by respondents on a response scale of 1 to 4 (German version), where 1 stands for “disagree strongly” and 4 for “agree strongly.” To calculate the PAM scores (from 0 to 100), the German response options were converted to the standardized metric (0-100). Higher scores indicated that the patient is more activated. On the basis of these scores, the patients were divided into levels. At level 1, patients may not understand their role in making decisions about their health and are more passive. Level 4 patients are able to manage their health on their own but may have problems doing so in stressful situations [16].

Process Evaluation

For the process evaluation, we also collected data via the written survey and additional interviews. We measured the evaluation of the TelePraCMan app via the User Experience Questionnaire (UEQ) [18] at T1 in the patient sample. We measured the perceived opportunities and barriers to using TelePraCMan in primary care practices at T0, as well as perception, use, and workload of TelePraCMan in primary care practices at T1 in the primary care worker sample.

Analyzing the user experience data, we used the UEQ Data Analysis Tool version 7 (UEQ Team [19]). The tool calculates the scale means and the mean and SD for each item. It groups the 26 items to create scores for six domains of attractiveness, perspicuity, efficiency, dependability, stimulation, and novelty. The mean scores were calculated for each domain. Values between -0.8 and 0.8 represent a more or less neutral evaluation of the corresponding scale, values >0.8 represent a positive evaluation, and values <-0.8 represent a negative evaluation [18].

A self-administered questionnaire was used to measure the perception and use of TelePraCMan among the practice staff. The questionnaire was based on the technology acceptance model and was tested within the interprofessional study team. It consisted of 21 questions for measurement at T0, which were divided into 5 subscales. The five subscales were as follows: “Perception and use of the VERAH-portal,” “Assessment in relation to the patients concerned,” “Changes brought by TelePraCMan for the patients,” “Workload in the practice,” and “General assessment.” The measurement at T1 consisted of 30 questions, which were divided into 7 subscales. The 5 subscales from the measurement T0 were taken over and extended by the subscales “Ease of use in patients” and “Training”. Each statement was rated by the practice staff from “strongly disagree” (score of 1) to “strongly agree” (score of 5). Mean values were calculated for each subscale, which ranged from 1 (minimum) to 5 (maximum). Values <2.5 stand for a negative evaluation, values of 2.5 to 3.5 for a more or less neutral evaluation, and values >3.5 stand for a positive evaluation.

Additional interviews were conducted with patients and practices after the end of the intervention. The interview guidelines were developed within the project team. Semistructured interviews included questions about the use of the app TelePraCMan, the feasibility of the app, and questions about the integration of the app into everyday (practice) life and about its practicability. All interviews were conducted via telephone between May 2020

and October 2020. The average length of the interviews was 30 minutes (range 13-53). All interviews were digitally recorded with consent of the participants and transcribed verbatim.

Data Analysis

Descriptive statistics were calculated for all variables included in the quantitative analysis to examine means, SD, distribution for continuous variables, and frequencies for categorical data. For this analysis, we excluded the technological affinity questionnaire and a patient support questionnaire.

To examine changes in mean PAM scores and SF-12 scores before and after the intervention, we conducted a paired *t* test (2-tailed). To examine if there is a difference in the control and intervention groups after the intervention, we conducted an unpaired *t* test. $P<.05$ was considered significant in all analyses. All analyses were performed using SPSS (version 25.0; IBM Corporation).

A deductive-inductive content analysis approach was used to analyze the interview data. A preliminary category system was developed deductively based on the CFIR (Consolidated Framework for Implementation Research [20]) and the interview guide used. To inductively identify additional themes, all transcripts were read thoroughly by 3 members of the research team (AB, NL, and LG). Subsequently, all interviews were coded line-by-line using the deductively formed category system, and additional themes were inductively added where appropriate. The analyses of the three coders were compared and modified if necessary. All data were managed and analyzed using MAXQDA (version 20; VERBI GmbH).

The STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guideline was used for reporting this study [21].

Ethics Approval

Ethics approval was obtained from the Medical Ethics Committee of the Medical Faculty of Heidelberg University (S-092/2019) before the start of the study. All participants provided written informed consent before participating in the study. Research conducted in this study was performed in accordance with the Declaration of Helsinki. The study was registered in the German Clinical Trial Register (DRKS00017320).

Results

Demography

A total of 27 patients were included in the study, of whom 25 completed a questionnaire at baseline T0 and 18 completed the questionnaire at follow-up T1. Of these 18 participating patients who completed the follow-up survey at T1, 9 (50%) were included in the intervention group, which could use the TelePraCMan app, and 9 (50%) patients were included in the control group (Table 1).

The patients were mostly male (T0: 16/25, 64%; T1: 13/18, 72%), with an average age of 64 (SD 11) years at T0 and 66 (SD 12) years at T1. Most participants stated that they had ≥ 2 chronic conditions. Most of them were retired (T0: 15/25, 60%;

T1: 12/18, 67%) and had a low educational background (T0: 16/25, 64%; T1: 10/18, 56%). Nearly all of them owned a smartphone (T0: 22/25, 88%; T1: 16/18, 89%), which they used in daily life mostly often (T0: 6/25, 24%; T1: 4/18, 22%), or very often (T0: 7/25, 28%; T1: 6/18, 33%; [Table 1](#)).

A total of 24 physicians and practice assistants at T0 and 21 at T1 participated in the quantitative study. They were mostly female (T0: 15/24, 62%; T1: 13/21, 62%), with an average age

of 47 (SD 10.1) years (T0) and 49.7 (SD 11.45) years (T1; [Table 2](#)).

The 4 participating physicians and 7 practice assistants in the additional interviews were, on average, aged 50 years (range 28-73 years) and had been working in the surveyed practices for an average of 20 years (range 6-39 years). The 4 patients interviewed were all retired and, on average, aged 71 years (range 66-78 years).

Table 1. Demographics of patients participating in the quantitative survey.

Demographics	Patients at T0 (n=25)	Patients at T1 (n=18)
Age (years), mean (SD; range)	64.25 (SD 11.3; 45-83)	66.00 (SD 11.64; 45-83)
Sex, n (%)		
Female	8 (32)	5 (28)
Male	16 (64)	13 (72)
No answer	1 (4)	N/A ^a
Chronic conditions, n (%)		
One chronic condition	7 (28)	5 (28)
Various chronic conditions	17 (68)	13 (72)
No answer	1 (4)	N/A
Marital status, n (%)		
Married or cohabiting	14 (56)	11 (61)
Unmarried or single	4 (16)	2 (11)
Divorced	2 (8)	1 (6)
Widowed	4 (16)	4 (22)
No answer	1 (4)	N/A
Residential situation, n (%)		
Living alone	9 (36)	7 (39)
Living with others	13 (52)	11 (50)
No answer	3 (12)	2 (11)
Number of inhabitants in the residence, n (%)		
<5000 inhabitants	1 (4)	N/A
Between 5000 and 20,000 inhabitants	11 (44)	8 (44)
Between 20,000 and 100,000 inhabitants	2 (8)	N/A
Over 100,000 inhabitants	9 (36)	9 (50)
No answer	2 (8)	1 (6)
Educational level, n (%)		
High educational level	2 (8)	2 (11)
Middle educational level	2 (8)	2 (11)
Low educational level (eg, elementary school)	16 (64)	10 (56)
No school-leaving qualification	3 (12)	3 (17)
No answer	2 (8)	1 (6)
Employment situation, n (%)		
Working	5 (20)	3 (17)
Retired	15 (60)	12 (67)
Not economically active	4 (16)	3 (17)
No answer	1 (4)	N/A
Owner of a smartphone, n (%)		
Yes	22 (88)	16 (89)
No	3 (12)	2 (11)
Using the smartphone in daily life, n (%)		
Seldom	4 (16)	3 (17)
Sometimes	5 (20)	3 (17)

Demographics	Patients at T0 (n=25)	Patients at T1 (n=18)
Often	6 (24)	4 (22)
Very often	7 (28)	6 (33)
Missing	3 (12)	2 (11)
Group allocation, n (%)		
Intervention group	N/A	9 (50)
Control group	N/A	9 (50)

^aN/A: not applicable.

Table 2. Demographics of physicians and practice assistants participating in the quantitative survey.

Demographics	Physicians or practice assistants at T0 (n=24)	Physicians or practice assistants at T1 (n=21)
Professional qualification, n (%)		
Physician	11 (46)	8 (38)
Practice assistant	13 (54)	12 (57)
No answer	0 (0)	1 (5)
Age (years), mean (SD; range)	47.14 (10.1; 27-65)	49.74 (11.45; 29-74)
Sex, n (%)		
Female	15 (62)	13 (62)
Male	9 (37)	7 (33)
No answer	0	1 (5)
Type of medical practice, n (%)^a		
Single-handed practice	4 (36)	N/A ^b
Joint practice	6 (55)	N/A
Other	1 (9)	N/A
Number of inhabitants in the location of the medical practice, n (%)^a		
<5000 inhabitants	1 (9)	N/A
Between 5000 and 20,000 inhabitants	8 (73)	N/A
Between 20,000 and 100,000 inhabitants	N/A	N/A
>100,000 inhabitants	2 (18)	N/A

^aNumbers are referring to physicians.

^bN/A: not applicable.

Outcome Evaluation

In 10 primary care practices, a total of 141 patients with multimorbidity were asked to participate in the study. Of these 141 patients, 114 (80.8%) did not want to participate in the study. The reasons for nonparticipation were mainly that patients did not own a smartphone (53/114, 46.5%), had no interest in participation (23/114, 20.2%), or had no access to the internet (16/114, 14% [Table 3](#)).

At date T0, the mean MCS-12 score was 44.1, with a median of 43.1 across all respondents, ranging from 29.03 to 61.17. At T1, the mean MCS-12 score (39.3) was slightly lower, with a median of 39.7 across all patients, ranging from 29.81 to 57.58. On average, all participants had a PCS-12 score of 36.8, with a median of 36.7, ranging from 25.73 to 54.60. Slightly higher, at date T1, the mean PCS-12 score was 39.9, with a median of 37.3, ranging from 30.73 to 54.45 ([Multimedia Appendix 2](#)).

Table 3. Reasons for not participating in the study named by patients and documented by practice assistants (N=114).

Reasons for nonparticipation in the study ^a	Value, n (%)
Technical requirement not met: no smartphone available	53 (46.5)
No interest	23 (20.2)
Technical requirement not met: no internet accessible	16 (14)
Mentally unable	13 (11.4)
No time	5 (4.4)
Language problems	4 (3.5)
Physically unable	4 (3.5)
Need personal contact	1 (0.9)
Spouse is responsible for technical and devices	1 (0.9)

^aMultiple answers were possible.

Across all respondents, the mean PAM score was 77.9, with a median of 76.9 at date T0, ranging from 28.2 to 100. More than half (14/21, 56 %) of all participants had patient activation scores of ≥ 72.5 . Only 1 participant reported lower activation scores at level 1. The PAM score across all patients at date T1 was 82.0, with a median of 82.0, ranging from 61.54 to 100. More than a quarter (14/16, 78%) of the participants had patient activation scores of ≥ 72.5 . None of the patients reported lower activation scores for levels 1 or 2 ([Multimedia Appendix 2](#)).

There was no significant difference in outcome measures SF-12 scores and PAM scores before and after the intervention as well as in the comparison of the intervention and control groups ([Multimedia Appendix 2](#)).

Process Evaluation

The overall perception of physicians and practice assistants regarding TelePraCMan was neutral at the beginning (T0). The

mean score of the perception of TelePraCMan was 3.6, with a median of 3.6 (SD 0.33) across all practices, ranging from 3.05 to 4.52. Looking at the topics of perception in detail, the use and help of the VERAH-Portal were evaluated as the best (mean 4.5, SD 0.34), whereas the perception of the amount of work was evaluated as the worst (mean 2.7, SD 0.73; T0). After using TelePraCMan for half a year (T1), the overall perception was still neutral and slightly worsened (mean 3.3, SD 0.56). The best evaluated topic was again the use and help of the VERAH-Portal (mean 4.3, SD 0.78), whereas the worst evaluated topic was the use in the patients (mean 2.8, SD 0.6). In the free text entries, practices expressed their perception of older adult patients who need primary care and continuity and still tend to feel a general rejection toward digitalization ([Table 4](#)).

Table 4. Perception and use of TelePraCMan among physicians and practice assistants.

	Physicians or practice assistants at T0 (n=24)	Physicians or practice assistants at T1 (n=21)
Perception and use of TelePraCMan (score), mean (SD)		
VERAH ^a -Portal and practice computer	4.5 (0.34)	4.3 (0.78)
Use in target patients	3.0 (0.54)	2.8 (0.60)
Changes for patients	3.7 (0.40)	3.2 (0.80)
Amount of work (VERAH or physicians)	2.7 (0.73)	3.3 (1.32)
General assessment for VERAH or physicians	3.8 (0.79)	4.5 (0.81)
Easy use	N/A ^b	2.9 (1.10)
Training	N/A	3.6 (0.89)
Overall score (all items), mean (SD; range)	3.6 (0.33; 3.05-4.52)	3.3 (0.56; 2.50-4.37)

^aVERAH: Versorgungsassistent/in in der Hausarztpraxis.

^bN/A: not applicable.

Evaluating the UEQ, the 8 patients in the intervention group evaluated TelePraCMan as mainly positive. The mean score in the aspect of attractiveness was 1.39 (SD 0.76), in the aspect of efficiency it was 0.87 (SD 1.12), in the aspect of dependability it was 1.12 (SD 0.76), and in the aspect of stimulation it was 1.13 (SD 0.57). Only the aspects of perspicuity and novelty

were evaluated as neutral. The mean score in the aspect of perspicuity was 0.71 (SD 0.85) and in the aspect of novelty it was 0.75 (SD 0.73).

Interviews

In the interviews, we found that TelePraCMan was perceived as useful for some patients. However, contextual issues and problems with implementation negatively affected the use of the app with patients. Overall, the app and the entire project were rated as very good and important, respectively, by the respondents. However, the respondents agreed that the app would be well accepted in 5 to 10 years, as now the patients who need care still tend to feel a general rejection toward digitalization.

Implementation Activities

Regarding the implementation activities, physicians and practice assistants described the initial training as good and clear. The launching at the practice computers as well as the dealing with the VERAH-Portal were unproblematic. It was described as being easy and user-friendly.

In contrast, recruiting patients for this study was described as difficult and tedious. Practices reported on the COVID-19 pandemic as a reason for low participation of patients. Patients were rarely visiting the practice and it was less time for recruiting owing to other priorities concerning practice management in this time. Nevertheless, the narratives also focused on the fact that the wrong target group was being addressed as a reason for the low participation. Primary care workers reported that PraCMan mainly includes “high-risk” patients with multimorbidity who are commonly old, who often do not own a smartphone, or do not have access to the internet (see the Outcome Evaluation section in Results for reasons for nonparticipation). Practices reported that this group of patients was not interested or had a general rejection of digitalization. The use of smartphones or the internet was not commonplace in this target group:

Then,...came the Corona period. So, our VERAH...assured me that they addressed patients and then had the experience that those they addressed did not react positively to it, i.e., that it was not possible to convey what it was about or that a device was not even used or available. So, to say, the affinity for technology of those addressed was close to zero. But there were only four or five patients that we addressed and then it was Corona chaos anyway.... It was so that the dominance of the urgent pushed it into the background. [Physician 1]

The implementation and setup on the patients’ smartphones were mostly done together with practice assistants or friends and family. Technical problems within the first registration of the patients were observed, which could mostly be solved after consultation of the practice assistants or a project team member.

Patients’ Individual Context: Facilitators and Barriers

Barriers to the use of TelePraCMan were, in the view of the respondents, in some cases too much effort for the patients to learn how to use the app or because of the financial situation of some patients that they could not afford a smartphone. Moreover, they mentioned technical problems such as a mobile phone that was too old, problems with registration or a virus on the smartphone. A lack of patient compliance, a lack of

acceptance, or a lack of skills was also in the forefront of interviewees’ minds:

It was very complicated for those who could actually do it. You could tell that they were maybe a bit familiar with the mobile phone and that they might be able to send a message, but it was difficult to use a special app. So, I think young people up to 60 are fit, not necessarily up to 60. The young people who have just grown up with these smartphones, who know how to use apps.... There are things like health records or video conferences that you can do with your mobile phone. But for those who need a video conference because they have difficulty walking or are multimorbid, they can’t use it. So, I see that as difficult, and everyone wants that. They used to get by without a mobile phone, why should they want to use a mobile phone now? If I explain to them that we can communicate with them, then there is actually an app, or there is a mobile phone and there is an app, and we can communicate with them, no, the older people actually want to have personal contact. [Practice assistant 1]

Patients’ previous experience of using similar apps and a support network in case of technical problems were mentioned as beneficial for them and their use of TelePraCMan. Patients mentioned the simple condition of the app, which did not take much time for them. Patients also articulated enjoying the use of the app:

It may not be the same for everyone, but I had no problem with it at all and honestly, I was pleasantly surprised by the program. It was good, I enjoyed it. [Patient 1]

Impact

Different factors were mentioned regarding the impact of TelePraCMan on health care. The only negative aspect mentioned was that the physician-patient relationship could possibly deteriorate because of the personal contact and the “emotionality” that might be lost. However, one patient also found it positive that small things occurred in the app that can be discussed over the phone; for example, concerning medication.

Physicians and practice assistants also said that TelePraCMan can increase and improve the physician-patient relationship because of the fact of talking on the same information basis. The shared information could also partially change the communication by better involving the patient in the monitoring. However, some practice assistants and physicians did not perceive any changes in communication or in the monitoring appointments.

The release of data to the practice was seen as positive by all respondents. In this context, an aspect that was frequently valued was the quick detection and reaction to situations that require treatment or an intervention from a long distance. Furthermore, respondents described that the app could gain relevance in pandemic situations such as the COVID-19 pandemic because it helps to care for chronically ill patients outside the practice:

And then the person who can react to this has all the values from me and just these two three keywords that I have given to the computer in the evening via TelePraCMan, which can then be looked at by anyone who is important, so that it is not forgotten afterwards. [Patient 2]

Interviewees also supported that TelePraCMan motivated patients and thus promoted self-management and informed them about the actual state of their own health:

Right, for me it was always interesting because I could always see where I stood every week. I knew exactly when I had sinned, what I had done with my cholesterol or my sugar levels, and that was interesting. [Patient 1]

Another positive effect mentioned was that it relieved the workload of the practice assistants and physicians, as the values were directly accessible to them and did not have to be requested by the patient:

Often it's like this, you call the patient, and then the patient says "Oh yes, I'm doing so well," and then you start asking a little bit and then and "Ah yes right, there was something once." I think it would possibly also shorten the time, because you have everything at a glance, you see it, ah ok this and that happened, good, and you can deal with it straight away. And often it's like this, you're on the phone with the patients and you spend an incredibly long time...because you have to pull everything out of their noses. Not that they don't notice that they don't want to tell me, maybe it just doesn't occur to them at that moment. And so, everything would just be listed, it would all be there, this and this and this and this has already happened, the blood pressure was like this and I think that would make the work a lot easier. [Practice assistant 2]

Suggestions for improvement from the respondents were the possibility to enter the values more flexibly in terms of time, a simpler setup and registration, and that the values can be called up in the long term. Enhancements to the app were mentioned in terms of a graphical representation of the values, a pedometer, and a food diary, as well as the inclusion of the medication plan and a plan of what needs to be done if a threshold (eg, blood pressure) is exceeded.

Discussion

Principal Findings

First, the participation rate (27/141, 19.2%) was low in this study. Documentation and respondents in the interviews traced it back to the COVID-19 pandemic, as many patients asked to participate did not have an appropriate smartphone or had no interest in participation. Our quantitative findings indicate no effects on patient activation or health-related quality of life. However, the user experience of patients using the app was mainly positive. Practitioners' perceptions of TelePraCMan was predominantly neutral. Within the qualitative study, we found that the interviewees perceived that the intervention was

useful for some patients. However, contextual issues and problems with implementation negatively affected the use of the app with patients. Overall, the app and the entire project were rated as very good and important by the respondents and will be more accepted in recent years.

According to primary care workers, the COVID-19 pandemic had an impact on recruitment and the low participation rate. However, recruitment took place from November 2019 to March 2020; therefore, only the beginning of the pandemic was part of the recruitment time. Thus, the low participation rate may be due to an interaction of different factors. The primary care workers' narrative as well as the documentation of the reasons for nonparticipation revealed that the addressed target group showed other needs, as older adults commonly do not use smartphones as much as younger people. In terms of figures, 46% (53/114) of the nonparticipating patients did not own an appropriate smartphone. However, the respondents agreed that the app will be well accepted in 5 to 10 years, as now the patients who need the care still tend to feel a general rejection toward digitalization.

Comparison With Prior Work

mHealth interventions such as TelePraCMan are often not used in the "real" world [22]. Therefore, it is crucial to check the development and implementation for understanding and learning for future digital projects. For this purpose, the person-based approach for digital interventions from Yardley et al [23] can be used. The approach reflects the four stages: planning, design, development and evaluation of acceptability and feasibility, and implementation and trialing of an intervention; and offers a systematic means of addressing the user experiences.

The target of the planning phase is to identify the key behavioral needs and issues the challenges have to address, mainly via qualitative research [23]. Within TelePraCMan, primary care physicians, VERAHs, and patients were involved in the development of TelePraCMan via focus groups, interviews, and questionnaires to gain insights to their wishes and needs [13].

In the design phase, it is crucial to create guiding principles for the developers with the features of the intervention [23]. Within TelePraCMan, the evaluations of the previously named data sources were combined in the project team, and a concept for the app was derived. This concept was first translated into a paper prototypes. These paper prototypes served as the basis for further short interviews with patients and teams in primary care practices. These results were then used to design the app in the form of so-called "action sheets." These comprised relevant features, characteristics of the target group, potential barriers and facilitators, and possible variations for each page of the app. This process allows apps to be tailored to the specific target group [24]. The action sheets were given as a list of requirements to the computer scientists who programmed a prototype of the app based on them. Throughout the process, all scientists and programmers worked closely together. In addition, primary care physicians were involved in the process as experts.

In the development and evaluation phases of acceptability and feasibility, the intervention components should be evaluated

and optimized from the user perspective via user reactions to every intervention element and detailed longitudinal mixed methods case studies. Within TelePraCMan, the app prototype was initially tested by employees of the department. After appropriate adjustments, the prototype was tested during an advanced training course of the department with primary care physicians and VERAHs. These test runs were performed without initial explanations or instructions to enable the most intuitive handling. Comments, questions, uncertainties, or technical problems of the test runs were recorded in writing, evaluated, and adjusted in the app together with the computer scientists. With regard to the person-based approach, we realized the analyzing of the user reactions but did not perform an iterative cycle moving between user feedback and changes to the intervention and did not perform longitudinal case studies where the target group could use the app at a certain time on their own. Performing these two aspects may have led to improvements of the app and insights into how the target group of patients with chronic diseases perceive and use the app. We might also gain insights into their internal motivation for using the app and may gain ideas of the target group to motivate other people to participate in the study.

In the implementation and trialing phase, the intervention should be evaluated in real life via mixed methods process analyses to identify further modifications for future implementations [23]. Within TelePraCMan, a randomized controlled trial and a process evaluation were performed, and the results are included here and discussed in comparison with prior work.

Although data from the German Federal Statistical Office showed that the number of people owning a smartphone declines with increasing age [25], the latest survey from the German Federal Statistical Office [26] concerning the use of information and communication technologies in private households showed that in extrapolations, 10,683 of 16,640 (64.2%) people aged ≥ 65 years used the internet for private concerns. Of these 10,683 people, 74% (7905/10683) used a smartphone to access the internet for private concerns, but only 3% used devices connected to the internet for monitoring of blood sugar, blood pressure, or weight [26]. Nevertheless, the data from the German Federal Statistical Office showed that older adults are not commonly averse to use smartphones. In contrast, primary care workers in our study raised concerns that digitalization is widely implemented in the health care sector; still, there are people who need the interventions the most but are not able or not ready to use mHealth interventions. It remains open how to deal with and meet the concerns of this patient group in relation to eHealth and mHealth. Addressing their concerns during the recruitment phase may have enhanced participation.

A study by Steele Gray et al [27] evaluating a tool of electronic patient-reported outcomes in a 4-month trial showed no changes in outcomes of patient activation and quality of life, which was traced back to the small sample size of the study. The authors also explored factors for nonparticipation, these were mainly that patients were overwhelmed with the management of their diseases and patients did not want to add another responsibility, unawareness of having health goals they could facilitate, no self-identification with having a chronic condition, and only in fourth place concerns and less experience with technology [27].

In contrast, the most frequent reason for nonparticipation in our study was the unavailability of an appropriate smartphone or internet access as well as uninterest in participation. The unavailability might be an ostensible reason for patients, so they do not have to tell that they are already overwhelmed with their management of their diseases. It is questionable whether the use of smartphones in our study would have increased participation. A previous study with potential users of TelePraCMan found that older patients with multimorbidity preferred personal support over internet-based support [13]. In every case, the information on the benefits of using an mHealth tool could be facilitated for older patients. This was also found in a larger trial concerning a telehealth service with regular phone calls and standardized scripts, where 609 patients with depression and 641 patients with cardiovascular disease were recruited, showing only modest effect for self-management [10]. In an embedded qualitative study with practitioners and patients, they found that contextual issues in patients' lives, such as motivation to improve their health or the interest in the intervention, as well as some problems with implementation reduced the impact. Furthermore, the authors concluded that to enhance patient engagement in telehealth-motivated staff that offer the intervention with continuity is a crucial factor. Moreover, the intervention should be tailored to individual patients' needs as well as the content, time required, and benefits should be clearly communicated to potential users [10].

Another crucial point discussed in the interviews was the possible loss of the physician-patient connection and the influence on communication. Our findings are supported by a study with nurse practitioners, which found that they believed that it is difficult to communicate by telehealth owing to difficulty in perceiving nonverbal signals. They concluded that interpersonal communication should be a part of their professional training [28]. Some participants in our study feared the loss of the connection, whereas others pointed out that the app could facilitate communication since patients and providers are talking on the same information basis. The aim of the study was not to replace consultations but to make it easier for patients to spend time between appointments, so only the information basis changes, which was described as positive from respondents. A study from China found that face-to-face patient-provider communication had a positive and direct effect on web-based patient-provider communication at a later point. In addition, patient trust and patient satisfaction had a positive impact on the relationship between face-to-face and web-based patient-provider communication [29]. This could also apply to our participants as chronically ill patients who often have a strong connection with their primary care physicians.

We also collected data on practitioners' perceptions on the app. We found that after using TelePraCMan for half a year, the overall perception was neutral. Primary care workers evaluated the use and help of the portal where they could see patients' data the best but were skeptical for the use of patients. Our findings are supported by a systematic review on factors that could facilitate or act as a barrier for health professionals to use mHealth in their work. They found various factors at the individual, organizational, and contextual levels associated with

the use of mHealth tools. The most important factors were usefulness and ease of use of the app in patients [30].

Strengths and Limitations

One strength of this study was the inclusion of different perspectives via primary care physicians, practice assistants, and patients using the intervention in both parts of the study. One of the most important limitations in our study, which we already named, is the small sample size in the quantitative part, which was only partly contingent on the COVID-19 pandemic. Owing to the small sample size, the values had to be interpreted very carefully, as the coefficients may result solely from sampling effects. Furthermore, transferability and comparability with other samples may not be possible. However, the data from the process evaluation served as a possible explanation for the outcome evaluation and provided deeper insight.

Conclusions

This prospective observational study is one of the first studies concerning an mHealth intervention for chronically ill patients in a primary care setting in Germany. The app TelePraCMan was developed involving physicians, practice assistants, and patients and was adapted to their demands. However, this study showed that it was hardly implemented. Owing to the small sample size, the effects on patient activation and quality of life could not be determined. Currently, this app may be a support system for only a few patients in the target group. Future interventions should facilitate the information on the benefits of using an mHealth tool for older patients, and it is crucial to involve motivated staff who offer the intervention with continuity to the patients. Overall, the app and the entire project were rated as very good and important by the participants. However, the respondents agreed that the app would be well accepted in 5 to 10 years, as now the patients who need the care still tend to feel a general rejection toward digitalization.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Screenshots of TelePraCMan.

[[DOCX File , 151 KB - formative_v6i8e34786_app1.docx](#)]

Multimedia Appendix 2

Results of the outcome measures and comparison of patient outcomes before (T0) and after (T1) the intervention and between the intervention and control group.

[[DOCX File , 14 KB - formative_v6i8e34786_app2.docx](#)]

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Abbreviations

CFIR: Consolidated Framework for Implementation Research

MCS: mental component summary

mHealth: mobile health

PAM: patient activation measure

PCS: physical component summary

SF-12: 12-Item Short Form Survey

STROBE: Strengthening the Reporting of Observational Studies in Epidemiology

UEQ: User Experience Questionnaire

VERAH: Versorgungsassistent/in in der Hausarztpraxis

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Original Paper

Heart Rate Variability Biofeedback to Treat Anxiety in Young People With Autism Spectrum Disorder: Findings From a Home-Based Pilot Study

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Abstract

Background: People with autism spectrum disorder (ASD) frequently experience high levels of anxiety. Despite this, many clinical settings do not provide specialist ASD mental health services, and demand for professional support frequently outstrips supply. Across many sectors of health, investigators have explored digital health solutions to mitigate demand and extend the reach of professional practice beyond traditional clinical settings.

Objective: This critical appraisal and pilot feasibility study examines *heart rate variability (HRV) biofeedback* as an approach to help young people with ASD to manage anxiety symptoms outside of formal settings. The aim is to explore the use of portable biofeedback devices to manage anxiety, while also highlighting the risks and benefits of this approach with this population.

Methods: We assessed the feasibility of using home-based HRV biofeedback for self-management of anxiety in young people with ASD. We adopted coproduction, involving people with ASD, to facilitate development of the study design. Next, a separate pilot with 20 participants with ASD ($n=16$, 80% male participants and $n=4$, 20% female participants, aged 13-24 years; $IQ>70$) assessed adoption and acceptability of HRV biofeedback devices for home use over a 12-week period. Data were collected from both carers and participants through questionnaires and interviews; participants also provided single-lead electrocardiogram recordings as well as daily reports through smartphone on adoption and use of their device.

Results: Pre-post participant questionnaires indicated a significant reduction in anxiety in children ($t_6=2.55$; $P=.04$; Cohen $d=0.99$) as well as adults ($t_7=3.95$; $P=.006$; Cohen $d=0.54$). Participant age was significantly negatively correlated with all HRV variables at baseline, namely high-frequency heart rate variability (HF-HRV: $P=.02$), the root mean square of successive differences in normal heartbeat contractions (RMSSD: $P=.02$) and the variability of normal-to-normal interbeat intervals (SDNN: $P=.04$). At follow-up, only SDNN was significantly negatively correlated with age ($P=.05$). Levels of ASD symptoms were positively correlated with heart rate both before ($P=.04$) and after the intervention ($P=.01$). The majority (311/474, 65.6%) of reports from participants indicated that the devices helped when used. Difficulties with the use of some devices and problems with home testing of HRV were noted. These initial findings are discussed within the context of the strengths and challenges of remotely delivering a biofeedback intervention for people with ASD.

Conclusions: HRV biofeedback devices have shown promise in this pilot study. There is now a need for larger evaluation of biofeedback to determine which delivery methods achieve the greatest effect for people with ASD.

Trial Registration: ClinicalTrials.gov NCT04955093; <https://clinicaltrials.gov/ct2/show/NCT04955093>

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KEYWORDS

autism; anxiety; biofeedback; remote intervention; mobile phone

Introduction

Background

Autism is a lifelong developmental disability that affects how people communicate and interact with the world [1]. Substantial changes to how autism is understood and defined have taken place over the years since the term was initially described [2]. Autism is currently viewed as a neurodevelopmental disorder that develops in childhood, and the terms *Kanner autism*, *Asperger disorder*, *childhood disintegrative disorder*, and *pervasive developmental disorder not otherwise specified* have been replaced with the collective term *autism spectrum disorder* (ASD) [3]. All participants in this study had been diagnosed with ASD in specialist health service assessments clinics using standardized measures. None of the participants were diagnosed with a learning disability, and all had attended mainstream education. Although the term Asperger syndrome is still used by both clinicians and some able people with autism, the term ASD will be used throughout this paper to describe the condition.

Approximately 1% of the British population are likely to have some form of ASD, with studies reflecting this prevalence both in children [4] and adults [5]. Epidemiological studies have shown a dramatic increase in the numbers of people being diagnosed with ASD. In the United States, the Centers for Disease Control and Prevention reported a prevalence rate of ASD in children of 1 in 88 [6], which was updated to 1 in 59 in 2018. The reasons for these apparent increases have been debated but may be related to changing definitions of the disorder, increased awareness of the condition in women, and recognition of the condition in people with no learning disability [7].

People with ASD can experience a range of mental health difficulties [8,9] and present with high levels of anxiety [10]. A range of interventions exist to treat anxiety in ASD [11]. There is some evidence for effectiveness of nonpharmacological interventions such as cognitive behavioral therapy adapted for people with ASD [12], but availability of such interventions is limited by poor adoption rates [13] and scarcity of mental health services for people with ASD [14].

There is evidence that digital health interventions can aid compliance with traditional treatments and help to reduce increasing demands on health provision, while extending the reach of professional practice beyond traditional clinical settings [15].

Digital Health Interventions

Digital solutions can be tailored to the needs of people with ASD and can be associated with less stress than that reported in face-to-face interventions [16]. Technology may be used both to deliver interventions and augment communication and social interaction [17]. Emerging digital health interventions are being investigated to help those with ASD to understand and control their reactions [18] and to help them better interpret social situations [19]. A type of intervention that has been found to

reduce symptoms of anxiety in a range of populations makes use of *biofeedback* [20,21], which has been defined as “a self-regulation technique through which patients learn to voluntarily control what were once thought to be involuntary body processes” [22]. Biofeedback actively involves the user, enabling them to change certain physiological responses to improve health [23].

Biofeedback

A variety of biofeedback equipment now exists for both psychophysiological stress profile assessment [24] and for biofeedback training [23], typically categorized into two types: large professional systems and small portable devices intended for personal use. Treatment protocols exist for a wide range of physical and mental health conditions, using either a single sensor or multiple sensors with evaluations of efficacy for each condition [25].

Although biofeedback has been used since the 1970s, there is now growing interest in its use in stress management [26]. Several systematic reviews highlight evidence supporting biofeedback as a cost-effective intervention to help manage anxiety in clinical populations [21,27]. A review of the types of biofeedback modalities and devices currently being evaluated for stress management has been carried out by Yu et al [28]. Many devices have only been tested in nonclinical populations or in laboratory environments, and the importance of testing devices in real-world situations with diverse types of clinical populations has been noted [29].

To date, the most widespread use of biofeedback in individuals with ASD has involved the use of neurofeedback [30,31]. Recent studies show some positive effects in areas such as attention and social skills; however, systematic reviews investigating neurofeedback in ASD have not shown significant results in reducing symptoms such as anxiety [32,33]. An alternative type of biofeedback that has been used to manage anxiety has been termed *resonant frequency feedback*, more commonly known as *heart rate variability* (HRV) biofeedback [34].

HRV Biofeedback

HRV was first recognized 60 years ago as an indicator of fetal distress [35] and then found to be affected by breathing frequency [36]. HRV reflects the activity of both the sympathetic and parasympathetic activities of the autonomic nervous system and is reported in both time and frequency domains [37]. A review of HRV metrics has been produced [38], with population norms identified [39]. HRV is affected by age [40], the environment, breathing rate, and blood pressure, and it is subject to regulation of the autonomic nervous system [41]. HRV is frequently used as a physiological marker in stress detection [42]. It is also an index of adaptability and of the ability to self-regulate behavior [43].

A number of theoretical models have been proposed describing the links between HRV and health, mediated through connections between the heart and the brain [44,45]. The polyvagal theory suggests that impairments in the autonomic

nervous system involving vagus nerve regulation, termed the *social engagement system*, are features of several disorders, including ASD.

HRV has been used in conjunction with sensor technology to develop *HRV biofeedback* [46,47]. Training in HRV biofeedback involves *resonant frequency breathing*, which has been associated with *respiratory sinus arrhythmia* where heart rate acceleration and deceleration rates synchronize with respiration and occur when breathing is slowed to a rate between 4.5 and 7.0 breaths per minute [41]. To support the maintenance and development of resonant frequency breathing, individuals can practice paced breathing or use portable *home trainer* biofeedback devices.

Portable biofeedback devices typically derive HRV using infrared photoplethysmography (PPG), which measures blood flow, usually through either the fingertip or the earlobe. Peripheral blood flow can be used to assess heart rate and to estimate HRV [23]. Several such devices conform with health, safety, and environmental protection standards. They can be adjusted by the user to different breathing rates but are usually set at a default rate of 6 breaths per minute. Assessment of the accuracy of some devices has also been carried out [48,49]. A growing number of research studies have also now investigated their effectiveness when used as stand-alone interventions.

There are wide variations in study design, using different devices, training protocols, and outcome measurements. Nevertheless, systematic reviews and meta-analyses have concluded that HRV biofeedback can be an effective treatment for symptoms in a range of different populations, including both adults [20,21] and children [50]. Providing interventions for symptoms such as anxiety that affect people with ASD has been emphasized as a vital area for research [51], and reviews have acknowledged the need to involve the ASD community directly in research [52,53]. HRV biofeedback has been used in a range of populations for anxiety management. To date, no studies have investigated the feasibility of using portable biofeedback devices as a home-based intervention to help people with ASD manage anxiety.

For people with ASD, biofeedback may provide specific advantages for the management of anxiety. First, it provides a technique for developing control over specific symptoms without the need for verbally based techniques designed for non-ASD populations or behavioral interventions that may be anxiety provoking for people with ASD [54]. Second, biofeedback can present structured visual information in a systematic manner, a factor suited to the typical communication strengths of people with ASD. Third, biofeedback also aims to increase awareness of physiological reactions, which can be reduced or impaired in people with ASD [55].

Finally, people with ASD show a range of different physiological reactions compared with non-ASD peers [56]. The different HRV responses of people with ASD have been debated [57,58]. Further investigation into interventions to help improve *interoceptive ability* or to develop physiological reactions may be particularly important for this population.

Accordingly, we proceeded with an exploratory study to investigate the use of HRV biofeedback outside of clinical settings as a potential intervention to help people with ASD by reducing symptoms of anxiety.

Methods

Overview

The aim of this pilot and feasibility trial comprised two main objectives: first, to explore the use of HRV biofeedback as a suitable methodology to support people with ASD to manage anxiety outside of clinical settings and, second, to assess the risks, benefits, and challenges of using HRV biofeedback within this population.

We involved adults with ASD and professionals working in the field in the initial study development and design. We then recruited a separate group of young people with ASD in an experimental design with appropriate pre- and postintervention outcome measures.

We recorded demographic data and mental health status and used participant anxiety and depression as the primary outcome measures. Statistical analyses were carried out to assess mean group differences in reported anxiety and depression. A per-protocol analysis was used. This led to several participants being excluded after randomization because they met the exclusion criteria, and their pre-post data were therefore not included in the quantitative data analysis. The pre-post data sets were analyzed using a standard statistical package (SPSS software [version 24.0; IBM Corp]). Correlational analyses were also used to review associations between baseline measurements and HRV data.

To assess the risks, benefits, and challenges we used several methods of data collection, including daily monitoring of device use, perceived participant stress levels using a questionnaire delivered through smartphone, standardized interviews, and short debriefing reports. Participants who dropped out early or had continuing difficulties using their biofeedback device or had electrocardiogram (ECG) recording difficulties after randomization had their monitoring data included for further analysis, provided that they had consented for these data to be collected. The aim of the study was to ensure methodological robustness and feasibility, with a focus upon potential risks, problems, or difficulties as well as potential benefits of using HRV biofeedback.

Participants

The sample was drawn from a population of patients with an existing diagnosis of ASD who had attended regional health services for help with anxiety. The young people with ASD were invited to participate in experimental adoption of a portable HRV biofeedback device over a 12-week period. All participants in this study had been diagnosed with ASD in specialist health service assessments clinics using standardized measures. None had a learning disability, and all had attended mainstream education. Additional preassessment screening of participants was carried out using the *Social Communication Questionnaire* [59], yielding a mean score of 20, which is above the cutoff level for diagnosis of ASD. Participants were excluded if they

had pre-existing addiction; a diagnosed cardiac condition; a learning disability; or where suicidal risk, psychosis, or severe eczema or psoriasis had been noted; or if they were taking medications known to suppress HRV, such as benzodiazepines or tricyclic antidepressants [60]. All participants received appropriate information about the study and gave consent or assent in addition to consent from a parent or carer. No incentives were offered for participation.

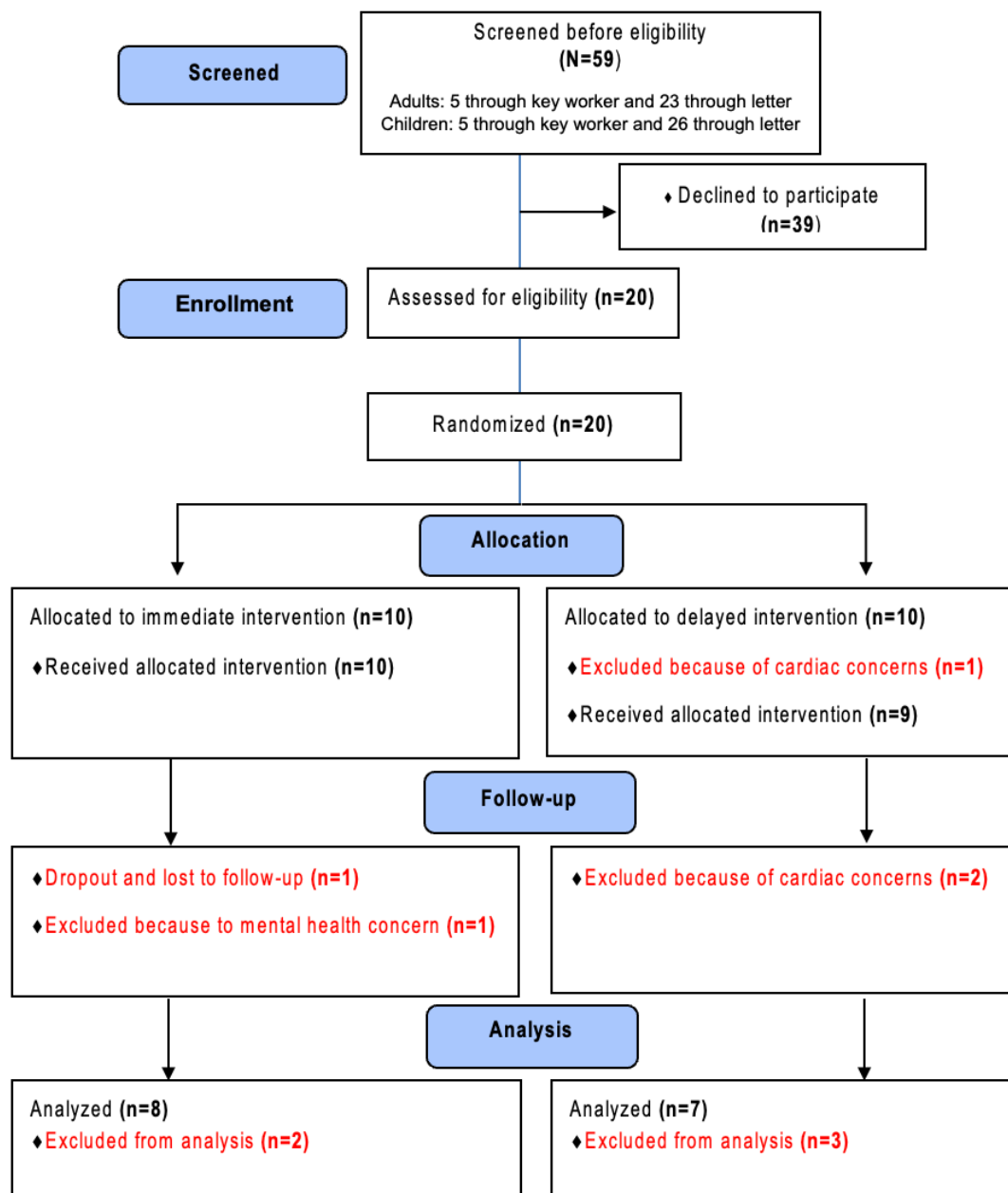
Ethics Approval

Ethics approval was granted by the regional National Health Services ethics committee (15/NI/0255; IRAS: 139122). After review by the regional National Health Services ethics committee, approval was granted under the UK governance arrangements for research ethics committees.

Recruitment

Potential participants were recruited using two methods: either through direct contact with their therapist or through letters sent to patients who were already discharged. It was not possible to determine the exact reasons for nonparticipation in the study because of the ethical constraints regarding contacting those who declined to participate through their therapist or those who did not respond to the invitation letters. Initially, 20 people took part: 16 (80%) male participants and 4 (20%) female participants. Their ages ranged from 13 to 22 (mean 16.2, SD 2.63) years. Detailed demographic information is presented in [Multimedia Appendix 1](#) [61], and participant flow through the study is presented in [Figure 1](#).

Figure 1. CONSORT (Consolidated Standards of Reporting Trials) flow diagram summarizing the processes adopted for screening and enrollment, allocation into groups, follow-up, and final analysis. Participant numbers are provided for each stage.



Randomization

To decrease the risk of group allocation bias, random assignment to treatment group or control group was carried out *after* all preintervention assessments; therefore, the researcher was initially blind to who was allocated to each group during all baseline assessments.

Allocation was made in blocks to ensure that adequate numbers of participants were allocated to each condition. A randomized number sequence was generated through computer.

Between-group comparisons were planned to compare 6 weeks of intervention in the immediate group with 6 weeks of no intervention in the delayed group. The small sample size and additional exclusions from the study prevented these comparisons from being carried out.

Equipment

HRV home trainer devices differ in terms of form, feedback mechanisms, data storage, training guidelines, and underlying software, all of which may affect user experience and effectiveness. For this study, biofeedback devices were selected based on evidence of their use in previous research. To explore whether these aspects were of any concern, participants were allocated to 1 of 2 different biofeedback devices (Figure 2).

Group A participants were provided with a home trainer biofeedback device that used PPG ear sensors [62]. Group B participants were provided with a home trainer biofeedback device that used a fingertip PPG sensor contained within a stand-alone device [63]. A wireless single-lead ECG recorder, worn on the chest, was used to measure participant heart rate and HRV from a single lead before and after the intervention [64]. This lightweight device is battery powered and does not require any external leads or Velcro to connect to the recorder.

Figure 2. We used 2 personal home trainer devices to provide biofeedback during pilot testing: StressEraser, left, and Inner Balance, right (Inner Balance image reproduced with permission of HeartMath).



Measures

Participants were invited to complete anxiety and depression questionnaires before and after the intervention. The measures included *Beck Anxiety Inventory* [65], *Beck Depression Inventory-II* [66], and *Beck Youth Inventories-II* for people aged 13 to 17 years [67] as appropriate to age. The parent or family carer was also invited to complete short before-and-after interviews, rating any changes in participant behavior over the course of the intervention period.

During the intervention period, participants were asked to complete short daily reports on stress levels and device use. This enabled us to track participant stress levels and monitor perceived usefulness of the device. The progress report was devised based on initial phase 1 evaluations and served a 2-fold purpose: tracking participant stress levels and monitoring use of the device over the course of the intervention. This short

report asked questions on sources of stress, levels of stress, and use of the biofeedback device.

At the end of the intervention, participants and carers independently completed a short debriefing interview, and participants completed equipment usability ratings using the *System Usability Scale* [SUS]. This questionnaire provides a standardized assessment of the usability of different technology products [68]. The scale comprises 10 short statements rated on a 5-point scale. Item scores are summated and then rescaled in the range from 0 to 100, with higher scores indicating higher usability. Empirical evaluations of the SUS indicate good reliability [69]. A summary of the measures used is provided in [Multimedia Appendix 2](#) [70,71,65,66,67,72,73,68].

Intervention

All participants were offered initial assessment and training in their own home, with their carer present. This was carried out

by a chartered clinical psychologist with certified training in HRV biofeedback (HC). The training involved sending video clips and written instructions produced by the device manufacturers to participants before an agreed home visit in which a direct demonstration of device use was given. Participants were then all seen and assessed by the first author (HC) who offered 2 training sessions (lasting for 30 minutes each) of home instruction in use of the allocated biofeedback device. No other intervention regarding anxiety management was provided. The HRV biofeedback intervention was available to use daily for a period of 12 weeks. Self-tailoring of intervention intensity was allowed to gauge acceptability and record self-reported compliance. Use was encouraged by the first author (HC) at the outset and indirectly through monitoring uptake. Information on participant anxiety and depression was collected through questionnaire measures completed before and after the intervention.

Participant HRV was measured in the home through a psychophysiological stress profile assessment using a single-lead ECG recorder before and after the intervention. Once the intervention commenced, remote monitoring continued daily, using SMS text message prompting at preset intervals agreed with participants. Questions used to monitor use of the intervention were sent to participants at an agreed time in the evening, recording whether they had used the device that day and whether it had been perceived as useful. Finally, additional information on risks, perceived problems, and benefits of the intervention and equipment usability was collected in face-to-face interviews with participants and their carers at the end of the intervention. This information was also collected from those who dropped out and those whose pre-post data were excluded, provided they consented to provide these data. This was seen as crucial to capture information on any potential difficulties and ensure a representative assessment of risks and benefits. Further details on the intervention are presented in the CONSORT (Consolidated Standards of Reporting Trials) and Template for Intervention Description and Replication checklists ([Multimedia Appendices 3 and 4](#)) and the study protocol ([Multimedia Appendix 5](#) [68,74,75,76,64,77,73,78,79,24,80,81,82]).

Results

Demographic Information

All participants were nonsmokers, and none reported taking illegal drugs. Of the 20 participants, 10 (50%) reported prescribed medication. Of these 10 participants, 6 (60%) were prescribed selective serotonin reuptake inhibitor antidepressants, and 4 (40%) took stimulant medication. Sleep disturbance was reported by 75% (15/20) of the participants; 15% (3/20) reported

needing to carry auto injectors with adrenaline (EpiPen). Of the 20 participants, 16 (80%) were employed or were students.

Carers were asked standardized questions regarding their main concerns about participant behavior, including whether there were any triggers for participant anxiety attacks or *meltdowns* and any strategies used to manage anxiety. The main concern reported was anxiety. The main triggers for anxiety attacks reported by 70% (14/20) of the families were sensory issues such as “loud noise,” “bright lights,” or “touch”; other triggers reported were “changes in routine” and increases in workload or examinations. Busy or crowded places, for example, “shopping centers” or *school*, were also mentioned as frequent triggers for anxiety by 55% (11/20) of the families. The most frequently reported strategy to help manage anxiety described by 85% (17/20) of the families involved reducing sensory information; for example, “reduce noise” or “turn down lights.” Other strategies reported were engaging in favorite activities or physical activity, spending time with parent or carer or pet, listening to music, and escaping from the source of stress by fighting or running away. All carers and participants reported more than one strategy for managing anxiety.

Participant Anxiety and Depression

Of the 20 participants, 4 (20%) were excluded after randomization because of the identification of cardiac concerns ($n=3$, 75%) and significant mental health concerns ($n=1$, 25%), whereas 1 (5%) dropped out and declined further questionnaire and physiological assessment, leaving 15 participants ($n=11$, 73%, male participants and $n=4$, 27%, female participants) for before-and-after data analysis ([Figure 1](#)).

Statistical analyses were carried out using SPSS software (version 24.0) to assess mean group differences in reported anxiety and depression. Parametric statistical tests were conducted using paired sample 2-tailed t tests. Anxiety scores at baseline did not deviate from normality on either the Kolmogorov-Smirnov test ($P=.20$) or the Shapiro-Wilk test ($P=.23$). As different measures were necessarily used for children and adults, separate analyses were performed for these groups.

Of the 15 participants, 1 (7%) adult participant did not complete the initial depression questionnaires: 14 sets of depression data were analyzed. Parametric statistical tests were also conducted using paired sample 2-tailed t tests. Again scores at baseline did not deviate from normality on either the Kolmogorov-Smirnov test ($P=.20$) or the Shapiro-Wilk test ($P=.78$).

Data collected from children and adults showed statistically significant reductions in mean score for anxiety after the intervention; the results for both adults and children showed no significant reduction in mean scores for depression ([Table 1](#)).

Table 1. Participant questionnaire data showing mean scores for anxiety and depression before and after using heart rate variability biofeedback (N=15).

Participants (aged 13-24 years)	Before the intervention, mean (SD)	After the intervention, mean (SD)	Mean difference (SD)	Coefficient, <i>r</i>	<i>t</i> test (<i>df</i>)	<i>P</i> value (2-tailed)	Cohen <i>d</i> (adjusted)
Anxiety							
BYI-A ^a (children: n=7)	24.43 (8.98)	14.43 (10.97)	10.00 (10.39)	0.472	2.55 (6)	.04	0.99
BAI ^b (adults: n=8)	21.12 (11.2)	15.00 (11.49)	6.12 (4.39)	0.925	3.95 (7)	.006	0.54
Depression							
BYI-D ^c (children: n=7)	20.43 (14.04)	13.71 (14.16)	6.71 (9.53)	0.077	1.86 (6)	.11	0.48
BDI ^d (adults ^e : n=7)	17.0 (12.74)	13.86 (10.91)	3.14 (4.85)	0.928	1.72 (6)	.14	0.25

^aBYI-A: Beck Youth Inventory, Anxiety scale.

^bBAI: Beck Anxiety Inventory.

^cBYI-D: Beck Youth Inventory, Depression scale.

^dBDI: Beck Depression Inventory.

^eAn adult participant did not complete the depression questionnaire.

Carer Reports on Behavior

Carers were asked to rate the frequency of participant behavioral outbursts or meltdowns at the initial and debriefing interviews. Carer ratings indicated a significant reduction (Wilcoxon signed-rank test) in the frequency of behavioral outbursts comparing initial interview data with debriefing interview data ($Z_{14}=-3.33$; $P=.001$; $r=0.6$).

ECG Assessment

Attempts were made to record wireless ECG data to detect changes in HRV over time using a psychophysiological stress test [24] before and after the intervention, but it was not possible to standardize this procedure because of the wide variations in the timing of assessments, differing home environments, and

the use of HRV data from both children and adults. However, baseline ECG recordings did enable within-subject comparisons. Pearson bivariate correlations compared heart rate and HRV variables with age and level of ASD symptoms (Table 2). Before the intervention, age was significantly negatively correlated with all HRV variables at baseline, namely high-frequency heart rate variability ($P=.02$), the root mean square of successive differences in normal heartbeat contractions ($P=.02$) and the variability of normal-to-normal interbeat intervals ($P=.04$). ASD symptoms were positively correlated with heart rate both before ($r=0.54$; $P=.04$) and after the intervention ($r=0.74$; $P=.001$), and negatively correlated with HF HRV recorded at the final assessment ($r=-0.56$; $P=.03$). In addition, HRV indices were negatively correlated with heart rate both before and after the intervention.

Table 2. Pearson bivariate correlation statistics before and after the intervention between physiological measures of heart rate and heart rate variability recorded with participant age and level of ASD (autism spectrum disorder) symptoms as measured by the Social Communication Questionnaire [59].

	Age	ASD	HF-HRV ^a	RMSSD ^b	SDNN ^c	HR ^d
Age						
Before the intervention	1	-0.250	-0.580 ^e	-0.596 ^e	-0.548 ^e	-0.001
After the intervention	— ^f	—	-0.389	-0.381	-0.522 ^e	-0.062
ASD^g						
Before the intervention	—	1	-0.221	-0.134	-0.184	0.541 ^e
After the intervention	—	—	-0.557 ^e	-0.442	-0.504 ^e	0.743 ^h
HF-HRV						
Before the intervention	—	—	1	0.929 ^h	0.902 ^h	-0.562 ^e
After the intervention	—	—	—	0.892 ^h	0.905 ^h	-0.733 ^h
RMSSD						
Before the intervention	—	—	—	1	0.946 ^h	-0.514 ^e
After the intervention	—	—	—	—	0.910 ^h	-0.616 ^e
SDNN						
Before the intervention	—	—	—	—	1	-0.465
After the intervention	—	—	—	—	—	-0.694 ^h
HR						
Before the intervention	—	—	—	—	—	1
After the intervention	—	—	—	—	—	—

^aHF-HRV: high-frequency heart rate variability (a frequency domain index that can indicate parasympathetic nervous system activity).

^bRMSSD: root mean square of successive differences in normal heartbeat contractions or interbeat intervals measured in milliseconds (a time domain heart rate variability index that can be associated with parasympathetic nervous system activity).

^cSDNN: SD of the normal heartbeat contractions; that is, normal-to-normal interbeat intervals measured in milliseconds.

^dHR: heart rate measured in beats per minute.

^e $P < .05$ (2-tailed).

^fNot applicable.

^gAutism spectrum disorder symptomatology measured using the Social Communication Questionnaire [59].

^h $P < .01$ (2-tailed).

Adoption of Biofeedback Device During Intervention

Across the study, 474 web-based surveys were collected providing data on sources of stress and use of biofeedback devices throughout the intervention period. Participants who had difficulties using their biofeedback device or ECG recorder had their monitoring data included, provided they had consented.

Participants were asked during the intervention period whether the device had helped them when used. The majority (311/474, 65.6%) of the reports provided indicated that the biofeedback

device had been used and that “it helped” when used. Only 4% (19/474) of the reports indicated that the device “didn’t help” when used. Regarding use, 88% (417/474) of the reports indicated that the device had been used for between 0 and 10 minutes, with 12% (57/474) of the reports indicating that the device had been used for >10 minutes.

Participants were also asked to report the reasons for not using the device. A summary of 144 reports provided by participants detailing a range of reasons is presented in Table 3.

Table 3. Participant reported effect of biofeedback device when used (n=144).

Reported reason for not using device	Responses, n (%)
“Not stressed” today	65 (45.1)
No clear reason given	24 (16.7)
“Busy” or “away”	20 (13.9)
“Device not with me”	17 (11.8)
“Forgot to use”	9 (6.2)
“Practicing later”	6 (4.2)
“Error on device”	3 (2.1)

The most frequent reason reported for not using the device was simply that the participant did not feel stressed. Other reasons reported were “too busy” (20/144, 13.9%), “device not with me” (17/144, 11.8%), “forgot to use it” (9/144, 6.3%), “practicing the device later” (6/144, 4.2%), and “error on device” (3/144, 2.1%). Of all reports submitted, 16.7% (24/144) offered no clear reason for not using the device.

Equipment Usability

Usability ratings were captured on the 2 biofeedback devices, an ECG recorder, and a web-based survey (Table 4). The benchmark for the SUS is 68, with scores above this value considered to be acceptable [83]. Average ratings for the equipment used in this study indicated good usability.

Table 4. Participant ratings of 2 types of biofeedback devices, an electrocardiogram (ECG) recorder, and SMS text monitoring using the System Usability Scale (SUS) [68].

Type of equipment used ^a	SUS score, mean (SD; range)	Benchmark SUS score ^b , mean (SD)
StressEraser (n=9)	76.60 (16.25; 47.5-92.5)	68 (12.5)
Inner Balance (n=9)	83.61 (8.94; 70.0-92.5)	68 (12.5)
Actiwave ECG recorder (n=9)	70.00 (7.80; 60.0-77.5)	68 (12.5)
SMS text message survey (n=15)	78.50 (9.05; 65.0-100.0)	68 (12.5)

^aA total of 18 ratings of biofeedback devices were completed: 9 for StressEraser and 9 for Inner Balance; 9 ratings were completed regarding the electrocardiogram recorder; and 15 ratings were completed regarding the SMS text message report.

^bBenchmark calculation of average SUS scores [83].

Risks and Benefits

During the debriefing at the end of the study, participants and carers reported perceived benefits and any problems. Unexpectedly, many of the participants reported cold fingers during initial training, with 70% (7/10) of those initially allocated to the StressEraser reporting difficulty using this device at some point during the study.

Clinical disclosures included previously unrecognized cardiac irregularities (3/20, 15%) and severe mental health difficulties

(1/20, 5%). These were identified *after enrollment* after initial screening.

A range of positive benefits were reported by both participants and their carers, with the most frequent benefit reported being feeling *calm* or *relaxed*. A smaller number of problems were reported overall, mainly relating to difficulties with the fingertip sensor device. The results presented in Tables 5 and 6 show the frequency counts of key phrases reported in debriefing reports from participants.

Table 5. Participant reported problems of using biofeedback device (n=24).

Reported problems	Responses, n (%)
Finger sensor errors	5 (21)
Difficulty using while stressed	5 (21)
Lack of practice	4 (16)
Device functions difficult	3 (13)
Needed reminders	3 (13)
Didn't find it helped	2 (8)
Ear sensor difficulty	2 (8)

Table 6. Participant reported benefits of using biofeedback device (n=43).

Reported benefits	Responses, n (%)
Felt calm or helped	11 (25)
Ease of use	9 (21)
Helped breathing	5 (11)
Helped sleep	4 (9)
Good video tutorials provided	3 (7)
Visual or can “see” results	3 (7)
Helped when not using	2 (5)
Helped focus	2 (5)
Portable	2 (5)
Efficient	2 (5)

Discussion

Principal Findings

This pilot study highlights potential positive effects of HRV biofeedback in people with ASD, with fewer symptoms of anxiety being reported after using HRV biofeedback devices at home. Carers also reported fewer behavioral *meltdowns*. Remote monitoring indicated that although most (417/474, 88%) of the participants only used the device for short periods of time (0-10 minutes), the majority (311/474, 65.6%) indicated that the device helped when it was used. Notably, only 4% (19/474) of the reports highlighted instances where the device did not help. However, difficulties surrounding the usability of the finger-type sensor device were reported.

A perceived strength of this study was the experimentation of a new intervention in a population where there is high need and where little research exists on issues that affect the lives of people with ASD [84]. A further strength was the assessment of people with ASD by embedding self-reporting in place of traditionally used carer reports. Indeed, self-reports from young people with ASD can be reliable over time [85], and the use of remote monitoring, self-report questionnaires, and debriefing reports from participants combined with carer reports adds strength to the validity of the study findings. Overall, the findings confirmed that *young people with ASD can independently use portable HRV biofeedback devices, and such devices seem to help them manage anxiety*.

We note the discovery of previously undetected cardiac irregularities and deteriorating mental health. This highlights the mental and physical health vulnerabilities in this population [86,87] and the importance of providing them with both assessment and ongoing support. Pre- and postintervention data also indicated that a child participant and an adult participant showed increases in anxiety after the intervention. The debriefing reports indicated that usability issues with the device may have increased anxiety. The unforeseen instances of participants presenting with cold fingers, which affected the quality of the signal acquisition using the PPG finger sensor integrated into the StressEraser, was an unexpected finding. Cold fingers in some individuals have previously been correlated

with a shutdown in peripheral circulation as a result of stress [88]. Equipment checks did not indicate any fault with the equipment, and this device has previously been used successfully in several other populations [89,90]. These difficulties highlight the importance of personalizing digital health solutions to promote use and adoption alongside the need for ongoing clinical support when problems occur. Although the StressEraser is no longer being marketed, other devices using finger sensors may need to be used with caution in people with ASD.

Limitations

Several limitations are acknowledged in this pilot study. A necessary limitation was the small sample size and the inherent risk of error and bias when using self-report measures. It was not possible to determine the exact reasons for nonparticipation in the study because of the ethical constraints regarding contacting those who declined to participate. All participants contacted had already attended services for anxiety. It may be that those who did not participate were not now experiencing problems with anxiety or that they were concerned about participating in research into an untested intervention. Future studies should address this issue to further assess whom this treatment might be beneficial for.

It is possible that reductions in self-reported anxiety may have been related to other outside factors or to nonspecific therapeutic variables. However, it is of note that no time was spent with participants talking about their anxiety or providing any other type of intervention—the training given only involved a review of existing instruction guidelines in the use of each biofeedback device. It is also possible that unconscious bias may have occurred within carer interviews and participant reports because of a wish for the treatment to succeed; however, the debriefing reports indicated that several participants and their carers did report at the end of the intervention that the device did not help despite their initial hopes that it would be beneficial, and participant reports and carer reports were in concordance regarding the changes noted.

This study attempted to carry out before-and-after HRV assessment analysis by means of a single-lead ECG recorder using a psychophysiological stress test within participants' homes. This type of test paradigm assessment proved

unsuccessful because of the lack of standardized test conditions inherent within multiple home environments. This type of stress assessment is one which is unlikely to be useful outside of clinical settings. Before embarking on home intervention programs, future interventions using physiological monitoring such as ECG assessments may require an initial clinic appointment to carry out full mental and physical health checks [75].

In addition, individuals with ASD have also been found to exhibit both hyperarousal and hypoarousal responses to stress tasks, suggesting that the classic paradigm of a stress profile assessment designed for non-ASD populations is unlikely to provide a clear picture when used in people with ASD [56,91]. Recent research has suggested that it is preferable to carry out a longer assessment to obtain more accurate information on HRV, particularly in relation to psychological stress [92]. Because of the mental health difficulties and physiological differences observed in many people with ASD, this type of longer-term monitoring could be particularly valuable.

Usability assessment indicated that both ECG monitoring and remote smartphone monitoring of stress levels were found to be acceptable in people with ASD. Small wireless ECG monitors can now be used for 24-hour recordings, and the approach of remote stress monitoring combined with longer ECG recordings could be used in future studies to provide much needed data on anxiety and the physiological profile of people with ASD.

Comparison With Prior Work

A review of HRV biofeedback studies [93] concluded that, although positive outcomes are reported in many studies, there is not always concordance between questionnaire reports and physiological measurements, and the exact mechanisms of the effect underlying HRV biofeedback have been debated [46]. Our findings suggest that there may be anxiety reduction through use of smaller portable HRV biofeedback devices, but further research using standardized physiological assessments is needed to establish whether this has any long-term effect on underlying participant HRV.

Importantly, some participants in this pilot may not have been able to develop the specific type of resonant frequency breathing using home trainer biofeedback devices, which is argued to increase HRV [94]. The use of multichannel biofeedback equipment may be important for initial training sessions to increase HRV levels; however, for the large numbers of people now requiring intervention, this would require significant outlays in terms of time, training, and resources. Future studies could carry out initial psychophysiological monitoring in a controlled clinic setting and then provide participants with wearable technologies for home use.

This preliminary work has provided vital information for further studies, which could now test effectiveness of HRV biofeedback for home-based remote management of anxiety in an adequately powered randomized trial using a comparator intervention with matched intervention time. This approach was used with non-ASD populations in 2 recent studies that reported positive effects from biofeedback in comparison with control interventions, such as mindfulness and walking [90,95].

Studies investigating comparative interventions could use a breathing pacer app for smartphone use, which could assess paced breathing alone in comparison with HRV biofeedback. Future investigations should capture device data, enabling information to be gathered regarding length and type of breathing practice, which may help to address questions relating to any dose-response relationship for HRV biofeedback. Finally, this initial study only targeted young people aged 13 to 24 years with no known learning disability. A key step in further work will be to assess this methodology and intervention in other groups of people with ASD, such as older adults and people with intellectual disability.

Conclusions

ASD is now a common condition. Reports suggest high costs of supporting people with ASD; yet, little research has been undertaken into new types of interventions specifically designed to meet their needs [51].

Conditions such as ASD pose a significant cost to individuals, health care providers, and society as a whole [96]. Since the data were collected, limited access to interventions for mental health conditions such as anxiety has been exacerbated by health service imperatives to address the COVID-19 pandemic. It has been argued that the current health crisis demands a “digital mental health revolution” [97]. Digital health can provide important tools to help reduce the burden of mental illness and intervene with increasing numbers of people whom traditional models of *face-to-face* therapy cannot support [98].

Digital technology may represent a useful method of engaging people with ASD by using some of their characteristic strengths and interests, without the complex social and communication demands of traditional cognitive and behavior therapies [54] and without the potential risks of medication.

The application of home-based solutions to difficulties experienced by people with ASD also represents what has been termed a “naturalistic developmental behavioral intervention” that can help with the generalization of skills because of their use in real-world interactions [99]. Methods of remote monitoring to assess the symptoms as well as the effectiveness of interventions such as biofeedback may be useful for people with ASD, which should be trialed. These techniques may also assist practitioners striving to provide personalized *connected health* ASD intervention support at a distance.

Systematic reviews have outlined developments in biofeedback across a range of modalities as well as some of the challenges to be addressed in future investigations [28]. HRV biofeedback may be an important adjunct to existing interventions for non-ASD populations with mental health conditions [100,101], and people with ASD should not be excluded from developments in this area. Despite the limitations, this study provides preliminary information on the use, risks, and perceived benefits of HRV biofeedback for anxiety in people with ASD. Importantly, the direct reports from both participants and their carers provide a unique insight into the risks and difficulties as well as the potential benefits of this intervention. Although the exact mechanism of the effect remains unclear, our findings

suggest that further research is warranted to clarify its effectiveness.

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Authors' Contributions

HC was responsible for the conception of this study. HC, MD, and WGK were responsible for the study design. HC and MD drafted the article, which was critically revised by all the other authors. HC was responsible for data collection and for clinical evaluations. HC, MD, and JM were responsible for data analysis.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Participant demographic information.

[DOCX File, 20 KB - [formative_v6i8e37994_app1.docx](#)]

Multimedia Appendix 2

Measures.

[DOCX File, 21 KB - [formative_v6i8e37994_app2.docx](#)]

Multimedia Appendix 3

CONSORT (Consolidated Standards of Reporting Trials) 2010 checklist of information to include when reporting a randomized trial.

[DOCX File, 24 KB - [formative_v6i8e37994_app3.docx](#)]

Multimedia Appendix 4

The Template for Intervention Description and Replication checklist.

[DOCX File, 32 KB - [formative_v6i8e37994_app4.docx](#)]

Multimedia Appendix 5

Study protocol.

[DOCX File, 134 KB - [formative_v6i8e37994_app5.docx](#)]

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Abbreviations

- ASD:** autism spectrum disorder
- CONSORT:** Consolidated Standards of Reporting Trials
- ECG:** electrocardiogram
- HRV:** heart rate variability
- PPG:** photoplethysmography
- SUS:** System Usability Scale

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Original Paper

Development of a Noninvasive Blood Glucose Monitoring System Prototype: Pilot Study

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Abstract

Background: Diabetes mellitus is a severe disease characterized by high blood glucose levels resulting from dysregulation of the hormone insulin. Diabetes is managed through physical activity and dietary modification and requires careful monitoring of blood glucose concentration. Blood glucose concentration is typically monitored throughout the day by analyzing a sample of blood drawn from a finger prick using a commercially available glucometer. However, this process is invasive and painful, and leads to a risk of infection. Therefore, there is an urgent need for noninvasive, inexpensive, novel platforms for continuous blood sugar monitoring.

Objective: Our study aimed to describe a pilot test to test the accuracy of a noninvasive glucose monitoring prototype that uses laser technology based on near-infrared spectroscopy.

Methods: Our system is based on Raspberry Pi, a portable camera (Raspberry Pi camera), and a visible light laser. The Raspberry Pi camera captures a set of images when a visible light laser passes through skin tissue. The glucose concentration is estimated by an artificial neural network model using the absorption and scattering of light in the skin tissue. This prototype was developed using TensorFlow, Keras, and Python code. A pilot study was run with 8 volunteers that used the prototype on their fingers and ears. Blood glucose values obtained by the prototype were compared with commercially available glucometers to estimate accuracy.

Results: When using images from the finger, the accuracy of the prototype is 79%. Taken from the ear, the accuracy is attenuated to 62%. Though the current data set is limited, these results are encouraging. However, three main limitations need to be addressed in future studies of the prototype: (1) increase the size of the database to improve the robustness of the artificial neural network model; (2) analyze the impact of external factors such as skin color, skin thickness, and ambient temperature in the current prototype; and (3) improve the prototype enclosure to make it suitable for easy finger and ear placement.

Conclusions: Our pilot study demonstrates that blood glucose concentration can be estimated using a small hardware prototype that uses infrared images of human tissue. Although more studies need to be conducted to overcome limitations, this pilot study shows that an affordable device can be used to avoid the use of blood and multiple finger pricks for blood glucose monitoring in the diabetic population.

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KEYWORDS

diabetes; deep learning; machine learning; glucose concentration; noninvasive monitoring; optical sensors; glucose monitoring

Introduction

Background

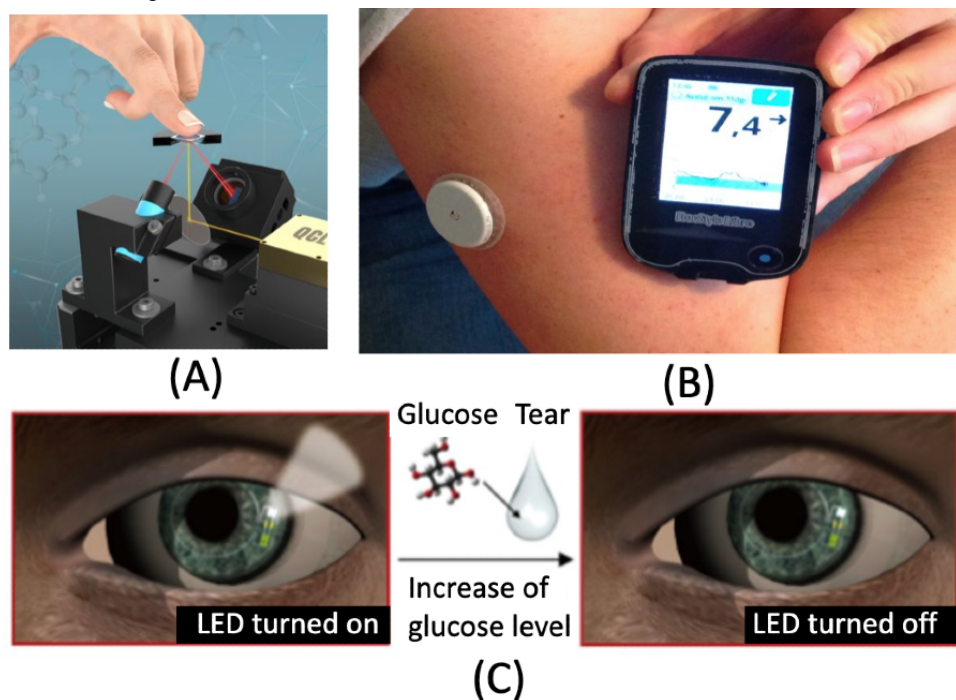
Diabetes affects approximately one out of every 10 people in the United States [1]. Its prevalence has increased from 23.4 million Americans in 2015 to 30.3 million in 2021 and continues to rise at an alarming rate [2].

Successful management of diabetes involves monitoring blood glucose levels multiple times per day. The standard method for monitoring blood glucose concentration is through the use of a glucometer [3]. This device determines glucose concentration from a droplet of blood obtained from a finger prick or a

laboratory blood draw. Taking repeated finger pricks over the course of a day is painful and creates a risk of infection at the collection site [4]. Therefore, noninvasive methods are an attractive alternative, however, those that are available today have several limitations.

Three main types of noninvasive glucose monitoring devices are currently available: (1) noninvasive optical glucose monitoring (NIO-GM), based on optical glucose monitoring, (2) noninvasive fluid sampling (NIFS-GM), based on fluid sample glucose estimation, and (3) minimally invasive devices (MI-GM), which use a sensor inserted into the subcutaneous tissue [5]. Figure 1 illustrates an example of each type of noninvasive and minimally invasive blood glucose monitoring.

Figure 1. Examples of (A) NIO-GM (adapted from Lubinski et al [6]), (B) MI-GM (adapted from Sjö [7], published under Creative Commons Attribution-Share Alike 4.0 International License [8] and (C) NIFS-GM (adapted from Park et al [9] published under Creative Commons Attribution NonCommercial License 4.0 International License [10]). MI-GM: minimally invasive device; NIFS-GM: noninvasive fluid sampling; NIO-GM: noninvasive optical glucose monitoring.

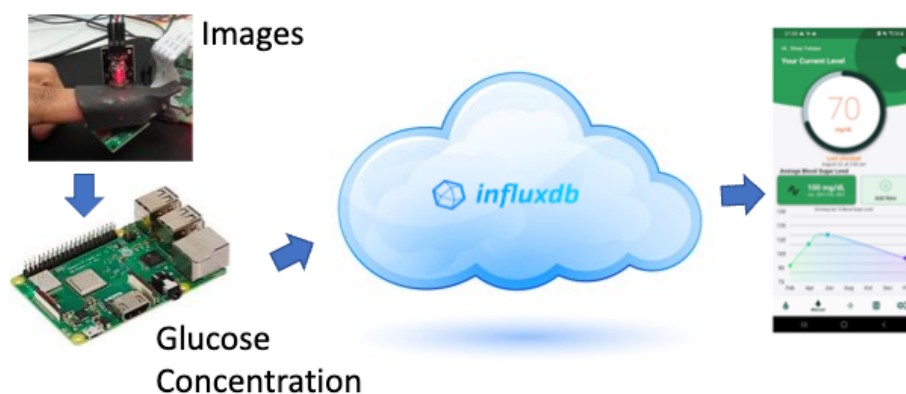


NIO-GM estimates glucose concentration from energy absorption, reflection, or scattering of a light beam directed through the tissue [11]. These devices have the advantage of being both portable and inexpensive. NIO-GM technology includes fluorescence spectroscopy, which may lead to toxicity from fluorophores [12,13]; Raman spectroscopy, criticized for its lengthy spectral acquisition time and poor signal-to-noise ratio [14,15]; photoacoustic spectroscopy, which introduces noise from its sensitivity to environmental factors [15,16]; optical coherence tomography, which is overly sensitive to skin temperature [17]; and occlusion spectroscopy, known to result in signal drift [18]. In contrast, we have developed a NIO-GM device using near-infrared absorption spectroscopy, which is more practical and cost-efficient than those described above [19-23].

Objectives

Here, we describe the development of a novel noninvasive glucose monitoring system that uses the computing power of sensors and Internet of Things devices to continuously analyze blood glucose from a microcomputer and a sensor embedded within a clip positioned on the finger or ear. The prototype uses infrared spectroscopy to create images of the rotational and vibrational transitions of chemical bonds within the glucose molecule, and incident light reflection to measure their corresponding fluctuation. The images are converted into an array list, which is used to provide entries for an artificial neural network (ANN) to create an estimate of blood glucose concentration. The prototype is easy to use and is paired with a mobile app for free-living environments. Figure 2 shows an overview of the proposed system.

Figure 2. Overview of the proposed noninvasive blood glucose monitoring system.



Methods

Physical Theory

Our prototype detects blood glucose concentration using noninvasive absorption spectroscopy optical glucose monitoring [24]. It is based on the Beer-Lambert law of absorption that is shown in equation 1 [24].

$$I = I_0 e^{-\mu_a l}$$

where I_0 is the initial light intensity (W/cm^2), I is the intensity of the i^{th} at any depth within the absorption medium in W/cm^2 , l is the absorption depth within the medium in centimeters, e is the molar extinction coefficient in $L/(mmol\ cm)$, and c is the concentration of absorbing molecules in $mmol/L$. The product of e and c is proportional to the absorption coefficient (μ_a).

The concentration of absorbing molecules is based on the above equation. However, the effect of other blood components and absorbing tissue components affects the amount of light absorbed. As a result, the total absorption coefficient is the summation of the absorption coefficients of all the absorbing components [25]. Then, to minimize the absorption due to all the other components, the wavelength of the light source should

be chosen so that the light source is highly absorbed by glucose and is mostly transparent to blood and tissue components.

Hardware Configuration

We used Internet of Things technologies to leverage power computing and low energy consumption of sensor devices and a Raspberry Pi camera for building the glucose-monitoring prototype [26]. Although the Raspberry Pi camera captures images, a laser light captures absorption. The specifications of the laser light can be found in Table 1.

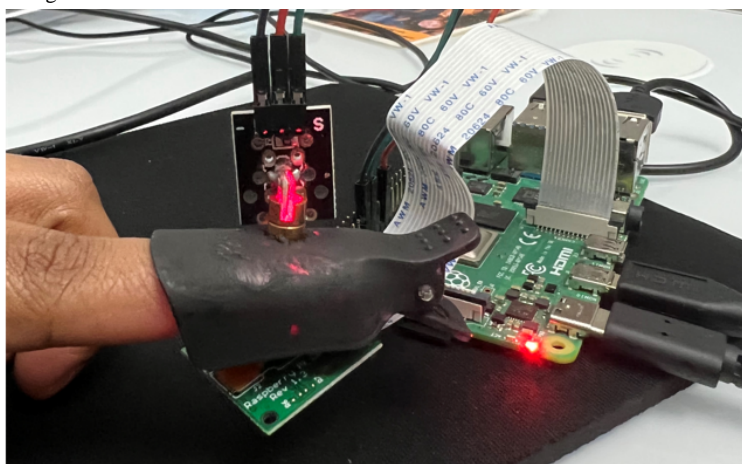
A small clip that can be positioned on a finger or earlobe holds the laser on the top half and the camera on the bottom. Figure 3 depicts the elements of the prototype (Raspberry Pi, camera, and laser light). The prototype has been named GlucoCheck.

The Raspberry Pi camera captures one image every 8 seconds over 2 minutes, for a total of 15 images. Brightness and contrast levels are set to 70 cycles/degree, camera ISO sensitivity is set to 800, and resolution is set to 640×480 . Figures 4 and 5 show the prototype attached to the finger and ear, respectively.

The materials for the GlucoCheck prototype cost approximately US \$79-\$154 in 2022, depending on the availability of chips, which has been an ongoing issue in recent months. Typically, computer boards are abundant, but 2022 saw a shortage of chips, leading to inflated prices compared to previous years.

Table 1. Light laser specifications.

Brand	Icstation
Model number	KY-008 5mW Red Laser Transmitter
Module	Infrared
Part number	276810
Working voltage	5 mW
Wavelength	>650 nm
Size	24 × 15 mm or 0.94 × 0.59 inches (length × width)

Figure 3. GlucoCheck device.**Figure 4.** Prototype clipped to the finger.**Figure 5.** Prototype clipped to the ear.

ANN Model

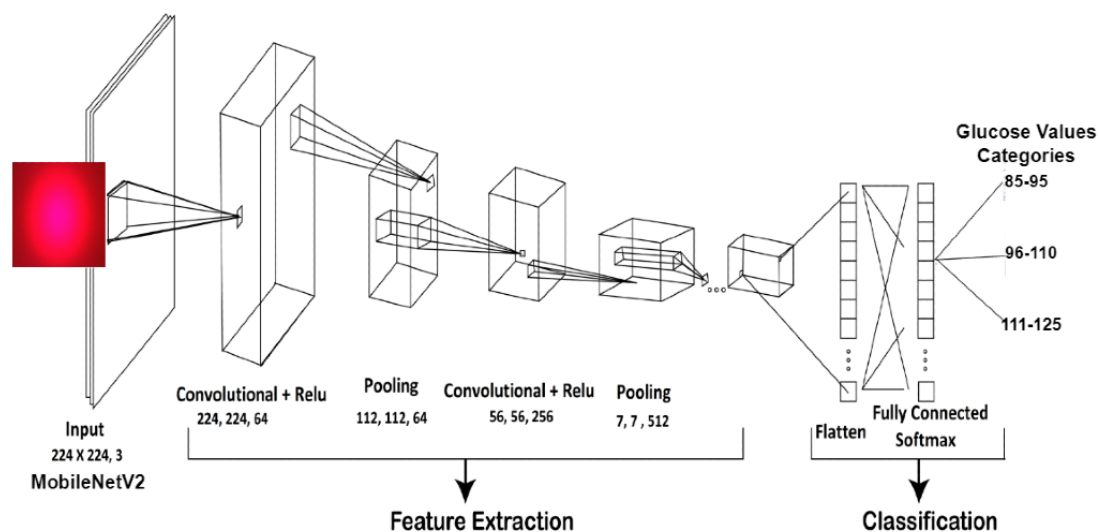
Due to the large number of images used by our prototype, we use a convolutional neural network (CNN/ConvNet) approach. The convolutional layer is the first layer of a CNN network and is the main building block that handles most of the computational work. We imported necessary libraries including

Tensor Flow, Keras, MobileNetV2, Matplotlib, and Numpy. The image data set was converted into arrays with preprocessing, then stored in a list format with assigned labels. Finally, the images were appended to a single data array with a corresponding label array and data augmentation techniques were used to train our model, including cropping, zooming, height and width shift, and horizontal flipping.

Our base model, MobileNet-v2, is a lightweight, 53-layer deep CNN method used to improve the classification of images with a limited data set. The next step was to build the head model, which sits on top of the base model. The next layer is the activation layer, which uses the rectified linear unit (ReLU) activation function [27]. The ReLU is a piecewise linear function that will output the input directly if it is positive; otherwise, it will output zero. It has become the default activation function for many types of neural networks because a model that uses it is easier to train and often achieves better performance [28]. The next layer is the pooling layer, which incorporates feature-down sampling. It is applied to each layer in the 3D volume. The fully connected layer, which involves flattening,

is the final step. The entire pooling feature map matrix is transformed into a single column, which is then supplied to the neural network for processing. We put these attributes together to make a model using the fully linked layers. Finally, we classified the output using a “Softmax” activation function. The ANN model was trained using the Adam technique, which included a total of 20 epochs, a batch size of 1, and an initial learning rate of $1e-4$, and a 0.5 dropout was considered. The next step was to train and test the model; 80% of the data was used for training the model, and 20% was used for testing the model. Figure 6 shows the ANN used for our glucose estimation process.

Figure 6. Artificial neural network model used for glucose estimation. ReLu: rectified linear unit.



Cloud Integration for Real-time Measures

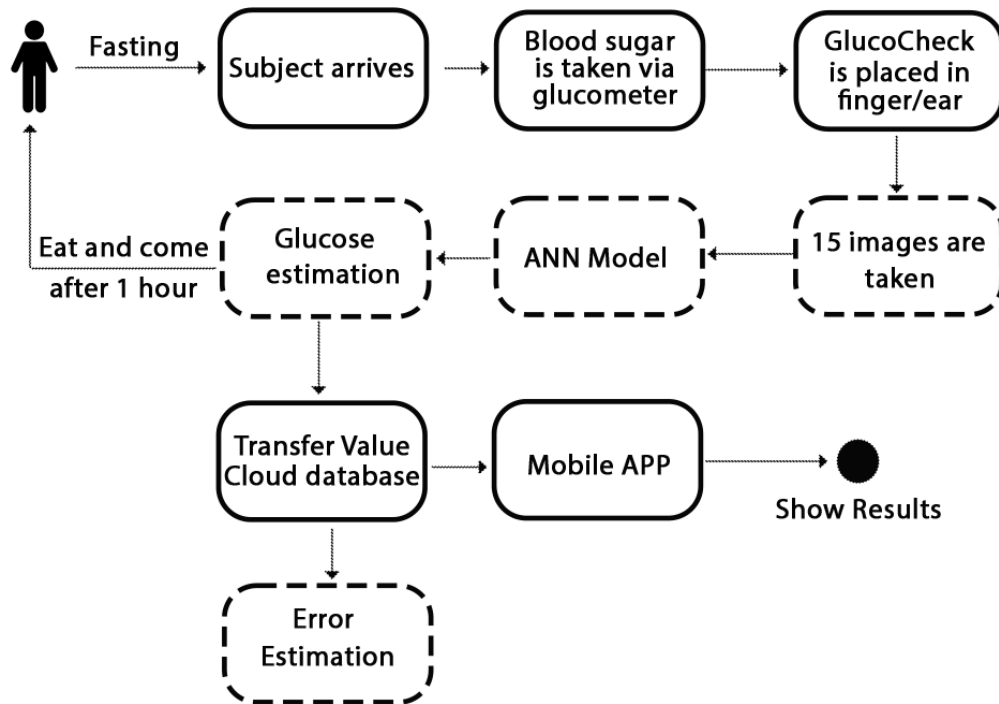
The glucose concentration obtained from the ANN model is sent to the cloud using HTTPS. Next, we configure an InfluxDB [29] database in the cloud to store the data. InfluxDB is an open-source time-series database developed by the company InfluxData. It is written in the Go programming language for storing and retrieving time series data in fields such as operations monitoring, application metrics, Internet of Things sensor data, and real-time analytics. InfluxDB is flexible enough to store data from each subject separately using tags. The integration with the cloud uses the Raspberry Pi, which is connected in real time, and the computed values are displayed on a mobile app for the user.

Model Testing

Glucose data from 8 individuals were used to train and test the model. Each participant was asked to fast for one hour following

an unstructured meal prior to the testing visit. Blood glucose concentration was estimated using a commercially available glucometer (FORA 6 Connect BG50 Blood Glucose Starter Testing [17]), according to manufacturer instructions. The GlucoCheck prototype was used to capture images from each participant at two positions: the index finger and the earlobe. As mentioned previously, 80% of the data was used for training the model and 20% of the data was used for testing. The LabelBinarizer module of the Python library sklearn was used to convert the image data to a binary format and store it in an array associated with its corresponding labels/categories (85-95 mg/dL, 96-110 mg/dL, 111-125 mg/dL). Data augmentation (cropping, zooming, height and width shift, horizontal flipping) was used to enlarge our data set for training and testing the model. The data were then passed to our model for glucose estimation. Separate models were developed for images from the finger and images from the earlobe. Figure 7 illustrates the workflow of the protocol.

Figure 7. Method workflow.



Ethical Considerations

For this pilot study, the following ethical considerations were in place. First, the Institutional Review Board of Kennesaw State University approved the study (IRB-FY22-318). In addition, participation in the study was voluntary. Participants were free to opt in or out of the study at any time. Informed consent was required to inform the participant about the study's purpose, risks, and funding before they agreed or declined to join. Finally, any personally identifiable data were anonymized and kept confidential for the research group.

Results

Experimental Data

Figure 8 shows images collected from a finger. The images were taken after the finger prick at seconds 8 (top left), 16 (top right), 24 (bottom left), and 32 (bottom right). Figure 9 shows images collected from an earlobe at seconds 8, 16, 24, and 32 after the finger prick.

All the images were then appended to a single data array with a corresponding label array. Then, we performed data augmentation (cropping, zooming, height and width shift, horizontal flipping), which allowed us to expand the variety of data available for training the model as we had a minimal amount of data. The data were then passed to our model for glucose estimation.

Figure 8. Fingertip images collected from volunteers.

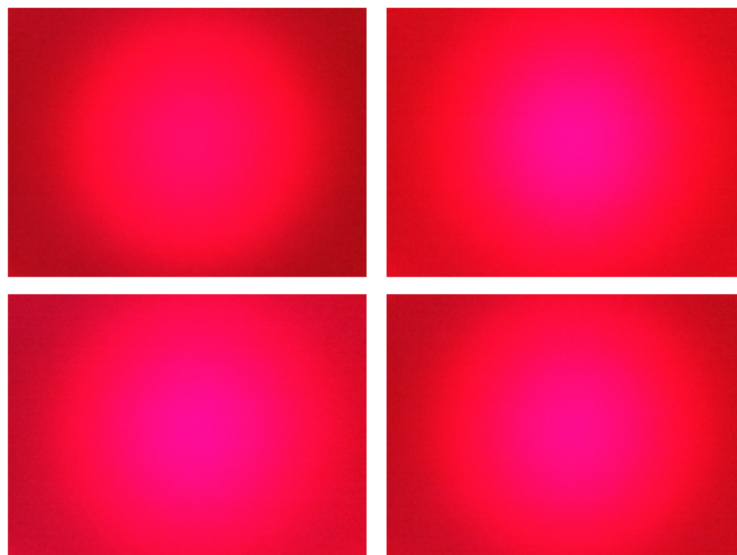
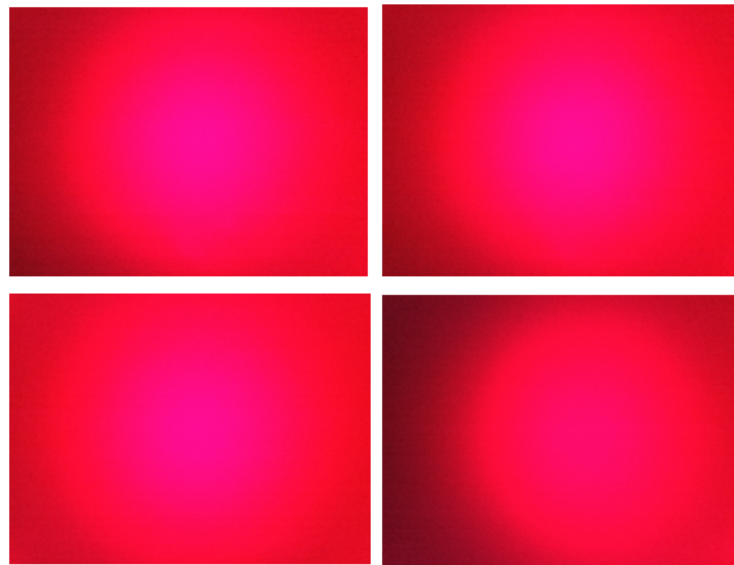


Figure 9. Ear/earlobe images collected from volunteers.



Accuracy Evaluation

The accuracy of the model was assessed with a confusion matrix, which illustrates the proportion of images that were correctly classified. Blood glucose values were grouped as 111-125 mg/dL, 85-95 mg/dL, and 96-110 mg/dL, shown along the x and y axes.

Figure 10 shows the confusion matrix for the glucose estimates when worn on the finger, and indicates a 79% accuracy of the ANN model. The ANN model classified 8 images correctly and 4 images incorrectly in the 111-125 mg/dL category. For the 85-95 mg/dL category, 18 images were correctly classified and

0 images were classified incorrectly. All 3 images in the 96-110 mg/dL category were incorrectly classified. This poor level of accuracy is due to the limited data set for these values.

Figure 11 shows the results of the ANN model for the ear image data set, which achieved around 62% accuracy. The model classified 5 images correctly and 4 images incorrectly in the 111-125 mg/dL category. In addition, 6 images were correctly classified and 0 images were classified incorrectly in the 85-95 mg/dL category. Finally, 2 images were correctly classified and 4 images were incorrectly classified in the 96-110 mg/dL category.

Figure 10. Confusion matrix of finger artificial neural network model. The x-axis refers to the correct estimates, while the y-axis shows incorrect estimates. The unit for all x and y values is mg/dL.

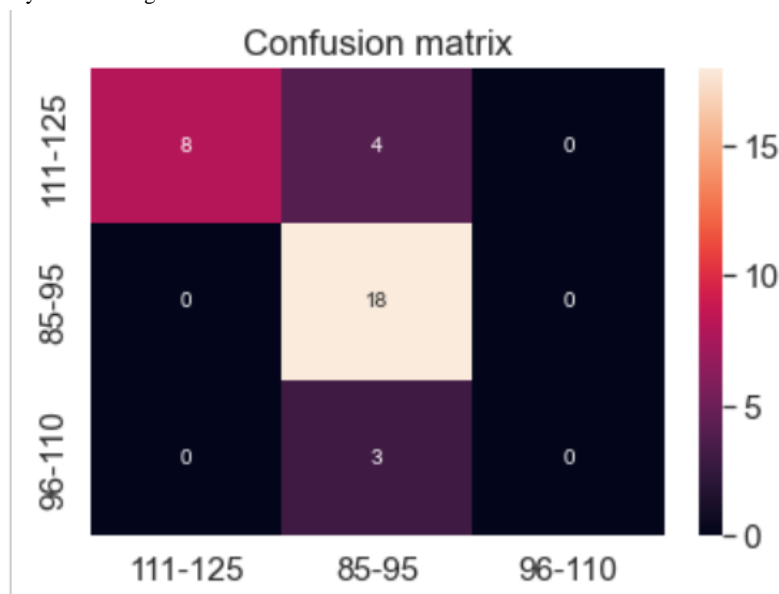
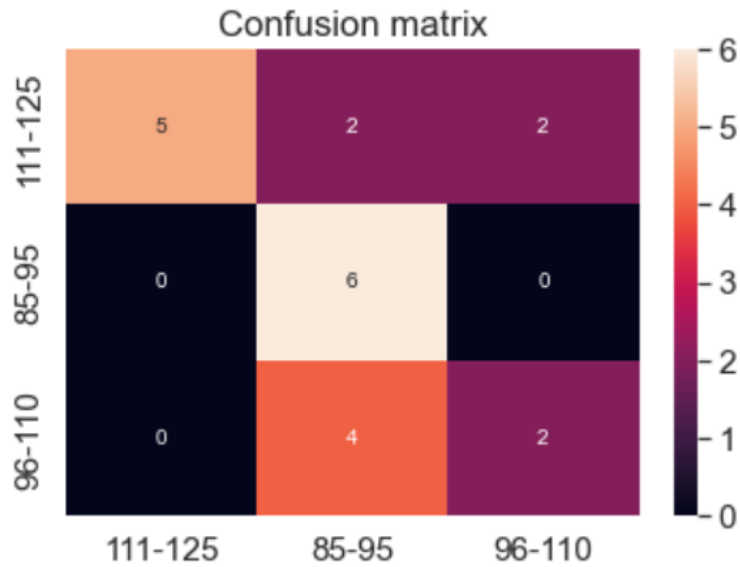


Figure 11. Confusion matrix for ear artificial neural network model. The unit for all x and y values is mg/dL.



Mobile App

Our mobile app “GlucoCheck” is connected to our cloud InfluxDB database and provides continuous glucose monitoring and history data for users. Users can review their current glucose measurement and also view a chart of their previous measurements, allowing them to track glucose variation over a

specific period of time. Figure 12 shows the initial screen on the app (left) and the display of glucose readings from the prototype (right).

Users may also enter readings from a glucometer into the app to track and compare measurements from other devices, as illustrated in Figure 13.

Figure 12. Mobile app interface showing blood glucose level.

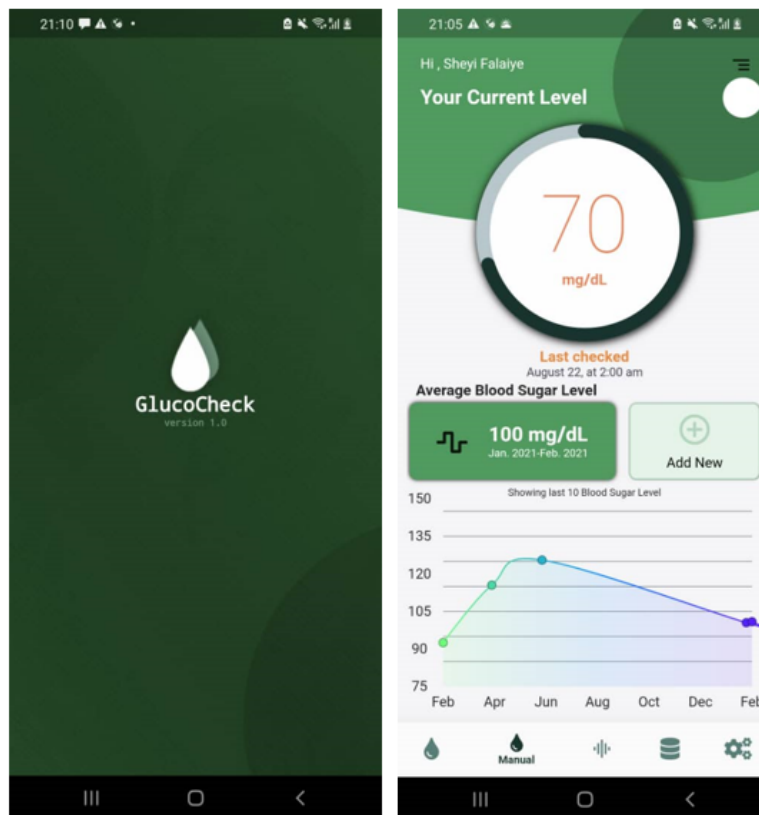
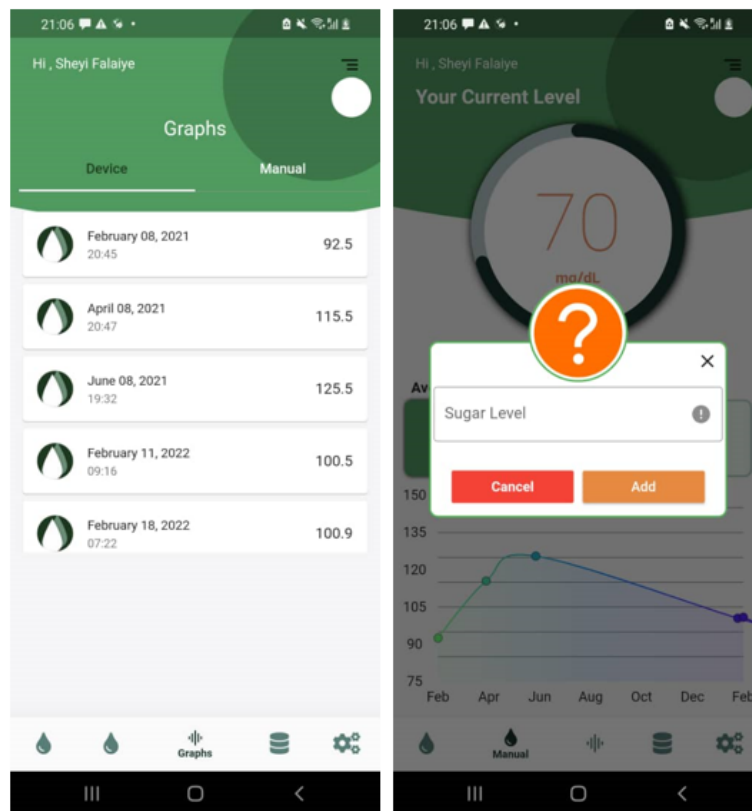


Figure 13. Option to enter glucose level manually. GlucoCheck readings (left) can be compared with other glucometer measures, entered by the user manually (right).



Discussion

Principal Findings

Here we detail and test a novel NIO-GM prototype that relies on an ANN and camera-based technology and is associated with an app that is user-friendly. Results indicate that these optical techniques and machine learning methodologies can effectively measure blood glucose when the light is transmitted and absorptive through the skin tissue. GlucoCheck had an acceptable 79% accuracy when images from fingers were

analyzed and 62% accuracy for images from the earlobe position.

Table 2 compares GlucoCheck with previously tested techniques. The potential of GlucoCheck is comparable with other studies, but it has advantages over other technologies. The use of an integrated computer board (Raspberry Pi) and integration with the cloud gives GlucoCheck the unique ability to display values in real time via a mobile app. Additionally, the optional earlobe position of GlucoCheck is unique and allows for the device to be developed as an earring.

Table 2. Comparison of this study with previous work.

Study	Body part	Technique	Number of subjects	Accuracy	Real-time	Mobile app	Year
This study (GlucoCheck)	Finger/earlobe	Binary format of image and convolutional neural network	8	79%	Yes	Yes	2022
[19]	Finger	Infrared-multivariate calibration model	3	N/A ^a	No	No	1992
[20]	Finger	Histogram and artificial neural network	514	90%	No	Yes	2019
[21]	Oral mucosa	Attenuated total reflection and hollow fibers	131/414	86.3%	No	No	2018
[22]	Finger and wrist	Reflected optical signal	12	Correlation of 0.86	No	No	2019
[23]	Forearm	Spectra analysis of tissue light path	1	87.5%	No	No	2003

^aN/A: not applicable.

Limitations

Future research is needed to address several limitations in the development of a more reliable noninvasive blood glucose prototype based on light. First, a large amount of data is needed for training a machine learning and deep learning model for complicated tasks. Collecting data from people with diabetes is often time-consuming and expensive compared with other tasks. Consequently, many studies face a shortage of data during their research cycles [30-35]. In this preliminary work, we used data augmentation techniques to compute additional data points from our preliminary data set. Additional data will be needed for the ANN model to detect the exact glucose value instead of a range.

Second, depending on the type of radiation used, a viable NIO-GM must account for differences in skin pigmentation, surface roughness, skin thickness, breathing artifacts, blood flow, body movements, and ambient temperature [36]. Accurate measures of the absorption (scattering) properties within human skin remains challenging in biomedical optics and biomedical engineering [37]. Similarly, skin roughness and pigmentation can affect light distribution when propagating through the skin [38]. These factors must be addressed in future technology.

Finally, the prototype enclosure design must be comfortable and usable to be effective.

Conclusion

In this paper, we have presented a noninvasive glucose monitoring system that leverages the computational power of Internet of Things devices and can be used for diabetes management. The prototype is based on images taken from the finger or ear, and does not require blood samples. An ANN model was used to classify and estimate blood glucose concentrations from the images. When using images from the finger, the accuracy of GlucoCheck was 79%. For images taken from the ear, the accuracy was attenuated to 62%. Though the current data set is limited, these results are encouraging. Future studies are needed to address three main limitations: (1) the size of the database (by expanding the data collection process); (2) the prototype enclosure design (by working with biomedical and hardware engineers); and (3) the external factors (by analyzing the impact of skin color, skin thickness, and ambient temperature, among others). If successful, this prototype will be an attractive, life-changing technology for people with diabetes.

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Conflicts of Interest

None declared.

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Abbreviations

ANN: artificial neural network
CNN: convolutional neural network
MI-GM: minimally invasive device
NIFS-GM: noninvasive fluid sampling
NIO-GM: noninvasive optical glucose monitoring
ReLU: rectified linear unit

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Original Paper

Predicting Psychological Symptoms When Facebook's Digital Well-being Features Are Used: Cross-sectional Survey Study

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Abstract

Background: Prior research has linked social media usage to poorer mental health. To address these concerns, social media platforms have introduced digital well-being tools to help users monitor their engagement. Nonetheless, little is known about the effectiveness of these tools.

Objective: In this study, we focused on Facebook to assess users' awareness and usage of the following six Facebook well-being tools: the *Unfollow*, *Snooze*, *Off-Facebook Activity*, *Your Time on Facebook*, *Set Daily Reminders*, and *Notification Settings* features. Additionally, we examined whether the use of these tools was associated with better mental health outcomes.

Methods: We conducted a cross-sectional survey of 598 Facebook users. The survey comprised questions about (1) baseline Facebook use, (2) the adoption of Facebook's digital well-being tools, and (3) participant demographics. These were used to predict the primary outcome measure—scores on the 21-item Depression, Anxiety, and Stress Scale.

Results: Most participants (580/598, 97%) knew about Facebook's digital well-being tools, but each tool was used by only 17.4% (104/598) to 55.5% (332/598) of participants. In turn, the use of two tools was associated with better well-being; although participants who spent more time on Facebook reported higher levels of depression, anxiety, and stress, those who managed their feed content or notifications by using the *Unfollow* or *Notification Settings* features had lower scores on each of these measures. However, the use of the *Snooze*, *Off-Facebook Activity*, *Your Time on Facebook*, or *Set Time Reminder* features was not associated with lower depression, anxiety, or stress scores.

Conclusions: Of the 6 Facebook digital well-being tools, only 2 were associated with better mental health among users. This underscores the complexity of designing social media platforms to promote user welfare. Consequently, we urge further research into understanding the efficacy of various digital well-being tools.

Trial Registration: ClinicalTrials.gov NCT04967846; <https://clinicaltrials.gov/ct2/show/study/NCT04967846>

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KEYWORDS

mental health; social media; digital well-being; depression; anxiety; stress

Introduction

Background

Over the past decade, social media platforms have been scrutinized for their potential impact on mental health. Among the general public, claims about social media harms have been widely publicized in both television documentaries [1] and whistleblower accounts [2]. Within the academic literature, multiple studies have also linked social media usage to symptoms of depression [3,4], psychological distress [5], poorer well-being [5,6], and lower self-esteem [7].

Two theories have been proposed to explain why social media platforms may compromise mental health [1,2]. First, such platforms allow users to compare themselves with celebrities or peers whose web-based posts portray more ideal lives than those of typical users [8,9]. This form of upward social comparison may result in users feeling worse about themselves, placing them at risk for poorer mental health [8,9]. Second, social media platforms are designed to draw users' attention for as long as possible [10,11]. In turn, this allure may result in excessive social media consumption, again impairing well-being [10,11].

To address public concerns about these social media harms, app developers have introduced digital well-being features to help users manage their engagement [12,13]. Nonetheless, it remains unclear (1) whether users know or use these features and (2) whether the use of these features predicts better psychological well-being. Consequently, this study examines these questions by focusing on Facebook as a case study.

Facebook's Digital Well-being Features

With 2.9 billion users worldwide, Facebook is the most widely used social networking platform in the world [14]. Given its popularity, it has also been the focus of most research studies that document the link between social media usage and poorer mental health [7,9,15]. As a result, Facebook developers consulted mental health experts and launched a series of digital well-being features, with the high-level goal of making subsequent Facebook usage "intentional, positive and inspiring" [16].

Facebook's digital well-being features broadly address the two proposed theories for social media harms. First, to minimize the amount of social comparisons, several features allow users to curate the content that they see. For example, the *Unfollow* option allows users to hide posts from selected friends, pages, or groups, while the *Snooze* option hides these posts for a 30-day duration [17]. Further, the *Off-Facebook Activity* feature allows users to customize how the platform integrates information from external apps to customize their feeds [17].

Based on prior surveys, content curation features seem to be adopted when users want to avoid friends' boastings, inappropriate posts (eg, racist content), content that they disagree with (eg, on account of political ideology), or excessive and irrelevant posts [18-21]. In turn, deploying these features can cause users to feel unburdened [22]. Consequently, we sought to examine whether the adoption of these features predicts better mental health.

In the second category, a separate set of digital well-being features enables users to monitor their usage patterns and curb excessive use. For example, the *Your Time on Facebook* feature displays the amount of time that a user has spent on Facebook over the past week, while the *Set Daily Reminders* feature notifies users when a predetermined cutoff has been reached (eg, 45 minutes of Facebook use) [17]. Additionally, the *Notification Settings* feature allows users to manage the in-app notifications that they receive, minimizing the amount of content that draws the users' attention.

As we are not aware of any study linking Facebook's digital well-being tools to mental health, we conducted a cross-sectional survey to address our two primary aims. First, we sought to document the extent to which Facebook users know and use the six outlined features—the (1) *Unfollow*, (2) *Snooze*, (3) *Off-Facebook Activity*, (4) *Your Time on Facebook*, (5) *Set Daily Reminders*, and (6) *Notification Settings* features. Second, we sought to replicate previous findings that linked Facebook usage with poorer mental health and examine whether participants' use of the well-being features was associated with better outcomes.

Methods

Study Design and Population

The participants were 608 Facebook users who were recruited from Amazon's web-based panel (Mechanical Turk) in June 2021. All participants met the following eligibility criteria: (1) individuals aged 21 years or older, (2) individuals who were proficient in English, (3) individuals based in the United States, and (4) individuals with a positive track record on the platform (human intelligence task approval rate: >95%; number approved: >500).

Ethics Approval

Participants gave their written consent in accordance with the Declaration of Helsinki, and were given a nominal sum of US \$0.50 upon study completion. This study was approved by the Yale-NUS College Ethics Review Committee (approval number: 2021-CERC-001) and was preregistered on ClinicalTrials.gov (trial number: NCT04967846).

Predictor Variables

Predictor and outcome variables were measured through a 10-minute survey that was hosted on the Qualtrics website (Qualtrics International Inc) [23]. The questions were written for a seventh-grade reading level and were pilot-tested before this study.

Baseline Facebook Usage

The first set of questions captured participants' baseline Facebook usage. Following studies that linked Facebook use to mental health, participants estimated the daily number of hours that they spent on Facebook over the past week [24].

To provide a context for these metrics, participants also reported how frequently they engaged in the following nine Facebook activities: reading their news feed, posting status updates, posting photos, posting original content, browsing friends'

timelines, viewing friends' photos, commenting on friends' posts, sharing friends' content, and using Facebook Messenger [24]. These were rated by using 7-point scales anchored with "never" and "more than once a day."

Awareness and Adoption of Facebook Well-being Features

Central to this study, participants also reported their awareness and adoption of the following six Facebook digital well-being tools: the *Unfollow*, *Snooze*, *Off-Facebook Activity*, *Your Time on Facebook*, *Set Daily Reminders*, and *Notification Settings* features.

First, participants were shown screenshots of each feature and reported whether they had heard of the features ("yes" or "no"). If participants responded "yes," they were then asked if they had used the features ("yes" or "no"). For features that were designed for repeated use (*Unfollow*, *Snooze*, *Off-Facebook Activity*, and *Your Time on Facebook*), participants reported how frequently they used each feature (using a 5-point scale anchored with "never" and "daily").

Demographics

As the final category of predictors, participants reported their age, gender, race, religion, marital status, education level, employment status, family income, household size, and living setting.

Outcome Measures

As an assay of mental health, participants completed the 21-item Depression, Anxiety, and Stress Scale (DASS-21) [25]. The DASS-21 has been well validated and widely used, consisting of 7 items for each of the following subscales: depression (eg, "I couldn't seem to experience any positive feelings at all" and "I found it difficult to work up the initiative to do things"; Cronbach $\alpha=.87$), anxiety (eg, "I was aware of dryness of my mouth" and "I felt I was close to panic"; Cronbach $\alpha=.89$), and stress (eg, "I found it hard to wind down" and "I tended to over-react to situations"; Cronbach $\alpha=.89$). Each item was rated on a 4-point scale (ranging from "0: did not apply to me at all" to "3: applied to me very much or most of the time"), and scores were summed and multiplied by 2.

Statistical Analysis

As part of data cleaning, we first verified that participants had read the questions through two verification items that asked participants to check boxes as instructed (modeled after the widely used CAPTCHA technique on the internet) [26]. Of the 608 participants, 10 (1.6%) failed the verification and were removed from the data set, resulting in a final sample of 598

participants. We then summarized participants' baseline characteristics by using medians (with IQRs) and counts (with percentages). For count data, error margins for the 95% CIs of proportions were computed by using the *prop.test* function in R (R Foundation for Statistical Computing).

As the primary analyses, we ran a series of linear regression models, using each DASS-21 subscale score (depression, anxiety, and stress) as an outcome measure. In the first model, we sought to replicate the oft-reported link between one's duration of Facebook use and poorer mental health [8]. To this end, we entered the number of hours that participants spent using Facebook as a predictor. As the visual inspection of the data revealed a right-skewed distribution, this variable was log-transformed to achieve linearity (model 1).

In the second model, we addressed this study's primary aim—examining whether the adoption of Facebook's well-being features predicted better mental health (having controlled for the duration of Facebook use). Correspondingly, model 1 was repeated with 6 additional predictors that coded for the use of each feature (*Unfollow*, *Snooze*, *Off-Facebook Activity*, *Your Time on Facebook*, *Set Daily Reminders*, and *Notification Settings*; model 2). For each predictor, nonusage was coded as "0" and usage was coded as "1."

Finally, we assessed the robustness of our findings by repeating model 2 with the inclusion of demographic variables (age, gender, race, religion, marital status, education, employment, family income, household size, and living setting; model 3).

Across the models, the type 1 decision-wise error rate was controlled at an level of .05, with adequate statistical power (0.80) for detecting small effect sizes ($f^2=.05$). All statistical analyses were carried out on SPSS 27 (IBM Corporation) and R version 4.0.3 (R Foundation for Statistical Computing).

Results

Participant Characteristics and Baseline Facebook Usage

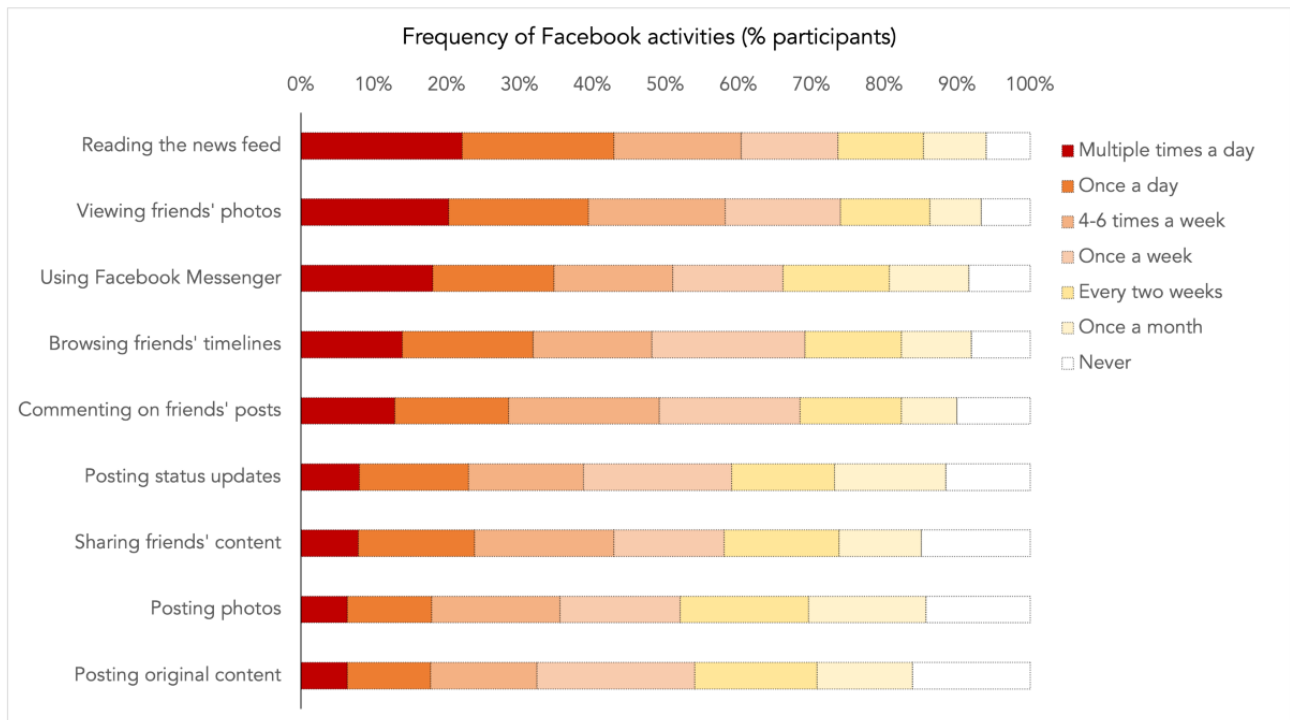
Of the 598 participants, 309 (51.6%) were aged <35 years, and slightly over half of the participants (360/598, 60.2%) self-identified as men (Table 1). In terms of baseline Facebook usage, participants reported using the platform for a median of 3 (IQR 1-7) hours each day in the preceding week. Further, 289 (48.3%, 95% CI 44.3%-52.3%) participants accessed Facebook multiple times a day, while 130 (21.7%, 95% CI 18.4%-25%) logged in once a day (Table 1). On Facebook, participants were most likely to view a friend's photos or to read the news feed (Figure 1).

Table 1. Baseline characteristics of survey respondents (N=598).

Characteristic	Participants, n (%)
Age group (years)	
<35	309 (51.6)
≥35	289 (48.4)
Gender	
Women	237 (39.6)
Men	360 (60.2)
Nonbinary/third gender	1 (0.2)
Race	
White	475 (79.4)
Black or African American	84 (14)
Other	39 (6.5)
Asian	20 (3.3)
American Indian or Alaska Native	9 (1.5)
2 or more races	6 (1)
Other	4 (0.7)
Religion	
No religion	81 (13.5)
Christianity (Protestant)	370 (61.9)
Christianity (Catholic)	107 (17.9)
Other	121 (20.2)
Buddhism	17 (2.8)
Hinduism	10 (1.7)
Islam	3 (0.5)
Other	10 (1.7)
Marital status	
Married/partnered	464 (77.6)
Single	116 (19.4)
Other	18 (3)
Divorce	16 (2.7)
Separated	2 (0.3)
Education level	
Less than high school	1 (0.2)
High school diploma or equivalent	26 (4.3)
Associate degree	26 (4.3)
Bachelor's degree	398 (66.6)
Some college but no degree	37 (6.2)
Postgraduate degree (eg, master's degree or doctoral degree)	68 (11.4)
Professional degree (eg, JD or MD)	42 (7)
Employment status	
Full-time: 40 hours or more per week	507 (84.8)
Not full-time	91 (15.1)
Part-time: up to 39 hours per week	42 (7)

Characteristic	Participants, n (%)
Self-employed	25 (4.2)
Retired	8 (1.3)
Unemployed; looking for work	7 (1.2)
Unemployed; not looking for work	5 (0.8)
Unable to work	2 (0.3)
Student	2 (0.3)
Family income level (US \$)	
<30,000	68 (11.4)
30,000-49,999	149 (24.9)
50,000-74,999	212 (35.5)
75,000-99,999	115 (19.2)
≥100,000	54 (9)
Household size (number of household members)	
1	57 (9.5)
2	88 (14.7)
3	219 (36.6)
4	185 (30.9)
≥5	49 (8.2)
Living setting	
Large city	195 (32.6)
Suburb	117 (19.6)
Rural	107 (17.9)
Large town	94 (15.7)
Small town	84 (14)
Other	1 (0.2)
Average frequency of Facebook use	
Never	15 (2.5)
Once a week	21 (3.5)
2 to 3 times a week	52 (8.7)
4 to 6 times a week	89 (14.9)
Once a day	130 (21.7)
Multiple times a day	289 (48.5)

Figure 1. For each of the nine Facebook activities, participants rated whether they used it (1) multiple times a day, (2) once a day, (3) 4 to 6 times a week, (4) once a week, (5) every 2 weeks, (6) once a month, or (7) never. Each horizontal bar indicates the percentage of participants who chose each option.



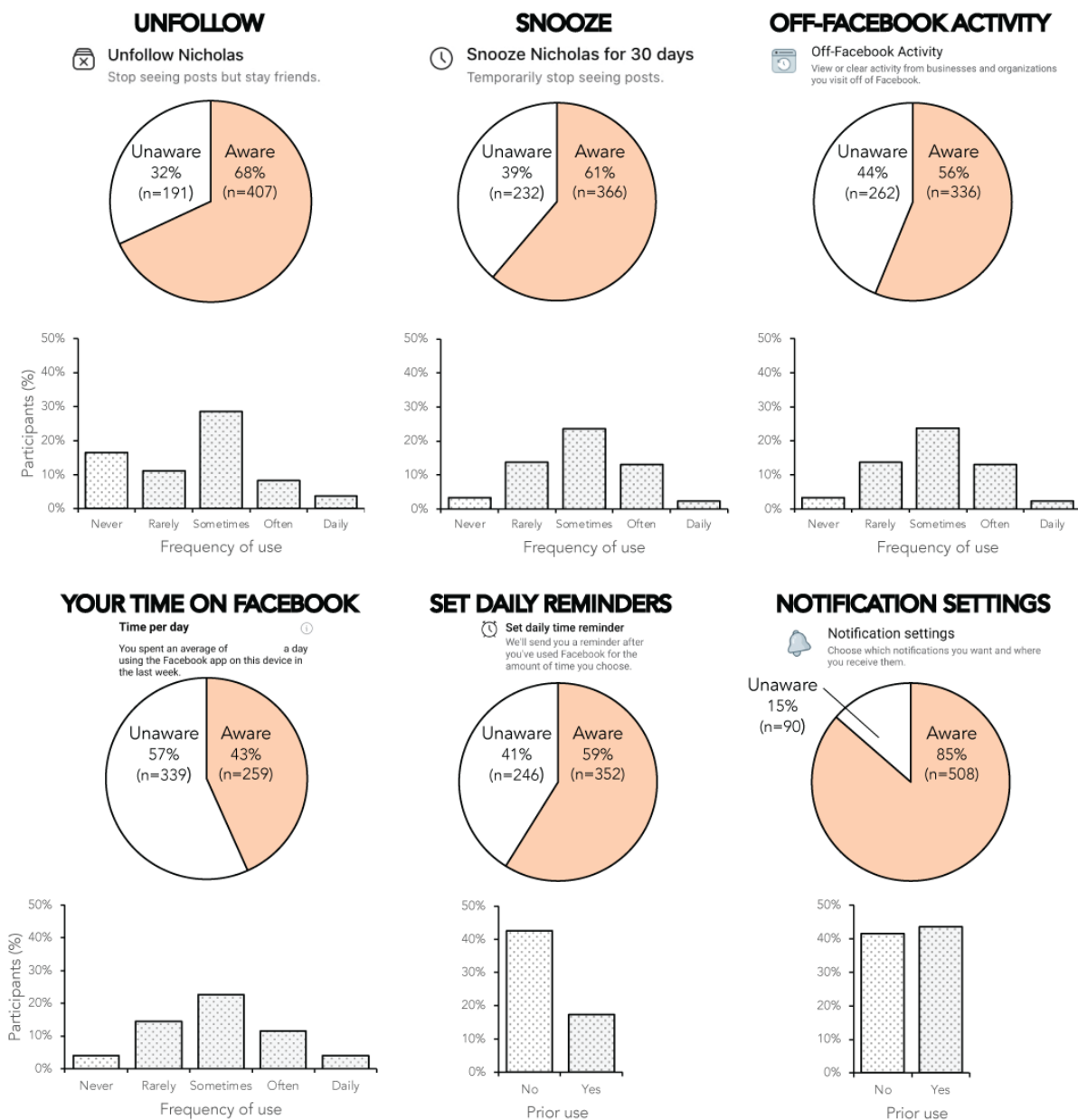
Awareness and Use of Facebook Well-being Features

Of the 598 participants, 580 (97%, 95% CI 95.6%-98.4%) were aware of at least one of Facebook's well-being features (Figure 2). However, awareness levels differed across features. For example, while 508 (85%, 95% CI 82.1%-87.9%) had heard of the *Notification Settings* feature, only 259 (43.3%, 95% CI 39.7%-47.3%) of participants knew about the *Your Time on Facebook* feature.

In terms of usage, of the 598 participants, 332 (55.5%, 95% CI 51.5%-59.5%) had used the *Snooze* feature, 316 (52.8%, 95%

CI 48.7%-56.7%) had used the *Off-Facebook Activity Tracker* feature, 315 (52.7%, 95% CI 48.6%-56.6%) had used the *Your Time on Facebook* feature, and 309 (51.7%, 95% CI 47.7%-55.7%) had used the *Unfollow* feature. Less than half had adjusted *Notification Settings* (n=260, 43.5%, 95% CI 39.5%-47.5%), and fewer still had used the *Set Time Reminder* feature (n=104, 17.4%, 95% CI 14.4%-20.4%). Where the repeated use of features was possible, participants were most likely to report using them "sometimes" on an ad hoc basis rather than on a routine basis (based on the median ratings for *Snooze*, *Off-Facebook Activity*, *Your Time on Facebook*, and *Unfollow*; Figure 2).

Figure 2. Participants indicated their awareness and usage of Facebook’s in-app digital well-being tools (*Unfollow*, *Snooze*, *Off-Facebook Activity*, *Your Time on Facebook*, *Set Daily Reminders*, and *Notification Settings*).



Use of Facebook Well-being Features and Psychological Symptoms

For the primary research question, we sought to predict participants’ depression, anxiety, and stress scores as a function of whether they used Facebook’s well-being features.

Depression

In terms of depression, we first replicated the well-documented association between Facebook usage and depression symptoms; namely, the more time that participants spent using Facebook, the higher their depression scores (model 1: $\beta=2.754$; $P<.001$; model 2: $\beta=1.357$; $P<.001$; model 3: $\beta=1.586$; $P<.001$; Table 2).

Factoring whether participants used Facebook’s well-being features increased the amount of variance in depression scores accounted for, from 8.7% (model 1) to 29.1% (model 2). Although the use of the *Notification Settings* feature ($\beta=-1.579$; $P=.003$) and the *Unfollow* button ($\beta=-1.319$; $P=.02$) was associated with lower depression scores, the use of the *Off-Facebook Activity* feature ($\beta=4.905$; $P<.001$) and the *Snooze* function ($\beta=2.337$; $P<.001$) was associated with higher depression scores. There was no significant association between depression scores and participants’ use of either the *Your Time on Facebook* feature or the *Set Time Reminder* feature (smallest $P=.48$).

Each of these findings was robust, and they persisted even when demographic variables were controlled for in model 3.

Table 2. Predicting depression symptoms as a function of Facebook usage patterns.

Variable	Models (dependent variable: depression subscale scores [DASS-21 ^a])		
	Model 1 ($R^2=0.87$), β estimate (95% CI)	Model 2 ($R^2=0.291$), β estimate (95% CI)	Model 3 ($R^2=0.342$), β estimate (95% CI)
Time spent on Facebook (hours per day) ^b	2.754 ^c (2.036 to 3.471)	1.357 ^c (0.667 to 2.047)	1.586 ^c (0.878 to 2.294)
Use of <i>Notification Settings</i> feature	N/A ^d	-1.579 ^e (-2.634 to -0.525)	-1.413 ^e (-2.459 to -0.367)
Use of <i>Unfollow</i> feature	N/A	-1.319 ^f (-2.444 to -0.195)	-1.252 ^f (-2.369 to -0.135)
Use of <i>Off-Facebook Activity</i> feature	N/A	4.905 ^c (3.604 to 6.206)	5.256 ^c (3.894 to 6.617)
Use of <i>Snooze</i> feature	N/A	2.337 ^c (1.060 to 3.613)	2.398 ^c (1.141 to 3.656)
Use of <i>Your Time on Facebook</i> feature	N/A	0.420 (-0.753 to 1.592)	0.384 (-0.784 to 1.553)
Use of <i>Set Daily Reminders</i> feature	N/A	0.115 (-1.323 to 1.554)	0.130 (-1.311 to 1.572)
Age group (base: <35 years)	N/A	N/A	-0.725 (-1.740 to 0.290)
Gender (base: women)	N/A	N/A	-0.645 (-1.660 to 0.370)
Race (base: White)			
Black or African American	N/A	N/A	-1.704 ^f (-3.123 to -0.286)
Other	N/A	N/A	0.18 (-2.023 to 2.059)
Religion (base: no religion)			
Catholic	N/A	N/A	-3.113 ^e (-5.036 to -1.191)
Protestant	N/A	N/A	-1.391 (-3.027 to 0.244)
Other	N/A	N/A	-2.129 (-4.522 to 0.265)
Marital status (base: single)			
Married	N/A	N/A	-1.090 (-2.551 to 0.370)
Other	N/A	N/A	0.820 (-2.259 to 3.898)
Education level	N/A	N/A	0.506 (-0.279 to 1.291)
Employment status (base: full-time employment)	N/A	N/A	-0.701 (-2.330 to 0.929)
Income level	N/A	N/A	-0.748 ^c (-1.204 to -0.292)
Household size	N/A	N/A	0.306 (-0.207 to 0.819)
Living setting (base: rural)			
Large city	N/A	N/A	-1.495 ^f (-2.925 to -0.064)
Suburb	N/A	N/A	-1.289 (-2.902 to 0.323)
Large town	N/A	N/A	-0.677 (-2.343 to 0.988)
Small town	N/A	N/A	-1.351 (-3.095 to 0.394)

^aDASS-21: 21-item Depression, Anxiety, and Stress Scale.

^bLog-transformed.

^cSignificant at the $P<.001$ level.

^dN/A: not applicable.

^eSignificant at the $P<.01$ level.

^fSignificant at the $P<.05$ level.

Anxiety

As with depression symptoms, the duration of Facebook use predicted increased anxiety scores (model 1: $\beta=4.331$; $P<.001$;

model 2: $\beta=2.270$; $P<.001$; model 3: $\beta=2.1846$; $P<.001$; [Table 3](#)).

Again, the inclusion of variables that coded for participants' use of Facebook's well-being features increased the amount of variance accounted for, from 13.8% in model 1 to 40.3% in

model 2. Namely, while the use of the *Notification Shortcut Bar* ($\beta=-2.387$; $P<.001$) and *Unfollow* functions ($\beta=-1.603$; $P=.02$) emerged as protective factors, the use of the *Off-Facebook Activity* ($\beta=6.760$, $P<.001$) and *Snooze* functions ($\beta=3.134$; $P<.001$) predicted higher anxiety. We found no

evidence that anxiety scores were linked to the use of either the *Your Time on Facebook* feature or the *Set Time Reminder* feature (smallest $P=.07$). Each of these findings persisted when we controlled for demographic variables in model 3.

Table 3. Predicting anxiety symptoms as a function of Facebook usage patterns.

Variable	Models (dependent variable: anxiety subscale scores [DASS-21 ^a])		
	Model 1 ($R^2=0.138$), β estimate (95% CI)	Model 2 ($R^2=0.403$), β estimate (95% CI)	Model 3 ($R^2=0.452$), β estimate (95% CI)
Time spent on Facebook (hours per day) ^b	4.331 ^c (3.459 to 5.203)	2.270 ^c (1.479 to 3.062)	2.184 ^c (1.376 to 2.992)
Use of <i>Notification Settings</i> feature	N/A ^d	-2.387 ^c (-3.596 to -1.177)	-2.064 ^c (-3.257 to -0.871)
Use of <i>Unfollow</i> feature	N/A	-1.603 ^e (-2.893 to -0.314)	-1.593 ^e (-2.868 to -0.319)
Use of <i>Off-Facebook Activity</i> feature	N/A	6.760 ^c (5.268 to 8.252)	6.151 ^c (4.598 to 7.705)
Use of <i>Snooze</i> feature	N/A	3.134 ^c (1.670 to 4.598)	3.326 ^c (1.891 to 4.760)
Use of <i>Your Time on Facebook</i> feature	N/A	1.225 (-0.120 to 2.569)	0.884 (-0.449 to 2.217)
Use of <i>Set Daily Reminders</i> feature	N/A	0.327 (-1.323 to 1.977)	0.078 (-1.556 to 1.723)
Age group (base: <35 years)	N/A	N/A	-0.996 (-2.155 to 0.162)
Gender (base: women)	N/A	N/A	-1.165 ^e (-2.323 to -0.006)
Race (base: White)			
Black or African American	N/A	N/A	-1.227 (-2.846 to 0.391)
Other	N/A	N/A	-0.503 (-2.832 to 1.826)
Religion (base: no religion)			
Catholic	N/A	N/A	-1.864 (-4.057 to 0.329)
Protestant	N/A	N/A	0.027 (-1.839 to 1.894)
Other	N/A	N/A	-0.968 (-3.699 to 1.763)
Marital status (base: single)			
Other	N/A	N/A	-3.877 ^e (-7.390 to -0.365)
Married	N/A	N/A	-0.742 (-2.409 to 0.924)
Education level	N/A	N/A	0.879 (-0.016 to 1.774)
Employment status (base: full-time employment)	N/A	N/A	-1.606 (-3.465 to 0.254)
Income level	N/A	N/A	-0.737 ^f (-1.258 to -0.217)
Household size	N/A	N/A	0.411 (-0.175 to 0.996)
Living setting (base: rural)			
Large city	N/A	N/A	-1.958 ^e (-3.590 to -0.326)
Suburb	N/A	N/A	-2.398 ^e (-4.238 to -0.558)
Large town	N/A	N/A	-0.997 (-2.897 to 0.903)
Small town	N/A	N/A	-1.385 (-3.375 to 0.605)

^aDASS-21: 21-item Depression, Anxiety, and Stress Scale.

^bLog-transformed.

^cSignificant at the $P<.001$ level.

^dN/A: not applicable.

^eSignificant at the $P<.05$ level.

^fSignificant at the $P<.01$ level.

Stress

The time spent on Facebook was again linked to increased stress

scores (model 1: $\beta=3.851$; $P<.001$; model 2: $\beta=1.825$; $P<.001$; model 3: $\beta=2.103$; $P<.001$; [Table 4](#)).

Table 4. Predicting stress symptoms as a function of Facebook usage patterns.

Variable	Models (dependent variable: stress subscale scores [DASS-21 ^a])		
	Model 1 ($R^2=0.083$), β estimate (95% CI)	Model 2 ($R^2=0.299$), β estimate (95% CI)	Model 3 ($R^2=0.353$), β estimate (95% CI)
Time spent on Facebook (hours per day) ^b	3.851 ^c (2.822 to 4.881)	1.825 ^c (0.843 to 2.806)	2.103 ^c (1.098 to 3.108)
Use of <i>Notification Settings</i> feature	N/A ^d	-2.980 ^c (-4.480 to -1.480)	-2.677 ^c (-4.161 to -1.193)
Use of <i>Unfollow</i> feature	N/A	-1.731 ^e (-3.331 to -0.132)	-1.778 ^e (-3.363 to -0.193)
Use of <i>Off-Facebook Activity</i> feature	N/A	7.124 ^c (5.274 to 8.974)	7.321 ^c (5.388 to 9.253)
Use of <i>Snooze</i> feature	N/A	2.845 ^f (1.030 to 4.660)	3.015 ^c (1.231 to 4.800)
Use of <i>Your Time on Facebook</i> feature	N/A	1.297 (-0.371 to 2.964)	1.251 (-0.407 to 2.909)
Use of <i>Set Daily Reminders</i> feature	N/A	-0.453 (-2.499 to 1.593)	-0.314 (-2.360 to 1.732)
Age group (base: <35 years)	N/A	N/A	-1.362 (-2.803 to 0.079)
Gender (base: women)	N/A	N/A	-1.321 (-2.761 to 0.120)
Race (base: White)			
Black or African American	N/A	N/A	-2.051 ^e (-4.064 to -0.038)
Other	N/A	N/A	1.260 (-1.637 to 4.156)
Religion (base: no religion)			
Catholic	N/A	N/A	-4.459 ^c (-7.187 to -1.731)
Protestant	N/A	N/A	-1.621 (-3.942 to 0.700)
Other	N/A	N/A	-1.575 (-4.972 to 1.822)
Marital status (base: single)			
Married	N/A	N/A	-1.336 (-3.408 to 0.737)
Other	N/A	N/A	-2.086 (-6.455 to 2.283)
Education level	N/A	N/A	0.971 (-0.143 to 2.084)
Employment status (base: full-time employment)	N/A	N/A	-1.090 (-3.403 to 1.223)
Income level	N/A	N/A	-0.897 ^f (-1.544 to -0.250)
Household size	N/A	N/A	0.241 (-0.488 to 0.969)
Living setting (base: rural)			
Large city	N/A	N/A	-2.148 ^e (-4.178 to -0.118)
Suburb	N/A	N/A	-2.251 (-4.540 to 0.037)
Large town	N/A	N/A	-0.674 (-3.037 to 1.689)
Small town	N/A	N/A	-1.324 (-3.799 to 1.152)

^aDASS-21: 21-item Depression, Anxiety, and Stress Scale.

^bLog-transformed.

^cSignificant at the $P<.001$ level.

^dN/A: not applicable.

^eSignificant at the $P<.05$ level.

^fSignificant at the $P<.01$ level.

When we added participants' use of Facebook features as predictors, the amount of variance accounted for increased from

8.3% (model 1) to 29.9% (model 2). Once again, we found that participants who used the *Notification Shortcut Bar* function

($\beta=-2.980$; $P<.001$) and *Unfollow* button ($\beta=-1.731$; $P=.03$) had lower stress scores, but those who used the *Off-Facebook Activity* feature ($\beta=7.124$; $P<.001$) and the *Snooze* button ($\beta=2.845$; $P=.002$) had higher stress scores. These associations remained significant in model 3, for which demographic variables were controlled. Across both models 2 and 3, there were no significant associations between stress scores and the use of either the *Your Time on Facebook* feature or the *Set Time Reminder* feature (smallest $P=.13$).

Sensitivity Analyses

For our sensitivity analyses, we (1) repeated models 2 and 3 without factoring participants' duration of Facebook use and (2) reran model 3, with *age group* entered as an ordinal variable (using the following age categories: 21-25, 26-35, 36-45, 46-55, ≥ 56 years). As shown in Tables S1-S3 in [Multimedia Appendix 1](#) and Tables S1-S3 in [Multimedia Appendix 2](#), the key findings pertaining to Facebook's digital well-being tools did not change.

Discussion

Principal Findings

In this paper, we present the first empirical study to evaluate Facebook's digital well-being tools. First, echoing prior studies [8], we found that participants who spent more time on Facebook had more symptoms of depression, anxiety, and stress. Accounting for Facebook consumption alone explained one-tenth of the variance (range 8%-13%) in participants' well-being. Consequently, we examined (1) whether participants used the platform's digital well-being tools and (2) whether usage was associated with better mental health.

Although most participants (580/598, 97%) knew about Facebook's well-being tools, each tool was used by only 17.4% (104/598) to 55.5% (332/598) of participants largely on an ad hoc basis. These adoption rates are lower than those of mainstream Facebook features that were introduced much earlier to the platform. For example, an estimated 4 in 5 Facebook users have deployed the *Unfriend* feature to remove contacts [27], while 3 in 4 have used the *Untag* feature to remove their name from a photograph [28].

Participants who used either the *Notification Settings* feature or the *Unfollow* tools reported fewer symptoms of depression, anxiety, and stress. Conversely, those who used either the *Snooze* feature or the *Off-Facebook Activity* feature had higher scores on each of these measures. Finally, there was no evidence that the *Your Time on Facebook* feature or the *Set Daily Reminders* feature was associated with well-being. This set of findings was robust and was observed regardless of whether we controlled for participants' duration of Facebook use or their sociodemographic factors.

Taken together, our findings underscore the complexity of designing social media platforms to optimize user welfare. Of the 6 digital well-being tools we examined, only 2 were associated with a decreased risk for mental health symptoms—(1) a feature for toning down the amount of content that is brought to a user's attention (*Notification Shortcut Bar* function) and (2) a feature that allows users to customize their news feeds (*Unfollow* feature), which, in theory, minimizes the

amount of social comparisons made on the platform. Nonetheless, it remains unclear why two other features that supported the customization of news feeds (*Snooze* and *Off-Facebook Activity*) predicted a higher risk for mental health symptoms. Further research is thus needed to understand these patterns.

It is noteworthy that we found no significant associations between the use of time-monitoring features (*Your Time on Facebook* and *Set Daily Reminders*) and well-being. This finding is counterintuitive because the time spent on Facebook has been linked repeatedly to poorer mental health outcomes (including in this study) [8]. Consequently, most social media developers have incorporated time-monitoring features into their digital well-being programs, allowing users to track how much time they have spent on a platform or set limits on usage (eg, on YouTube, Instagram, Facebook, and TikTok) [13,16,29]. Nonetheless, we found no empirical support for this widely used strategy, consistent with "digital detox" studies reporting that interventions for curbing social media use have a limited impact on mood and well-being [30].

Implications

Moving forward, our study has several implications for research and practice. First, it appears that the current well-being measures taken by social media platforms may be insufficient. This begs the question of how digital well-being tools should be designed to maximize users' benefits. Despite widespread calls for app developers to prioritize their users, there remains limited empirical data for guiding platforms in carrying out this mandate. We thus urge researchers to address this gap, thereby allowing for an evidence-based toolkit of in-app well-being features to be developed.

Limitations

In reporting our findings, we noted several limitations of our study. First, we chose the design of an epidemiological survey [31,32]. In a new area of research, this allowed us to (1) document baseline adoption rates for digital well-being tools and (2) examine multiple tools at the same time. Nonetheless, correlation does not equate to causation, and our findings need to be followed up with randomized controlled trials. Second, we recruited participants within the general population of internet users; the participant demographics were comparable to that of US Facebook users [33]. Nonetheless, it is possible that stronger effects would be observed in vulnerable groups, such as among individuals with problematic forms of Facebook usage [34] or among adolescents. Further research should thus explore this possibility. Finally, we focused on Facebook because of its widespread popularity. It is currently unclear whether our findings would generalize to other social networking services (eg, Instagram).

Conclusion

In the 2022 State of the Union Address, President Joe Biden called for social media platforms to be held accountable and for companies to pursue users' benefits over profits [35]. Amid these petitions, there is a need to understand how social media platforms can be designed to optimize users' well-being. Accordingly, our study provides the first line of evidence that

two digital well-being features may be linked to improved mental health. At the same time, we also caution app developers that (1) not all well-being features are alike and (2) certain features could backfire. Moving forward, we urge further research to develop and carefully investigate the impact of digital well-being tools on social media.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Sensitivity analyses.

[[DOCX File, 86 KB - formative_v6i8e39387_app1.docx](#)]

Multimedia Appendix 2

Sensitivity analyses: regression analyses with age group as an ordinal variable.

[[DOCX File, 24 KB - formative_v6i8e39387_app2.docx](#)]

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Abbreviations

DASS-21: 21-item Depression, Anxiety, and Stress Scale

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Original Paper

Insights Into Needs and Preferences for Mental Health Support on Social Media and Through Mobile Apps Among Black Male University Students: Exploratory Qualitative Study

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Abstract

Background: Black college-aged men are less likely than their peers to use formal, therapeutic in-person services for mental health concerns. As the use of mobile technologies and social media platforms is steadily increasing, it is important to conduct work that examines the future utility of digital tools and technologies to improve access to and uptake of mental health services for Black men and Black men in college.

Objective: The aim of this study was to identify and understand college-attending Black men's needs and preferences for using digital health technologies and social media for stress and mental health symptom management.

Methods: Interviews were conducted with Black male students (N=11) from 2 racially diverse universities in the Midwestern United States. Participants were asked questions related to their current mental health needs and interest in using social media platforms and mobile-based apps for their mental health concerns. A thematic analysis was conducted.

Results: Four themes emerged from the data: current stress relief strategies, technology-based support needs and preferences (subthemes: mobile-based support and social media-based support), resource information dissemination considerations (subthemes: information-learning expectations and preferences and information-sharing preferences and behaviors), and technology-based mental health support design considerations (subtheme: relatability and representation). Participants were interested in using social media and digital technologies for their mental health concerns and needs, for example, phone notifications and visual-based mental health advertisements that promote awareness. Relatability in the context of representation was emphasized as a key factor for participants interested in using digital mental health tools. Examples of methods for increasing relatability included having tools disseminated by minority-serving organizations and including components explicitly portraying Black men engaging in mental health support strategies. The men also discussed wanting to receive recommendations for stress relief that have been proven successful, particularly for Black men.

Conclusions: The findings from this study provide insights into design and dissemination considerations for future work geared toward developing mental health messaging and digital interventions for young Black men.

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KEYWORDS

Black or African American men; college; mental health; social media; mobile apps; mobile phone

Introduction

Background

Mental health has become an increasingly prevalent issue on college campuses. In 2019, the American College Health Association released a survey with data from 67,972 college students from 98 institutions, including public, private, and 2- and 4-year institutions, within the United States [1]. In this survey, 60% of the students reported “overwhelming anxiety,” and 40% had difficulty functioning because of their depressive symptoms [1]. The mental health needs of college students have only increased during the COVID-19 pandemic [2,3]. During the pandemic, anxiety among college students increased by a factor of almost 7 [4], and there have been significant increases in clinically reported depression and anxiety symptoms among young individuals [5]. These increasing trends and risks of poor mental health have put growing strain on current systems of intervention such as face-to-face campus counseling centers [6,7].

Research shows that minorities and, more specifically, Black students bear a larger psychological burden because of extraneous stressors [8,9]. Specifically, among Black male students, the risk of experiencing poor mental health is increasing, resulting from overexposure to social and economic disparities rooted in race and racism [10-12] and compounded by stressors associated with college life [13,14]. However, Black male students seek and use mental health services at lower rates compared with their peers [15] and have been less likely to seek face-to-face therapy or counseling [15-17] for mental health concerns. From the current mental health literature, we see that this underuse of services is often due to discomfort and lack of trust as well as other attitudinal factors influenced by racial discrimination [17], medical mistrust [18], and stigma [19]. Despite efforts to attenuate such factors and improve mental health outcomes among minority populations [20], existing mental health resources such as campus counseling centers and services are chronically underused by minority students [21-25].

The current burden on health care systems and the continued underuse of formal services among minority students necessitate creative intervention strategies in digital mental health that are practical and user-oriented [26]. It is imperative that we find other avenues to address the unique mental health challenges currently facing college-aged Black men and to improve uptake and access to mental health support services [27,28]. Digital mental health programs may be an optimal way to engage Black men as they can be informal in nature and widely accessible [29]. Digital health equity research demonstrates that digital tools and mental health programs are effective in decreasing mental health issues and increasing access to services among minority populations [30]. However, many digital tools and health programs lack relevance to Black men and do not attenuate the social and attitudinal factors affecting young Black men’s engagement, use, and uptake of digital mental health resources [31] or their barriers to help seeking [24,32,33]. An approach to attenuating these factors and improving relevancy is to focus on understanding Black men’s current mental health

needs and examine their use of digital tools such as social media and mobile technologies.

Social media and mobile technology use has increased significantly in the last few years [34], especially among young adults with mental illnesses [35]. Among young adults aged 18 to 25 years, 96% own a smartphone [36], and an overwhelming majority of those aged 18 to 29 years (84%) consistently use social media platforms [29]. More than 65% of Black American adults use social media platforms on a daily basis [29]. Social media provides a potential platform to address the increasing mental health needs of students in higher education in a way that is user-friendly, accessible, and convenient [35]. Social media is increasingly used as a stress-coping or mood management tool [37], indicating its potential as a support structure to reduce the effects of stress, provide social support, and encourage well-being among users [38-40]. Despite the high use of social media platforms and their increasing popularity among Black young adults [34,41,42], there is little research assessing the acceptability and effectiveness of social media in mental health promotion and prevention among young Black men. This is a missed opportunity as social media tools may be especially effective for disseminating novel health resources [43,44] and have been the leading medium for communication and dissemination of information during the pandemic [45].

Digital mental health programs should aim to use tools that are relevant to Black men and are already being used by Black men and to understand the feasibility and acceptability of such tools in mental health promotion. Recent studies have found that most (85%) social media users expressed interest in using social media to access programs for well-being to cope with their mental health symptoms [46]. This body of evidence suggests a high potential for digital and social media-based interventions to begin to bridge the gaps in mental health care. Moreover, our lack of understanding of the factors that affect Black men’s uptake and engagement with current digital health interventions and tools is a critical barrier to expanding mental health services and achieving mental health equity. Digital mental health programs would also need to include culturally sensitive components, center the experiences of men, and use components that are created with Black men’s needs and interests in mind [47-49]. The relevance of such programs and the development of culturally appropriate components can be learned from Black men if researchers create opportunities for Black men to engage with them in the research and design processes [48,50].

This Study

This qualitative study was exploratory and aimed to identify college-aged Black men’s needs and preferences for using social media and mobile-based technologies to manage their stress and mental health symptoms. The specific aims were 3-fold: (1) to determine Black male college students’ current mental health challenges and strategies for stress relief, (2) to identify ways in which social media and mobile-based technologies can support their mental health needs and stress relief strategies, and (3) to identify digital health app features and social media platform features that are suitable for Black male college students who wish to manage their symptoms and seek help via

nontraditional methods. The results will point to considerations for designing and developing social media–based mental health interventions that are tailored to Black male college students' needs.

Methods

Overview of IntelliCare for College Students

This study was designed as a supplement to a larger study [51] focused on the dissemination and implementation of the mental health app IntelliCare for College Students. This app was adapted for college students from the IntelliCare platform, a self-guided mental health app [52] providing users with interactive apps, cognitive skills, behavioral strategies, and knowledge focused on depression and anxiety. Recent studies have shown significant improvements in anxiety and depression outcomes among IntelliCare users from various settings [51-53]. IntelliCare for College Students was implemented on the campuses of 2 racially diverse Midwestern universities. Preliminary findings from the larger study showed that Black male students were neither enrolling nor downloading this app despite it being free and accessible. Thus, this study was designed to investigate the potential reasons for low enrollment, identify mental health needs, and determine preferences for technology-based mental health and wellness resources among Black male students.

Recruitment

Participants were recruited from 2 universities. The first author (KDAW) sent direct emails and flyers to relevant student organizations serving the general students, organizations serving Black and diverse students (eg, Black student associations and Greek organizations), and counseling centers on these campuses. Word of mouth and web-based advertisements via social media were also used to recruit participants. Eligible participants could not have engaged with the app that is a part of the larger study and had to self-identify as Black or African American men, be between the ages of 18 and 35 years, be enrolled as undergraduate or graduate students at one of the participating universities, and have access to a computer or mobile device with a Wi-Fi connection. Emails and recruitment materials included information about the study and contact information for research staff whom students could contact if interested in participating. For students who responded and were interested, a link was provided in a follow-up email to gather their consent and conduct eligibility screening through REDCap (Research Electronic Data Capture; Vanderbilt University), a secure web-based survey instrument. After a student was screened as eligible for the study and completed a web-based consent form, an interview session was scheduled.

Study Procedure

Sessions were conducted by KDAW on a university-secured Zoom (Zoom Video Communications) account, and participants were given the option to have their video on or off for the interview. Participants were interviewed for 30 to 60 minutes using a semistructured interview guide to prompt an open-ended discussion related to the study goals and objectives. The

interview guide was developed by KDAW in consultation with the senior author (EGL) combined with feedback received from research team members. The interviews focused on understanding the men's mental health needs and ways in which social media and mobile-based apps could support their stress management strategies. Discussions also centered on the perceived acceptability of using social media and mobile-based platforms for mental health support and concerns. Sample interview questions included "Are you interested in using social media/mobile apps for stress management or for self-care?" and "What would make you interested or disinterested in using social media or mobile apps for stress management for self-care?" Prompt questions were asked for clarification purposes and as an aid to help students reflect on their own lived experiences as Black male students. The interviews were audio-recorded. After the interviews, participants were compensated for their time with a US \$20 Amazon gift card.

Data Analysis

Qualitative data were transcribed verbatim from the audio recordings by a professional transcription service. The transcripts were analyzed by 2 coders, who were both research assistants with training in qualitative analysis and worked under the supervision of KDAW. The coders used an inductive thematic analysis approach aligned with the methods described by Braun and Clarke [54]. First, an initial reading and open coding of each transcript was conducted for the coders to become familiar with the transcripts and data. The initial codes were grouped according to the study aims. KDAW and the 2 coders then developed a detailed codebook, which included the code name, the definition of each code, and illustrative examples such as quotations. The 2 coders independently analyzed the data using a web-based research app (Dedoose; SocioCultural Research Consultants) and met to compare, critique, and refine the coding process and discuss and resolve any disagreements. Finally, the coders, along with KDAW, derived salient themes from the data related to the study aims.

Ethical Considerations

Before the interviews, all participants were informed of the study and the study's purpose through recruitment emails during the screening for eligibility process and at the start of the interview sessions. Consent was gathered from all participants before their interview session. Participants were informed that the data collected for these interviews would only be used for research purposes and manuscript preparation. Importantly, all study procedures were approved (STU00205589) by the appropriate Institutional Review Board offices at the relevant institutions in which the study was conducted and from which the participants were recruited.

Results

Sample

A total of 11 men (n=4, 36% undergraduate and n=7, 64% graduate students) consented and completed the interview sessions. Their ages ranged from 18 to 35 (mean 26.90, SD 7.11) years. Table 1 shows the sample characteristics.

Table 1. Sample characteristics (N=11).

University and grade level	Age (years)
University 1	
Undergraduate	20
Undergraduate	18
Undergraduate	20
Undergraduate	19
Graduate	26
Graduate	28
Graduate	34
University 2	
Graduate	25
Graduate	35
Graduate	35
Graduate	35

Themes

Overview

Four major themes emerged from the data: (1) current stress relief strategies, (2) technology-based support needs and

preferences, (3) resource information dissemination considerations, and (4) technology-based mental health support design considerations. [Table 2](#) presents a summary of the primary themes and subthemes, which are described in detail in the following sections.

Table 2. Brief summary of the themes.

Number	Primary theme	Subthemes
1	Current stress relief strategies	<ul style="list-style-type: none"> • ___^a
2	Technology-based support needs and preferences	<ul style="list-style-type: none"> • Mobile-based support • Social media-based support
3	Resource information dissemination considerations	<ul style="list-style-type: none"> • Information-learning expectations and preferences • Information-sharing preferences and behaviors
4	Technology-based mental health support design considerations	<ul style="list-style-type: none"> • Relatability and representation

^aThere was no subtheme for the primary theme listed.

Theme 1: Current Stress Relief Strategies

The men reflected on their established stress management activities. In general, participants cited the importance of creating dedicated time for self-care. A participant described this as “disconnecting from work, or school, and just taking time to take care of my mental health” as a strategy for dealing with their stress. In terms of specific activities for stress management, common ways of managing stress were either technology-enabled, such as watching YouTube videos, or nontechnology-enabled, such as going for a walk. Several men talked about how listening to music or watching funny videos on their computers or on television helped them relieve stress. For example, a participant described watching videos to boost his mood:

I believe part of the strategy to actually boost your mental wellness is to be happy from inside, to have this kind of joy. That’s why I kept on mentioning funny

videos because when you laugh, of course, you know that it’s part of mental wellness as well. You laugh, you just forget about some worries and some stress that might be holding you down.

Another student went into detail about specific television shows that provide stress relief:

I mean, TV does that in general, but Insecure specifically just takes me out of my problems of the day and the stress of the day, and I can just focus in on what’s happening. Just how engaging it is.

Multiple men discussed how they would go for walks, work out, and go to the gym to relieve their stress and see friends. A participant strongly emphasized the social component of seeing friends as a means of stress relief:

For me, I normally go to friends. Even if you’re required to drive, I go and then have some nice times with them and feel good before coming back.

Multiple men mentioned Calm, a meditation app, as a way in which they were currently relieving their stress. The men used Calm to meditate and as a resource to get their mind off stressors, such as schoolwork, or right before engaging in something stressful, such as work responsibilities. Some students mentioned appreciating having the time to sit, relax, and be still:

[It] just allows me to recalibrate myself and not get so stressed out and focus on sitting and thinking really deeply about how you're feeling and what you're going through.

Some men discussed already engaging with social media to disconnect from their current environments or seek positive interactions. For example, a participant reported using social media platforms to look for motivational quotes and wanting to obtain encouragement from positive words on social media platforms.

Theme 2: Technology-Based Support Needs and Preferences

There was discussion about how mobile-based apps and social media could support the men's current stress relief and management practices. The men were primarily interested in using social media and mobile-based apps for mental health support and stress management if social media and apps could connect them with resources, provide words of affirmation and encouragement, and provide stress relief recommendations.

Mobile App-Based Support

Students mentioned several areas in which mobile-based apps could support their mental health, including promoting physical activity or exercise, providing them with a space to watch television and movies (and offering suggestions), providing reminders to engage in activities that relieve stress, and helping them maintain a routine. Help with maintaining a routine, particularly through notifications, was a commonly discussed support preference. Regarding notifications, the men wanted to be reminded or encouraged to engage in stress relief activities or activities that allowed them to take care of themselves. A participant described how he could envision notifications being useful:

Maybe have the app say, "What do you wanna do to help you feel better? What do you think you can do to mitigate your problems?" and say, "Well, hey, I like to ride bikes." So, maybe have it set to say, "Hey, it's Saturday," or whatever. "Don't forget that you wanted to ride your bike," or do whatever you wanna do. For me, it's really I need an app that has a feature to remind me. I know you have life going on, but don't forget about this that you put time and effort into thinking about. So, honestly, notifications to help keep you on track is kind of the best way for an app to get you back on track.

Another participant mentioned that notifications could be important and help with their goal setting:

Not only ask you how you're doing—I think with a freeform answer, that would be hard, but preset things so that it could use that information to act upon it or

give you some kind of notification, but also to set up a goals, like what do you wanna accomplish this week or this month. And let's say somebody like me who's busy but on the weekends.

The men also discussed wanting mobile apps to be synced with their calendar and notify them of time and space to take to mediate or debrief from their day. Students described wanting apps to notify them with inspirational quotes, videos, or something funny that encouraged them to do something positive and have positive thoughts. A participant was particularly interested in being sent messages about positivity and "stress relieving quotes."

Another topic that emerged was how apps could provide some of the benefits of social media without the known detriments of existing social media tools to mental health. A student explained their views on how a mental health app could be a form of "healthy social media":

I think an app can work as a piece for healthy social media because social media, in general, can be very draining. So, whether it's just sharing ideas with people, or having a platform to where it's kinda like, the resource for different activities, like mindfulness activities, and self-reflect activities, or actualization activities, or introspection. So, I think stuff like that, and just have little activities and a way to where you can communicate with people outside of just the craziness that's going on. That way you can have a platform where you can like, ah, feel good today. Then I go to this, and I might just do a cool crossword puzzle or something, and then I feel better. You know?

Social Media-Based Support

The men were asked about the types of mental health support they would want or expect to see on social media. Participants discussed wanting to see visual examples of people dealing with stress as a means for them to learn to deal with their own stress. A man discussed a desire to see the following:

...other people's experiences on how they manage their stress, examples, more tutorial on the different kinds of stress and how to manage them. If there's daily tweets or daily comments one could register for that would help one to manage stress each day, I think that would go a long way.

Furthermore, several participants described how social media platforms could provide knowledge about symptoms and offer helpful strategies for dealing with symptoms while helping reduce stigma around mental health among Black men. A participant stated the following:

Honestly, I think just talking about it because even as you say symptoms, I really don't know all of the symptoms. So, a platform actually talking about mental health within the Black community. And even—well, mental health within the Black male community is too because that could definitely be separated. I feel like that would be important to—just to start a discussion.

The latter sentiment speaks to mental health stigma and the common perceived notion that mental health is not discussed among Black men or within the Black community. A student went further to talk about the importance of addressing mental health stigma by increasing awareness:

A big part is awareness because a big part of social media is bringing awareness to a lot of the issues going on in today's society. So, well, there's like, "Hey, have you been struggling with mental health? Here's who to contact." Mental health is real; making sure like eliminating the stigma around it because a lot of people just don't talk about mental health, which isn't healthy.

As with mobile-based app support, the men reported wanting social media to provide positive affirmations as a support method. A participant mentioned how receiving positive affirmations helped them "feel better" and "feel more confident." Positive affirmations were also mentioned to create a supportive environment in which people could be vulnerable with each other. The men also discussed ways to promote mental health on social media, including partnering with established communities, organizations, or influencers. Specifically, a participant mentioned an Instagram feature, Instagram Live, that would be useful for promoting mental health via established entities. The student suggested having someone who could relate to Black men or a person who was knowledgeable of mental health and its etiology use Instagram Live to talk about mental health issues:

I've seen big or maybe it doesn't have to be a big psychologist or whatever but having someone talk about mental health. Everybody tunes in and have an honest conversation. And again, with my previous point where I mentioned not it just being a one-way street where you tell us all the statistics about stress within Black men, stress within Black women, stress within the Black [community]

This student continued to talk about how this may help with increasing awareness and starting conversations about mental health. The men also thought it would be helpful to partner with and use already established outlets on social media, for example, tapping into Instagram influencers who may be already focused on mental health needs and promoting mental health in communities or among students.

Theme 3: Resource Information Dissemination Considerations

Another major theme related to how the men might expect or want to hear about mental health resources and how they personally might share information related to mental health support or resources with peers.

Information-Learning Expectations and Preferences

One of the ways in which the men would expect to hear about mental health resources included their interest in attending conferences and seminars organized by their institutions and that aimed to inform students such as them about mental health support or programs. For example, a student mentioned interest in learning about mental health resources via new student

orientations or student orientations specifically related to them. Specifically, if they were a premedical or international student, then they would prefer to hear about such support via that specific orientation or organization. Similarly, other ways the men discussed of hearing about resources for mental health were through admissions offices. A student went further to suggest what these programs and offices could do to disseminate information about mental health resources:

Those are good places where if you had a little card deck or something like that or a flyer, because as people are registering or getting admitted into school, the stressors of life come into play there a lot, so I think those would be good places for outreach.

Other suggestions included the men wanting and expecting to hear about resources through the mental health offices or "self-care parts of campus" and from campus-oriented wellness teams. The men would also expect to learn about resources from organizations and email listservs specific to people of color and from programs related to "ethnicity or religion or gender." A participant recalled a particular outlet through which they typically received campus information to explain how they might expect and would like to receive mental health information:

...newsletters from our BGSA [Black Graduate Student Association]; they send out emails probably once a week regarding how to cope with schoolwork, like outside of class, and just things relating to people of color.

Another student mentioned a preference toward receiving mental health information from "niche little mailing lists like the BGSA; I pay attention to those as opposed to the student-wide ones."

Information-Sharing Preferences and Behaviors

Through the interviews, participants shared potential ways in which they would be interested in sharing information about the mental health resources they were using or knew of through word-of-mouth discussion (ie, in-person, casual conversations with their friends). Word of mouth involved students having "casual" conversations with their friends and mentioning the resources. If sharing information about resources by phone, students would text words such as "This is a great app. Everybody should go check it out" and send the associated mental health resource website or app link along with that SMS text message. Participants mentioned that they might feel compelled to share and suggest a useful resource with the intention of helping another friend who might be dealing with issues or "feeling down." They imagined that, if they were talking with their friends and realized that their friends felt down, they could take it as an opportunity to share the resource:

And also, just reaching out to friends, seeing how they're doing and if they feel that they need a resource, I feel like bringing this up with them and sharing with others the resources that I use could be helpful.

As an example of how one might share a resource with a friend, a participant indicated that they might say something to the effect of the following:

“Hey, I’ve been using this app that’s pretty cool. It manages stress.” So, I mean, a lot of people have been feeling stressed out lately, so I could recommend it to my friends just casually.

A few men mentioned that their willingness to share a resource depended on whether they themselves used it and were able to benefit from it. A participant stated that “there is a common saying that if you have used, and it has worked for you, then you’ll be ready to recommend it.” Another participant suggested that, if they used it and it worked, they’d be willing to share it through the following avenues:

...ads and also sharing [with] groups everywhere on Facebook, on Twitter, sharing those types of information; shar[ing] it with friends.

Although word of mouth was popular for sharing information, the men discussed preferences using social media to share information about mental health resources. Using platforms such as Instagram and Twitter was frequently mentioned. The men would “tweet about it.” Hypothetically, a student discussed how, if they were using a resource, they would post comments and image-based posts showing personal “experiences concerning [mental health]; that way people who see it in such similar conditions would be interested in it.” The men also talked about the popularity of social media in addressing social issues, explaining this notion as a reason they might expect to hear and share information pertaining to mental health resources on social media:

Instagram, Snapchat, more Instagram, just because I know a lot of my friends on Instagram post a lot about social issues, whether it’s mental health or other parts of our society that are important. But even Snapchat too, just because I know that’s a lot of platforms that people might use.

A participant explained that social media is useful for promotion and would expect the following:

...a lot of events and apps or anything like [mental health-related] is really through social media. Social media, everybody uses that to post whatever is going on.

A participant went further to offer the sentiment that “any type of media promotion is usually how people at school learn about anything that’s going on at this point.”

Theme 4: Technology-Based Mental Health Support Design Considerations

Overview

The final theme focused on the men’s visual- and text-based preferences regarding features for social media-based or mobile app-based mental health resources. A common preference was for visuals that were primarily image-based or had minimal wording:

Pictorial representation of the message you are passing across gets people’s attention [better] than the words...If I see a picture of someone laughing or something so fascinating, I might be tempted to just click on it.

The men also mentioned wanting to see a social media platform that included testimonials, voice notes, or podcasts portraying individuals who looked like them and who had dealt with mental health issues. In these images or testimonials, they also would want men to describe the strategies they had used to deal with stress. The men also cited the use of clear and concise language as another factor to consider when designing platforms or resources for mental health support. Students explained this preference in relation to Instagram captions. The men would like Instagram captions to be simple in nature and less wordy, making them more attractive and easier to digest. The men noted that simple language would also be useful in suggesting a resource or stress relief activity.

The men noted that they would be drawn to platforms that provided resources for broad mental health concerns rather than specific disorders. A participant described how, as not everyone would resonate with having a specific mental illness, being broader with mental health messaging should be a consideration:

Mental health as opposed to specific terms for mental disorders...might not relate to everyone: “Well, that doesn’t really pertain to me right now,” so it doesn’t grab my attention. But yeah, I think something that’s more open to the entire umbrella.

Relatability and Representation

Emerging from this theme were discussions of the men wanting advertisements of resources to be portrayed in a way that resonated with their lived experiences. Probing questions were asked to gain more insight. Some men were able to provide examples, suggesting that platforms should include components or images that “portray men who look like them and are using resources or an app/platform for their issues” or “relate to their everyday lives as students or iPhone/droid users.” The men also described a preference for seeing resources or advertisements that showed Black men and used specific wording:

[I’m] drawn to someone who looks like me. And the words “Black men”...so I feel like I would personally be drawn to that once I—if I saw it somewhere.

The men were interested in seeing platforms that used words and phrases that focused on mental health and the stigma surrounding mental health challenges. The men discussed the lack of existing resources focused on helping and supporting Black men’s needs as well as the dearth of resources focused on dismantling the stigma associated with Black men and mental health:

And I’m a Black man, and back home in my culture we consider stress as a form of weakness, and people who go through a lot of stress. So, if more effort can go into putting the word out that going through stress is a normal thing and there are ways one could manage it. At this age now, I want to just have an idea of what this stuff is all about, like managing stress.

Another participant discussed wanting resources to use specific words to address stigma and provide help without judgment:

And then, the “doesn’t judge” part I think is really important. A lot of people don’t reach out because they’re scared of what people might think, so making that clear that we’re not going to judge, we’re here to help. That is comforting.

For digital mental health resources to be used by Black men and to increase men’s engagement with such tools, the resources, programming, and prevention efforts need to include visual- or text-based components that are visually appealing to men’s lives and lived experiences. Importantly, mental health efforts for Black men’s needs should be relatable and include evidence-based components that have been successful in addressing Black men’s mental health needs.

Discussion

Principal Findings

Overview

This study examined Black male college students’ needs and preferences for using social media and mobile-based apps for their mental health symptoms, stress management, and self-care. This qualitative study stemmed from a larger study [51] aimed at examining the uptake of a mental health app on 2 university campuses. In line with previous research indicating that minority students underuse existing mental health resources [24,55], early data indicated that Black male students were not enrolling in the parent study or downloading the stress management app despite its wide availability. To help address this limitation of the parent study, our qualitative study tackled a critical topic in digital health equity research—specifically, understanding and identifying digital mental health support needs and preferences among Black male students [31].

Primary existing methods of stress reduction included engagement with physical activity (ie, working out), watching television or YouTube videos, and spending time with friends. In terms of support needs and preferences, major themes included a desire for stress relief recommendations and positive messages, the helpfulness of notification-based support, and support via social media. Regarding dissemination considerations, overall, we found that the underuse of mental health services by Black male students does not reflect a lack of interest, nor does it reflect their lack of interest in learning about or sharing resources. Design considerations highlighted a need for visual-based content delivery and greater representation in how resources are advertised.

Stress Relief

Our findings regarding physical activity as an existing means of stress relief align with established literature on stress relief and mental health coping among young Black men in college; for example, Goodwill et al [56] similarly found that Black male students relieved stress through exercise, sports, or hobbies. Extending previous literature, our interviews revealed that physical activity provided stress relief for Black men. Specifically, within this study, physical activity included taking walks as a key form of stress relief [56]. Various men discussed taking walks as a form of self-care, which is a sentiment not often highlighted in the current literature.

A form of self-care and stress relief was mentioned in relation to social support which, in mental health research, is a common social-ecological factor that protects against mental health risk [57]. The men discussed spending time with friends and engaging in activities that promoted social support as a form of self-care and relief that helped them cope with stress. This sentiment aligns with recent broader mental health research examining the need for social components in apps. In recent work, we see that social support and social connectedness via social networking sites are preferred, associated with lower levels of depression and anxiety [58], and associated with higher engagement with apps [59]. We also see that, in other areas broadly related to mental health research, app users are more motivated to use the app and change their behavior if there is a social support component [60,61]. For example, Gowarty et al [61] found that participants with serious mental illnesses would be more motivated to quit if a smoking cessation app included a social support component. Notably, there is ambiguity in the mental health literature regarding which types of social support serve as a buffer for mental health among Black men and which do not. For the men in our study, engagement with friends was the primary source of social support that relieved their stress, which aligns with certain studies [57,62,63] but contrasts with others that suggest that social support via significant others or romantic partners is a stronger protective factor [64,65]. The stronger emphasis on social support from friends than from romantic partners in our study may be due to our college-aged sample; however, more research is needed examining the preferred social support among Black male college students.

Another important insight from this study involved the ways in which Black male students were already harnessing technology to cope with stress, which still points to design considerations for future digital health interventions. Multiple men reported watching YouTube videos and using social media platforms to seek encouragement from motivational quotes. This finding aligns with existing knowledge about preferred social media platforms from publicly available reports. Entities such as the Pew Research Center indicate that YouTube is the most popular of the social media platforms [29,42], and our results suggest that this preference also holds true among Black men.

Support Needs and Preferences

The men provided valuable insights into factors that make mental health services more relevant and effective for them. A common theme was a desire for notifications and reminders. Persuasive system design suggests that the personalization of digital tools (eg, through notifications) can promote engagement [66], leading to greater symptom improvement [53]. In line with this, the men in our study suggested that personalized notifications would help them maintain a routine and that calendar integration would be especially effective in promoting the carving out of space to practice stress relief methods. At the same time, this type of personalization is likely useful for the broader population and not necessarily specific to Black men. Black male students also discussed ideas on how to support self-guided digital mental health tools. Although there is a rich literature on using human support (in the form of a coach or clinician) to increase engagement with digital mental health tools [67], participants in this study were not asked about the

potential role of a human supporter, nor did they independently identify human support alongside a digital mental health tool as a valued strategy [67,68].

Dissemination Considerations

The results of this study offer insights into Black male students' preferences and needs in relation to learning about mental health resources. A finding from this study is the potential role of minority-focused or Black-focused campus-based organizations in disseminating mental health information to increase access to care for college-aged Black men. The men consistently mentioned wanting to learn about mental health support from campus-based organizations, particularly those specifically geared toward students such as them and that matched to their race or gender. This finding is consistent with literature suggesting that people from underserved populations are more receptive to information or resources delivered by people of a similar background, which promotes confidence and trust [69]. Notably, the results present a connection between dissemination preferences and potential ways to increase men's engagement with mental health support. Overall, the men in this study were interested in mental health services but, without evidence of the services being effective, they were less likely to engage. The men expanded on this further, stating how they would be more likely to share information about a mental health resource if it *works* and, importantly, if it *works* for Black men. This finding speaks to the role of evidence-based mental health services and peer dissemination practices in promoting engagement with mental health support among Black male students and further promoting receptivity and believability. This consideration would be important to incorporate, aiding in the likelihood of mitigating factors related to stigma and medical mistrust [18,19] and improving young Black men's access to and uptake of digital mental health support [27,28] down the road.

Previous research also underscores the importance of social media in disseminating political information for Black Americans [42] as well as for mental health promotion. The men discussed how they might be more open to specific social media platforms that promote mental health specific to college-aged Black men who are dealing with the same issues and concerns. Watkins et al [70] tested a Facebook-based intervention with content related to mental health education and support specifically for Black men. Qualitative analysis indicated that the men who engaged with this intervention had increased awareness not only of their own mental health and needs but also of the mental health needs of other Black men [70]. Our results similarly suggest that social media can be an acceptable tool for health promotion. The men in our study also discussed that they would willingly use social media to share mental health-related information with friends and peers, stating that social media would be an effective way of reaching them and their friends. The men indicated that they were already accustomed to receiving information about other health and social issues via social media, as were their friends. However, it is important to note that social media comes with limitations, namely, potentially misleading and inaccurate mental health resources and information, lack of mental health literacy, and the triggering of negative behavior [71]. Given the prevalence of social media use as a part of informal help seeking, future

investigations should examine how to consider the quality and accuracy of mental health information and resources on social media and other web-based platforms for this population.

Nonetheless, future work should examine how best to promote mental health via social media outlets such as Instagram, Snapchat, YouTube, and Twitter. Previous qualitative research suggests that the dissemination of health information via social media can be achieved using various strategies, including contests, interactive campaigns (eg, with educational polls), and community building [72]. At the same time, it will be important for future studies to address the challenge of using social media as a platform for health promotion while reducing the risk of misinformation.

Design Considerations

Overview

A key finding regarding design considerations involved the role of social modeling in health promotion. Behavior change research suggests that the modeling of a behavior leads to optimal behavior change outcomes [73,74]. In this study, Black male students indicated that they would be more likely to engage with a resource on a mobile-based app or social media platform if it offered testimonials portraying positive mental health. This sentiment, indeed, speaks to the need for relatable and representative content in mental health app research.

Relatability and Representation

Although it was difficult for the men to explain what they meant by relatability, they primarily related this concept to representation. The men wanted to see themselves, see advertisements and resources made for them and that include images or message components related to their lives—as students, as Black men, and as emerging adults in college. The men discussed that seeing themselves in advertisements or components would make the resources more relatable. This design consideration aligns with the need for targeted design efforts in mental health research, which can diverge from research focused on inclusive design among other minority populations [75]. In our study, this preference for representative components and relatable content aligns more with targeted design in which these men prefer visual representations that are made for them and reflect Black men's mental health needs. Importantly, the men also discussed that this preference stems from the observations that they do not see their lives, experiences, or needs reflected in current available resources and prevention efforts; therefore, their desire and comfort level to engage is limited. There is little research targeted to men from Black populations [76], which perpetuates disparities that further increase the risk of poor mental health and low treatment use among Black male students [77]. This gap also makes it difficult for researchers to develop mental health support that is effective in drawing Black male students in and engaging them in prevention efforts.

With targeted and tailored design approaches, specifically those that are culturally sensitive and appropriate, Black male students would be more likely to engage and resources would be better able to meet their needs [27]. This study focuses specifically on Black male students' needs, creating a space for them to

share those desires and needs, which will provide insights for designing targeted efforts that are visual, text-based, and reflective of the mental health experiences of Black men generally and in college settings. Thus, it will be important for campus-based practitioners and researchers to examine ways to tailor advertisements and intervention components specifically to Black men's lived experiences. The current lack of representation in mental health research may prevent researchers and clinicians from accurately recognizing mental health difficulties at initial onset among Black men and understanding how mental health difficulties may present within the context of a college campus [78].

Stigma

This study provides insight into appropriate visual- and text-based components to include in design efforts and more representative digital tools focused on addressing stigma, a factor that remains a significant barrier to treatment use among minority populations [19,76,79]. In particular, in a study conducted by Lipson et al [76] with a sample size of 40,000 students (13,000 students of color), male students had higher levels of perceived stigma. In our study, Black male students discussed their desire for mental health apps and social media mental health support that included visual- and text-based components that indicated a need to normalize the discussion of mental health in the Black male community. The men discussed how, today, mental health remains a public health concern that is not discussed and almost ignored, a finding that aligns with previous research on mental health as a "taboo" subject among this population [80,81]. Social media is widely accessible, reaching individuals who are typically underserved and providing an outlet for these individuals to engage with mental health promotion materials and resources to increase mental health awareness [29]. Given the stigma surrounding traditional avenues of mental health discussion and treatment in the Black male community, social media-based mental health support may represent an initial, more accessible form of treatment to reach college-aged Black men as well as a means of normalizing conversations around mental health [80,81].

Audio and Visual Components

The findings also offer insights into specific preferences for mental health support on social media. The men reported a preference for audio and visual content delivery, such as experiencing mental health support through podcasts and listening to voice notes. There is little research focused on the role of podcasts and voice notes as methods for mental health promotion among Black men and, specifically, among Black men in college; however, there has been work focused on the role of podcasts in mental health education [82]. Willis [82] showed how podcasts create an opportunity for psychiatry residents not only to better understand course material related to mental health promotion but also to provide them with skills that can better prepare them to treat patients and aid in attenuating risk factors that influence mental health disparities. A similar approach may be effective in providing mental health psychoeducation for the purposes of increasing awareness and promoting mental health among Black male college students. Further work should be conducted to determine the role of podcasts in mental health promotion among Black male students

and explore the feasibility of podcasting or audio in intervention work as a means of promoting desired behavioral health outcomes.

Our findings regarding design considerations suggest that text-based images are preferred avenues for health promotion. The men in our study preferred mental health support and resources that were image-based or had pictorial representations of mental health issues and safety. This is consistent with literature that suggests that methodologies related to photo elicitation are useful in promoting mental well-being [83,84] and should be further considered when designing mental health programs and interventions.

Strengths, Limitations, and Future Directions

The strengths and limitations of this study point to directions for future research. Our study was exploratory and targeted a small Midwestern sample, potentially limiting the transferability of the findings to college-aged Black men from this region. Importantly, in relation to the study aim, there is research to suggest that saturation can be met with small sample sizes in qualitative research [85]. We do not know how focal characteristics from this study, such as digital mental health treatment preferences or openness to social media use for mental health treatment, vary across subgroups (eg, in rural vs urban areas and across regions). In addition, our sample included a range of ages and more graduate than undergraduate students, including exclusively graduate students from university 2. However, there was no qualitative difference in how needs varied between undergraduate and graduate students or between younger and older men. In future work, it would be worthwhile to examine the potential differences in how young Black men's needs and preferences vary at different ages.

Selection bias may be a concern as well. The men in this sample may have been more motivated to participate in the study, especially if they heard about the study through a friend. However, we consider this a strength as well. These men's thoughts and experiences are important within the mental health space and will provide unique insight into appropriate dissemination strategies and design ideas that can also be adapted for recruitment efforts that are better able to engage Black male students in future research [86,87]. The study findings should also be interpreted in consideration of the COVID-19 situation at the time. Given that the study was conducted during the peak of the COVID-19 pandemic, when college students were overwhelmed by a sudden transition to digital and computer-enabled classes and communications, the findings may potentially be influenced by their digital fatigue [51]. Participants' perception of using web-based resources and digital tools may also be altered because of this.

Conclusions

Our qualitative investigation to understand Black male students' needs and preferences surrounding nontraditional methods of mental health promotion provides key insights into addressing current mental health access barriers. Our findings provide evidence for leveraging social media and digital tools to introduce mental health services in an informal way, making tools more widely accessible and more appropriate to meet their

needs [88]. Digital tools and social media platforms are already being used to discuss mental health concerns [89] and have the potential to reach large numbers of individuals who are less likely to use traditional mental health services [29,42,90], such as Black men. As the pandemic continues to disrupt the ways in which mental health support is provided and increase the demand for services, it is critical to understand how minoritized groups are seeking mental health support and address key factors affecting adequate mental health care and overall access. The insights from this study can serve as a stepping-stone for

researchers to develop work that is contextually and culturally relevant to Black male students, ultimately improving access and use rates of mental health services among Black men throughout their life span. Researchers, campus-based practitioners, and policy makers should aim to conduct work that promotes the role of social media and mobile-based technologies in mental health promotion and in supporting the unique mental health needs of Black male students and their communities.

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Conflicts of Interest

EGL has received consulting fees from Modern Health and honoraria from Streamline Healthcare Solutions, LLC.

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Abbreviations

REDCap: Research Electronic Data Capture

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Original Paper

Examining Hashtag Use of #blackboyjoy and #theblackmancan and Related Content on Instagram: Descriptive Content Analysis

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Abstract

Background: Social media is widely accessible and increasingly utilized. Social media users develop hashtags and visual, text-based imagery to challenge misrepresentations, garner social support, and discuss a variety of mental health issues. Understanding how Black men are represented on social media and are using social media may be an avenue for promoting their engagement with and uptake of digital mental health interventions.

Objective: The aim of this study was to conduct a content analysis of posts containing visual and text-based components related to representations of Black men's race, gender, and behaviors.

Methods: An exploratory, descriptive content analysis was conducted for 500 Instagram posts to examine characteristics, content, and public engagement of posts containing the hashtags #theblackmancan and #blackboyjoy. Posts were selected randomly and extracted from Instagram using a social network mining tool during Fall 2018 and Spring 2019. A codebook was developed, and all posts were analyzed by 2 independent coders. Analyses included frequency counts and descriptive analysis to determine content and characteristics of posts. Mann-Whitney U tests and Kruskal-Wallis H tests were conducted to assess engagement associated with posts via likes, comments, and video views.

Results: Of the 500 posts extracted, most were image based (368/500, 73.6%), 272/500 (54.4%) were posted by an individual and 135/500 (27.0%) by a community organization, 269/500 (53.8%) were posted by individuals from Black populations, and 177/500 (35.4%) posts contained images of only males. Posts depicted images of Black men as fathers (100/500, 20.0%), Black men being celebrated (101/500, 20.2%), and Black men expressing joy (217/500, 43.4%). Posts (127/500, 25.4%) also depicted Black men in relation to gender atypical behavior, such as caring for children or styling their children's hair. Variables related to education and restrictive affection did not show up often in posts. Engagement via likes (median 1671, $P<.001$), comments ($P<.001$), and views ($P<.001$) for posts containing #theblackmancan was significantly higher compared with posts containing #blackboyjoy (median 140). Posts containing elements of celebrating Black men ($P=.02$) and gender atypical behavior ($P<.001$) also had significantly higher engagement.

Conclusions: This is one of the first studies to look at hashtag use of #blackboyjoy and #theblackmancan. Posts containing #blackboyjoy and #theblackmancan promoted positive user-generated visual and text-based content on Instagram and promoted positive interactions among Black and diverse communities. With the popularity of social media and hashtag use increasing, researchers and future interventional research should investigate the potential for such imagery to serve as culturally relevant

design components for digital mental health prevention efforts geared towards Black men and the communities they exist and engage with.

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KEYWORDS

Black/African American men; mental health prevention; social media; Instagram; hashtags; content analysis; Black masculinity

Introduction

Background

Social media is extremely popular and widely accessible [1,2]. More than 80% of young adults use social media platforms extensively [1], with typical activity exceeding 6 hours per week [2,3]. Social media networking sites are also now dominant sources of health information and health promotion [4,5]. According to the Pew Research Center, 72% of adult users search for news and health information online [6,7] and 26% of adults in the United States learn about health experiences from others on social media platforms [6]. Despite the increasing popularity of social media and its use, user statistics about Black men on these platforms is extremely limited. However, more than 65% of Black adults in the United States are using social media platforms on a daily basis [1]. Understanding how Black men are represented on and use social media may be an avenue for promoting their engagement with and uptake of digital mental health interventions [8]. The conversations on social media include discussions about sensitive mental health topics and the sharing of individuals' personal experiences with mental health issues [9], as well as interactions where people are connecting with one another and seeking social support [8]. Content analyses on photo-based platforms, such as Instagram, could provide a unique approach for researchers to examine how social media platforms can promote mental well-being among underserved groups.

Instagram and #theblackmancan #blackboyjoy

Instagram, launched in 2010, is a free, widely accessible, photo- and video-sharing social networking site [10]. In the United States, Instagram is one of the more popular social networking platforms, more widely used than Twitter [11], with a national user base of over 170 million and a global user base of over 1.3 billion people [12,13]. In particular, Instagram is very popular among young Black adults [14,15].

The popularity of hashtags, which are phrases or words strung together with a hashtag (#) placed in front of it, has grown exponentially and gained traction on platforms such as Instagram. Hashtags are widely used and can be started by anyone, defying the limits typically associated with traditional media and news outlets, and can lead to significant political and social movements [15,16]. In 2017, the hashtag #MeToo sparked a social movement in global support of sexual assault and harassment survivors. Within the Black community, the hashtag #BlackLivesMatter, coined in 2013, continues to be an important campaign, set against violence and systemic racism toward Black people. Similarly, celebrities, such as Kid Cudi, and athletes, such as Dak Prescott, used social media and relevant hashtags to discuss their personal issues with bipolar disorder

and depression. The practical effects of these hashtags and movements are overwhelming, resulting in structural changes in both the entertainment industry and society at large. Despite this increased popularity and galvanizing nature of hashtags, there is little research focusing on the use of hashtags among diverse communities and the potential role they can play in mental health promotion.

The hashtags #theblackmancan and #blackboyjoy are popular among the Black male and Black community. The hashtag #theblackmancan was created by a nonprofit organization, TheBlackManCan, Inc., founded by Brandon Frame, to share stories aimed at empowering Black boys and men [17]. TheBlackManCan, Inc. started as a blog in April 2010, with the aim to empower Black men and has since become a "social community that reflects positive images of Black boys and men of color" [17]. The organization's Instagram now has over 898,000 followers [18]. The #blackboyjoy is another hashtag created specifically to promote positive imagery and images about Black boys and men to counter the negative stereotypes that are placed on Black men in today's society [19,20]. This hashtag was popularized in 2016 by Danielle Young [20], writer for *The Root*, an African American-oriented online magazine, after watching Black male musician and producer Chance the Rapper displaying happiness at an award show. This hashtag, used over 1,832,953 times on Instagram [21], has evolved, and is widely used to create and highlight online spaces for Black men to express and display sentiments of joy, happiness, and laughter. To date, there are no published analyses looking at these hashtags. Importantly, there is little research examining social media hashtag use as a possible avenue for mental health promotion, creating a gap in our understanding of the efficacy of utilizing these, and other hashtags, in promoting culturally relevant design elements for interventional efforts geared toward minority men's mental health.

Related Work

Much of our knowledge of social media platforms and related user-generated content excludes social representations of Black men [22], focuses heavily on understanding data dissemination [23], and is often focused on Twitter [24,25]. For example, one study examined characteristics of #fitspiration content on multiple social media platforms, finding that the majority of the posts depicted women, and presented imagery of women reinforcing the "thin" ideal, which is negatively associated with unhealthy behaviors [26]. This analysis, among others [27], provides direction for researchers investigating which ideals are most pervasive in reinforcing unhealthy social norms. Researchers, then, can develop messages that appropriately counter such norms and, instead, encourage healthy behaviors [26]. Few studies have taken this approach in relation to Black men's health behaviors and mental health, making this a critical

focus area. Content analyses have also examined the formation of social representations via images, which are important in health-promotion efforts [22]; examining health behaviors; understanding risk for health issues among underserved populations; and learning about the lived experiences of marginalized individuals [28]. However, there remains a paucity of content analyses focused on Black men, their interests, and their lived experiences. This lack of understanding and knowledge likely reinforces stigmatized beliefs related to Black men, their mental health, and their overall lived experiences.

Guiding Framework

There is a growing literature base in social media content analyses, providing insight into the role post content and hashtags can play in understanding the lived experiences of traditionally excluded populations. Such insight creates opportunities for researchers to design mental health-promotion efforts that are culturally and contextually relevant to those they wish to serve. Because there were no existing codebooks on the topic, this study utilized a framework informed by formative literature and relevant theoretical concepts, including Tyree et al [29] and Gray's [30] framework for Black masculinity, the Gender Role Conflict Scale, and aspects from The Black Man Can Institute's mission statement and Black Boy Joy's website.

Masculinity and Black Masculinity

Ideals associated with masculine norms are important to assess as social constructions of masculinity are significant barriers to the uptake of mental health-promotion efforts and often negatively impact mental well-being among Black men [31-33]. According to gender role conflict constructs [34], due to masculine norms and expectations, men have difficulty balancing workplace and family demands and are socialized to be competitive, emotionally restrictive, and refrain from showing affection for other men [34]. The extent to which men adhere and conform to these ideals can cause high levels of stress for men, as well as for their interpersonal relationships [35]. Studies report direct links between measures of masculine adherence and lack of adherence to medical and mental health-related help and treatment [35]. Black men are not only socially expected to conform to masculine norms but are also presented with unique societal expectations, resulting from negative stereotypes associated with Black masculinity and Black masculine positionality [29,30]. These stereotypes often stem from misrepresentations in the media [36]. Jackson [37] and Tyree and colleagues [29] provide a framework of Black masculinity and positionality, proposing that there needs to be a redefining in which Black men are defined by ideals more closely associated with their experiences as Black men in society [29,30]. Black men often relate to certain ideals of masculinity—struggle, recognition, independence, achievement, and community—that define their manhood, masculinity, and position in society [29,30]. Other characteristics of Black men that are positive and ascribed to include presenting a “cool pose” or exhibiting a comedic nature [29,30]. This study aims to analyze posts related to Black men's masculine identity. Findings may be translated to other work, serving as targets for conducting mental health work within the realm of social media.

Current Study

This exploratory, descriptive study employed content analysis to identify characteristics of Instagram post content containing the hashtags #blackboyjoy and #theblackmancan. This content analysis examines how diverse users, including Black men, are generating content and social media messages that present positive images and lived experiences of Black men. We also aimed to examine public engagement with posts to see how visual and text-based social media messages and user-generated content promoted engagement or interactions. The overarching research questions were:

- How are posts containing #blackboyjoy and #theblackmancan portrayed on Instagram and what are the characteristics of these posts?
- To what extent do these posts challenge stereotypes associated with Black men's race and gender?
- Do these posts garner interactions or support?

Methods

Study Design

A social media content analysis [38,39] was conducted to examine the content of posts related to Black men on a social media platform, Instagram. A random sample of public Instagram posts was collected using Netlytic [40], a web-based social network mining tool, during the Fall of 2018 and Spring of 2019. Posts containing the hashtags of interest, #theblackmancan and #blackboyjoy, were extracted. Posts were assessed visually for inclusion in analysis if they (1) contained either or both hashtags and (2) were in English or could be translated into English using Instagram's translation feature. Posts were excluded if they did not contain either hashtag or if the link for access was no longer active at the time of coding. The poster source, caption, post, and post components were examined for this study. Posts were coded for a variety of variables related to the study's aims and objectives and were coded by 2 independent coders (KDAW and SAD). Two coders received extensive training on the utilization of the codebook. An iterative process was conducted in which weekly meetings were established to discuss discrepancies, determine consensus, and reach agreement between coders; 10.0% (n=50) of the Instagram posts were independently analyzed by the coders to reach an agreement as assessed by Cohen κ [41]. Guidelines for reliability analyses in content analyses suggest that there must be agreement on at least 10% of the study's sample with a κ statistic near the recommended cut-off value of 0.70 [41]. For this study, intercoder reliability for coding and analysis showed a coefficient of agreement (κ) between coders no lower than 0.69.

Codebook Development

Given the dearth of evidence on content analyses related to Black men and relevant hashtags, there is no established codebook to use or adapt for this analysis; therefore, a codebook was developed specifically for this content analysis (codebook is available in [Multimedia Appendix 1](#)). The first author (KDAW) first developed and operationalized codes based on current literature, study objectives, and variables of interest.

The codebook went through multiple phases of revisions based on feedback from 2 university faculties with expertise in conducting quantitative content analyses on social media. These revisions focused mostly on the development and iteration of codes related to visual components of the posts. After revisions were made, the codebook was reviewed by 2 Black, male graduate students. These men's perspectives in choosing and developing codes were important to ensure appropriate interpretation of Instagram posts including variables related to Black culture and Black men. This technique mirrors member checking, providing feedback on study methods, and approaches by members of the intended target population, which promoted validity of the research methods and findings [42].

Variables of Interest

Post Characteristics

The initial set of codes focused on visual and face-value content and included codes related to the visual components. Variables included focused on poster source (ie, who is posting), the kind of visual (eg, text or image based), and people present in post (eg, number of people), among other aspects.

Post Content

Variables were then added to assess context and content. Such variables assessed aspects related to masculinity and gender roles and were informed by items from the Gender Role Conflict Scale, Gray [30] and Tyree et al's [29] framework for Black masculinity, as well as components of The Black Man Can Institute's mission statement [17] and Black Boy Joy's website. For example, posts were coded for whether (1=Yes) or not (0=No) they indicated aspects related to a creation of a safe space, displays of community service, the celebration of Black boys and men, protection, and if men could be seen displaying joy (ie, a boy or man smiling). Posts were also coded for whether (1=Yes) or not (0=No) they focused on aspects related to Black boys or men in educational contexts, receiving or giving mentorship, and men's attire.

Post Engagement

Codebook variables also included codes for assessing public engagement. The included variables were informed by engagement features typically used by Instagram users, analyzing how many likes, comments, and video views (all Instagram application features) were attached to each post.

Data Analysis

All statistical analyses were conducted using SPSS, version 26 (IBM, Inc.). Upon completion of data collection and coding,

frequency counts and descriptive statistical analysis of the coded variables were conducted. Three different types of engagement, namely, likes, comments, and views for videos, were evaluated using nonparametric tests, as Instagram engagement frequencies were not normally distributed. Specifically, Mann-Whitney *U* tests were used to investigate differences in the level of public engagement for variables containing a range of dichotomous variables; and Kruskal-Wallis *H* tests were used to investigate differences in engagement for nominal variables with 3 or more levels.

Ethical Considerations

This study did not directly involve human subjects and did not meet the regulatory definition of human subjects' research; therefore, this study was excluded from institutional review board review at the institution in which this study took place.

Results

Characteristics of Posts

The first research question focused on how posts containing #blackboyjoy and #theblackmancan are being portrayed on Instagram and the characteristics of these posts (see Table 1 for descriptive analyses). Approximately half of the sample either included the hashtag #theblackmancan (248/500, 49.6%) or #blackboyjoy (225/500, 45.0%). Only 27/500 (5.4%) of the posts included both hashtags. All posts contained a poster source, that is, the person or entity who posted the actual post with the hashtag. Of 500 posts, 272 (54.4%) were posted by an individual person, whereas 135 (27.0%) were posted by a community organization. It is important to note that the community organization code captured posts that were also posted by The Black Man Can Institute; however, the software that extracted the posts did so randomly and only extracted posts based on the hashtag itself.

Among posts that had a poster source, only 17/500 (3.4%) were posted by commercial sites. As many as 194/500 (38.8%) of the posts were posted by men and 81/500 (16.2%) were posted by women. Of these posters, 269/500 (53.8%) were posted by individuals from the Black populations. The types of visuals (ie, image or video) included were still images (368/500, 73.6%) and videos (106/500, 21.2%). Among these visuals, 177/500 (35.4%) contained only males, and 179/500 (35.8%) posts contained individuals who were Black. Of the 500 posts, 272 (54.4%) posts containing multiple people were Black. Furthermore, of these posts containing multiple people, 184/500 (36.8%) were of mixed gender and 122/500 (24.4%) posts contained multiple males.

Table 1. Characteristics, descriptions, and post content among posts tagged with #theblackmancan and #blackboyjoy (N=500).

Variable and category/item	Value, n (%)
Characteristics	
Hashtag	
#blackboyjoy	248 (49.6)
#theblackmancan	225 (45.0)
Both	27 (5.4)
Poster source	
Individual	272 (54.4)
Commercial	17 (3.4)
Community Organization	135 (27.0)
Poster source gender: male	194 (38.8)
Poster source race: Black	269 (53.8)
Visual type	
Image	368 (73.6)
Text	7 (1.4)
Mix of image/text	12 (2.4)
Drawing	4 (0.8)
Video	106 (21.2)
Person in visual	
Only one person present	179 (35.8)
Individual present is Black	179 (35.8)
Individual present is male	177 (35.4)
Multiple persons in visual	
Only multiple people present	312 (62.4)
Single race: Black	272 (54.4)
Single gender: only men	122 (24.4)
Multiple persons in visual can be^a	
Children	32 (6.4)
Friends	18 (3.6)
Colleagues	15 (3.0)
Love	48 (9.6)
Family	55 (11.0)
Brotherhood	17 (3.4)
Fatherhood	100 (20.0)
Other	35 (7.0)
Content focused	
Related to #blackboyjoy	
Safe space	3 (0.6)
Community service	4 (0.8)
Celebration of boys	101 (20.2)
Protection	19 (3.8)
Related to #theblackmancan	
Finding joy	217 (43.4)

Variable and category/item	Value, n (%)
Education	44 (8.8)
Mentorship	9 (1.8)
Casual attire wear	254 (50.8)
Business casual wear	36 (7.2)
Professional attire wear	36 (7.2)
Formal attire wear	50 (10.0)
Stereotypically dressed	6 (1.2)
Related to gender roles and conflict	
Gender behavior	127 (25.4)
Restricted affection	29 (5.8)
Restricted emotion	7 (1.4)
Conflict	5 (1.0)
Power and competition	17 (3.4)
Graduation themed	9 (1.8)
Cool pose	154 (30.8)

^aThese variables were visually assessed along with the captions associated with posts.

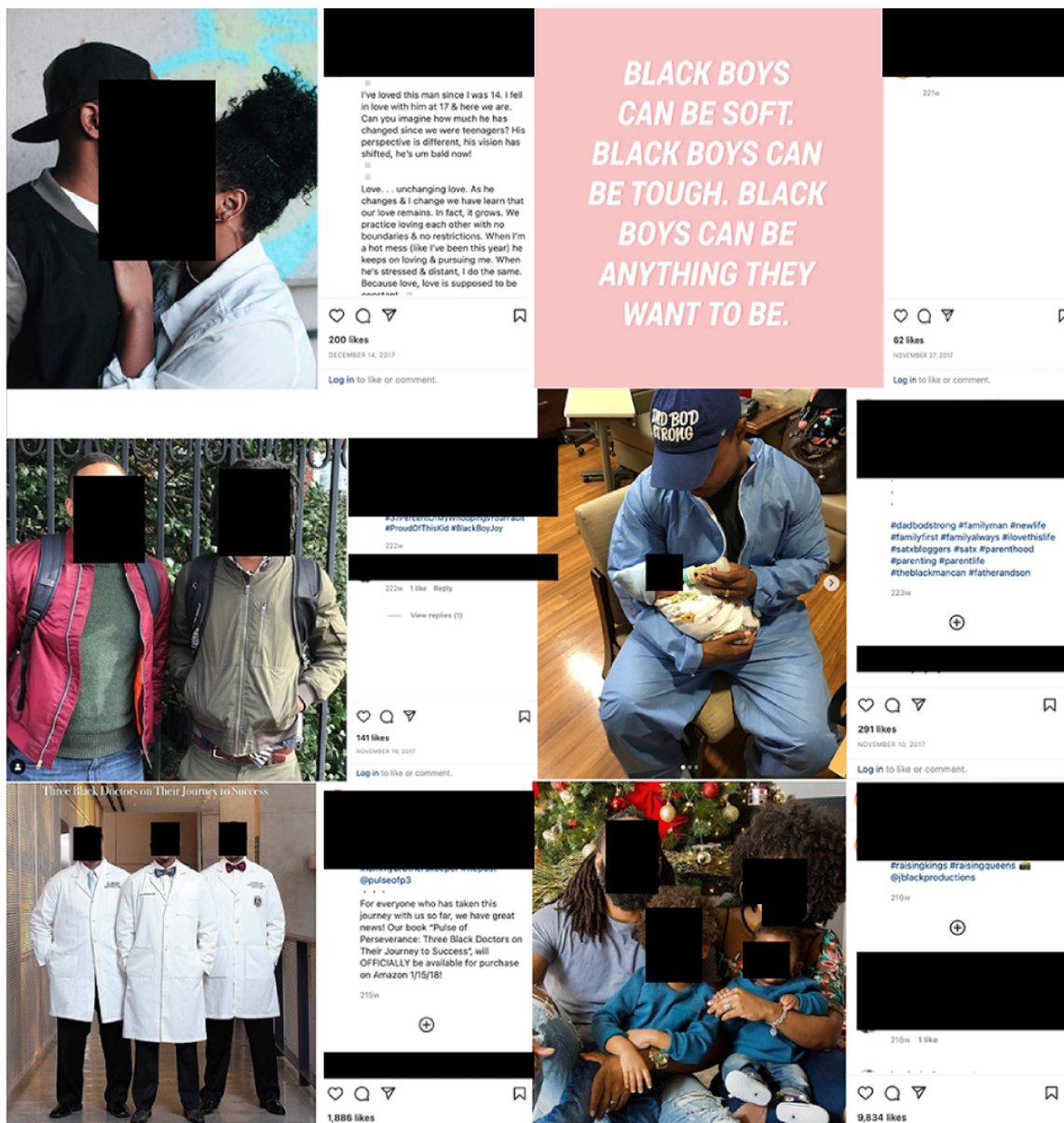
Post Content

The second research question focused on how these posts challenge stereotypes associated with Black men's race or gender and to what extent the public engages with these posts. For the variable assessing the type of imagery depicted in the visual (Table 1), descriptive analyses show that 32/500 (6.4%) posts solely depicted children, 48/500 (9.6%) posts portrayed praise for significant others, and 55/500 (11.0%) posts showed portraits of families (father, mother, and a child or children); 100/500 (20.0%) posts presented images or videos of Black men portrayed as fathers (see Figure 1 for examples of posts).

Among the codes assessing values associated with the mission statement of The Black Man Can Institute, analyses revealed posts celebrating or showing praise for Black men/boys

(101/500, 20.2%) and Black men/boys smiling and expressing joy (217/500, 43.4%). Attire of individuals in these posts were also of interest, as negative stereotypes often show Black men dressed in a manner that is indicative of being criminals and thugs. As many as 254/500 (50.8%) posts included persons who were dressed casually. Other posts showed persons who were dressed formally (50/500, 10.0%), business casually (36/500, 7.2%), and professionally (36/500, 7.2%); 1.2% (6/500) of the posts showed Black men dressed negatively or similar to that of a gang member or thug. Specific to gender roles, posts (127/500, 25.4%) showed men engaging in gender atypical behavior, such as caring for children, doing a child's hair, or engaging in a form of dance other than hip-hop (eg, ballet). However, not necessarily surprising, only 29/500 (5.8%) posts showed men who challenged the norm of restricted affection toward or among men.

Figure 1. Examples of posts portraying aspects related to finding joy, fatherhood, and celebration of Black boys or men.



User Engagement

Analyses revealed statistically significant differences, showing that engagement by likes was higher for posts using #theblackmancan (median 1671) compared with engagement scores of posts only using #blackboyjoy (median 140, $P<.001$). Similarly, for comments, there were significantly higher levels of engagement for posts using #theblackmancan compared with those using #blackboyjoy ($P<.001$). For engagement via views, there were significant differences in engagement between posts using #blackboyjoy and posts using both ($P<.001$) such that #theblackmancan showed higher levels. Mann-Whitney *U* tests were conducted for the variables in Table 2. For celebration of boys, there were significant levels of engagement across all types of engagement (likes, $P=.02$; comments, $P<.001$; views, $P<.001$). Similarly, for posts including men engaging in gender

atypical behaviors (eg, taking care of children, braiding child’s hair), there were higher levels of engagement displayed by likes ($P<.001$), comments ($P<.001$), and views ($P=.001$). Engagement by likes, comments, and views varied for several variables examined, and there were no significant differences for any types of engagement among multiple variables. Specifically, there were no significant differences in types of engagement for posts containing the mentorship (likes, $P=.83$; comments, $P=.47$; views, $P=.39$), community service (likes, $P=.95$; comments, $P=.64$; views, $P=.30$), safe space (likes, $P=.13$; comments, $P=.16$; views, $P=.71$), education (likes, $P=.57$; comments, $P=.47$; views, $P=.65$), conflicts between work and family (likes, $P=.89$; comments, $P=.28$; views, $P=.87$), or competition/power variables (likes, $P=.05$; comments, $P=.22$; views, $P=.22$).

Table 2. Median engagement scores for posts containing race and gender variables in this analysis (N=500 unless otherwise noted).

Variable and engagement variable	Median (present)	Median (absent)	U test	Z score	P value
Celebration of boys					
Likes	1076.00	370.00	24,115.500	3.058	.002 ^a
Comments	27.00	15.00	24,494.000	3.351	<.001 ^a
Views	0	0	23,588.000	3.696	<.001 ^a
Finding joy					
Likes	619.00	410.00	32,658.500	1.220	.22
Comments	17.00	17.00	31,666.000	0.600	.55
Views	0	0	34,830.000	3.591	<.001 ^a
Atypical gender behavior					
Likes	1779.00	313.00	31,077.000	5.256	<.001 ^a
Comments	43	13	28,941.500	3.739	<.001 ^a
Views	0	0	26,968.000	3.254	.001 ^b
Restricted affection					
Likes	231.00	491.00	6651.000	-0.236	.81
Comments	18.00	17.00	6519.500	-0.411	.68
Views	0	0	8478.500	3.045	.002 ^b
Protection					
Likes	3449.00	424.00	6076.500	2.440	.02 ^a
Comments	67.00	17.00	6055.500	2.406	.02 ^a
Views	0	0	4826.000	0.579	.56
Mentorship					
Likes	403.00	462.00	2304.500	0.221	.83
Comments	33.00	17.00	2519.500	0.722	.47
Views	0	0	1944.000	-0.862	.39
Community service					
Likes	279.00	475.50	972.000	-0.069	.95
Comments	14.00	17.00	1125.500	0.464	.64
Views	0	0	778.000	-1.037	.30
Safe space					
Likes	102.00	489.00	364.500	-1.527	.13
Comments	7.00	17.00	394.000	-1.409	.16
Views	0	0	813.000	0.377	.71
Education					
Likes	455.00	458.00	10,551.000	0.567	.57
Comments	23.00	17.00	10,688.000	0.717	.47
Views	0	0	10,333.000	0.459	.65
Wedding party (attire; n=63)					
Likes	2854.50	941.00	491.500	1.316	.19
Comments	37.00	36.00	426.500	0.327	.74
Views	0	0	448.000	1.028	.30

Variable and engagement variable	Median (present)	Median (absent)	<i>U</i> test	Z score	<i>P</i> value
Atypical gender behavior					
Likes	1779.00	313.00	31,077.000	5.256	<.001 ^a
Comments	43.00	13.00	28,941.500	3.739	<.001 ^a
Views	0	0	26,968.000	3.254	.001 ^a
Restrictive affection					
Likes	231.00	491.00	6651.000	-0.236	.81
Comments	18.00	17.00	6519.500	-0.411	.68
Views	0	0	8478.500	3.045	.002 ^a
Restrictive emotion					
Likes	879.00	452.00	1721.500	-0.011	.99
Comments	15.00	17.00	1647.000	-0.207	.84
Views	5237.00	0	2817.000	4.009	<.001 ^a
Conflicts between family and work					
Likes	373.00	489.00	1284.000	0.145	.89
Comments	67.00	17.00	1582.000	1.072	.28
Views	0	0	1199.000	-0.167	.87
Competition/power					
Likes	122.00	519.00	2968.500	-1.942	.05
Comments	6.00	18.00	3390.500	-1.222	.22
Views	0	0	4629.000	1.223	.22
Cool pose					
Likes	352.50	607.50	24,622.500	-1.354	.18
Comments	18.00	17.00	26,060.000	-0.390	.70
Views	0	0	23,774.500	-2.681	.007 ^b
Comedic presence					
Likes	2332.00	426.00	4614.000	1.772	.08
Comments	106.00	16.00	5420.500	3.236	.001 ^a
Views	7575.00	0	5817.000	5.514	<.001 ^a

^aSignificant at $P < .05$.

^bSignificant at $P < .05$, but not significant in practice as both medians are 0.

Kruskal-Wallis H tests showed significant differences in engagement via comments ($\chi^2_7=15.961$, $P=.002$) for the attire type variable and via views ($\chi^2_9=19.490$, $P=.02$) for the group type variable. There were differences in engagement scores for the group type variable and attire type variable. The group type variable included categories such as children, friends, colleagues, family, brotherhood (see the “Multiple persons in visual can be” variable in Table 1). According to analyses, there were significant differences between posts containing the family variable (median 0) and those containing the “other” variable (median 54.00, $P=.006$). The attire type variable included categories such as an individual wearing casual clothes, business casual, professional, formal, or stereotypically dressed clothing (ie, thug garb; Table 1). There were significant differences

between posts containing the casual (median 0) and other variable (median 29.00, $P=.03$) and between the casual variable and formal variable (median 43.50, $P=.05$), but not among other groups.

Discussion

Principal Findings

This study analyzed Instagram posts containing the hashtags #blackboyjoy and #theblackmancan. The findings offer direction for researchers who wish to use visual and text-based content in mental health-promotion efforts geared toward Black men.

Overall, most posts were primarily image based with only a small number including videos or video-based images. Analyses

showed that there were few posts that portrayed depictions related to education and restricted affection, and posts depicting ideals particular to #blackboyjoy included imagery where men were shown celebrating Black boys and men and finding joy. When analyzing whether posts were posted by an actual person, group, or community organization, we see that Black men and communities are, in fact, using these hashtags. Community organizations, in particular, used the #theblackmancan hashtag more often compared with #blackboyjoy. We also see that the images analyzed in this study foster positive interactions from viewers and users on Instagram.

According to analyses of engagement, public engagement was positive for posts containing variables related to celebrating men and boys, men engaging in gender atypical behavior, and posts displaying sentiments of protection. In addition, engagement via viewership was high for the following variables: cool pose, finding joy, restrictive affection and restrictive emotion, and comedic presence. The #theblackmancan hashtag showed more public engagement, eliciting more likes and comments from the public, suggesting that ideals and expressions related to the #theblackmancan were more popular and relatable at the time of analysis and produced more aesthetically appealing content than #blackboyjoy. It is difficult to ascertain why this is the case; however, it may be due to social media users' access or the fact that this hashtag is influenced by the organizational reach of The Black Man Can Institute. It could be that the #blackboyjoy movement, though popular, did not have the same reach. However, this is unclear and difficult to establish for certain as the #blackboyjoy movement received a lot of national attention by a large group of people, including celebrities who have either endorsed or not endorsed the hashtag's use.

Comparison With Prior Work

The finding that most posts were image based was expected as Instagram is primarily a photo-sharing platform and indicates that, despite the social media having a feature for the posting of videos, the posting of still images and pictures remain the primary behavior on this social media platform [43]. Consistent with emerging research, many of the images expressed personal beliefs and values, which has relevance for recent research examining the impact of photo sharing and photo elicitation and its role in mental health prevention and promotion [44]. In community-based participatory work, researchers utilize similar methods to understand the experiences of marginalized populations in an effort to promote health and understand lived experiences of minority populations [45].

Notably in this study are posts including images of mothers or wives offering support for their significant others and showing appreciation for the Black men and boys in their lives. Although these images showed up in less than 50% (101/500, 20.2) of the posts, this representation of "celebrating Black men" is important and suggests how community, and even researchers, can utilize outlets such as Instagram to empower Black men and men of color and their accomplishments, which is atypical according to traditional images put forth by traditional media [46]. Images with Black men being celebrated also included sentiments of men with their families. The posts in this study

depicted Black men as family men who engaged in "gender atypical behavior" (127/500, 25.4%) such as men taking their children to work or doing their daughter's hair. This positive representation of Black men engaging in fatherhood is often underrepresented or inaccurately represented in the media, such that men are portrayed as absent in the household or intentionally disengaging from family responsibilities [47,48], leading to reinforcement of negative stereotypes [49] that inevitably impact Black men [50,51].

Increased depictions of Black men in a positive light will promote positive representation of Black men within digital mental health spaces that are visual based. This representation can then lead to men's increased interest, engagement, and acceptability of current and future mental health visual-based interventions [22]. This study's findings, related to Black men displaying joy and positive engagement, highlight a potential visual or text-based characteristic that can be incorporated into a social media, mental health message geared toward Black men. There is already work being done in the mental health message space such that Robinson and colleagues [52] found that social media-based, suicide prevention messages are acceptable and safe among young adults. A recent paper by Seidler and colleagues [53] set forth a call for action for developing "gender-sensitive" and appropriate mental health care and how such approaches should emphasize a redefining of men's masculinities. This redefining can include positive imagery as that seen in this study and will aid in our ability to increase representation of Black males and their engagement with mental health prevention efforts, specifically help-seeking and mental health prevention campaigns [53].

There were few posts that included depictions of men related to education and restricted affection. This finding can be related to the fact that misrepresentations and stereotypes associated with Black men being uneducated [54] and Black men being unable to show affection are not as easy to counter in this medium. These ideals, combined with social norms criminalizing Black men and stigmatizing mental health within this community, (1) reinforce unrealistic expectations related to unhealthy masculine ideals, such as restrictive emotion [31]; and (2) make it particularly challenging and uncomfortable for Black men to engage with health-related efforts and programming [28]. Few depictions of men related to education may also be reflective of educational disparities that continue to exist for Black men as there are higher dropout rates and lower retention among this group [55]. Such disparities and representations may be harder to challenge in this medium; however, future research would be appropriate to investigate this further.

Future Work

With social media constantly evolving, further research should be conducted to examine how prevalent hashtags can counter and reshape narratives that promote ideal health behaviors and mental health outcomes among Black men [56]. There are various approaches and avenues that researchers can utilize as we move forward in the field of digital mental health. One approach is further examination of user-generated, asset-based content that gives insight into the various images and imagery

Black men choose to express themselves on a digital-based platform and using digital tools most relevant to them, such as hashtag use. From this study, we see that Black men are portraying themselves in a different light but also show which factors or norms may be more pervasive and relevant to Black men and their communities. This “flipping of the narrative” can hold much promise for the future of mental health prevention geared toward minority men and other populations such that programming can take a visual-based approach, utilizing positive imagery that is relevant to minority populations.

Researchers can further examine study variables as potential mutable factors for intervention work and include intervention design elements that are culturally appropriate, contextually relevant to Black men and, eventually, once translated and adapted, other minority men and their communities. For example, in the posts, there were a high number of images containing visuals of Black men being celebrated. Figuring out how to incorporate this positive aspect into programming and visual-based campaigns will draw Black men in to participate in research as well as empower them, increasing their self-efficacy and promoting adherence of therapeutic treatments in which the campaigns are advertising.

Findings from this study also begin to highlight how a social media platform, such as Instagram, can be manipulated to promote sentiments, such as celebrating men or destigmatizing restricted affection and emotion. Researchers, clinicians, and mental health professionals can expand on the study findings, engaging in intervention work that focuses on Instagram and other relevant platforms, and consider how this generated content promotes health and mental health support messages. For example, within this study, there is some indication of the potential role of peer support via family and loved ones, who are using these hashtags and posting appropriate and relatable content. Future research should investigate how to combine the use of visual-based and text-based images with human support to create and implement future mental health and suicide prevention efforts [9] that are useful and sustainable within Black male communities. Similar to photo elicitation work [57], further exploration into image-based messaging will allow researchers to examine and begin to understand how images promote ideals related to mental health, their lived experiences, and even, their mental and emotional safety [28,44,57]. In addition, as we see community organizations may be engaging with this hashtag, and others like it, it would be important to conduct work with and partner with community organizations to foster men’s engagement on a broader level and with wider impact.

Limitations

As with any study, there are limitations to acknowledge. Although efforts were made to address the concern for human error in this study, there may have been posts falsely excluded due to misjudgment by coders. There are variables included in this analysis that only allowed for “other” or “unsure” or “uncertain” or “cannot tell” and, due to the subjective nature of content analyses, this may have led coders to miss variables, limit codes, or include irrelevant variables. There may have been posts unable to be included in the analysis because an Instagram user’s profile was private or the link to a profile at time of analysis was deemed “no longer existing.” Mentions (an Instagram feature where the poster uses an “@” symbol followed by an individual’s Instagram handle) were not coded in this study. Coders, then, did not code for this under the category Public Engagement. At the time of analysis, the hashtags, #blackboyjoy and #theblackmancan, though still used, were popular and used often; however, in posts, these hashtags were not the only ones used. Our analyses only aimed to extract posts that contained these hashtags and posts included in this analysis could contain other hashtags. Despite these limitations, the codebook was thoroughly developed and updated continuously for a period of over 5 months in collaboration with members who matched the study’s sample by gender and race to ensure there were codes appropriate in capturing variables associated with study goals and objectives.

Conclusions

Digital mental health interventions can reduce health disparities and improve access to service; however, there is a paucity of digital mental health work geared toward Black men. When members from underserved and underrepresented populations see themselves in prevention efforts, they are more likely to engage [22]. By examining social media content celebrating Black men, this study can inform the design of digital tools that are visual based and relevant. Developing technology and digital programming effective in promoting mental health among minority populations and improving related health behaviors are of vital importance. This study is one of the first to explore the use of the hashtags #blackboyjoy and #theblackmancan on Instagram, illustrating the potential for hashtags, as digital tools, that express Black men’s values and beliefs, allowing these men to illustrate their lived experiences as Black men in society. As social media users continue to access the platforms to share experiences and communicate, there is a need to further examine how members from underserved populations interact with social media and how this technology can be harnessed to promote their well-being.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Codebook for: Examining social media and hashtags as digital tools: A descriptive content analysis of #blackboyjoy and #theblackmancan on Instagram.

[DOCX File , 299 KB - formative_v6i8e34044_app1.docx]

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Original Paper

Factors Influencing the Adoption of Voluntary Nonpharmaceutical Interventions to Control COVID-19 in Japan: Cross-sectional Study

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Abstract

Background: Trust in government is seen to facilitate crisis management and policy instrument adoption across numerous studies. However, in Japan, public support for government handling of the COVID-19 pandemic and trust in the government is low, yet the adoption of voluntary nondigital nonpharmaceutical interventions (NPIs) is high. This is an important tension this study seeks to unravel.

Objective: The aim of this study is to understand the antecedents of nondigital NPI and tracking app adoption in the COVID-19 pandemic in Japan.

Methods: A commercial company was contracted to deliver an online survey of 1248 Japanese citizens in December 2020. A quota technique was used to deliver a sample representative in terms of gender, age, residence, income, and education.

Results: The adoption of voluntary nondigital NPIs is predicted by confidence in public health scientists and a favoring of infection control over reducing economic and social costs. A novel and unexpected finding is that trust in government does not predict nondigital NPI use. Perceived risk and knowledge of infection did not increase the use of nondigital NPIs. Education and income were not significant factors, although female and older respondents demonstrated greater compliance. For the adoption of a phone tracking app, trust in government is important, as is urban residence, albeit with a lower use of the app compared to nondigital NPIs.

Conclusions: Voluntary compliance in the adoption of nondigital NPIs—if skillfully led by trusted scientific experts and in accord with societal norms—can be effectively achieved. We provide evidence that trust in government is effective in encouraging the use of the Japanese tracking app. Moreover, the technical efficacy of digital initiatives and perceptions of such will unsurprisingly affect citizen support and use of digital tools.

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KEYWORDS

COVID-19; nonpharmaceutical interventions; social distancing; phone tracing; trust in government; confidence in scientists

Introduction

Background

A body of literature suggests that trust in government facilitates crisis management and citizen compliance with government directives and suasion during the COVID-19 pandemic [1]. Moreover, trust in government initially increased in several countries, partly due to perceptions of effective pandemic management [2]. Trust in government remains low in Japan, however [3]. Moreover, despite the relatively low death toll, surveys show low levels of support for the Japanese government's handling of the pandemic. Indeed, according to the Pew Research Center [4], only 55% of Japanese respondents believed that the government had dealt properly with the COVID-19 pandemic, a portion lower than that of Italy (74%) and Sweden (71%), both of which recorded more COVID-19 deaths as a proportion of the population. However, compliance with voluntary nondigital nonpharmaceutical interventions (NPIs) has been high, as this study will show. Hence, the role of trust in government in Japan in the adoption of NPIs is likely to be more complex than other studies suggest.

Apart from vaccination, the Japanese government recommended a range of NPIs, including hand washing, face mask wearing, social distancing, staying at home, and the use of ventilation. Citizens were encouraged to avoid the so-called 3Cs: closed spaces, crowded places, and close-contact settings. A contact-tracing app, the COVID-19 Contact-Confirming Application (COCOA), was developed and launched by the government on June 16, 2020. In most cases, there was no penalty for flouting government directives due in part to constitutional constraints prioritizing individual privacy and freedom. Instead, the adoption of NPIs depended on voluntary citizen compliance with government guidelines, which was largely achieved, albeit with lower contract-tracing app use compared to other NPIs. This is in marked contrast to some other countries' use of coercive and legal means to enforce lockdowns and other NPI adoption [5,6].

This study seeks to clarify the factors associated with NPI and tracing app adoption. Drawing on an online representative survey of 1248 Japanese citizens and testing 3 groups of hypotheses, we show that the adoption of nondigital NPIs is predicted by confidence in public health scientists and support for infection control over economic and social costs. Trust in government does not predict nondigital NPI use—an unexpected and counterintuitive finding. Perceived risk or knowledge of infection does not increase nondigital NPI use. Education and income are not significant factors although females and older respondents demonstrate greater compliance. Regarding the adoption of a phone-tracking app, trust in government is important, as is urban residence, but confidence in public health scientists is not.

Hypotheses

A variety of NPIs have been used worldwide to control the pandemic including social distancing, mask wearing, lockdowns, staying at home, hand washing, ventilation, and the adoption of digital tracing. Border closures, curfews, and other measures could also be classified as NPIs. There are historical precedents

for NPI use, including in the Spanish flu and SARS (severe acute respiratory syndrome) epidemics, and quarantining and social distancing have long histories in previous pandemics. There is also recent empirical support for their efficacy. For example, Bo et al [7] examined the effectiveness of mandatory mask use, isolation or quarantine, social distancing, and traffic restrictions; they confirmed significant reduction in morbidity across the 190 countries studied. Haug et al [8] analyzed the impact of various NPIs and found support for their effectiveness. China, the United States, the United Kingdom, and the European nations have used contact tracing through digital means, which are claimed to be effective [9-12].

Trust in government may predict NPI adoption during a pandemic [13]. A large body of research suggests trust in government is associated with policy instrument adoption [1,2]. For example, Goldfinch et al [2] found that trust in government and confidence in public health scientists predicted phone-tracking app use in Australia and New Zealand. Studies in the United States found that trust in government and government sources was associated with adoption of social distancing [14]. Moreover, with citizens relying on experts' guidance, confidence in scientific expertise is likely to be related to the adoption of NPIs. A multinational survey company, Ipsos, reported that doctors and scientists are trusted more than are governments by citizens worldwide [15]. In the case of Japan, (medical) doctors are rated "the first most trustworthy" (52%) and scientists are rated "the second most trustworthy" (43%) [15]. Kazemian et al [16] found in the United States that scientific trust raised support (although adoption was not measured) for COVID-19 social-distancing policies [16]. Given the Japanese context, we focus on the 6 NPIs recommended by the government: wearing facemasks, washing hands, social distancing, refraining from going out, avoiding the 3Cs, and maintaining ventilation. This wide range of measures adds to the novelty of this study.

This discussion leads us to our first set of hypotheses: hypothesis 1a—trust in government is associated with compliance with preventive behavior directives; hypothesis 1b—confidence in public health scientists is associated with compliance with preventive behavior directives.

Perceived risk, fear, and knowledge of the disease might be a factor in NPI adoption [6]. For example, Pedersen and Favero's [5] online survey of US residents found willingness to maintain social distance was predicted by perceived risk of the pandemic. Harper et al's [17] UK study found that a leading antecedent for adopting NPIs was the fear of COVID-19. Webster et al's [18] review found factors affecting adherence to protective health behaviors included levels of knowledge about the disease outbreak and risk of disease. Moreover, NPIs can have marked economic effects, and aspects of social isolation involved with staying at home and social distancing have profound psychological impacts, which are yet to be fully determined [19,20]. The decision to adopt NPIs then may also be an act of balancing one perceived risk—that is, the disease—against the risk of economic and social disruptions. Moreover, individuals may be more likely to accept new and unorthodox measures if the perceived loss from not doing so is greater, so how relative risks are framed by them and others will likely affect behavior

[21,22]. Hence, an individual's attitude toward the trade-offs of pandemic control may affect NPI compliance and contact-tracing app use. From this discussion, we develop the following hypotheses: hypothesis 2a—compliance with NPI requirements is higher when risk perception (knowledge) is higher; hypothesis 2b—compliance with NPI requirements is higher when infection control is prioritized over economic and social effects; hypothesis 2c—contact-tracing app use is higher when infection control is prioritized over economic and social effects; hypothesis 2d—contact-tracing app use is higher when risk perception (knowledge) is higher.

In the case of digital tracing, there are added concerns about privacy of information that is shared with and gathered by the government although the Japanese contact-tracing app does not collect personal information. Hence, it deserves dedicated study. Chan and Saqib's [23] experiments suggest that the reluctance to download contact-tracing apps can be explained by privacy concerns. Horvath et al's [24] experimental study suggests that trust in the UK National Health Service mitigates respondents' concerns about privacy in tracing apps, with the benefit of using tracing apps perceived to be larger than the risks of privacy and security breaches. Oldeweme et al [25] found that transparency and trust in government foster tracking app adoption. Goldfinch et al [2] found that in Australia and New Zealand, trust in government and confidence in public health scientists predict the use of contact-tracing apps [2]. Trust in government then provides a proxy for addressing privacy and security concerns that might arise with digital engagement. Accordingly, we propose the following hypotheses: hypothesis 3a—contact-tracing app use is higher when trust in the government is higher; hypothesis 3b—contact-tracing app use is higher when confidence in public health scientists is higher.

Methods

Survey

A commercial company was contracted to deliver an online survey of 1248 Japanese citizens in December 2020. A quota technique was used to deliver a sample representative in terms of gender, age, residence, income, and education. Respondents included both men and women in the age groups of 18-24, 25-34, 35-44, 45-54, 55-64, and 65 years and above. Quota methods are widely used in public health, medical, and epidemiological research and are considered state of the art [26,27].

Variables

The dependent variables are compliance with preventative behavior (CPB) and use of the contact-tracing app (COCOA).

CPB was measured via the following question: "To what extent do you comply with the government recommended behaviors for protection from COVID-19?" The 6 nondigital NPIs recommended by the Japanese government are the following: (1) wearing face masks, (2) hand washing, (3) social distancing, (4) refraining from going out, (5) avoiding the 3Cs, and (6) ventilation.

Responses were given on a 4-point Likert scale ranging from 4 = "always" to 1 = "not at all." As the responses might have

had different weights, we performed principal component analysis and used a single principal component score. Although there are several methods for determining the number of factors, we adopted the most representative and easily understood eigenvalue-1 criterion [28].

Use of the contact-tracing app (COCOA) was measured by the response to the following question: "To what extent do you use COCOA?" Responses were on a 4-point Likert scale ranging from 4 = "always" to 1 = "not at all."

The independent variables were operationalized as follows. Trust in government (Trust government) was measured based on the response to the statement, "(level of government) is generally trustworthy." The response was marked on a 4-point Likert scale ranging from 4 = "strongly agree" to 1 = "strongly disagree." This was derived from Goldfinch et al [2]. The answers for the national and local governments were summed. Confidence in scientific expertise (Confidence expertise) was determined by asking, "How much do you believe that public health scientists act in the best interests of the public?", which was also derived from Goldfinch et al [2]. Responses were marked on a 4-point Likert scale ranging from 4 = "a great deal" to 1 = "not at all."

We measured the perceived risk of infection (knowledge) by loosely adapting questions from Wise et al [29]. The perceived risk of COVID-19 (Perception risk) was measured via responses to the following 3 questions: "Have you ever received any information that your families are infected?", "Have you ever received any information that your coworkers are infected?", and "Have you ever received any information that other related persons such as clients are infected?" The answers were 1 = yes and 0 = no. The answers were summed. Previous studies have inquired about hypothetical "average" people (eg, the average person in the neighborhood, state, and country). As the Japanese media's focus was on the number of cases in the country, we focused on the extent to which family members, coworkers, and others had information about the infected rather than specifying the geographic area.

Respondents' perceptions of the appropriate balance between infection control and society and economy (Economics) were derived from the following question: "To which element do you attach more importance: infection control or maintenance of economic and social activities?" Responses were on a 4-point Likert scale ranging from 1 = "emphasize infection control more than economic and social activities" to 4 = "emphasize economic and social activities more than infection control." This question was derived by the authors based on concerns about balancing economic performance with infection risk, which is often discussed in Japan.

Sociodemographic factors may also influence NPI compliance. Riou et al [30] found adoption of protective behaviors to be correlated with age and comorbidity risk in China. Females are more likely to comply with government directives in general [31]. Older people might feel less at ease using contact-tracing apps that demand some digital competence but may be more compliant with government directives [32]. Accordingly, our other independent variables were the following: gender (male = 1 or female = 0), age (1 = 18-24, 2 = 25-34, 3 = 35-44, 4 =

45-54, 5 = 55-64, and 6 = 65 years and above), education (from 1 = secondary school graduate to 5 = postgraduate), residence (urban = 1, rural = 0), and household income (1 = up to ¥2 million, 2 = ¥2-3 million, 3 = ¥3-4 million, 4 = ¥4-6 million, 5 = ¥6-8 million, 6 = ¥8-10 million, 7 = ¥10-12 million, 8 = ¥12-15 million, and 9 = ¥15 million and above; a currency exchange rate of ¥1=US \$0.007 is applicable).

Statistical Analysis

Adoption of NPIs (CPB) was analyzed using the ordinary least squares multiple regression model, as shown in equation 1. Use of the contact-tracing app (COCOA) was analyzed via an ordered logistic regression model by maximum likelihood estimation, as seen in equation 2. The estimated coefficients explain the change in log odds of using COCOA. Analysis was performed using Stata/IC 16.1 (StataCorp).

$$\text{CPB} = \alpha_1 + \alpha_2 \text{Trust government} + \alpha_3 \text{Confidence expertise} + \alpha_4 \text{Perceptionrisk} + \alpha_5 \text{Economics} + \alpha_6 \text{Gender} + \alpha_7 \text{Age} + \alpha_8 \text{Income} + \alpha_9 \text{Education} + \alpha_{10} \text{Urban} + \varepsilon_1 \text{(1)}$$

$$\text{COCOA} = \beta_1 + \beta_2 \text{Trust government} + \beta_3 \text{Confidence expertise} + \beta_4 \text{Perceptionrisk} + \beta_5 \text{Economics} + \beta_6 \text{Gender} + \beta_7 \text{Age} + \beta_8 \text{Income} + \beta_9 \text{Education} + \beta_{10} \text{Urban} + \varepsilon_2 \text{(2)}$$

Here, the dependent and independent variables *CPB*, *COCOA*, *Trust government*, *Confidence expertise*, *Perceptionrisk*, and *Economics* are calculated as shown in the previous subsection. *Gender* is a dummy variable which is 1 if a respondent is a man, 0 otherwise. The variables *Age*, *Income*, and *Education* are continuous variables from responses. *Urban* is a dummy variable which is 1 if a respondent answers as living in an urban area, 0 otherwise.

Ethical Considerations

Ethics approval was obtained from the chairman of the Committee for Assessing Ethics on Research at Kamakura Women's University. The survey company received full confirmation from the survey monitors to consent with its privacy policy and quality control. The final contract for the

survey was approved by the president of the university (application #110853).

Results

Descriptive Statistics

Reported adoption of (nondigital) NPIs was high. Approximately 80% of respondents said they “always” or “mostly” behave according to government guidelines, with 97.20% (1213/1248) wearing masks, 95.43% (1191/1248) washing hands, 85.98% (1073/1248) engaging in social distancing, 78.21% (976/1248) refraining from going out, 83.25% (1039/1248) avoiding the 3Cs, and 76.52% (955/1248) using ventilation (see [Table 1](#)). The use of COCOA was considerably lower, with 57.85% (722/1248) nonusage. Trust in government in Japan was alarmingly low, with strong agreement or “agreement that government are generally trustworthy” at 1.60% (20/1248) and 35.74% (446/1248), respectively—far lower than that of other OECD (Organization for Economic Co-operation and Development) countries [2]. This finding of low trust in government in Japan is supported by other studies [3]. Confidence in public health scientists was far greater: 42.15% (526/1248) of respondents had “a great deal” of confidence and 48.32% (603/1248) were “fairly” confident that they work in the public interest.

[Table 2](#) presents the respondents' demographic characteristics. Gender and age were manipulated to have the same percentages during the online survey phase. Annual household income was most frequently between ¥6 and ¥8 million yen, and approximately 46% of the respondents had a college degree or higher. This sample is broadly representative although respondents had a lower rate of higher education and slightly higher income than Japan has as a whole [33,34].

[Table 3](#) shows the Pearson correlation coefficients among the variables. The correlation coefficients between CPB and COCOA and the independent variables were consistent with the results of the regression analysis. All correlation coefficients were lower than 0.3; hence, the potential for multicollinearity was small.

Table 1. Compliance with nonpharmaceutical interventions and COCOA (N=1248).

	Always, n (%)	Mostly, n (%)	Little, n (%)	Not at all, n (%)
Wearing mask	962 (77.08)	251 (20.11)	28 (2.24)	7 (0.56)
Washing hands	832 (66.67)	359 (28.77)	51 (4.09)	6 (0.48)
Social distancing	380 (30.45)	693 (55.53)	158 (12.66)	17 (1.36)
Refraining from going out	354 (28.37)	622 (49.84)	231 (18.51)	41 (3.29)
Avoiding 3Cs ^a	370 (29.65)	669 (53.61)	189 (15.14)	20 (1.60)
Ventilation	343 (27.48)	612 (49.04)	271 (21.71)	22 (1.76)
Using contact-tracing apps (COCOA ^b)	214 (17.15)	126 (10.10)	186 (14.90)	722 (57.85)

^a3Cs: closed spaces, crowded places, and close contacts.

^bCOVID-19 Contact-Confirming Application.

Table 2. Demographic statistics (N=1248).

	Values
Gender, n (%)	
Men	624 (50)
Women	624 (50)
Age (years), n (%)	
18-24	208 (16.7)
25-34	208 (16.7)
35-44	208 (16.7)
45-54	208 (16.7)
55-64	208 (16.7)
65 or more	208 (16.7)
Age, mean (SD)	45.0 (16.8)
Residence, n (%)	
Rural area	666 (53.37)
Urban area	582 (46.63)
Income (yen^a), n (%)	
<2 million	80 (6.40)
<2 to 3 million	252 (20.20)
3 to <4 million	226 (18.10)
4 to <6 million	519 (41.59)
6 to <8 million	92 (7.40)
8 to <10 million	38 (3.00)
10 to <12 million	29 (2.30)
12 to <15 million	8 (0.60)
>15 million	4 (0.30)
Income, mean (SD)	3.1 (1.3)
Education, n (%)	
Junior high school graduate	25 (2.00)
High school graduate	364 (29.17)
College graduate	273 (21.88)
University graduate	539 (43.19)
Graduate degree	47 (3.77)

^aA currency exchange rate of ¥1=US \$0.007 is applicable.

Table 3. Pearson correlation matrix.

Variable	1, <i>r</i>	2, <i>r</i>	3, <i>r</i>	4, <i>r</i>	5, <i>r</i>	6, <i>r</i>	7, <i>r</i>	8, <i>r</i>	9, <i>r</i>	10, <i>r</i>	11, <i>r</i>
1 CPB ^a	— ^b										
2 COCOA ^c	0.214	—									
3 Trust in government	0.043	0.073	—								
4 Confidence expertise	0.206	0.073	0.176	—							
5 Perception risk	-0.047	0.026	-0.018	0.073	—						
6 Economics	-0.220	-0.010	0.055	-0.087	0.005	—					
7 Gender	-0.142	0.058	0.052	-0.065	0.051	0.120	—				
8 Age	0.087	-0.044	0.041	-0.029	-0.138	-0.150	0.007	—			
9 Income	-0.035	0.045	0.021	-0.011	0.126	0.077	0.076	0.045	—		
10 Education	0.014	0.056	0.063	0.006	0.116	0.013	0.191	-0.056	0.167	—	
11 Urban	0.026	0.053	0.003	0.020	0.067	0.044	0.000	-0.004	0.082	0.087	—

^aCPB: compliance with preventative behavior.

^bNot applicable.

^cCOCOA: COVID-19 Contact-Confirming Application.

Hypothesis Testing

Testing our hypotheses provided unexpected, counterintuitive, and novel results (Table 4). First, trust in government was not significantly associated with the adoption of NPIs. Hence, hypothesis 1a was not supported. Confidence in public health scientists had a positive and significant effect on NPI adoption. Therefore, hypothesis 1b was supported. However, risk perception or knowledge had a negative and significant relationship with preventative behavior. This was an unexpected and counterintuitive finding. Consequently, hypothesis 2a was rejected. As expected, a belief that greater attention should be paid to economic effects rather than to infection (Economics) had a negative and significant relation with NPI adoption, and thus hypothesis 2b was supported. This is consistent with other findings that framing COVID-19 as primarily a health issue promotes a preference for social distancing, whereas economic framing motivates the opposite [33]. Men (Gender) were less likely to comply with government recommendations, consistent with previous findings that women are more law abiding [31]. Older people (Age) were more likely to adopt recommended

NPIs, in line with studies finding a positive relationship between age and a law-abiding orientation [32]. Income (Income), education (Education), and residence (Urban) were not significantly associated with preventative behaviors.

To test hypotheses 2c-2d and 3a-b examining tracing app use (COCOA), an ordered logit analysis was implemented. The results, shown in Table 5, are not always as predicted. Trust in government (Trust government) had a positive and significant effect on the use of COCOA, supporting hypothesis 3a. However, in contrast to NPI adoption, confidence in scientific expertise (Confidence expertise) did not have a significant impact on using the contact-tracing app. As a result, hypothesis 3b was not supported. Attitudes toward the economic or infection trade-off (Economics) also did not have a significant effect on the use of the app. Hence, hypothesis 2c was not supported. Risk (Perception risk) was also nonsignificant, and hypothesis 2d was not supported. Additionally, no other independent variable, except residence (Urban), had a significant effect on using the app. However, people living in urban areas (Urban) were more likely to use the contact-tracing app compared to those living in rural areas.

Table 4. Regression results for CPB (N=1248)^a.

Variable	Predicted sign	CPB ^b values			
		<i>r</i>	<i>t</i>	<i>P</i> value	95% CI
Constant	N/A ^c	-1.879	-4.494	<.001 ^d	-2.700 to -1.059
Trust government	+	0.056	0.689	.46	-0.104 to 0.216
Confidence expertise	+	0.484	6.017	<.001 ^d	0.326 to 0.642
Perception risk	+	-0.140	-1.880	.07 ^e	-0.286 to 0.006
Economics	-	-0.899	-5.802	<.001 ^d	-1.203 to -0.595
Gender	-	-0.403	-4.108	<.001 ^e	-0.596 to -0.211
Age	+	0.006	2.185	.03 ^f	0.001 to 0.012
Income	Unknown	-0.022	-0.580	.54	-0.097 to 0.053
Education	Unknown	0.082	1.518	.11	0.053 to 0.188
Urban	Unknown	0.109	1.156	.25	-0.076 to 0.295

^aThe table shows the results estimated using the ordinary least squares regression model in equation 1.

^bCPB: compliance with preventative behavior.

^cN/A: not applicable.

^dStatistical significance at the 1% level.

^eStatistical significance at the 10% level.

^fStatistical significance at the 5% level.

Table 5. Ordered logistic regression results for COCOA (N=1248)^a.

Variable	Predicted sign	COCOAb values			
		<i>r</i>	<i>t</i>	<i>P</i> value	95% CI
Constant 1	N/A ^c	1.385	3.332	<.001 ^d	0.560 to 2.208
Constant 2	N/A	2.059	4.965	<.001 ^d	1.235 to 2.880
Constant 3	N/A	2.661	6.455	<.001 ^d	1.841 to 3.476
Trust government	+	0.247	2.616	.009 ^d	0.063 to 0.433
Confidence expertise	+	0.107	1.233	.22	-0.064 to 0.276
Perception risk	+	-0.139	-0.869	.41	-0.447 to 0.179
Economics	-	-0.005	-0.055	.60	-0.191 to 0.187
Gender	-	0.177	1.560	.11	-0.040 to 0.405
Age	+	-0.006	-1.647	.097 ^e	-0.012 to 0.001
Income	Unknown	0.049	1.126	.35	-0.049 to 0.131
Education	Unknown	0.030	0.504	.59	-0.086 to 0.150
Urban	Unknown	0.181	1.648	.097 ^e	-0.038 to 0.402

^aThe table shows the results estimated using the ordered logistic regression model in equation 2.

^bCOCOAb: COVID-19 Contact-Confirming Application.

^cN/A: not applicable.

^dStatistical significance at the 1% level.

^eStatistical significance at the 10% level.

Discussion

Principal Findings

The use of NPIs to control the COVID-19 spread will remain important as the global vaccination rollout progresses unevenly and new COVID-19 variants emerge. Moreover, the lessons from this pandemic will assist the management of the next one, if or when it arises. Japan provides a particularly useful field to examine NPI use and its antecedents, particularly because it relies on voluntary adoption rather than on the compulsory use and legal and other sanctions adopted by other OECD countries. Despite the voluntary nature of NPI adoption, respondents from our representative online quota sample reported high use of the 6 types of nondigital NPIs we measured in the 80% and above range. This is in remarkable contrast to the claimed 30%-40% noncompliance rates for use of NPIs in the United States and the European Union despite legal enforcement and significant penalties for noncompliance [5,6]. Moreover, trust in government—seen as a predictor of policy compliance in several studies—is low in Japan and does not predict the use of nondigital NPIs.

Comparison With Prior Work

How can these differences be explained? Drawing on the limited but growing literature on the adoption of NPIs, we tested hypotheses focused on trust in government, confidence in public health scientists, perceived trade-offs between infection control and socioeconomic effects, and perceptions of infection risk based on knowledge of infection among close contacts. Our results sometimes differ from those predicted or indicated by other studies, and, therefore, this study reports a few novel, unexpected, and counterintuitive findings. First, trust in government did not have a significant effect on NPI use. Attention to personal hygiene is often claimed to be an existing aspect of Japanese culture [35]. Moreover, readiness to adopt preventative behaviors in disease control, such as mask wearing, is commonly exhibited. Trust in government may have little or no relationship to this. The second and more perplexing finding is that respondents' risk perception inversely affected NPI adoption or was not significant in terms of phone app use. Our risk measure is a perception based on the reported knowledge of infection among those close to the respondents. Wise et al [29] also reported that risk perception or infection knowledge did not increase concerns about COVID-19 morbidity [29]. Perhaps perceived risk to oneself is not a key driver of NPI adoption or other COVID-19-related control behavior in Japan. Rather, prosocial motivation, social conformity, and cultural constraints may be more important [5,36-39].

Confidence in public health scientists predicts compliance with government NPI directives. Preventive behavior was recommended by a group of experts on COVID-19, and it was associated with scientific leadership rather than political. A generalizable point is that confidence in scientific expertise can encourage compliance with health policy even when trust in government is low. In the past, the Japanese public has demonstrated the capability to be guided by trusted experts in new control measures—particularly when information and responses are clearly articulated and communicated—and to

dramatically change behavior as a result [40]. This has been exhibited during the recent pandemic. In April 2020, Hayasaki [41] quoted a Japanese professor in political science, Koichi Nakano, noting “People remain largely ignorant of the basic principles of ‘social distancing’—a term that remains unknown and alien in Japan.” However, within a few months, social distancing became part of Japanese life. Moreover, this adaptation has been seen across educational, residential, and income categories. These new behaviors are locked in place, and compliance maintained perhaps more through cultural conformity and control than through government fiat, with Japanese culture categorized as collectivist and a premium being placed on compliance with societal norms and group solidarity [36-38]. Once the control measures are successfully signaled by trusted scientific authorities and adopted by a significant portion of society, there arises a social risk of not complying [42-45].

Trust in government and urban residence predicts tracking app use (COCOA). Confidence in public health scientific expertise, however, was not significantly associated with the use of the app. Moreover, reported use of the app was lower than that of other NPIs. This may reflect the troubled development of the app. There may be a disjunction between public scientific expertise related to disease control and an app developed by a contracted nongovernment commercial operation plagued by bugs and low reliability. In collectivist Japan, the less easily observable phone app use may lack the “virtue signaling” of other forms of NPI, such as mask wearing, and hence be less enforceable by societal norms and censure. Trust, privacy protection, and technical efficacy, as well as perceptions of such, are likely to be important in the citizen adoption of digital tools for public health in the future. People living in urban areas are more likely to adopt the contact app, which might be related to a more densely populated environment, with a higher number of contacts and a higher chance of infection. However, risk perception does not have a significant effect on the use of COCOA.

Limitations

Our study has a few limitations. First, the analysis was cross-sectional, and behavior, including adoption of NPIs, might change as fatigue and complacency sets in. To examine causal relations and behavioral changes over time, a longitudinal study would perhaps be useful. A better operationalization of the antecedents of NPI and COCOA adoption, such as personality and cultural factors, might improve the verisimilitude of our results. Our use of an online survey method might have excluded those marginalized by a “digital divide,” particularly important in COVID-19, which may produce unequal outcomes based on socioeconomic status. However, in a time of lockdowns, travel bans, and other controls, an online survey was likely the most pragmatic solution. Generalizability would be improved with further cross-national studies, including an investigation of institutional and cultural factors. Other studies using panel data, alternative methods of sample selection (including nondigital ones), experiments, new antecedents, qualitative interviews, and comparative studies might strengthen findings, by, for example, providing a better understanding of causal relationships.

Conclusions

What are the implications for the implementation and development of public health and health policies? First, we show that voluntary compliance in the adoption of nondigital NPIs—if skillfully led by trusted scientific experts and in accord with societal norms—can be effectively achieved. Despite the voluntary nature of NPI adoption, respondents reported high use of the NPI we measured in the 80% and above range. This contrasts with the 30%-40% noncompliance rates for use of NPIs in the United States and the European Union despite legal enforcement and significant penalties for noncompliance [5,6]. Second, digitalization in the public sector should balance trade-offs between perceived usefulness and privacy. This may

be resolved if trust in government can be developed and maintained, and we provide evidence that trust in government is effective in encouraging the use of digital government services at least in the case of the COCOA tracking app. Moreover, technical efficacy of digital initiatives and perceptions of such will unsurprisingly affect citizen support and use of digital tools. Perhaps this is generalizable to the adoption of other digital tools and e-government in policy and public health, in which Japan remains a laggard. Risk perception and how risk is framed and focused around social and health outcomes may improve NPI uptake, again underpinning the importance of clear and focused communication in developing support and citizen compliance in pandemic control found in other studies [46].

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Conflicts of Interest

None declared.

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Abbreviations

- 3Cs:** closed spaces, crowded places, and close-contact settings
COCOA: COVID-19 Contact-Confirming Application
CPB: compliance with preventative behavior
NPI: nonpharmaceutical intervention
OECD: Organization for Economic Co-operation and Development
SARS: severe acute respiratory syndrome

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Original Paper

Development of a Self-management and Peer-Mentoring Intervention to Improve Transition Readiness Among Young Adult Survivors of Pediatric Cancer: Formative Qualitative Research Study

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Abstract

Background: Childhood cancer survivors require lifelong risk-based follow-up care. It should be noted that less than one-third of adult survivors of childhood cancer report any survivor-focused care, and fewer than 1 in 5 obtain risk-based follow-up care. It is thought that this may be due to inadequate transition readiness, including low levels of knowledge, skills, motivation, and resources to make the transition to independent self-management of follow-up care. Interventions that focus specifically on improving the transition from parent-managed to self-managed care are needed. Theory and prior research suggest that targeting self-management skills and using peer mentoring may be innovative strategies to improve transition readiness.

Objective: This study aims to identify the content of a self-management intervention to improve transition readiness among adolescent and young adult (AYA) survivors.

Methods: Intervention development occurred in 3 stages: formative research with AYA survivors to identify barriers and facilitators to obtaining risk-based survivorship care, content development using feedback from multiple stakeholders (AYA survivors, parents, and providers), and content refinement (usability testing) of the initial proposed educational modules for the program. Content analysis, guided by the social-ecological model of AYA readiness for transition, was used to identify themes and develop and refine the content for the intervention.

Results: A total of 19 AYA survivors participated in the formative research stage, and 10 AYA survivors, parents, and health care providers participated in the content development and refinement stages. The major barrier and facilitator themes identified included knowledge of cancer history and risks; relationships with health care providers; relationships with family members involved in care; emotions about health, follow-up care, and transfer of care; and lifestyle behaviors and life transitions. These themes were translated into 5 self-management modules: understanding treatment history and the survivorship care plan, managing health care logistics and insurance, communicating with health care providers and family members involved in care, dealing with emotions, and staying healthy in the context of life transitions. Feedback from the key stakeholders indicated that the content was relevant but should include participative elements (videos and tailored feedback) to make the intervention more engaging. The AYA survivors were receptive to the idea of working with a peer mentor and expressed a preference for using SMS text messaging, telephone calls, or videoconference to communicate with their mentor.

Conclusions: Incorporating AYA survivors, parents, and providers in the design was essential to developing the content of a self-management and peer-mentoring intervention. AYA survivors confirmed the important targets for the intervention and

facilitated design decisions in line with our target users' preferences. The next step will be to conduct a single-arm trial to determine the feasibility and acceptability of the proposed intervention among AYA survivors of childhood cancer.

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KEYWORDS

self-management; peer mentoring; cancer survivorship; long-term follow-up care

Introduction

Background

Childhood cancer survivors are a growing population, with >500,000 in the United States [1,2]. As many as 67% to 95% of these survivors are at risk for developing chronic health conditions [3-6] as a result of cancer treatment; therefore, survivors require lifelong risk-based follow-up care to identify and treat late health effects based on the cancer treatment they received [7]. It should be noted that less than one-third of adult survivors of childhood cancer report any survivor-focused care and fewer than 1 in 5 obtain risk-based follow-up care [8,9].

The transition from pediatric to adult follow-up care is a critical period when many survivors are lost to follow-up [10]. This transition involves moving from parent-guided management to self-management of long-term follow-up care as survivors assume primary responsibility for tasks such as managing health records, making appointments, filling and taking prescriptions, and understanding late effects and how to follow-up with recommended screenings or treatments. This transition occurs during a critical developmental period when adolescents and young adults (AYAs) may be unaware of, or fail to recognize, their health risks and the need for regular follow-up [11]. Barriers to successful transition include survivors' lack of knowledge of their diagnosis and treatment, cancer-related anxiety and other emotional concerns, other life stressors common among AYAs that are perceived as a greater priority (eg, education and career), and failure or inability to assume personal responsibility for their own health [3,5,7].

Transition readiness refers to the capacity of the AYAs and their support network to prepare for, and complete, the process of moving to adult-oriented care [12]. The social-ecological model of AYA readiness for transition (SMART) [12] identifies modifiable factors related to transition readiness, including knowledge of health history, risks, and needs; self-management skills and self-efficacy for managing care; beliefs and expectations regarding the transition process or adult-oriented care (such as the belief that the adult provider will not understand the patient's needs); goals related to health transition; relationships with parents and providers; and psychosocial functioning of patients, parents, and providers (such as anxiety about the transition process or future health) [12].

To date, interventions targeting AYA survivors of childhood cancer have focused on educational conferences [13,14], providing survivorship care plans through mail [15] or through a mobile app [16], or SMS text messaging and a healthy peer navigator intervention [17]. These interventions have used

technology to overcome common barriers faced by AYA survivors, such as geographic mobility, lack of time, competing priorities, and the relatively small numbers of survivors at single institutions [18]. However, there is a gap in interventions focusing specifically on the transition from parent-managed to self-managed care. Peer mentoring has been recommended as an innovative approach to facilitate health care transitions for AYA survivors [19]. Qualitative and quantitative studies suggest that AYA survivors want to discuss their medical care needs with other AYA survivors [20-22]. The Adolescent and Young Adult Oncology Progress Review Group has recommended the development of standardized peer-to-peer programs as a strategy for supporting the psychosocial needs of AYA patients with cancer and AYA cancer survivors [14].

Objectives

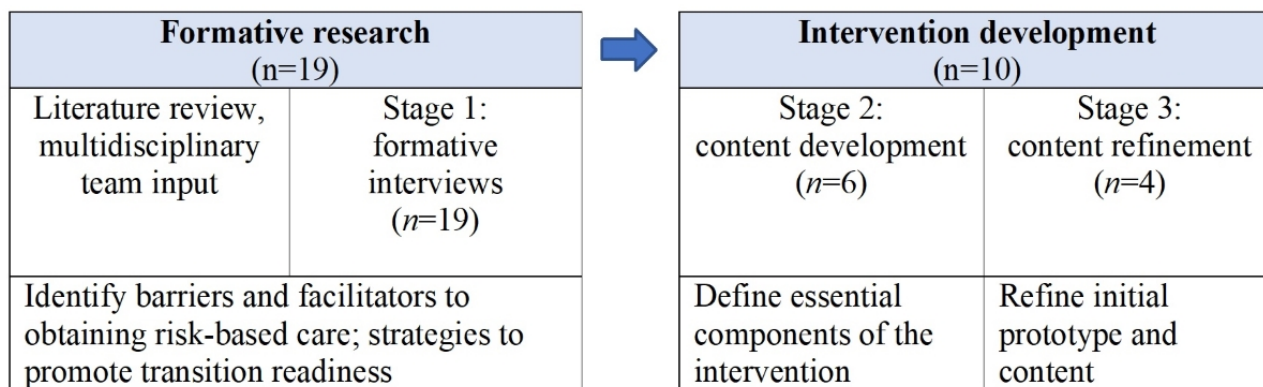
The goal of this work was to develop an intervention to improve transition readiness among AYA survivors of childhood cancer that would address their unique psychosocial and support needs. The development process involved identifying user needs (formative research), evaluating and applying relevant theory, and iteratively producing and refining the intervention product (ie, usability testing). We used principles of user-centered design, which propose an iterative process that identifies the needs and requirements of end users (ie, AYA survivors) and incorporates their feedback at multiple points in the intervention development [23]. The goal was to create an intervention that better meets the needs and expectations of the ultimate users of that intervention. In this paper we describe the user-centered design process used to develop a web-based self-management and peer-mentoring program to improve transition readiness of AYA cancer survivors.

Methods

Program Development

Similar to other intervention development studies [24-26], we used an iterative user-centered process in three stages: (1) *formative research* with AYA survivors to identify barriers and facilitators to obtaining risk-based survivorship care during the transition to adult health care; (2) *content development* using feedback from multiple stakeholders (AYA survivors, parents, and providers); and (3) *content refinement* of the initial proposed content and educational modules for the program with input from AYA survivors (Figure 1). Semistructured telephone interviews were conducted with survivors in stage 1; semistructured in-person or telephone interviews were conducted with survivors, parents, and providers in stage 2; and in-person usability testing was conducted in stage 3.

Figure 1. Managing Your Health intervention development stages.



Participant Eligibility

Eligibility criteria were consistent across the stages. Survivors were eligible if they (1) were aged 18 to 25 years at the time of informed consent, (2) had been diagnosed with any cancer between the ages of 0 and 21 years, (3) were at least 1.5 years after completion of cancer treatment (consistent with preparing to transfer to long-term follow-up), and (4) had no physician- or self-reported cognitive delay or impairment that would prevent self-management of health care. Parents were eligible if (1) they were a primary caregiver of a pediatric cancer survivor currently aged 18 to 25 years, (2) the survivor was at least 1.5 years after completion of cancer treatment, and (3) the survivor did not have physician- or caregiver-reported cognitive delay or impairment that would prevent self-management of health care. Health care providers (eg, physicians and psychologists) were eligible if they regularly provided clinical care to AYA pediatric cancer survivors.

Stage 1: Formative Research

The goal was to identify barriers and facilitators to obtaining risk-based survivorship care to understand the needs of AYA survivors transitioning from pediatric-oriented to adult-oriented care. AYA pediatric cancer survivors were recruited using advertisements posted on Twitter, web-based forums for cancer survivors, listservs of regional nonprofit organizations devoted to childhood cancer, and at the local clinic. This strategy was chosen to try to gain perspectives from survivors in various geographic locations who would represent a range of experiences with long-term follow-up care.

Individual semistructured interviews were conducted through telephone by the last author (KAD) and were audio recorded using digital recorders. Telephone interviews were chosen to allow participation from any geographic location and reduce respondent burden by not requiring an in-person visit. The semistructured interview guide was developed based on a model of factors associated with receipt of risk-based care [27] and the SMART model [12]. Questions elicited AYA survivors’ perspectives regarding survivor-related, provider-related, and health care system-related facilitators and barriers to receipt of care, including during the transfer from acute to long-term follow-up care and the transition from pediatric- to adult-oriented health care. Sample questions included the following: “What kind of follow-up care do you think is appropriate for cancer survivors? What care do you think you

need? Tell me about the transition from the end of your cancer treatment to long-term follow-up care. What barriers could or do prevent you from attending care visits? What could clinics or providers do to encourage childhood cancer survivors to attend? If you could change something about follow-up care, what would you change?” Participants also completed a brief demographic survey.

Each interview was transcribed using semiverbatim transcription. Interview transcripts were analyzed using content analysis, following the framework approach described by Pope et al [28]. An index of themes was created and applied systematically to the data by 2 coders. Themes were identified from the a priori models, and any new themes that emerged from participants’ data were added during the coding process. Data analysis continued until theme saturation occurred (ie, no new themes emerged from additional participants).

Stage 2: Content Development

The goal in this stage was to define the essential content components of the intervention. AYA survivors and caregivers were recruited from the local long-term survivorship clinic list. Health care providers (eg, physicians and psychologists) were recruited through email through the AYA and Survivorship Working Groups of the Children’s Oncology Group.

Semistructured individual interviews with AYA survivors, caregivers, and providers were conducted in person or through telephone and recorded for transcription and analysis. These interviews were guided by the SMART model and the results from the stage 1 formative research. The interview questions started by asking broadly about experiences with long-term follow-up care; for example, “What do you think is involved in the long-term follow-up care for your childhood cancer? What was challenging about beginning to take charge of your own health? What kinds of things were helpful to you in making the transition to taking charge of your health care?” Next, the themes from stage 1 were presented as the potential topics for a new intervention for survivors, and participants were asked to provide feedback on the proposed content. Questions included the following: “What seems useful to you? What does not seem useful? What are we missing?” The idea of matching survivors with a peer survivor who could serve as a mentor was proposed, and participants were asked about their receptivity to working with a mentor and preferred characteristics (eg, personality, cancer diagnosis, and gender). Participants were also asked to

provide feedback about the mode of delivery (eg, web based, videoconference, or SMS text messaging). Qualitative data were analyzed on a continuing basis following the same procedures as those followed in stage 1 and treating respondents as a group of key stakeholders rather than examining them separately by type (ie, survivor vs parent vs provider).

Stage 3: Content Refinement

AYA survivors were recruited from the local long-term survivorship clinic and completed the usability testing in person after their routine clinic visit. Participants were provided with the proposed structure of the program (ie, combination of web-based educational modules plus interaction with a peer mentor) and asked to review the prototype of web-based modules, which were accessible through Canvas, the Rutgers University web-based course management system, accessed through a computer or tablet provided by research staff. Survivors were asked to read through the program modules. Research staff asked questions about their overall impression of the program, the usability of the website, the content of each module, and suggestions for improvement. The staff asked survivors about their communication preferences (type of communication and frequency) and qualities they might prefer

in a mentor. This feedback was then used to modify and finalize the intervention content and format.

Ethics Approval

This study was approved by the institutional review boards at the University of Rochester Medical Center (RSRB00040459) and Rutgers Cancer Institute of New Jersey (Pro2013003819; Pro20150001955). All participants provided informed consent.

Results

Participants

In stage 1, a total of 19 AYA survivors from 12 different states in the United States participated. They were aged on average 22.8 (SD 1.6; range 20.0-25.0) years and were between 2.0 and 21.5 (mean 7.2, SD 6.2) years after completion of cancer treatment. In stage 2, a total of 6 key stakeholders participated: 2 (33%) AYA survivors, 1 (17%) parent of an AYA survivor, and 3 (50%) AYA oncology providers (of these providers, 1/3, 33% was an oncologist, and 2/3, 67% were psychologists). In stage 3, four new AYA survivors provided feedback on the initial prototype (Table 1).

Table 1. Adolescent and young adult survivor characteristics included in each stage of development.

	Stage 1: formative research (n=19)	Stage 2: content development (n=2) ^a	Stage 3: content refinement (n=4)
Age (years), mean (SD)	22.8 (1.6)	22 (1.4)	21.5 (1.5)
Sex, female, n (%)	17 (89)	2 (100)	1 (25)
Race, n (%)			
White	18 (95)	1 (50)	1 (25)
Asian	1 (5)	0 (0)	2 (50)
Black	0 (0)	1 (50)	1 (25)
Ethnicity, n (%)			
Hispanic or Latino	1 (5)	0 (0)	0 (0)
Non-Hispanic	18 (95)	2 (100)	4 (100)
Diagnosis, n (%)			
Blood cancer	15 (78.9)	1 (50)	4 (100)
Solid tumor	3 (15.9)	1 (50)	0 (0)
Brain tumor	1 (5.2)	0 (0)	0 (0)
Currently receive follow-up care^b, n (%)			
Yes	15 (78.9)	1 (50)	4 (100)
No	4 (21.1)	1 (50)	0 (0)

^aIn stage 2, interviews were also conducted with 4 stakeholders (ie, n=1, 25%, parent of an adolescent and young adult survivor and n=3, 75%, adolescent and young adult oncology providers).

^bThis reflects whether participants reported receiving survivorship follow-up care but not the extent to which they have successfully transferred to adult-oriented care or managed their own care.

Stage 1: Formative Research

In total, five themes were identified from survivors' responses: (1) knowledge of cancer history and risks; (2) relationships with health care providers; (3) relationships with family involved in

care; (4) emotions about health, follow-up care, and transfer of care; and (5) lifestyle behaviors and life transitions. Table 2 defines each theme, lists illustrative quotes, and provides examples of how the theme informed content development.

Table 2. Themes from the stage 1 formative research (N=19).

Theme	Definition	Illustrative quote	Translating into content
Knowledge of cancer history and risks	Lack of knowledge is a barrier to obtaining care. Having a written survivorship care plan and education about required ongoing care facilitates care	<ul style="list-style-type: none"> “I think it’s important to be knowledgeable about what you’ve been through and what could potentially happen. So I feel really lucky that I have that book [of my treatment summary and potential late effects] and I was educated.” [Female Hodgkin lymphoma survivor aged 23 years; 007] “I just want to control and see that everything is correct to get peace for my mind. But I usually go if I am starting to notice any signs what I had before I got the cancer.” [Female ALL^a survivor aged 25 years; 014] 	Help survivors to understand their treatment history and details of their survivorship care plan
Relationships with health care providers	Concerned that adult providers will not understand their unique needs. Difficulty moving on from trusted relationships with pediatric providers. Adult health care system is complex and difficult to navigate	<ul style="list-style-type: none"> “I probably wouldn’t go through the hassle or the time to find a new radiologist in [current location]...the fact that they know me and they know my history does play a big role in it.” [Male Hodgkin lymphoma survivor aged 24 years; 004] “Ideally it would be nice if you could find someone that understands everything you’ve been through. Because I’ve had some effects already happen and they just look at me like oh, that shouldn’t happen to someone your age, but they don’t see what I’ve been through.” [Female ALL survivor aged 21 years; 008] “I don’t really know how to describe it but when I see them it’s like aww, it’s like meeting a family member again after a while and so much fun. I can just laugh with them and they become your friends. You know, they...they take care of you and...I’m grateful to them.” [Female ALL survivor aged 23 years; 003] 	Strategies for identifying and communicating with new adult health care providers
Relationships with family members involved in health care	Parents provide emotional and logistical support; they want to remain involved because of concerns about their child	<ul style="list-style-type: none"> “Oh, [my mom’s] totally on top of it. ’Cause when I got sick, I couldn’t handle all the medical stuff. So she did all of it...no matter how much time passes I think that she’s always gonna want to be there. And I don’t mind her being there.” [Female ALL survivor aged 22 years; 016] “I don’t even know what insurance is anymore because my parents just deal with all of that, which is really nice. If I didn’t have my parents dealing with it, I would probably be lost.” [Male ALL survivor aged 21 years; 001] 	Communication with parents about ongoing involvement in health care
Emotions about health, follow-up care, and transitions in care	Anxiety during transitions in care; worries about future health problems because of surveillance measures; feeling alone or different from healthy peers	<ul style="list-style-type: none"> “It was kind of like being thrown out there with nothing to float with. I guess it’s just kind of a shock because I went from almost every day to not seeing a doctor for 3 months. And it was...hard to do that.” [Female non-Hodgkin lymphoma survivor aged 24 years; 011] “I said I don’t want any more chest x-rays. I don’t want them every 4 months at least. Because then I’m just gonna get breast cancer and it’s gonna be a whole nother mess...It’s so awful how...the preventive measures also give you cancer.” [Female Hodgkin lymphoma survivor aged 22 years; 017] “You just feel...kind of alone sometimes. And even afterwards it’s a scary time because, you know, the treatment may have worked or it may not have worked. And kind of in a waiting period it really helps to have some people to talk to that know what you’re going through.” [Female non-Hodgkin lymphoma survivor aged 25 years; 018] 	Strategies to cope with emotions about health and follow-up care; peer support

Theme	Definition	Illustrative quote	Translating into content
Lifestyle behaviors and life transitions	Focusing on other preventive health behaviors (eg, diet and exercise); prioritizing other important life milestones (eg, pursuing college and career)	<ul style="list-style-type: none"> “It’s all just prevention at this point, trying to stop complications from happening again or anything like that. So it’s really important to make sure that you’re staying healthy, [to do] extra things that other people your age probably don’t have to do and you do.” [Female AML^b survivor aged 21 years; 002] “Sometimes, you know, in the busy lives and as we get older, college and everything, I think we kind of just kind of forget about it, just put it in the back of our minds and then we just kind of ignore it.” [Female ALL survivor aged 20 years; 010] 	Encourage healthy lifestyle behaviors and focusing on health in the context of other important life milestones

^aALL: acute lymphoblastic leukemia.

^bAML: acute myeloblastic leukemia.

In the first theme, a lack of knowledge about personal risk for late effects was commonly reported as a barrier to care. Participants who had received a written survivorship care plan found it to be an important tool to educate themselves about their cancer history and risks for late effects that require ongoing monitoring. Participants reported attending follow-up care to monitor for potential late effects.

The second theme centered on how survivors’ relationship with health care providers influenced their beliefs about follow-up care and the likelihood of attending it. Survivors who continued to see their original treatment team for long-term follow-up care cited their personal relationship with these medical providers as a major factor in their obtaining care. Participants commented that they had developed a strong personal bond because of the time spent with the health care providers during treatment and the seriousness of cancer treatment. They trusted their providers and found familiar providers supportive. The survivors also indicated that feeling *cared for* as a person (not just a disease) was important to them. Similarly, the survivors reported that they would be unlikely to continue care if they had to switch providers because of (1) the close relationship developed with the primary oncologist; (2) distrust of a new provider unfamiliar with their treatment history; (3) inconvenience of, and difficulty with, finding a new adult provider skilled in survivorship care; and (4) having to relay complex medical history to a new provider.

The third theme centered on the role of family members, particularly parents, in their medical care. Although emerging adulthood is typically characterized by greater independence from family, participants indicated that their parents were still involved in their follow-up care. Parents had been responsible for their cancer treatment and wanted to remain involved in follow-up care for their own emotional relief, hoping that their child’s cancer would remain in remission. Parents could help by asking questions, remembering what doctors tell them, and providing emotional support during the visit with the survivors. By contrast, attending clinic on their own was a sign of independence and responsibility.

The fourth theme focused on emotions about health, follow-up care, and transitions in care. Attending long-term follow-up care provided reassurance for survivors and their family that their cancer had not recurred. This reassurance could be sought

when they experienced symptoms that reminded them of the symptoms leading to their diagnosis, or it could be seen as part of routine follow-up care. Survivors could experience anxiety preceding or during their visits because of triggering of unpleasant treatment memories, but the relief about their health status outweighed their anxiety. Concerns about potential negative effects of screening procedures, including increased risk of developing a second malignancy, were barriers to care. There were also reports of feeling *alone* and *different* from healthy peers. Peer support from others *who know* what they were going through was seen as useful.

The fifth and final theme that emerged related to general preventive health behaviors and a focus on other developmentally appropriate life milestones such as going to college and starting a career. Lack of symptoms or late effects and the belief that one was *in the clear* after a certain amount of time after treatment could reduce motivation to seek care in the context of other life priorities.

Stage 2: Content and Program Development

In this stage, qualitative interviews with 6 key stakeholders confirmed that the modifiable variables from the SMART model were relevant and important targets for intervention. Specifically, the SMART constructs included knowledge, self-management skills, self-efficacy, relationships and communication, and goals and motivation.

Knowledge, specifically about treatment and potential late effects, was identified as essential for successful self-management by all (6/6, 100%) stakeholders. The AYA survivors noted that their parents were the ones who initially may have received the information about their follow-up plan and potential late effects and that this information needed to be repeated and provided again as they continue into young adulthood. The AYA participants called for a written guideline or map of what they needed to do and when. Similarly, the parent participant echoed this call for more guidance about what care was necessary moving forward. All (3/3, 100%) of the providers mentioned that their respective institutions provided a written survivorship care plan for guideline-concordant follow-up care. They also confirmed how important it was for patients to obtain a copy of this plan and to know where it is and how to access it as well as to bring it with them to future appointments with other providers.

All (6/6, 100%) participants acknowledged that a lack of skills in navigating the logistics of the health care system was a significant barrier to successful self-management. In particular, both the patient participant and 67% (2/3) of the providers specifically mentioned challenges in dealing with insurance. The providers noted the lack of support (including social work, school, and vocation support) for AYA survivors once they leave their pediatric provider. Both the providers and the parent participant acknowledged that AYA survivors may rely on parents for basic logistics of scheduling and keeping appointments, suggesting that they may lack confidence in handling these tasks themselves. When asked what topics would be a priority for a self-management program, the logistics of navigating the health care system was listed by 83% (5/6) of the participants.

Communication, both with providers and with parents and family members, was another barrier to successful self-management and follow-up care confirmed by participant responses. The AYA survivors described feeling fearful of meeting with new providers because they worried that not all providers would *understand them* and are *not insightful of specific symptoms or feelings* that may be unique to survivors. Of the 3 providers, 1 (33%) echoed sentiments about lack of effective communication and stated as follows:

I don't think survivors are always equipped especially at that age to advocate for themselves...that's maybe a skill that can be developed—how to better advocate for themselves in the health care system, particularly when you're talking with your doctor.

The AYA survivors also mentioned difficulty with talking with their parents about their disease or about taking over some of the tasks related to follow-up care.

Finally, all (6/6, 100%) stakeholders mentioned the importance of learning about other healthy behaviors (both for disease prevention and health maintenance). The AYA survivors described the difficulty of coping with other life events such as school or finding a job in conjunction with maintaining healthy behaviors. The providers echoed this sentiment, reporting that many times survivors will focus on cancer follow-up while excluding other important healthy behaviors, including tobacco

use, safe alcohol use, and sun protection behaviors. All (6/6, 100%) felt that it would be appropriate to provide education about maintaining *general health* within the context of a self-management intervention. When presented with the idea of providing educational content through technology along with a peer mentor, the stakeholders were receptive to the approach. All (6/6, 100%) stakeholders reported that the use of technology such as video calling and SMS text messaging would appeal to survivors. Several (4/6, 67%) stakeholders suggested that mentors should be outgoing advocates; they also suggested matching by diagnosis, if possible, but recognized that finding other things in common would be important for building a relationship. The stakeholders did not identify any new topics outside of the model and themes from stage 1; therefore, we determined that there was thematic saturation after these 6 key stakeholder interviews and moved to creating prototype content for usability testing.

Guided by these results and the SMART framework, we developed a prototype of the web-based self-management skills and peer-mentor intervention. We proposed that the intervention would consist of two components: (1) web-based educational modules to improve self-management skills (using Rutgers Canvas) and (2) a peer mentor to provide support and facilitate engagement with the modules. The web-based self-management modules encompass five key areas: (1) understanding treatment history and the survivorship care plan, (2) managing the logistics of health care, (3) negotiating family involvement in survivorship care, (4) dealing with emotions about survivorship health and follow-up care, and (5) staying healthy in the context of life transitions. Given the amount of self-management education, we decided that a website would be optimal for housing the information and delivering it consistently to all participants. [Table 3](#) presents the proposed content, the SMART constructs targeted by each module, and an illustrative quote from a key stakeholder affirming the relevance of the content. We proposed that the peer mentor would meet with the participant to review the content of the module, discuss how the participant could apply the content, and offer support. Mentors would also remind participants to complete the modules before their meeting.

Table 3. Proposed modules based on formative research and content development interviews.

Proposed module	Module content	SMART ^a constructs targeted	Supportive quote
1. Understanding treatment history and survivorship care plan	<ul style="list-style-type: none"> Name diagnosis, treatments received, and risks for late health effects Understand your treatment history Risk of late effects Obtain (if needed) and store survivorship care plan 	<ul style="list-style-type: none"> Knowledge Goals and motivation 	“I think just like knowing about what I could see in the future, what’s common, what’s not. What’s common with like the treatment I received? And things like that, I think that like mostly what I’m concerned about.” [AYA ^b -1]
2. Managing your health care	<ul style="list-style-type: none"> Review self-management tasks (eg, make appointments and obtain screenings) Establish and maintain relationship with primary care physician Logistics of insurance and health care tasks Identify barriers to obtaining care and problem solve Review motivation and confidence to assume responsibility for care 	<ul style="list-style-type: none"> Self-management skills Self-efficacy Relationships and communication Goals and motivation 	“I think most of the AYAs have a sense of how the health care system runs but I think even just the basic logistics of who do you call to schedule an appointment. You know who do you ask for, for what resource? Where do you get your medications? Things that their parents take care of at a very detailed level, but they sort of understand what the process is because their parents have been doing it for them all along.” [HP ^c -1]
3. Negotiating family involvement in your care	<ul style="list-style-type: none"> Discuss challenges of parents who do not relinquish control and issues related to communication skills Discuss supportive ways to include family 	<ul style="list-style-type: none"> Relationships and communication 	“It more or less started when I went to the doctors and I was talking to them, it was before I went to college. And I guess after that day my mom kind of realized you know she’s older. I’m able to sign my own forms. I was able to be at the office by myself. She didn’t necessarily have to go to the office so when the doctor started directing the questions and the suggestions to only me and not my mom as well it kind of clicked that hey you know I’m going to have to be an adult. I’m going to have to start taking charge of my own health.” [AYA-2]
4. Dealing with emotions about your health and follow-up care	<ul style="list-style-type: none"> Coping with uncertainty of future health Communicating with providers and families about adult-oriented health care 	<ul style="list-style-type: none"> Self-management skills Relationships and communication 	“Well, I think that one of the major things is just worrying about her health. You know and hoping that everything still goes forward in the right direction.” [P ^d -1]
5. Staying healthy in the context of life transitions	<ul style="list-style-type: none"> Recognize that health must be maintained in the context of other important life transitions (eg, education, career, and relationships) Skills and resources for healthy diet, exercise, sexual health, fertility, education, and career Identify value in prioritizing health 	<ul style="list-style-type: none"> Goals and motivation Self-management skills Self-efficacy 	“My goal is that if you take good care of your body and make wise choices your survivorship will be no different than your peers. By thinking about that you know smoking you know or doing drugs or not wearing your seat belt when you’re in the car, all of those things are potential factors that could end your life sooner than, per se, your peers so based on all of the therapy that you received you’re fortunate that you’re here today and what can we do to make sure that your lifelong health is protected?” [HP-2]

^aSMART: social-ecological model of adolescent and young adult readiness for transition.

^bAYA: adolescent and young adult (survivor).

^cHP: health care provider.

^dP: parent.

Stage 3: Content Refinement

All (4/4, 100%) participants found the content in the modules to be relevant and important for managing their own health. The AYA survivors found the website easy to use and reported that the instructions for progressing through the program were

clear. In general, there was a desire for more participative content, including animated videos and tailored quizzes. The survivors indicated a preference for information distribution through infographics and illustrations versus a written *e-book*-type format. Participants made specific recommendations for word changes to improve readability.

There were requests for links to additional resources, including support groups, scholarships, and career resources. Of the 4 survivors, 1 (25%) suggested adding a group discussion forum for all participants. Participants also indicated that they would be likely to access the website on both a computer as well as their mobile phones, and as such, the website should be tailored for mobile use. In response to these suggestions, we added an animated *how-to* video, quizzes for each module, and changed some text to improve readability. We also added a specific *resources* section covering the array of topics suggested. We decided not to add a group discussion forum at this time, given that it would require resources to moderate and add complexity to the intervention. However, we decided we would add a section where mentors could upload a picture and brief biography to share their stories. Our goal was to incorporate as many suggestions as possible with our limited resources so that we could move quickly to a feasibility trial. Sample screenshots of the revised prototype are presented in [Multimedia Appendix 1](#).

When asked specifically about their preference for mode of contact with the peer mentor (ie, videoconference, telephone, SMS text message, and social media), all (4/4, 100%) survivors expressed a preference for communicating with a peer mentor through videoconference or telephone and SMS text message rather than social media. They were receptive to the idea of working with a mentor. Of the 4 participants, 1 (25%) suggested that it would be helpful for the mentor to have received the same diagnosis as they, but another (1/4, 25%) suggested that shared interests or mentor training would be important to successfully initiate a relationship. Although SMS text messaging offers convenience, we felt that video calling would be optimal to build a relationship. With our participants' preferences in mind, we decided that we would introduce the peer mentor-participant pairs through secure SMS text message and then the peer mentor would be responsible for initiating 6 videocalls with their mentee. The first call would focus on rapport building, whereas the remaining calls (5/6, 83%) would focus on discussing and applying the content of the 5 web-based modules (ie, 1 module per call). We also plan to train and supervise mentors closely to facilitate positive relationships.

Discussion

Principal Findings

Childhood cancer survivors are a growing population with a demonstrated need for developmentally appropriate and evidence-based interventions to improve their transition readiness and self-management skills. The goal of this study was to develop a theory-based intervention to improve transition readiness of AYA survivors.

In the first stage of the study, the formative stage, we identified barriers and facilitators to AYA survivors receiving risk-based care, including lack of knowledge about personal risk for late effects, relationships with their medical care team and parents, emotional reassurance about health and remission status, and motivation to remain healthy and pursue normative developmental milestones. Participants reported that their parents remained involved in their follow-up care. The survivors

discussed the emotional challenge of being *different* from healthy peers, with the implication that getting support from peers who had successfully navigated the transition and understood what it is like to be a survivor could be helpful. These results align well with the broader literature on barriers to recommended survivorship care, particularly during and after the transition to young adulthood [29,30]. Combined with the existing literature, our results suggested that a skills-based self-management intervention that also incorporates social support from a peer could address the needs of this population.

In the second stage of the study, key stakeholders (ie, AYA survivors, parent, and providers) confirmed that our identified self-management topics (from stage 1 formative research and the SMART framework) were relevant and important components for an intervention. The stakeholders highlighted the need for increased knowledge about the risk of late effects, enhanced skills for self-management and health care system navigation, strategies for communicating with health care providers and family members involved in care, coping with the emotions of long-term survivorship care, and incorporating healthy behaviors into their everyday lives. These topics were incorporated into a series of web-based modules created to help improve self-management skills. The use of peer mentoring alongside the self-management skills modules is intended to provide support and advice regarding emotional and practical barriers to transition from someone with similar experience. In addition, a peer mentor may serve as a supportive accountability agent, facilitating participants' engagement with the web-based modules. The program was designed such that the mentee participant would complete 1 module per week and review it with their peer mentor.

The web-based modules were well received by the AYA survivors in stage 3 usability testing and were seen as helpful and informative for managing their care. Suggestions to improve the modules were primarily to make them more participative to increase usability and engagement. The AYA survivors were receptive to having a peer mentor. Mentoring has been found to be an acceptable method of intervention among other AYAs with chronic illnesses such as irritable bowel disease, juvenile arthritis, chronic pain, and juvenile diabetes [31-34]. The AYA survivors expressed a preference for using SMS text messaging, telephone calls, or videoconference to communicate with their mentor. Of the 4 AYA survivors, 1 (25%) expressed a preference for being *matched* with their mentor based on cancer type. This preference aligns with the theory of social networks, which proposes that social network ties with those who have direct personal experience with a life event or *experiential similarity* are more likely to offer specialized health-related informational support. Peer survivors, particularly those who have had similar diagnoses and treatments, can offer informational and emotional support through empathic understanding of the concerns of AYA survivors regarding health care self-management, serve as role models, and provide advice and encouragement as AYA survivors take greater responsibility for managing their health care [35,36]. Using a peer survivor mentor is novel compared with existing interventions [17]. However, there may be challenges in recruiting mentors with the same diagnosis, given the relative rarity of some diagnoses.

Limitations

The limitations of this study include reliance on a small sample to move quickly through the stages of development. Although we believed that it was important to recruit beyond our own local clinic catchment area, advertisements through social media and web-based platforms yielded a sample that was primarily female and lacked racial and ethnic diversity, which could limit whether our proposed intervention meets the needs of unrepresented groups. The use of telephone interviews allowed recruitment of individuals from different geographic locations where survivorship care may be different. Telephone interviews (vs in-person interviews) have advantages and disadvantages; telephone interviews may increase disclosure of information by respondents but prohibit observation of nonverbal cues [37]. The SMART model and existing literature were used to form the interview guides and develop the intervention. This gives the content strong theoretical underpinnings but may have limited creativity because our questions were aligned with the framework rather than more open-ended creative design exercises. We also limited our inclusion criteria to AYA survivors currently aged 18 to 25 years because they are legally responsible for their health care and this period is a common

time of transfer from pediatric-centered to adult-centered health care. However, transition is a process that should start earlier in adolescence, and our design process did not capture the input of those who were in the earlier stages of the process.

Conclusions

In conclusion, AYA survivors of childhood cancer are interested in a self-management and peer-mentoring intervention that may improve their confidence and skills to manage their own care. Incorporating AYA survivors into this formative work helped us to confirm theoretically important targets for the intervention and make design decisions in line with our target users' preferences. Although our focus was on AYA survivors of childhood cancer, the barriers and essential intervention topics we identified may be relevant for AYAs with other chronic health conditions because a recent systematic review found that relationship, access to care, insurance, knowledge, and self-management skill barriers transcend illness conditions [38]. Future research is needed to understand the feasibility and acceptability of the proposed intervention. The next step is to conduct a single-arm trial to determine the feasibility and acceptability of the proposed intervention among AYA survivors of childhood cancer.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Sample screenshots of the prototype educational modules.

[[PDF File \(Adobe PDF File\), 576 KB - formative_v6i8e36323_app1.pdf](#)]

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Abbreviations

AYA: adolescent and young adult

SMART: social-ecological model of adolescent and young adult readiness for transition

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Original Paper

Wearable Neck Surface Accelerometers for Occupational Vocal Health Monitoring: Instrument and Analysis Validation Study

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Abstract

Background: Neck surface accelerometer (NSA) wearable devices have been developed for voice and upper airway health monitoring. As opposed to acoustic sounds, NSA senses mechanical vibrations propagated from the vocal tract to neck skin, which are indicative of a person's voice and airway conditions. NSA signals do not carry identifiable speech information and a speaker's privacy is thus protected, which is important and necessary for continuous wearable monitoring. Our device was already tested for its durable endurance and signal processing algorithms in controlled laboratory conditions.

Objective: This study aims to further evaluate both instrument and analysis validity in a group of occupational vocal users, namely, voice actors, who use their voices extensively at work in an ecologically valid setting.

Methods: A total of 16 professional voice actors (age range 21-50 years; 11 females and 5 males) participated in this study. All participants were mounted with an NSA on their sternal notches during the voice acting and voice assessment sessions. The voice acting session was 4-hour long, directed by a voice director in a professional sound studio. Voice assessment sessions were conducted before, during, and 48 hours after the acting session. The assessment included phonation tasks of passage reading, sustained vowels, maximum vowel phonation, and pitch glides. Clinical acoustic metrics (eg, fundamental frequency, cepstral measures) and a vocal dose measure (ie, accumulated distance dose from acting) were computed from NSA signals. A commonly used online questionnaire (Self-Administered Voice Rating questionnaire) was also implemented to track participants' perception of vocal fatigue.

Results: The NSA wearables stayed in place for all participants despite active body movements during the acting. The ensued body noise did not interfere with the NSA signal quality. All planned acoustic metrics were successfully derived from NSA signals and their numerical values were comparable with literature data. For a 4-hour long voice acting, the averaged distance dose was about 8354 m with no gender differences. Participants perceived vocal fatigue as early as 2 hours after the start of voice acting, with recovery 24-48 hours after the acting session. Among all acoustic metrics across phonation tasks, cepstral peak prominence and spectral tilt from the passage reading most closely mirrored trends in perceived fatigue.

Conclusions: The ecological validity of an in-house NSA wearable was vetted in a workplace setting. One key application of this wearable is to prompt occupational voice users when their vocal safety limits are reached for duly protection. Signal processing algorithms can thus be further developed for near real-time estimation of clinically relevant metrics, such as accumulated distance dose, cepstral peak prominence, and spectral tilt. This functionality will enable continuous self-awareness of vocal behavior and protection of vocal safety in occupational voice users.

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KEYWORDS

mechano-acoustic sensing; voice monitoring; wearable device; neck surface accelerometer

Introduction

Background

Neck surface accelerometers (NSAs), a type of mechano-acoustic sensor, have been adopted as mobile health (mHealth) wearables for voice and upper airway health monitoring [1-5]. The vocal folds, which are housed in the larynx, oscillate at high frequencies (>100 Hz) when we speak or sing. The generated acoustic waves travel along the vocal tract, which acts as a resonator to shape the sound into audible speech. Concurrently, these acoustic waves propagate laterally to the tracheal wall and the neck skin surface. NSAs are used to convert these mechanical accelerations into electrical signals for digital devices, which can be applied to monitor a person's vocal activity and health.

Compared with other mHealth wearables embedded with acoustic microphones, NSA-based wearables have advantages of protecting speaker's privacy and increasing signal quality for remote, continuous voice monitoring. For instance, the neck tissue acts as a low-pass filter by nature and restricts the signal bandwidth to 1.5 kHz at maximum [4]. As most recognizable phonetic features (eg, vowel formants) are within the high-frequency range (around 6-8 kHz), identifiable speech information is already filtered by the neck tissue and barely captured by NSAs [6]. Furthermore, NSAs possess anti-interference ability against background noise because they are only sensitive to contact vibration but not to air-borne acoustic waves.

From the clinical perspective, an individual's voice condition is evaluated through an array of acoustic and aerodynamic metrics such as fundamental frequency (f_0), cepstral peak prominence (CPP), sound pressure level (SPL), subglottal pressure as well as the difference between the first and second harmonic magnitudes (H1 – H2). These clinical metrics are typically obtained from conventional clinical instruments such as Computerized Speech Lab, electroglottography, and Rothenberg mask systems. These instruments are, however, large and expensive, which are not suitable for mHealth apps. Several research groups, including our team, have thus developed compact and lightweight NSA wearables to collect voice-related metric data continuously without causing users' discomfort or interruptions to their daily activity [3,4,7-11].

Voice-related metrics obtained from NSA devices were not found to differ from those obtained with conventional instruments [12-14]. For instance, NSA-derived and microphone-derived jitter and CPP values were relatively

comparable across vowels in both normal and deviated voices (both $r > 0.78$) [12]. Estimation error of SPL from NSA signals of voiced speech was less than 2.8 dB [13]. To estimate aerodynamic features of voice sounds, an impedance-based inverse filtering model was applied to derive glottal volume velocity from NSA signals [15]. NSA-derived and airflow-derived H1 – H2 values were found fairly comparable ($r = 0.72$) [16]. Similarly, moderate correlation ($R^2 = 0.63$) was reported between the NSA root-mean-square amplitude and intraoral pressure in vocally healthy speakers across vowels [17].

Growing evidence further supports the robustness of NSA signals in discerning normal versus deviated vocal health conditions. For example, one study collected NSA-derived acoustic metrics from a group of female patients with hyperfunctional voice disorders and their matched controls for over a week [18]. The patient group displayed overall higher SPL values and less H1 – H2 variability than matched controls [18]. By applying machine learning techniques, our group showed that distinctive voice types (normal, breathy, and pressed voice) could be classified from NSA signals with more than 80% accuracy [4]. That said, in reviewing published studies using conventional air microphones, inconsistent calculated values of acoustic voice metrics were reported between sustained vowels and continuous speech [19]. Although sustained vowel tasks were more common in clinical voice assessment, continuous speech tasks are more ecologically valid to represent an individual's natural speaking voice. A thorough evaluation of NSA-derived acoustic metrics across phonation tasks is thus imperative as part of instrument validation.

One target clinical population for voice monitoring wearables includes those who use their voices heavily in the workplace. Voice actors, singers, and teachers are examples of occupational voice users who tend to develop vocal fatigue and disorders [20-23]. A key functionality of NSA wearables is to provide real-time alerts when a user's vocal safety limit is reached at workplace. That way, the user can take immediate action rather than unknowingly surpass the threshold for safe voice use, which would result in chronic vocal fatigue and irreversible vocal injury. Vocal dose metrics are available to estimate the amount of voice use by quantifying the distance that vocal fold travels during phonation. Several vocal dose metrics such as distance dose (Dd), cycle dose, and time dose were successfully derived from NSA signals by our group and others [11,24-27]. However, inconclusive literature suggested that these metrics could be gender dependent, which may implicate the need for creating gender-specific vocal safety limits [28]. An investigation on

the quantitative relationship between vocal doses and NSA-derived acoustic metrics in both females and males is thus pivotal to validate this critical question.

Research Objectives and Hypotheses

This study represents our ongoing work to develop and validate an in-house NSA wearable system for voice and upper airway health monitoring. Our device has already been tested in controlled laboratory settings [4,11]. As one major application of this device is to monitor voice use at workplace, the next logical step would be to test whether the device could endure one such ecologically valid condition. This study thus aimed to test the instrument validity of our NSA wearables in a group of occupational voice users, namely, voice actors, during their voice acting routines in a professional sound studio.

Briefly, all participants were subject to a voice acting session in an ecologically valid setting plus 2 follow-up sessions of voice assessments. Vocal doses and acoustic metrics were collected with our in-house NSA wearables and self-perceived vocal fatigue was assessed by an online questionnaire. NSA acoustic metrics were extracted from both sustained vowels and passage reading tasks. Furthermore, certain voice actors have a routine of practicing vocal warm-up exercise as part of their acting. Participants were thus randomized to either a warm-up group or no warm-up group before their acting session to protect the ecological validity while minimizing potential confounding effects from an individual's warm-up history.

We hypothesized that NSA-derived acoustic metrics and self-perceived vocal fatigue ratings would show similar trends

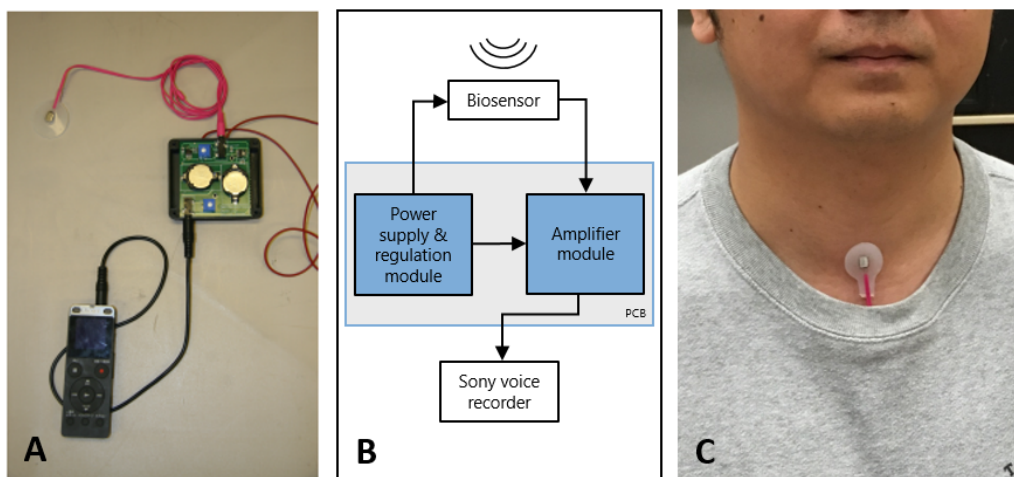
indicative of vocal fatigue and recovery. We also hypothesized that the acoustic metrics derived from passage readings would be comparable to those derived from sustained vowels. We further hypothesized that distance dose and NSA-derived acoustic metrics would be comparable between female and male participants in this study.

Methods

Hardware

Our in-house NSA system consisted of (1) an accelerometer (BU-27135; Knowles Inc.) set into a circular silicon pad with a diameter of 28 mm, thickness of 1.2 mm, and weight less than 20 g; and (2) a peripheral circuit containing 1 power supply module and 1 amplifier module on a printed circuit board (Figure 1). Four lithium coin batteries (CR2032; Panasonic Inc.) with a nominal voltage of 3 V and capacity of 225 mA hour were used as a power source. The peripheral circuit board was interfaced with the accelerometer using a 3.5-mm stereo audio cable. A Sony voice recorder (ICD-UX565F; Sony Inc.) was used as a data logger to save the NSA data in .wav audio format and transferred to a computer for signal processing and analysis. The total cost of each device was about CAD \$100 (US \$77). All NSA recordings were made using a linear pulse code modulation encoding mode with a 44.1-kHz sampling rate. A signal-to-noise ratio of 45 dB was achieved using the recorder's multiple modes for background noise suppression. Further details and verification tests of the NSA system were reported in our previous publications [4,5,11,29].

Figure 1. The NSA Wearable Device. (A) Hardware instrument, and (B) Schematic design. Adapted from "Figure 1. The physical prototype and schematic of the NSA", by Lei et al, 2019 [4] and licensed under CC BY 4.0. PCB: printed circuit board.



Participants

Participants were recruited via the Alliance of Canadian Cinema, Television and Radio Artists (ACTRA) (Montreal Chapter) network. A total of 16 professional voice actors aged 21-50 years consented to participate in the experiment. Participants were randomly assigned to either a *no warm-up* group (n=4 for both females and males) or a *warm-up* group (females: n=7;

males: n=1). All participants had basic voice acting experience defined as (1) having participated in at least one voice acting workshop organized by the ACTRA; or (2) having been contracted, on at least one occasion, to complete paid voice work on a project. All reported normal hearing bilaterally. Individuals with a smoking habit (>1 cigarette per day within the last year or any smoking habit within the last 2 months), current history of chronic (ie, lasting >2 weeks) voice problems,

or current use of medications that are considered to possibly affect an individual's voice (ie, diuretics, decongestants) were excluded from the study.

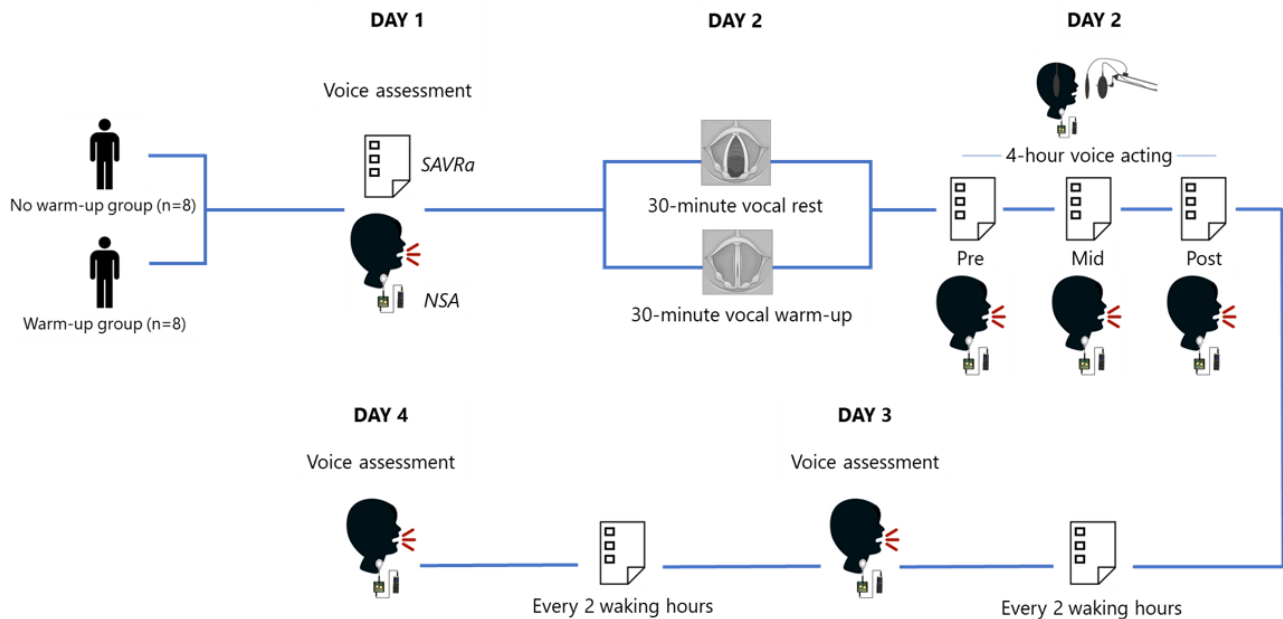
Experimental Design and Data Acquisition

Overview

The experimental protocol spanned across 4 consecutive days for various tasks (Figure 2). Voice assessments were conducted

on days 1, 3, and 4 at McGill University's Voice and Upper Airway Research Lab. Voice assessments and a professional voice acting session took place on day 2 at a professional recording studio. Upon arrival to the laboratory or the studio, an NSA was mounted onto a participant's neck surface around the glottal notch region. Two medical adhesives, (1) a conductive paste on the silicon pad to ensure adherence to the neck skin, and (2) a medical tape, were used to ensure the sensor did not shift during the study.

Figure 2. Human Protocol of Voice Assessments and Voice Acting. Voice assessments included Self-Administered Voice Rating questionnaire (SAVRa) and neck surface accelerometer (NSA)-derived acoustic voice evaluation.



Voice Acting Session

Participants were required to wear an NSA during the whole session. Before the voice acting, the warm-up group participants practiced a 30-minute vocal warm-up routine with a trained speech-language pathologist to ensure the warm-up exercise stayed consistent across participants. The no warm-up group participants were instructed to take vocal rest by refraining from using their voices completely during the 30 minutes preceding the acting session.

After that, all participants proceeded to perform a 4-hour-long voice acting session directed by a professional vocal director. The acting was based on a standardized script from the Assassin's Creed® video game. Participants were instructed to keep a mouth-to-microphone distance of 50 cm as much as possible without hindering their acting. The air microphone sound was purely used for on-site coaching purpose. Given the confidentiality in video game development, the air microphone data were prohibited for research use.

The acting session consisted of 2 parts: (1) part 1, consisting of low-intensity (eg, casual dialog) voice-over work; and (2) part 2, consisting of medium- (eg, barks, oh-noes) and high-intensity (eg, death cries) voice-over work. The voice director provided feedback to participants on their performance, in an effort to ensure that intensity levels and acting styles were consistent

across participants. As a common practice in voice acting, a 15-minute break was provided between parts 1 and 2. Further, participants had access to water and were encouraged to drink throughout sessions. The voice director would reinforce actors to take a drink during sessions when audible "mouth noises" were heard, as the resulting sounds could not be used in the game videos for technical reasons.

Voice Assessment Protocol

Time Points

The voice assessment protocol included self-perceptual ratings of vocal fatigue and acoustic voice evaluations derived from NSA measurements. The protocol was conducted at 6 study time points: (1) 24 hours before the voice acting session, as a baseline measure; (2) immediately prior to the voice acting session (pre-session); (3) halfway through the voice acting session (mid-session, ie, the 15-minute break between part 1 and part 2 of acting); (4) immediately after the voice acting session (post-session); (5) 24 hours after the voice acting session; and (6) 48 hours after the voice acting session. Participants were also asked to complete the self-perceptual rating questionnaire remotely every 2 waking hours following the voice acting session until the end of the study (Figure 2).

Self-Perceptual Ratings of Vocal Fatigue

The Self-Administered Voice Rating (SAVRa) questionnaire was administered to evaluate participants' perception of vocal fatigue [27]. Three SAVRa ratings were used in this study, namely, *current speaking effort level* (EFFT: 1=no effort, 10=extreme effort to speak), *laryngeal discomfort level* (DISC: 1=no discomfort, 10=extreme discomfort), and *inability to produce soft voice* (IPSV: 1=unproblematic soft voice,

10=extreme problems with producing the soft voice). An electronic version of the SAVRa was created on the SurveyMonkey website [30] for remote data collection.

Acoustic Voice Evaluation

To approximate a standard clinical protocol of acoustic voice evaluation, 4 phonation tasks were elicited from participants wearing an NSA (Table 1). A description of the 4 phonation tasks and related acoustic metrics is presented in Table 1.

Table 1. Phonation tasks.

Task number	Phonation task	Acoustic metrics
1	1-minute reading of the Rainbow Passage	<ul style="list-style-type: none"> • Cepstral peak prominence • Fundamental frequency • H1 – H2^a • Harmonic richness factor • Spectral entropy • Spectral tilt • Surface/skin acceleration level
2	Vowel phonation /a/ for 5 seconds	<ul style="list-style-type: none"> • Cepstral peak prominence • Fundamental frequency • H1 – H2 • Harmonic richness factor • Spectral entropy • Spectral tilt • Surface/skin acceleration level • Jitter • Shimmer
3	Deep breath and vowel phonation /a/	<ul style="list-style-type: none"> • Maximum phonation time
4	Glide on vowel /a/ from low to high pitch	<ul style="list-style-type: none"> • f_0 minimum • f_0 maximum

^aH1 – H2: difference between the first and second harmonic magnitudes.

Task 1 (Rainbow Passage task) was used to assess acoustic metrics during running speech. Participants were required to read the standard Rainbow Passage for a duration of 1 minute using a pitch, loudness, and pace similar to a natural conversational context. Seven metrics, namely, CPP, f_0 , H1 – H2, harmonic richness factor (HRF), spectral entropy (SE), spectral tilt (Tilt), and skin acceleration level (SAL), were extracted during this task.

Task 2 (sustained vowel task) was used to assess acoustic metrics in a more steady-state phonation style. Participants were asked to sustain the vowel sound /a/ for 5 seconds while maintaining a steady pitch and loudness. In addition to the aforesaid metrics, jitter and shimmer were quantified to measure pitch and loudness stability, respectively. Of note, the extraction of jitter and shimmer are only applicable for relatively stable and periodic signals, such as those of sustained vowels herein.






Task 3 (maximum phonation task) was used to measure the maximum time (in seconds) that a person can sustain phonation. Participants were instructed to take a deep breath and produce the vowel /a/ as long as possible, using a comfortable pitch and loudness.

Task 4 (pitch glide task) was used to evaluate an individual's pitch range. Participants were instructed to start saying /a/ at the lowest pitch possible and slowly glide their voice as high in pitch as possible. Minimum pitch (f_0 minimum) and maximum pitch (f_0 maximum) values were extracted for this task.

NSA Data Processing

All NSA-related data extraction and calculation were performed using the MATLAB (MathWorks) software. For the computation of acoustic metrics (see Table 2 for detailed algorithms), raw NSA data were first segmented into 45-ms long segments. The voice activity detection method, which was based on short-term energy and zero-crossing rate, was used to remove nonvoiced segments [31]. Only voiced segments were used to extract acoustic metrics and a Hamming window with fast Fourier transform was used to obtain NSA spectra [4]. For CPP, H1 – H2, HRF, Tilt, and SE computation, spectral amplitude normalization was further performed to normalize the amplitudes of all 45-ms spectral segments into the range [0,1]. Furthermore, peak-picking recognition function was applied to identify the harmonics location (ie, H1, H2, H3, ...) for the 4 harmonic-dependent metrics, namely, CPP, H1 – H2, HRF, and Tilt.

Table 2. Mathematical formulas and definitions of acoustic metrics.

Acoustic metrics	Mathematic formula	Units	Definition
CPP ^a	$Peak_max - (b_0 + b_1 * q)$ where Peak_max is the amplitude in decibels of the highest cepstral peak, b ₀ and b ₁ are the coefficients of the least-square linear regression model of the cepstrum, and q is the quefrency of the highest cepstral peak.	Decibels	The difference in amplitude between the cepstral peak and the corresponding value on the trend line through the overall spectrum, which represents how far the cepstral peak emerges from the cepstrum background.
f ₀ ^b	$1/T$ where T is the period.	Hertz	Frequency of vocal fold vibration that is the lowest of all the frequencies in the voice spectrum and is obtained by the reciprocal of the smallest period.
H1 – H2 ^c	$20\log(A1/A2)$ where A1 and A2 are the magnitudes of the first and second harmonics in the spectrum, respectively.	Decibels	The log-magnitude difference between the amplitudes of the first and second harmonics in the spectrum.
HRF ^d	 where H _r represents the magnitude of the rth harmonic.	Decibels	Ratio of the sum of the amplitudes at the harmonics above the fundamental frequency to the amplitude of the component at the fundamental frequency.
SE ^e	 where p _i is the normalized spectral density point (0-3000 Hz).	Relative value	Estimates the uniformity of signal energy distribution in the frequency domain.
Tilt ^f	 where H _n is the amplitude of spectral harmonics in decibels, b ₀ is the least-square linear regression intercept, and f is the spectral frequency.	Decibels/Hertz	Tilt of the trend line of the long-term average spectrum, which represents the degree to which intensity drops off as frequency increases.
SAL ^g	$20\log(\max[\text{data_frame}]/A_noise)$ where data_frame is voiced segment and A_noise is the system reference noise level and equal to 0.004 based on the nonvoice waveforms.	Decibels	The calculation is based on the maximum of each voiced segment amplitude for every 45-ms segment window.
Jitter _(relative)	 where T _i (i=1, 2, ..., N) is the period of each vocal cycle.	Percent	Average absolute difference between consecutive periods divided by average period, indicating the cycle-to-cycle variation of the fundamental frequency.
Shimmer _(relative)	 where A _i (i=1, 2, ..., N) is the peak magnitude in each vocal cycle.	Percent	Average absolute difference between the amplitudes of consecutive periods divided by average amplitude, indicating the cycle-to-cycle variation of vocal amplitude.
MPT ^h	T2 – T1 where T2 is the time at which the phonation of a vowel sound finishes and T1 is the time at which the phonation of a vowel sound begins.	Seconds	Measure of a maximally sustained vowel following a maximal inspiration, which provides an indication of the efficiency of the respiratory mechanism.

^aCPP: cepstral peak prominence.

^bf₀: fundamental frequency.

^cH1 – H2: difference between the first and second harmonic magnitudes.

^dHRF: harmonic richness factor.

^eSE: spectral entropy.

^fTilt: spectral tilt.

^gSAL: skin acceleration level.

^hMPT: maximum phonation time.

Conventionally, the computation of these acoustic metrics is based on glottal flow waveforms, which are derived from mouth-radiated acoustic pressure or airflow signals using inverse filtering estimation. However, as the NSA signals are based on

skin acceleration, no mouth-radiated pressure components are present for inverse filtering to obtain glottal flow pulses and thus the resulting waveforms. As such, algorithms of H1 – H2, SE, Tilt, and SAL were customized and parameterized in this

study [15]. For the calculation of H1 – H2, the first and second harmonics were derived from the NSA spectrum directly. For SE, this metric was computed to quantify the uniformity of signal energy distribution, that is, the degree of chaos, in the frequency domain of the NSA spectrum. From our previously published study [4], the SE was identified as a key acoustic metric in discriminating voice types, in which pressed voice showed higher SE value than those of normal and breathy voice. For the calculation of Tilt, the slope was equal to the amplitude of the spectral harmonics divided by the frequency. In this study, Tilt was computed as a least-square linear regression slope of the long-term average spectrum, which represents the degree to which intensity drops off as frequency increases. The first-order polynomial was used to calculate the slope of the spectral harmonics. For the calculation of SAL, the NSA background noise level was measured as an average value of A_{noise} , which is equal to 0.004. The SAL was calculated for every 45-ms voiced segments. The SAL was a logarithmic form of the NSA amplitude and showed positive correlation with SPL. Both our own and others work showed that SAL was a good estimate of the SPL outputs in phonation tasks [29,32].

Lastly, for distance dose, the algorithm was based on our previously published work [11]. In brief, equivalent SPL values were first estimated using a logarithmic curve-fitting model on SAL values. The location of each vocal cycle was then identified using the peak-picking recognition function. The equivalent SPL values were used to calculate the oscillating amplitude of vocal folds in each vocal cycle. The oscillating amplitude and the number of vocal cycles were finally used to calculate the total distance that the vocal folds traveled during the recorded time.

Statistical Analysis

Statistical Software

JMP Pro software (version 16.1.0; JMP Statistical Discovery LLC) was used for all statistical analyses. With the high number of contrasts carried out throughout this analysis, a more conservative α value of .01 was used to minimize the chances of a type 1 error.

SAVRa Scores

As SAVRa scores were obtained every 2 hours after the acting session, data were reduced by averaging the scores to the corresponding AM or PM of the day. For instance, day 3 scores obtained from 12:00 AM to 11:59 AM were averaged as day 3 AM, whereas those from 12:00 PM to 11:59 PM were averaged as day 3 PM. In addition, individual difference scores were computed for each participant by subtracting mean values at baseline (day 1) from means at each time point and then averaged as described above. Computing and analyzing

differences helped to normalize individual variation and allowed for analyses to highlight changes in vocal measurements and fatigue over time. Both means and difference scores were used for statistical analyses.

Mixed-effects ANOVA was performed on each SAVRa score (EFFT, DISC, and IPSV). Either study group (warm-up or no warm-up) or gender group (female or male) was treated as a between-subjects factor in separate mixed-effects ANOVAs. Full-factorial models were not conducted because of the uneven distribution of genders across study groups. *Time* was treated as a within-subjects factor (day 1, day 2 pre-session, day 2 mid-session, day 2 post-session, day 2 PM, day 3 AM, day 3 PM, day 4 AM, day 4 PM). Planned paired contrasts were performed for significant main effects ($P < .01$), for example, score on each day compared against day 1 (baseline). For analyses involving study group, individual difference scores were used instead of mean values to minimize the effects of the unequal distribution of males and females in each study group.

NSA-Derived Distance Dose

Accumulated distance doses for (1) the entire voice acting session (Total Dd), (2) the first part of the session (Dd part 1), and (3) the second part of the session (Dd part 2) were computed for each participant. No data normalization was performed for these data. Mixed-effects ANOVAs were conducted with session dose (Dd part 1 vs Dd part 2) as a within-subjects factor, and study group or gender group as a between-subjects factor. A separate *t* test was conducted for Total Dd.

NSA-Derived Acoustic Metrics

For NSA-derived acoustic metrics, mixed-effects ANOVAs were conducted using time as a within-subjects factor (day 1, day 2 pre-session, day 2 mid-session, day 2 post-session, day 3, day 4) and study group or gender group as a between-subjects factor. Planned paired contrasts were performed for significant main effects ($P < .01$). For analyses involving study group, individual difference scores (magnitude of change compared with baseline) were used instead of mean values.

Ethical Approval

This human protocol (A04-B21-17A) was approved by the Institutional Review Board at McGill University. The full purpose of the study was not communicated to participants until after completing the study to minimize participant bias on self-perceptual rating measures.

Results

Participant Demographics

The breakdown of participant demographics as functions of study group and gender group is shown in Table 3.

Table 3. Participant descriptive statistics.

Group	Age (years), mean (SD)	Voice acting experience (years), mean (SD)
Study group		
No warm-up	32 (5.1)	4 (2.9)
Warm-up	32 (5.5)	8 (5.7)
Gender group		
Female	32 (5.5)	7 (5.4)
Male	33 (4.7)	4 (3.2)

NSA Instrumentation and Analysis Validity

Participants performed their voice acting with NSA wearables for 4 hours in an ecologically valid setting. The wearables stayed in place for all participants regardless of active body movements during the acting session. All planned acoustic metrics were successfully extracted from NSA signals. To further validate

the NSA signal processing algorithm, numerical values of our acoustic metrics from the Rainbow Passage task were compared with those extracted from daily conversational speech by other research groups. Our data were found to be within a reasonable numerical range with others, supporting both the ecological and external validity of our instrument and analyses (Table 4).

Table 4. Acoustic metrics comparison.^a

Sources	f_0^b		CPP ^c	H1 – H2 ^d	Tilt ^e	Tilt Abs ^f
	Mode	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)
This study: Rainbow Passage						
No warm-up group						
T1	104	156.1 (49.0)	20.5 (3.7)	5.4 (17.1)	–0.048 (0.009)	–6.0 (5.3)
T2b	108	150.2 (88.0)	26.3 (8.9)	3.8 (17.4)	–0.044 (0.008)	–4.6 (4.0)
T3	99	151 (61.4)	29.5 (7.8)	5.2 (18)	–0.041 (0.007)	–6.0 (4.7)
T4	81	140.6 (48.8)	26.3 (7.7)	3.8 (16)	–0.045 (0.009)	–4.7 (4.0)
T6	85	146.4 (49.3)	21 (3.8)	4.6 (15.6)	–0.049 (0.009)	–4.9 (4.5)
T7	82	143 (53.8)	20.7 (3.7)	10.3 (16.2)	–0.049 (0.010)	–5.6 (4.4)
Warm-up group						
T1	176	183.3 (75.8)	21.1 (3.8)	8.2 (23.5)	–0.048 (0.011)	–1.2 (5.0)
T2a	173	184.9 (113.3)	23.6 (7.6)	7.4 (21.8)	–0.05 (0.011)	–.07 (5.2)
T2b	173	182.5 (76.5)	23.1 (7.6)	8.5 (23.5)	–0.048 (0.011)	–0.8 (4.8)
T3	186	182.2 (69.5)	26.7 (8.6)	10.1 (24.8)	–0.045 (0.012)	–1.2 (5.2)
T4	138	171.3 (75.0)	24.4 (6.4)	13 (23.3)	–0.045 (0.009)	–2.3 (5.8)
T6	151	176.5 (63.9)	21.4 (3.9)	8.7 (23.7)	–0.05 (0.011)	–1.3 (5.2)
T7	181	182.4 (70.2)	20.8 (3.9)	4.9 (22)	–0.052 (0.011)	–0.9 (5.7)
Van Stan et al [14]: Weeklong summary						
Patients with PVFL ^g	198.1	— ^h (76.1)	—	—	—	—
Matched controls	202.9	— (88.0)	—	—	—	—
Mehta et al [10]: Weeklong summary						
Patients with PVH ⁱ	197.2	— (75.3)	23.2 (4.4)	—	—	–14.4 (2.4)
PVH controls	201.4	— (89.6)	22.9 (4.5)	—	—	–14.1 (2.4)
Patients with NPVH ^j	193.8	— (73.5)	21.4 (4.2)	—	—	–13.6 (2.5)
NPVH controls	192.9	— (70.1)	22.8 (4.4)	—	—	–14.1 (2.4)
Van Stan et al [18]: Weeklong summary						
Patients with PVH	196.1	— (73.5)	23.1 (4.4)	4.4 (6.1)	—	—
Matched controls	199.4	— (86.7)	22.7 (4.4)	5.1 (7.0)	—	—
Toles et al [33]: Weeklong summary						
Combined phonation (healthy)	205.7	— (91.6)	22.7 (4.5)	5.5 (7.2)	—	—
Singing (healthy)	325.4	— (94.6)	21.5 (4)	9.7 (7.3)	—	—
Speech (healthy)	203.5	— (62.4)	23.1 (4.5)	4.2 (6.6)	—	—
Van Stan et al [34]: Weeklong summary						
Patients with NPVH	202.4	— (68.1)	20.6 (3.9)	2.6 (6.7)	—	—
Matched controls	182.8	— (68.6)	22.1 (4.3)	2.5 (6.5)	—	—

^aMode and mean (SD) data for the acoustic metrics f_0 , CPP, H1 – H2, Tilt, and Tilt Abs are presented for our Rainbow Passage task as well as for conversational speech from related research studies.

^b f_0 : fundamental frequency.

^cCPP: cepstral peak prominence.

^dH1 – H2: difference between the first and second harmonic magnitudes.

^eTilt: spectral tilt.

^fTilt Abs: tilt absolute.

^gPVFL: phonotraumatic vocal fold lesions.

^h—: data not available.

ⁱPVH: phonotraumatic vocal hyperfunction.

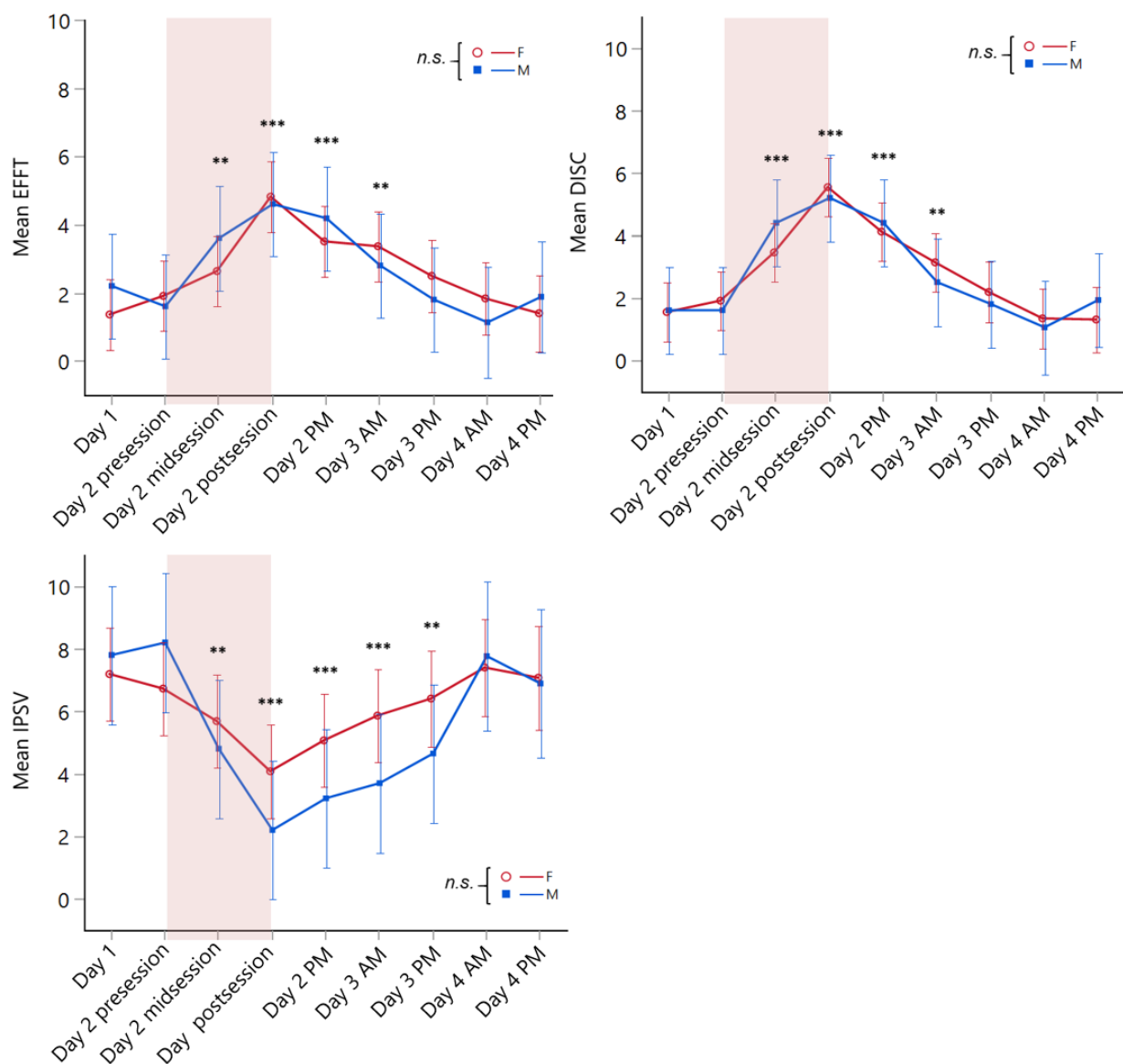
^jNPVH: nonphonotraumatic vocal hyperfunction.

SAVRa

No significant effects of study group or gender group were observed for SAVRa measures, but a main effect of time was found on all 3 SAVRa scores (all $P < .001$; Figure 3; see Multimedia Appendices 1 and 2 for detailed test statistics). Post hoc tests showed that EFFT and DISC scores were all

significantly higher than baseline from day 2 midsession to day 3 AM (all $P < .01$). IPSV scores were significantly lower than baseline starting from day 2 midsession to day 3 PM (all $P < .01$). These results suggest that professional voice acting could induce self-perceived vocal fatigue as early as 2 hours after the start of acting, with potential recovery occurring 24-48 hours after the completion of acting session.

Figure 3. Means and standard errors (error bars) of Self-Adminstrated Voice Rating questionnaire (SAVRa) as functions of Time and Gender Group. The voice acting session is highlighted in the pink region. Asterisks denote statistically significant differences between a specific time point and Day 1 (** $P \leq .01$, *** $P \leq .001$). DISC: laryngeal discomfort level; EFFT: current speaking effort level; IPSV: inability to produce soft voice; n.s.=no significant differences.



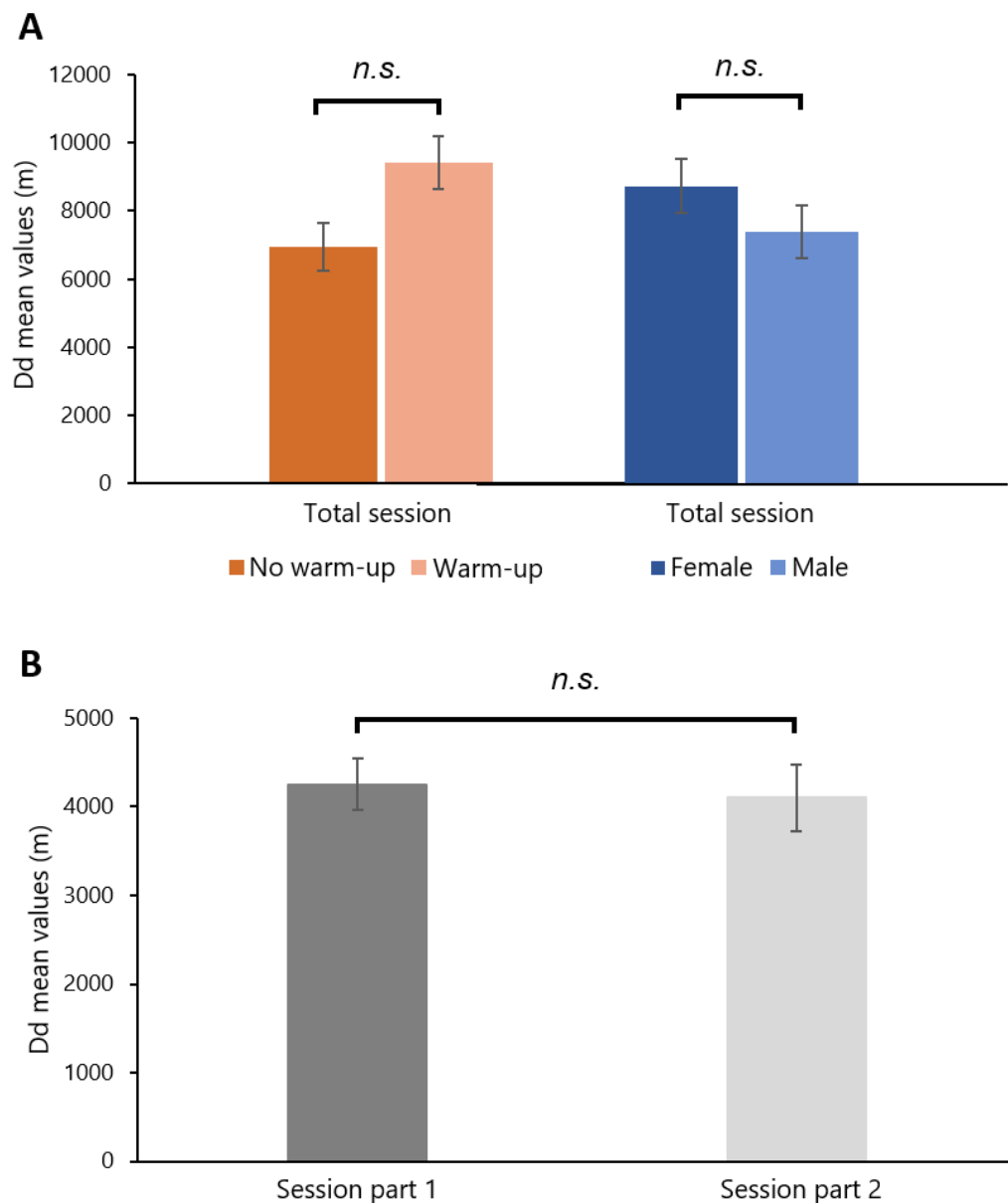
NSA-Derived Distance Dose

No significant main effects of study group, gender group, or session dose were found on independent tests of distance dose. The averaged Total Dd was approximately 8354.35 m (SD

2301.84 m) for a 4-hour voice acting across participants. The averaged Dd was approximately 4250.24 m (SD 1408.31 m) for part 1 and 4104.11 m (SD 1086.22 m) for part 2 of the acting

session (Figure 4; see Multimedia Appendix 3 for detailed test statistics).

Figure 4. Means and standard errors (error bars) of accumulated distance dose (Dd) as functions of Study Group and Gender Group. (A) Total 4-hour sessions. (B) First and second parts of session. n.s.=no significant differences, ie, $P>.01$.



NSA-Derived Acoustic Metrics

Overview of Tasks

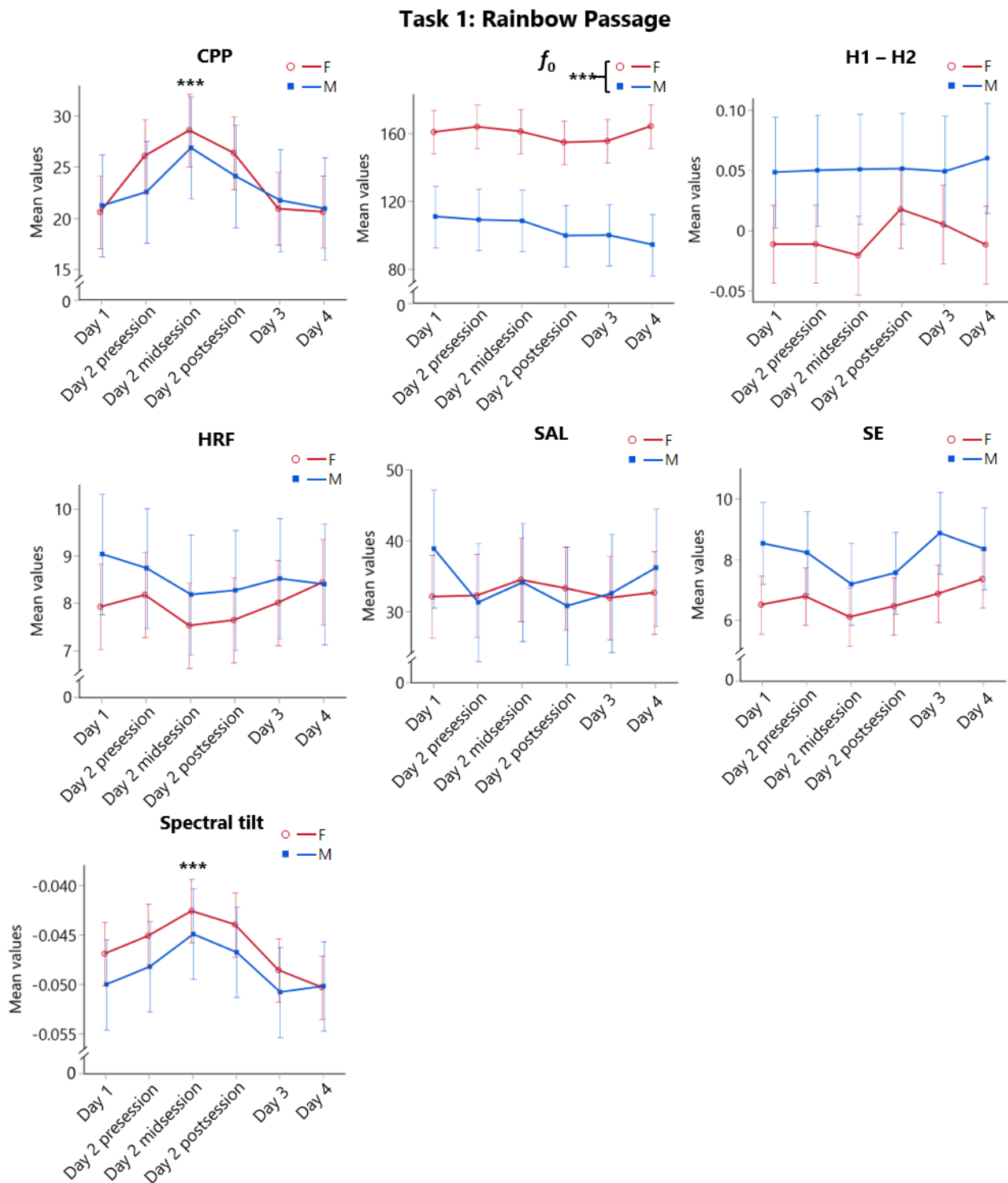
Across all phonation tasks, no study group effects (ie, main effect of study group or interaction of study group and time) were noted for acoustic metrics. By contrast, main and interaction effects of gender group and time were found in certain acoustic metrics depending on the phonation task.

Rainbow Passage Task

There was a main effect of time for CPP and Tilt (both $P<.001$) measures, but no significant gender group or interaction effects (Figure 5; see Multimedia Appendices 4 and 5 for detailed test

statistics). Both measures followed a similar trajectory as those observed in SAVRa, with values increasing from day 1 to day 2 midsession and then decreasing thereafter. Post hoc tests showed that values at day 2 midsession were significantly greater than baseline values (day 1) for both measures (CPP: $P<.001$; Tilt: $P=.001$). Testing also yielded a significant main effect of gender group for f_0 ($P<.001$), with females demonstrating higher f_0 values throughout. The gender difference on f_0 was expected because females generally have higher conversational pitches than males in vocally healthy populations. No significant gender group, time, or interaction effects were found in other acoustic metrics (see Multimedia Appendix 4 for detailed test statistics).

Figure 5. Means and standard errors (error bars) of neck surface accelerometer-derived acoustic metrics in the Rainbow Passage Task as functions of Time and Gender Group. Asterisks denote statistically significant differences (1) between the female (F) and the male (M) participant groups, as well as, (2) between a specific time point and Day 1 (*** P<.001). CPP: cepstral peak prominence; f_0 : fundamental frequency; H1 – H2: difference between the first and second harmonic magnitudes; HRF: harmonic richness factor; SAL: skin acceleration level; SE: spectral entropy.



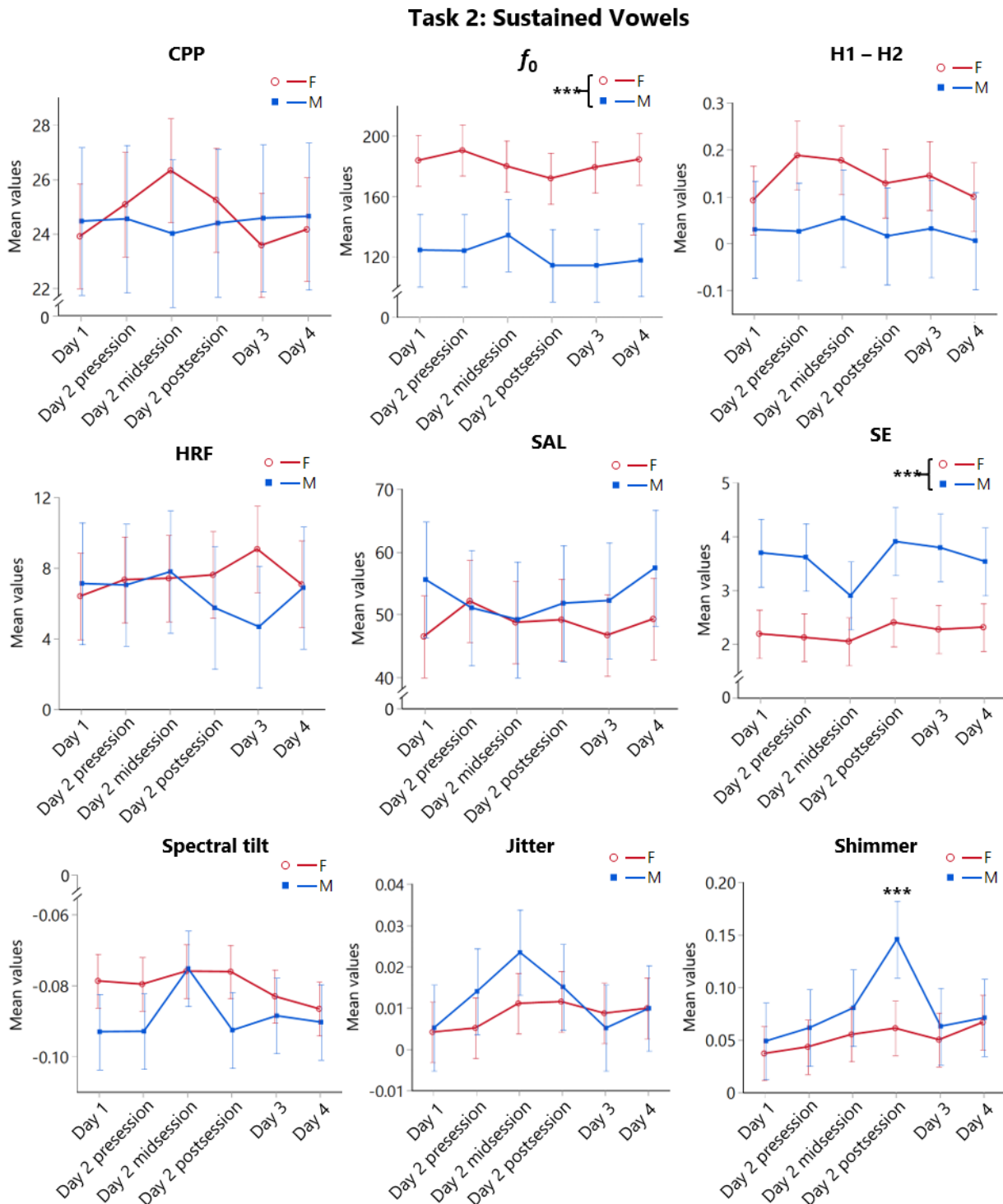
Sustained Vowel Task

There was a significant main effect of time for shimmer (P<.01), with values peaking at day 2 postsession and then dropping off afterward (Figure 6; see Multimedia Appendices 6 and 7 for detailed test statistics). Post hoc tests indicated that shimmer values at day 2 postsession were significantly higher than

baseline values (P=.001). This appeared to be driven by the male group, whose overall values at day 2 postsession were higher than the female group; however, effects of gender group did not reach significance (see Multimedia Appendix 6 for detailed test statistics). The main effects of gender group were also noted for SE and f_0 (both P<.001). For SE, males had higher values throughout, while females showed higher values

throughout for f_0 . No significant gender group, time, or interaction effects were found in other acoustic metrics (see [Multimedia Appendix 6](#) for detailed test statistics).

Figure 6. Means and standard errors (error bars) of neck surface accelerometer-derived acoustic metrics in the Sustained Vowel Task as functions of Time and Gender Group. Asterisks denote statistically significant differences (1) between the female (F) and the male (M) participant groups, as well as, (2) between a specific time point and Day 1 (***) $P \leq 0.001$. CPP: cepstral peak prominence; f_0 : fundamental frequency; H1 – H2: difference between the first and second harmonic magnitudes; HRF: harmonic richness factor; SAL: skin acceleration level; SE: spectral entropy.



Maximum Phonation Time and Pitch Glide Tasks

No effects of gender group, time, or their interaction were noted for maximum phonation time (MPT), f_0 minimum, and f_0 maximum (Table 5).

Table 5. Group-based means (SD) for the maximum phonation time and pitch glide tasks.^a

Acoustic metrics and gender groups	Experimental time points, mean (SD)						ANOVA		
	Day 1	Day 2 pre-session	Day 2 mid-session	Day 2 post-session	Day 3	Day 4	Time	Gender	Time × gender
MPT^b							$F_{5,65}=1.38$; P=.25	$F_{1,13}=2.37$; P=.24	$F_{5,65}=0.81$; P=.54
Female	25.29 (7.53)	22.60 (6.42)	25.68 (6.84)	24.12 (7.38)	22.22 (6.86)	24.90 (7.90)			
Male	30.08 (8.51)	26.74 (11.35)	30.41 (15.36)	30.56 (10.65)	30.87 (12.11)	28.59 (10.50)			
f_0 min^c							$F_{5,65}=3.02$; P=.02	$F_{1,13}=3.65$; P=.08	$F_{5,65}=3.24$; P=.011
Female	13.98 (4.88)	12.85 (0.41)	12.83 (0.62)	12.87 (0.42)	15.03 (7.62)	12.63 (0.61)			
Male	12.77 (0.68)	16.80 (8.80)	14.06 (3.57)	13.08 (0.56)	18.81 (8.43)	25.18 (16.20)			
f_0 max^d							$F_{5,65}=0.84$; P=.53	$F_{1,13}=2.37$; P=.15	$F_{5,65}=1.57$; P=.18
Female	929.14 (335.34)	870.47 (269.30)	911.29 (211.76)	934.05 (301.39)	842.46 (242.24)	864.20 (231.92)			
Male	694.61 (259.44)	689.70 (281.84)	661.19 (188.34)	626.75 (191.97)	823.09 (614.29)	574.22 (249.39)			

^aThere are no statistically significant effects ($P < .01$).

^bMPT: maximum phonation time.

^c f_0 min: f_0 minimum.

^d f_0 max: f_0 maximum.

Discussion

Principal Findings and Comparison With Prior Work

Accumulated distance doses are used to estimate a person's voice use [24,25]. Individuals with healthy voices were reported to have accumulated distance doses of around 18,000 m/week and 228 m/hour [10]. For individuals with disordered voices, the numbers were found to be notably higher with around 27,000 m/week and 345 m/hour [10,14]. In this study, for a total of 4-hour typical voice acting, accumulated distance doses were 8354.35 m on average, with approximately 2089 m/hour. Compared with the literature data, voice actors who engaged in 4 hours of voice acting in this study accumulated almost 46% of a typical person's weekly voice use (8354/18,000, 46.41%). In real-world situations, professional voice actors are often booked with more than 1 acting session in a week, suggesting an exceptionally high vocal demand at the acting workplace. A recent study further investigated the vocal doses from singers with vocal injury in their regular weeks [33]. Results showed that most distance doses in these singers were associated with speaking voice (about 268 m/hour) rather than singing voice (about 103 m/hour) in their weekly summaries (about 370 m/hour). Taken together, these results suggest the need for continuous voice monitoring in voice actors and other occupational voice users, not only in the workplace but also in daily life, to support further self-awareness and management of safe voice use.

Based on the SAVRa data, participants started to perceive significant increases in vocal effort and discomfort after the first part of the acting. The scores increased during acting, reached their peak right after acting, and gradually returned to baseline within 48 hours after acting. This arc-shaped trajectory replicated the same SAVRa variations obtained from our previous vocal loading study, in which participants were required to reach a distance dose of 500 m in each of the 6 consecutive voice sessions [11]. Among all NSA-derived metrics across phonation tasks, only *CPP* and *Tilt* from the Rainbow Passage most closely mirrored the temporal trends of the SAVRa with significant changes over time in both genders. These results are encouraging as *CPP* is already regarded as a robust measure of vocal fatigue and voice deviation with air acoustic microphone signals [35,36]. Even though our NSAs have more restricted bandwidth (around 3 kHz), the clinical robustness of *CPP* seemed to be preserved. For *Tilt*, a decreased slope of *Tilt* is suggested to correlate with perceived creaky voice, whereas an increased slope can be associated with breathy voice [37,38]. Our results showed that the *Tilt* measure increased with the time of voice acting. Individuals may tend to deviate from their modal voice type to a breathier phonation with the vocal fatigue ensued from acting. Overall, results from our current and previous study [11] agreed that, among all NSA acoustic metrics, *CPP* and *Tilt* were most robust to reflect an individual's voice variations and vocal fatigue.

In sum, both female and male actors showed comparable accumulated distance doses from voice acting, suggesting a

gender-specific vocal safety limit may not be necessary. Similar to the observation from air microphone signals, NSA-derived acoustic metrics performed differently between sustained vowels and running speech, whereby the latter is more ecologically valid [19]. In particular, NSA-derived *CPP* and *Tilt* from running speech were equally robust for the detection of voice variations in both genders. These 2 NSA metrics can thus be used as universal surrogates of vocal health biomarkers. One key application of this NSA wearable is to prompt occupational voice users when their vocal safety limits are reached for duly protection. However, continuous, real-time monitoring of an individual's body sound signals requires substantial computing power. Algorithms can thus be focused on processing selected metrics that are the most clinically relevant, such as accumulated distance dose, *CPP*, and *Tilt*. Machine learning techniques can be further applied to learn the time history of an individual's voice features, capture their detrimental variations, and predict risk levels of vocal injury. This functionality will enable continuous self-awareness of vocal behavior and protection of vocal safety in occupational voice users.

Limitations and Future Directions

The NSA system used in this study was a wired version, which poses challenges for users to wear it for long periods. The data transfer was also through a physical recorder and then to a personal computer. No user-device interaction such as

biofeedback of voice use was built into the current NSA system. To address these issues critical to mHealth, a wireless version of NSA wearable is now under development in our group. The NSA data will be transmitted through Bluetooth low-energy technology to a smartphone device. An in-house mobile app is also in development with features of NSA data visualization and vocal health feedback. We have already developed machine learning algorithms that are lean and efficient enough to classify upper airway symptoms such as cough and throat clearing on the NSA board [5]. The aforesaid system upgrades will broaden the NSA functionality to be more interactive and suitable for all-day monitoring.

Conclusions

Laboratory NSA wearable devices were deployed to a group of professional voice actors who underwent a 4-hour voice acting session. The devices were able to tolerate the strenuous body movements and ensued body movement noise from voice acting. Vocal dose measures and a regular check of clinical evaluation metrics (SAVRa and NSA-derived acoustic metrics) were included in this investigation to validate the instrumentation of the device, the NSA-derived acoustic metrics, and NSA's algorithm for voice monitoring. Future field tests are warranted to evaluate aforesaid new instrument and algorithm functions in predicting voice and airway health for occupational voice users and those with chronic airway diseases.

Acknowledgments

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Group-based means for SAVRa scores. Means (standard deviation) for each SAVRa item are presented for females and males across time points. F-values, degrees of freedom, and *P* values and from ANOVA testing are also reported for each factor (Time, Gender) and their interaction (Time x Gender). Statistically significant effects ($P < .01$) are indicated in bold.

[[DOCX File, 42 KB - formative_v6i8e39789_app1.docx](#)]

Multimedia Appendix 2

Post hoc testing results for SAVRa scores. *t* Ratios, *P* values and Cohen's *d* effect sizes are presented for post hoc analyses of significant main effects of Time. For each SAVRa item, planned paired contrasts comparing scores at each time point against Day 1 (baseline) were conducted. Statistically significant effects ($P < .01$) are indicated in bold.

[[DOCX File, 37 KB - formative_v6i8e39789_app2.docx](#)]

Multimedia Appendix 3

Group-based means for Distance Dose measures. Means (standard deviation) for each distance dose measure are presented by Study Group (No Warm-Up and Warm-Up) and Gender Group (Females and Males). F-values, degrees of freedom, and *P* values from ANOVA testing are reported for each factor (Session Dose, Study Group, Gender) and their interaction (Time x Study

Group, Time x Gender). *t*-values, degrees of freedom, and *P* values from *t*-testing are also reported. There are no statistically significant effects ($P < .01$).

[[DOCX File , 36 KB - formative_v6i8e39789_app3.docx](#)]

Multimedia Appendix 4

Group-based means for the Rainbow Passage task. Means (standard deviation) for each voice metric are presented for females and males across time points. *F*-values, degrees of freedom, and *P* values from ANOVA testing are also reported for each factor (Time, Gender) and their interaction (Time x Gender). Statistically significant effects ($P < .01$) are indicated in bold.

[[DOCX File , 53 KB - formative_v6i8e39789_app4.docx](#)]

Multimedia Appendix 5

Post hoc testing results for the Rainbow Passage task. *t* Ratios, *P* values and Cohen's *d* effect sizes are presented for post hoc analyses of acoustic measures showing significant main effects of Time (CPP and Tilt) and Gender (f_0). For main effects of Time, planned paired contrasts comparing scores at each time point against Day 1 (baseline) were conducted. For the main effect of Gender, Female values were compared against Male values. Statistically significant effects ($P < .01$) are indicated in bold.

[[DOCX File , 29 KB - formative_v6i8e39789_app5.docx](#)]

Multimedia Appendix 6

Group-based means for the Sustained Vowel task. Means (standard deviation) for each voice metric are presented for females and males across time points. *F*-values, degrees of freedom, and *P* values from ANOVA testing are also reported for each factor (Time, Gender) and their interaction (Time x Gender). Statistically significant effects ($P < .01$) are indicated in bold.

[[DOCX File , 54 KB - formative_v6i8e39789_app6.docx](#)]

Multimedia Appendix 7

Post hoc testing results for the Sustained Vowel task. *t* Ratios, *P* values and Cohen's *d* effect sizes are presented for post hoc analyses of acoustic measures showing significant main effects of Time (Shimmer) and Gender (f_0 and SE). For the main effect of Time, planned paired contrasts comparing scores at each time point against Day 1 (baseline) were conducted. For main effects of Gender, Female values were compared against Male values. Statistically significant effects ($P < .01$) are indicated in bold.

[[DOCX File , 29 KB - formative_v6i8e39789_app7.docx](#)]

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Abbreviations

ACTRA: Alliance of Canadian Cinema, Television and Radio Artists
CPP: cepstral peak prominence
CRBLM: Centre for Research on Brain, Language and Music Research
Dd: distance dose
DISC: laryngeal discomfort level
EFFT: current speaking effort level
 f_0 : fundamental frequency
H1 – H2: difference between the first and second harmonic magnitudes
HRF: harmonic richness factor
IPSV: inability to produce soft voice
mHealth: mobile health
MPT: maximum phonation time
NSA: neck surface accelerometer
SAL: skin acceleration level
SAVRa: Self-Administered Voice Rating questionnaire
SE: spectral entropy
SPL: sound pressure level
Tilt: spectral tilt

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Original Paper

Refining a Multicomponent Intervention to Increase Perceived HIV Risk and PrEP Initiation: Focus Group Study Among Black Sexual Minority Men

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Abstract

Background: Increased preexposure prophylaxis (PrEP) initiation is needed to substantially decrease HIV incidence among Black sexual minority men (BSMM). However, BSMM perceive others as PrEP candidates instead of themselves and are less likely than other groups to use PrEP if prescribed. Peers and smartphone apps are popular HIV prevention intervention tools typically used independently. However, they could be useful together in a multicomponent strategy to improve perceived HIV risk and PrEP initiation for this group. Information regarding attitudes and preferences toward this multicomponent strategy is limited.

Objective: The goal of this study is to obtain attitudes and perspectives regarding the design of a multicomponent intervention that uses a smartphone app and a peer change agent (PCA) to increase perceived HIV risk and PrEP initiation. The intervention will be refined based on thematic findings for a culturally responsive approach.

Methods: Data were obtained guided by life course theory and the health belief model using 12 focus groups and 1 in-depth interview among HIV-negative BSMM from Baltimore, MD, between October 2019 and May 2020 (n=39). Groups were stratified by the following ages: 18 to 24 years, 25 to 34 years, and 35 years and older. Participants were provided details regarding an existing mobile app diary to self-monitor sexual behaviors and a hypothetical PCA with whom to review the app. Facilitators posed questions regarding perceived HIV risk, attitudes toward the app, working with a PCA, and preferences for PCA characteristics and approaches.

Results: Most participants identified as homosexual, gay, or same gender-loving (26/38, 68%), were employed (26/38, 69%), single (25/38, 66%), and interested in self-monitoring sexual behaviors (28/38, 68%). However, themes suggested that participants had low perceived HIV risk, that self-monitoring sexual behaviors using a mobile app diary was feasible but could trigger internalized stigma, and that an acceptable PCA should be a possible self for BSMM to aspire to but they still wanted clinicians to “do their job.”

Conclusions: HIV-negative BSMM have dissonant attitudes regarding perceived HIV risk and the utility of a mobile app and PCA to increase perceived HIV risk and PrEP initiation. Future research will explore the feasibility, acceptability, and preliminary impact of implementing the multicomponent intervention on perceived HIV risk and PrEP initiation among BSMM in a pilot study.

KEYWORDS

sexual health; life course theory; health belief; possible; HIV; preexposure prophylaxis; mHealth; smartphone; health app; digital health

Introduction

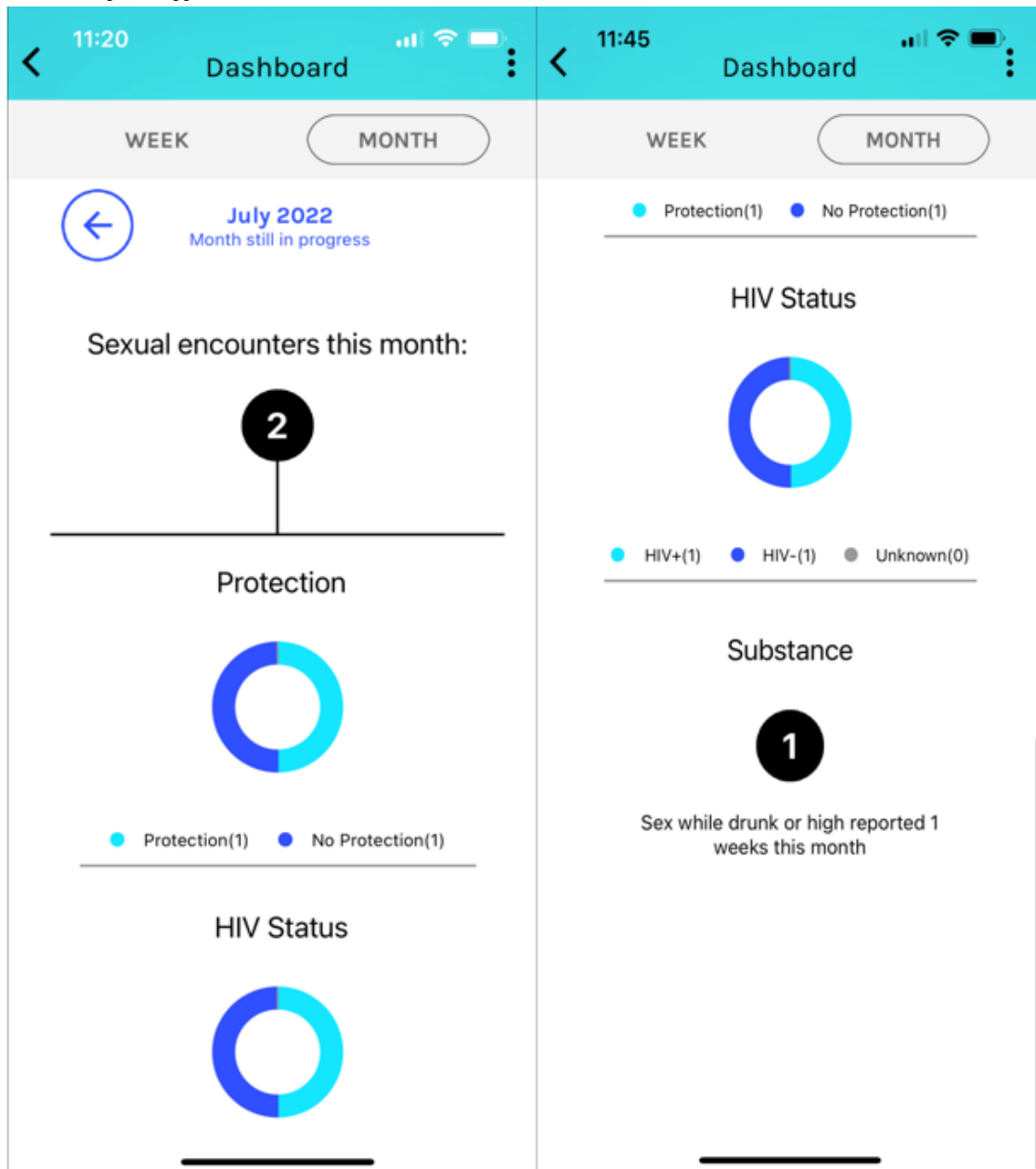
The United States will not reach its plan to end the HIV epidemic unless HIV incidence among Black sexual minority men (BSMM) substantially decreases [1,2]. Between 2015 and 2019, HIV incidence increased by 6% among BSMM aged 25 to 34 years; in 2019, BSMM accounted for 26% of HIV infections among US gay and bisexual men [1,3]. Approximately 75% of BSMM newly diagnosed with HIV are under the age of 35 years [1]. Preexposure prophylaxis (PrEP) use, however, remains substantially lower for BSMM than for other racial/ethnic groups of gay and bisexual men [4,5]. Increased PrEP initiation is urgently needed to substantially decrease HIV incidence for this group [2,6]. To achieve the US plan to end the HIV epidemic, incidence among BSMM must substantially decrease [1,2]. Between 2015 and 2019, HIV incidence increased by 6% among BSMM aged 25 to 34 years; in 2019, BSMM accounted for 26% of HIV infections among US gay and bisexual men [1,3]. Approximately 75% of BSMM newly diagnosed with HIV are under the age of 35 years [1]. Increased PrEP initiation is urgently needed to substantially decrease HIV incidence for this group [6].

Despite increased awareness, multilevel factors such as insufficient insurance coverage, medication costs, stigma, problems with patient-clinician communication, medical mistrust, concerns regarding side effects, and low perceived HIV risk are barriers to PrEP initiation for BSMM [7-11]. Some BSMM perceive others as at higher risk for HIV infection than themselves and do not view themselves as PrEP candidates because they view their current behaviors as relatively lower risk than their past or their peers [12,13]. Perceived HIV risk among BSMM is also influenced by decreased stigma regarding living with HIV due to data showing that individuals living with HIV can live healthy lives and that individuals with an undetectable viral load cannot transmit the virus [14,15]. However, in a high-prevalence subpopulation, low perceived HIV risk inadequately identifies their objective risk. BSMM with higher perceived HIV risk have greater PrEP interest and use than those with lower perceived HIV risk [16,17]. Since multilevel factors affect sexual behaviors, perceived HIV risk, and PrEP initiation among BSMM, interventions that address these barriers are needed.

Peers and smartphone apps are popular HIV prevention tools. Some interventions leverage in-group members as peer change agents (PCAs) who disseminate health-related information within the population for behavior change [18-21]. Other interventions use apps as electronic diaries because self-monitoring risk behaviors facilitates reflection and reactivity to reduce risks [22-26]. PCAs and apps as intervention tools can address multilevel barriers to PrEP by reducing stigma, circumventing discriminatory health care services, and improving access to care. However, these tools have typically been used independently. Few studies have incorporated PCAs and mobile app-based diaries in a multicomponent strategy, which could be useful to increase perceived HIV risk and PrEP initiation among BSMM.

We designed a multicomponent intervention that consists of an existing smartphone app called PrEPme [18] and a PCA to increase perceived HIV risk and willingness to initiate PrEP among BSMM. Briefly, PrEPme is a smartphone app designed for Maryland users to obtain statewide PrEP service information and navigation support from a community health worker [18]. PrEPme also allows users to self-monitor sexual risk behaviors, view a graph of sexual risk behaviors by week and month (Figure 1), and chat with the in-app community health worker to obtain PrEP service information [18]. In our intervention, we planned for a PCA to meet with HIV-negative BSMM during 2 sessions one month apart. In the baseline session, the PCA would conduct a motivational interview-consistent conversation with HIV-negative BSMM to assess their lifestyles, personal goals and values, HIV risk behaviors, perceived HIV risk, and relative PrEP interest [14,27]. At the end of the session, BSMM would be asked to download PrEPme to record their sexual risk behaviors during the month. In the second session, the PCA would review the diary with BSMM and conduct another motivational interview-consistent conversation to explore motivations for relative HIV risk behaviors, check alignment with goals and values, and assess their PrEP interest. A key utility of the PCA includes sharing health-related information regarding relative and acute risks for HIV, answering questions regarding PrEP efficacy and side effects, and tailoring prevention messaging to improve perceived HIV risk given the information in the PrEPme dashboard. At the end of each session, the PCA would collaborate with BSMM to help interested participants obtain PrEP services.

Figure 1. PrEPme smartphone app dashboard.



Guided by life course theory (LCT) [28-30] and the health belief model (HBM) [31,32], we hypothesize that this approach could prove feasible and acceptable, mitigate multilevel barriers, and improve perceived HIV risk and PrEP initiation among BSMM. LCT suggests that age-related differences in exposures to risk, timing of major life events, and accumulated risks impact health behaviors and outcomes [28-30,33]. The HBM posits that perceived disease susceptibility can lead to increased engagement in healthy behaviors [32,34]. Together, this framework informed the design of our multicomponent intervention. Perceived HIV risk and PrEP initiation could be improved by providing BSMM with PrEPme to self-monitor sexual risk and a PCA to change attitudes toward HIV acquisition and introduce PrEP. However, the success of an intervention among BSMM relies upon a culturally responsive strategy prior to its implementation and requires clarity regarding the components and potential barriers [14,35-37]. Therefore, the aim of this study is to explore attitudes toward

the intervention guided by our theoretical framework and identify ways to refine the strategy based on feedback from the target population. Findings from this formative research will be used to finalize the study protocol and implement the multicomponent intervention.

Methods

Ethics Approval

All study procedures were approved by Johns Hopkins School of Medicine institutional review board (IRB00211578).

Recruitment and Study Sample

Data were obtained from 12 focus groups and 1 in-depth interview among BSMM from Baltimore, MD, between October 2019 and May 2020 [38]. Participants were recruited using a combination of active (eg, contacting participants from previous studies who provided written consent to be called for future

research) and passive (eg, advertising on Craigslist, obtaining participant referrals) strategies [35,37]. Participants were eligible based upon the following criteria: self-identifying as Black or African American, self-identifying as a man, aged 18 years or older, self-reporting as HIV negative, having oral/anal sex with at least 1 male partner in the previous 6 months, and residing in Baltimore, MD.

Study Procedures

Most focus groups (n=9) were conducted in a private designated research space at Johns Hopkins School of Nursing. The protocol for the last 3 focus groups was updated to a virtual, synchronous format for safety due to COVID-19. Details regarding the protocol for virtual, synchronous focus group conduct have been published elsewhere [35]. The focus group guide was designed using LCT and HBM constructs, and groups were stratified by 3 age groups: 18 to 24 years, 25 to 34 years, and 35 years and older. Groups were limited to 5 or fewer for feasibility and to allow all participants to respond to each question [35,37]. An in-depth interview was conducted because only 1 participant attended a scheduled focus group and still wanted to be a part of the study and share thoughts regarding the intervention [14,38]. Two facilitators led the focus groups (and interview). One moderated discussions and recorded notes; the other recorded notes, observed group dynamics, and conducted administrative activities [35,37]. In-person participants provided written informed consent; virtual participants provided oral informed consent that was documented by the study team prior to beginning the focus group [35].

Data collection included reflexive debriefing among the facilitators before and after every focus group to review research intentions, identify potential biases, explore personal challenges of the investigative team, and explore preliminary themes [35,39,40]. Data collection began with a written or online survey via Qualtrics assessing demographic and behavioral characteristics along with perceived HIV risk, assessed using the 8-item Perceived Risk of HIV scale [41], the scores for which ranged from 10 to 40, indicating low-to-high perceived HIV risk. Focus groups were conducted after the survey and lasted 50 to 75 minutes. Facilitators began by asking participants for details regarding their current lifestyles and social activities and how their lives and self-image would change if they received a positive HIV test result to learn more about their perceived severity of disease. Facilitators also targeted domains regarding participants' thoughts about their behaviors and their risk relative to learning the high HIV prevalence within the city and likelihood of infection for BSMM nationally [6]. Facilitators then shared details regarding PrEPme using handouts and live demonstrations on a smartphone and asked questions regarding attitudes toward using the app to self-monitor sexual risk behaviors. After obtaining attitudes toward the app, facilitators

asked questions regarding the usefulness of a PCA in the intervention, attitudes toward sharing their PrEPme diary with the PCA, ideal PCA characteristics, and potential barriers to working with a PCA. All participants were compensated \$80 [35].

Data Analysis

All focus groups were audiorecorded and transcribed verbatim by an IRB-approved company. The first author reviewed all transcriptions for fidelity to audio files and revised text files as needed prior to coding in ATLAS.ti (version 8.4, ATLAS.ti Scientific Software Development GmbH). The facilitators reviewed all focus group recordings, transcripts, and notes and then designed a codebook for descriptive thematic analysis using the questions in the focus group guide ([Multimedia Appendix 1](#)). The first author coded transcripts and systematically identified themes using an adapted pile-sorting approach whereby quotes associated with specific codes in ATLAS.ti were into an Excel (Microsoft Corp) spreadsheet and organized [15,40,42]. The facilitators then reviewed the quotes associated with codes and sorted them into piles for similarity within Excel to represent themes. Facilitators identified themes as patterns or novel responses associated with specific codes or focus group questions. To identify a range of themes, novel responses that at least 1 person in the group mentioned were also considered [40,43]. Between-group analysis was conducted to identify potential thematic differences by age.

Results

Demographic Characteristics and Descriptive Data

Data resulted in 5 groups of BSMM aged 18 to 24 years, 4 groups aged 25 to 34 years, 3 groups aged 35 years and older, and 1 in-depth interview with a participant aged 18 to 24 years (n=39). All except 1 participant completed the survey ([Table 1](#)). Most who completed the survey identified as homosexual, gay, or same gender-loving (26/38, 68%), were employed (26/38, 69%), and single (25/38, 66%). A total of 34% (13/39) of participants had ever been diagnosed with an STI, of whom 38% (5/13) had repeated at least one STI. Perceived Risk of HIV scores ranged from 13 to 40 (\bar{x} =22.4, s =5.3), and HIV Incidence Risk Index for Men Who Have Sex With Men scores ranged from 5 to 28 (\bar{x} =16.2, s =5.7). Most (26/38, 68%) were interested in using a smartphone app to self-monitor their sexual behaviors. Half (19/39, 50%) of surveyed participants had ever used PrEP; 12 out of the 39 reported being current PrEP users.

Focus groups yielded important themes regarding perceived HIV risk and attitudes toward the proposed multicomponent intervention.

Table 1. Demographic and behavioral characteristics among Black sexual minority men (n=38).

Variable	Value
Sexual orientation, n (%)	
Heterosexual or straight	2 (5)
Homosexual, gay, or same gender-loving	26 (68)
Bisexual	5 (13)
Pansexual	2 (5)
Not sure or questioning	1 (3)
Highest level of education completed, n (%)	
Grade 11 or less	2 (5)
Grade 12 or GED equivalent	16 (42)
Some college	6 (16)
Associate degree	3 (8)
Bachelor's degree	5 (13)
Some graduate work	2 (5)
Graduate degree	4 (10)
Employment status, n (%)	
Full-time	22 (58)
Part-time	4 (10)
Unemployed	9 (24)
Other	3 (8)
Relationship status, n (%)	
Single	25 (66)
In a committed relationship	8 (21)
In an open relationship	4 (10)
Married to a man	1 (3)
Ever diagnosed with STI^a, n (%)	
Repeated STIs	13 (34)
Last HIV test^b, n (%)	
Never	1 (3)
Less than 1 month ago	17 (45)
1-3 months ago	12 (32)
3 months ago or longer	6 (16)
App interest, n (%)	
Yes	26 (68)
No	6 (16)
Don't know	6 (16)
Ever used PrEP^c (yes), n (%)	
Current PrEP use (among ever users)	19 (50)
PrEP telehealth interest, n (%)	
Yes	16 (42)
No	15 (39)
Don't know	7 (18)

Variable	Value
PrEP injectable interest, n (%)	
Yes	22 (58)
No	13 (34)
Don't know	3 (8)
Interest in doxycycline for syphilis PrEP, n (%)	
Yes	20 (53)
No	10 (26)
Don't know	8 (21)
HIRI-MSM ^d score, mean (SD)	16.2 (5.8)
Perceived risk of HIV score, mean (SD)	22.4 (5.3)

^aSTI: sexually transmitted disease.

^bOne participant who completed the survey did not provide information regarding their last HIV test.

^cPrEP: preexposure prophylaxis.

^dHIRI-MSM: HIV Incidence Risk Index for Men Who Have Sex With Men.

Low HIV Risk Perceptions While Perceiving Others as Risky

Across and within age groups, participants provided polarizing responses regarding perceived HIV risk. They mentioned that HIV infection would impact their mental health due to lifestyle changes and anticipated stigma from society and potential partners, but they expected to overcome those challenges since contemporary medications improved longevity and quality of life. Despite being presented with Centers for Disease Control and Prevention data regarding HIV prevalence and incidence among BSMM locally and nationally, participants across age groups still perceived their HIV risk as low—even if they disclosed drug use or condomless sex. Each group used positive terms such as goal-oriented and caring to describe themselves and reckless, impulsive, and drug addict to describe individuals they thought were likely to acquire HIV. However, they also mentioned they occasionally had the same characteristics as someone they perceived as high risk for HIV despite not equating their current sexual behaviors as high risk. BSMM in the 2 youngest groups specifically compared their current behaviors to their past and their friends who they believed had riskier behaviors or who had acquired HIV.

Textbox 1. Group aged 18 to 24 years (December 14, 2019).

S2: 42:29 “Some people will have sex to escape from their reality. Some people have sex because they’re sex addicts. Then you see it as offensive because it’s basically in your face like know what you’re doing. You’re constantly reminded that you,—“

S3: 42:42 “You’re being a ‘THOT’”

S2: 42:43 “—you’re being a sexually active person—it’s nothing wrong with having sex. Sex is a natural desire of man. Let’s say I’ve got the app ‘cause I’m trying to work on myself. And I see that I had 12 partners this week. I see that as offensive because now I’m like, ‘All right, I had 12 partners this week,’ and now I start attacking myself... This [gonna] make me feel insecure about myself because it’s right there in front of my face. I can’t deny. I can’t lie to the app.”

Concerns Regarding Privacy From App Developers and In-App Community Health Workers

The youngest 2 age groups mentioned concerns that their sexual diary could be hacked by app developers or seen by community

Self-monitoring Sexual Behaviors Triggers Internalized Stigma and Shame

Across groups, participants reported barriers regarding using PrEPme such as remembering to use it and providing honest responses. Those aged 18 to 34 years generally agreed that having a smartphone app diary could be useful for individuals with higher risk behaviors (eg, individuals who use drugs, practice condomless sex with multiple partners), but men age 35 years and older did not think it would be useful or used among BSMM. Participants across all age groups reported that seeing their sexual activities summarized on the dashboard could trigger feelings of internalized stigma regarding their risk behaviors (see [Textbox 1](#)).

Participants agreed that having an in-app dashboard of sexual risk behaviors would decrease BSMM’s willingness to provide honest responses and use PrEPme for long. Some added that seeing their condomless sex and receptive anal sex activities in the app could exacerbate internalized stigma and shame that would cause them to discontinue use because society, gay men, and clinicians stigmatize those behaviors.

health workers who were in-app support systems for PrEP linkage. These concerns could be related to anticipated stigma and shame regarding the sexual behaviors documented in the app. However, participants did not mention this explicitly or associate these directly.

The PCA as a Future Self

Overall, most participants across age groups affirmed that having another BSMM to discuss sexual health and PrEP before visiting a PrEP-prescribing clinician was acceptable if he was relatable and trustworthy. They specified that the PCA should be Black and a current PrEP user so they could share their experiences with side effects and maintaining adherence (see [Textbox 2](#)).

These and other characteristics such as aesthetics (eg, style of dress), language use, personal disclosures, and neighborhood familiarity served as indicators for BSMM to use to anticipate how stigmatizing, trustworthy, or relatable the PCA would be.

Despite agreeing that having another BSMM as a PCA was acceptable in a clinical intervention, there were age group

differences regarding additional PCA characteristics and the practical role of the PCA. Specifically, those aged 18 to 24 years shared preferences for having a PCA who was older or a Black woman, partly due to anticipated within-group stigma from another BSMM who might judge their sexual behaviors as risky. Older participants shared that they would prefer not to engage with a PCA in practice because they did not want to relieve clinicians of the responsibility of asking detailed and personal questions to know them as patients. They also mentioned concerns that working with a PCA prior to visiting a clinician could be another barrier to PrEP initiation for interested BSMM. Still, the older men agreed that the PCA should be a BSMM who was professional yet relatable to discuss specific cultural issues and PrEP-related concerns such as side effects, efficacy, and relative risks for HIV infection by sexual positioning.

Textbox 2. Group aged 35 years and older (February 1, 2020).

S3: 35:45 “I feel like some people will share with people that they see some of their self in that person. So, like, for you, for example, I feel more comfortable talking to you about this—”

S6: 35:59 “Yeah.”

S3: 36:00 “—because you are—I do see a lot of myself in you. I know we’re two completely different people but, rather than sitting here talking to like an older straight white lady. It would be a little uncomfortable ‘cause she don’t know this lifestyle like you do. She don’t know what we go through as a young Black gay male.”

S2: 36:24 “Yeah.”

S3: 36:25 “And to even see you have, like, your style—your hair, all that, that helps out... So when you have somebody like you in a room and just to know you a doctor and you still look like me. You’re still young. You groomed, you got the haircut. It just makes you more comfortable.”

S2: 37:19 “Yeah, you right because it took me a long time to open up to my doctor, she’s white.”

S2: 1:01:35 “He made a good example how he sees himself in you—sometimes that’s a good thing as well. You sitting there like, ‘That’s my past and I’m their future self, so I can give a little bit more insight on certain things, so they don’t have to worry about going through what they went through.’”

Sharing App Data With PCA to Avoid Negative Patient-Clinician Communications

Across groups, participants acknowledged that a benefit of a PCA in this intervention included being able to discuss sexuality freely and trusting the PCA’s cultural competency more than that of a clinician who was not a BSMM (see [Textbox 3](#)).

They mentioned that a PCA could help circumvent potentially stigmatizing or unsatisfactory conversations with clinicians regarding sexual risks but were not interested in the PCA discussing health concerns with the clinician on their behalf. Their interest in sharing their PrEPme dashboard with a PCA or clinician was contingent on their perception of how judgmental and trustworthy either would be.

Textbox 3. Group aged 25 to 34 years (May 5, 2020).

S2: 37:39 “I think that for the sake of like having a real conversation, if it’s somebody that I’m uncomfortable with, I would rather have the conversation in a real tone that’s a peer.”

S3: 37:57 “And someone who looks like me.”

S2: 37:59 “Yeah. And, and they got all the real information, you know what I mean? And they can turn that around and give that to the doctor, because the doctor doesn’t know how to talk to me. The doctor is saying to me, you know, *receptive*, you know what I mean? Versus the peer is saying to me, *bottom*, like, you know. And it’s like, I understand the two roles— like the two roles. But like I don’t think that that’s necessary to repeat myself, if the rapport with the doctor that I have is great. But if the rapport is trash, and that doctor is trash, and I don’t feel comfortable with that doctor, then I’m fine with talking to somebody else to make sure that the point is really internalized.”

Discussion

Principal Findings

We designed a multicomponent strategy to increase perceived HIV risk and PrEP initiation among BSMM and obtained in-group perspectives regarding the intervention components for refinement. Overall, BSMM had low-to-moderate perceived HIV risk. Using a PCA as an interventionist could be feasible

and acceptable among younger BSMM. However, findings are inconclusive regarding feasibility of using the diary in PrEPme to record and review sexual behaviors for this group. We found age-related differences in attitudes toward the intervention components, which could result from different exposures to HIV-related deaths by age group and changes in personal agency and perceived support needs due to older age [14,44]. Novel

insights regarding stigma and shame also emerged that informed considerations for intervention refinement.

BSMM held dissonant attitudes between their sexual behaviors and HIV risk, perceiving their risk as low. Other studies among BSMM have found similar results [17,45]. Having lower perceived HIV risk could be an attempt to combat stereotype threat, which is a perceived risk of conforming to negative stereotypes about a group [46,47] that exacerbates poor patient-clinician communication, refusal of clinical recommendations, and medication nonadherence among Black patients [47,48]. For BSMM, the threat of being stereotypically high risk or sexually deviant could be an important, understudied phenomenon impacting HIV and PrEP initiation. Anticipated and internalized stigma and shame regarding self-monitoring sexual behaviors, discussing sexuality with professionals, and receiving an HIV diagnosis were salient. Additionally, practicing receptive anal sex, or being a bottom, can also carry specific shame and stigma among BSMM due to masculinity stereotypes [49,50]. However, stereotype threat decreases with race-concordant clinicians [43,51]. Therefore, a PCA must be a trained professional with substantial sexual health literacy who understands the issues concerning internalized stigma, shame, and stereotype threat and can help BSMM navigate their perceived HIV risk to make decisions about PrEP. A culturally responsive PCA could circumvent some of the multilevel barriers to perceived HIV risk and PrEP initiation among young BSMM with cultural familiarity, acceptable language, explanation of privacy protocols, and personal disclosures to build trust [35,43].

Findings regarding perceived susceptibility and severity of HIV among BSMM expanded our perspectives regarding the intervention framework. Based upon findings that BSMM had low perceived HIV risk, internalized stigma and shame regarding sexual risk behaviors, and preferences for a culturally congruent PCA, we incorporated possible selves theory [52,53] along with LCT and HBM to refine the intervention strategy. Possible selves represent individuals' ideas of what they could and want to become in addition to what they are afraid of becoming and can incentivize future behavior [53,54]. Therefore, an intervention using a PCA should consider how congruent with and relatable the peer is with a future self for HIV-negative BSMM beyond race and sexuality concordance [14,35,43]. Factors such as cultural familiarity, professionalism, open-mindedness, sexual health literacy, and PrEP use could be key additional PCA characteristics that build trust, mitigate stereotype threat, and increase willingness to initiate PrEP among BSMM [35,37].

Future research should explore the relative impact of implementing this multicomponent strategy on perceived HIV risk and PrEP initiation among BSMM. Since a sexual health diary app could trigger internalized stigma and clinical research teams are not culturally congruent with BSMM, future research should implement interventions led by culturally congruent investigators familiar with these psychosocial barriers among this population. Future research could explore the potential impact of the dual role of an investigator or clinician as a PCA. Having PrEP clinical trials led by BSMM researchers and clinicians could be an important yet understudied structural, social, and psychological factor in HIV prevention among BSMM.

Limitations

Limitations should be considered. This study included a convenience sample and is not representative of HIV-negative BSMM. HIV status was self-reported. Groups were intentionally conducted with a small number of participants to increase rapport, trust, and privacy and to ensure that everyone could respond to every question if desired [35,37]. Information regarding implications of the intervention regarding on-demand and injectable PrEP was limited.

Conclusion

Qualitative studies are crucial to designing culturally relevant interventions for BSMM because they identify how socioecological factors such as stigma impact HIV risk for this group [55]. Despite the proliferation of smartphone apps for health promotion and HIV prevention [56], we found that using PrEPme to record and review sexual risk behaviors may not be as innocuous as anticipated. Therefore, we plan to train the PCA to anticipate stereotype threat and manage insider-outsider dynamics to demonstrate relatability, trustworthiness, care, and professionalism. In the refined intervention, we plan to encourage participants to use the diary in PrEPme and ensure that the PCA is a nonjudgmental possible self who can help BSMM navigate feelings of stigma, shame, low perceived HIV risk, and PrEP hesitancy as participants reflect on their behaviors. Since providing objective HIV risk scores alone does not increase PrEP uptake among BSMM [7], the PCA will be trained in motivational interviewing to partner with BSMM to explore their health goals, perceived HIV risk, and relative interest in PrEP given their responses to the diary in PrEPme. We named the refined intervention strategy *Possible* based upon findings from this study.

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Data Availability

The data set generated and analyzed during this study is not publicly available to protect participant confidentiality but is available from the corresponding author on reasonable request.

Conflicts of Interest

JEF holds the technology transfer license with Johns Hopkins University for PrEPme. The app was developed in collaboration with Emocha Mobile Health, Inc.

Multimedia Appendix 1

Focus group guide.

[DOCX File , 31 KB - [formative_v6i8e34181_app1.docx](#)]

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Abbreviations

- BSMM:** Black sexual minority men
- HBM:** health belief model
- LCT:** life course theory
- NIH:** National Institutes of Health
- PCA:** peer change agent
- PrEP:** preexposure prophylaxis

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Original Paper

Validation of the Mobile App Version of the EQ-5D-5L Quality of Life Questionnaire Against the Gold Standard Paper-Based Version: Randomized Crossover Study

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Abstract

Background: Study participants and patients often perceive (long) questionnaires as burdensome. In addition, paper-based questionnaires are prone to errors such as (unintentionally) skipping questions or filling in a wrong type of answer. Such errors can be prevented with the emergence of mobile questionnaire apps.

Objective: This study aimed to validate an innovative way to measure the quality of life using a mobile app based on the EQ-5D-5L questionnaire. This validation study compared the EQ-5D-5L questionnaire requested by a mobile app with the gold standard paper-based version of the EQ-5D-5L.

Methods: This was a randomized, crossover, and open study. The main criteria for participation were participants should be aged ≥ 18 years, healthy at their own discretion, in possession of a smartphone with at least Android version 4.1 or higher or iOS version 9 or higher, digitally skilled in downloading the mobile app, and able to read and answer questionnaires in Dutch. Participants were recruited by a market research company that divided them into 2 groups balanced for age, gender, and education. Each participant received a digital version of the EQ-5D-5L questionnaire via a mobile app and the EQ-5D-5L paper-based questionnaire by postal mail. In the mobile app, participants received, for 5 consecutive days, 1 question in the morning and 1 question in the afternoon; as such, all questions were asked twice (at time point 1 [App T1] and time point 2 [App T2]). The primary outcomes were the correlations between the answers (scores) of each EQ-5D-5L question answered via the mobile app compared with the paper-based questionnaire to assess convergent validity.

Results: A total of 255 participants (healthy at their own discretion), 117 (45.9%) men and 138 (54.1%) women in the age range of 18 to 64 years, completed the study. To ensure randomization, the measured demographics were checked and compared between groups. To compare the results of the electronic and paper-based questionnaires, polychoric correlation analysis was performed. All questions showed a high correlation (0.64-0.92; $P < .001$) between the paper-based and the mobile app-based questions at App T1 and App T2. The scores and their variance remained similar over the questionnaires, indicating no clear difference in the answer tendency. In addition, the correlation between the 2 app-based questionnaires was high (> 0.73 ; $P < .001$), illustrating a high test-retest reliability, indicating it to be a reliable replacement for the paper-based questionnaire.

Conclusions: This study indicates that the mobile app is a valid tool for measuring the quality of life and is as reliable as the paper-based version of the EQ-5D-5L, while reducing the response burden.

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KEYWORDS

quality of life assessment; EQ-5D-5L questionnaire; mobile app; test-retest reliability; mobile phone

Introduction

Background

Questionnaires are increasingly used to determine the health-related quality of life and specifically the care needs of patients; for example, as part of patient-reported outcomes [1]. Although questionnaires are perceived as an easy and noninvasive tool by researchers, study participants and patients often perceive filling out long or repeated questionnaires as burdensome. Although quality of life is often used as an outcome measure in studies, not all questionnaires used are suitable for long-term monitoring of a patient to be able to measure the course of health status over time [2,3]. Long-term monitoring of a patient's quality of life is important for health care evaluation and may provide better insight into the actual value of interventions [4,5]. Therefore, there is a need to provide easy-to-use, patient-friendly, and valid health questionnaires. This study investigated the possibility of measuring health status in a simple and valid way using a mobile app developed by Q1.6 (Q1.6 mobile app). Using this mobile app, the response burden for participants was reduced by presenting 1 question at a time instead of requesting the complete questionnaire all at once.

Conducting paper-based questionnaires in studies is prone to errors, such as unintended skipping of questions or selecting multiple answers when 1 answer is expected [6]. In addition, data from paper-based questionnaires must be manually processed, which is time consuming, before analyses can be performed and manual entry can lead to data entry errors. With the emergence of apps for questionnaires that can be completed on smartphones, such inaccuracies can be prevented [7].

The use of smartphones and electronic devices has increased in our daily lives and in health care settings. Studies have shown that the use of smartphone app in intervention studies, for example, for self-monitoring, has become more accepted over time [8]. The use of eHealth services can lead to increased self-management of health complications [8,9]. Various patient-reported outcome measures can be queried using electronic devices [1]. The use of electronic devices is an advantage for both the individual patient and the researcher or physician: questionnaires can be answered at a convenient moment for the patient, which saves researchers' or physicians' and patients' time [10]. Flexible completion could increase the frequency with which a patient is willing to complete a smartphone-based questionnaire. In addition, because of the completion of the questionnaire on the web, the data are immediately available, are stored, and can easily be compared with previously completed questionnaires. Therefore, a patient can be monitored effortlessly by the physician or researcher, and the patient does not have to make separate appointments with the physician or researcher. From a data perspective, the benefits of completing questionnaires via a smartphone app include easy to retrieve data, reliable data, and prevention of data loss due to backup systems [11]. Before a mobile questionnaire app can be deployed in a clinical setting, it is essential that this new method is validated against the traditional method [12].

In this study, a validation of a new mobile method of the well-known EQ-5D-5L questionnaire, a short questionnaire in which the quality of life of a person was examined, was performed. A comparison of the gold standard, a traditional paper version of the EQ-5D-5L questionnaire, with a digitized, mobile measurement method of (subjective) health-related quality of life via a mobile app was examined. The EQ-5D-5L questionnaire is available in various modes of administration, including smartphones [13]. Several studies have used the electronic version of the EQ-5D-5L questionnaire and indicated the electronic version valid and reliable [10,14-16]. However, the Q1.6 mobile app of the EQ-5D-5L is designed to reduce the response burden of questionnaires by presenting a single question at a time and only querying 2 questions a day rather than the whole questionnaire at once. To validate the method, the EQ-5D-5L version of the EQ-5D Health Status Questionnaire was used. This is a standardized measure of the health-related quality of life questionnaire developed by the EuroQol group [17]. EQ-5D is the most widely used tool for obtaining health outcomes from a patient's perspective [18].

In this validation study, a comparison using correlation analysis was made between the mobile app version of the EQ-5D-5L questionnaire and the gold standard paper-based version of the EQ-5D-5L. To avoid possible bias due to time of the day (morning and afternoon), the questions in the mobile app were provided twice, referred to as time point 1 (App T1) and time point 2 (App T2), in a randomized order and differing in moment of the day (morning and afternoon).

Health-related quality of life measurement instruments must be both valid and reliable [19]. The validity of a questionnaire pertains to the degree to which the measurement reflects a construct of interest. Specifically, convergent validity is the degree to which a new scale is related to other pre-existing measures of the same construct [20]. Convergent validity between the paper, which is a pre-existing measure, and the mobile version of the EQ-5D-5L will be assessed through correlation analyses. Reliability is the consistency that the instrument measures, with test-retest reliability evaluating the consistency between 2 time points. Test-retest reliability assumes that no alterations emerge between measurements when the test is repeated and is the main aspect of reliability considered in this study [21].

Correlation analysis is the most commonly used method in validation and test-retest reliability studies and is the preferred method for this study [22]. Polychoric correlation was used for all EQ-5D-5L questions, except for the visual analog scale (VAS), because this construct uses a 5-point Likert scale [23]. Likert scales are ordinal scores, characterized by the assumption that the intervals between the scores are not equal (eg, the difference between categories 1 and 2 may not be as large as the difference between categories 2 and 3), with a limited number of possible scores. These polychoric correlations are the preferred correlational methods [24].

Owing to the longitudinal nature of the study, it was important to ensure that the differences we found were owing to differences in assessment methods and not owing to differences over time. As such, the correlation was checked between the

average mobile app score (mean of both time points) and the paper score, between App T1 and the paper score, between App T2 and the paper score, and also between the 2 time points in the mobile app to study the longitudinal correlation or the test-retest validity.

Objectives

The main objective of this study was to validate an innovative way to measure perceived health using the EQ-5D-5L questionnaire requested via the mobile app. In the validation study, a comparison using correlation analysis was made between the mobile app version of the EQ-5D-5L questionnaire and the gold standard a paper-based version of the EQ-5D-5L, in a large group of people.

In the next section, we will discuss our methods, including our study design and the statistical analyses used, followed by the results obtained by these statistical analyses and a discussion of what these results mean for the validation of the digitized Q1.6 version of the EQ-5D-5L questionnaire.

Methods

Study Population

Participant recruitment and data collection (questionnaires) were conducted by the research bureau MSI Advanced Customer Insights (MSI-ACI Europe BV). The participants were provided with a participant information sheet. Participants willing to participate sent in their signed and completed informed consent form digitally. To obtain a representative sample of the Dutch population, participants were selected to approximate the population distribution of age, gender, education, and place of residence. Of the 661 interested participants, 350 (52.9%) were eligible, and 261 (39.5%) eventually participated in the study. Participants were declared eligible when they met the following

inclusion criteria: aged ≥ 18 years, healthy at their own discretion, in possession of a smartphone with at least Android version 4.1 or higher or iOS version 9 or higher, digitally skilled enough to download the mobile app, and able to read and answer questionnaires in Dutch. Participants who completed the study received an incentive (digital bol.com store voucher) of €10 (US \$12).

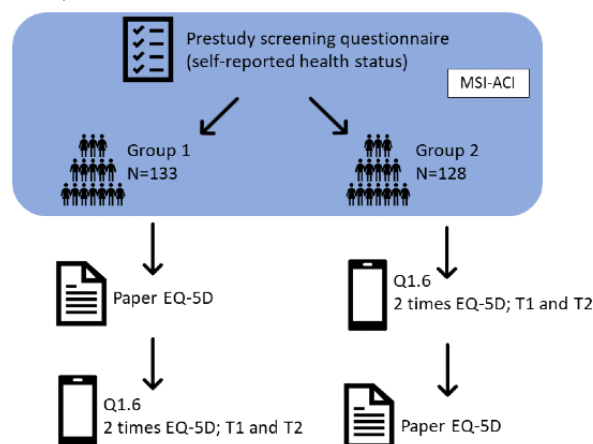
Ethics Approval

The study plan was approved by the Internal Review Board of TNO (Netherlands Organisation for Applied Scientific Research) on February 12, 2021 (number 2021-009). The study was conducted in accordance with the current assembly (64th) of the Declaration of Helsinki (Brazil, October 2008), which was updated by the WMA (World Medical Association) General Assembly in 2013. The study was conducted in March 2021 and completed in 4 weeks.

Study Design

This was a randomized, crossover, and open study. Eligible participants ($n=261$) were assigned to groups 1 or 2. A total of 50.9% (133/261) of participants were assigned to group 1. The participants in group 1 first received a paper-based questionnaire. They were given a maximum of 1 week to complete the questionnaire on paper and return it by postal mail. Thereafter, the participants were informed by email to start with the mobile app. A total of 49% (128/261) of participants were placed in group 2. Participants in group 2 first completed the mobile app questionnaire, followed by the paper-based questionnaire, which was sent by postal mail. Of the 261 participants, 255 (97.7%) participants completed both the paper-based version of the EQ-5D-5L and the mobile app version. A schematic overview of the study design is shown in Figure 1.

Figure 1. Study design. The figure shows the order of paper-based version and the mobile app questionnaires for groups 1 and 2. With exception of a visual analog scale score, questions of the EQ-5D-5L were asked twice via the mobile app. A single question was requested once in the morning and once in the afternoon on 5 consecutive days. MSI-ACI: MSI Advanced Customer Insights; T1: time point 1 (app question answered first time); T2: time point 2 (same app question answered second time).



The EQ-5D Paper-Based Questionnaire

The EQ-5D is a standardized measure of health-related quality of life questionnaire developed by EuroQol. The EQ-5D is the most widely used tool for obtaining quality of life from a patient's perspective [18]. The EQ-5D is a descriptive instrument

that focuses on five dimensions of health: mobility, self-care, usual activities, pain or discomfort, and anxiety or depression. Two versions of the EQ-5D are available: EQ-5D-5L (the 5-level version, each domain consisting of 5 levels; "1=no problems, 2=slight problems, 3=moderate problems, 4=severe problems, and 5=extreme problems") and EQ-5D-3L (the 3-level version,

each domain consisting of 3 levels; “1=no problems, 2=some problems, and 3=extreme problems”). Lower scores indicate better quality of life. The EQ-5D-5L questionnaire was used in this study. The second part of the paper-based questionnaire comprises a standard vertical 20-cm line representing a scale from 0 to 100, also known as the VAS. The respondents are asked to score their current health status on the scale and write the corresponding number in an adjacent box. A higher VAS score represents a better perceived health status.

The Q1.6 Mobile Phone App

The company Q1.6 developed a mobile app that prompts a participant to answer a short question about their health twice a day. For this study, the EQ-5D-5L was configured in the Q1.6 app ([Multimedia Appendix 1](#)). The participants were notified to download the mobile app to their personal mobile phones. For 5 consecutive days, the participants received notifications for 2 EQ-5D-5L questions per day. A single question was posed once in the morning and once in the afternoon. The EQ-5D-5L questions were randomized to be presented in the morning or afternoon to increase generalizability. On the fifth day, the participants also had to complete the VAS score. In total, all questions were asked twice spread over 5 consecutive days, with the exception of the VAS score, which was asked only once. Notifications prompting the participant to answer a question were sent to the participants' smartphones between 8 AM and 10:30 PM and closed automatically. Participants in possession of an iPhone received a notification every consecutive hour until the question was answered. On Android, questions were prompted when a user unlocked their phone until the question was answered.

Subjective evaluation of the mobile app was requested via an evaluation questionnaire in the mobile app to gain insight into the usability of the mobile app.

Sample Size

The number of participants needed in the study was based on a power calculation assuming a correlation of 0.7 with an α of .05 and a power of 0.90. To allow for the fact that any correlation is inherent in health measurements in general, no test against finding no correlation was performed, but the estimation of power was made to distinguish between the expected correlation of 0.7 and a more general correlation of 0.5, which may be found in any 2 health-related questionnaires. On the basis of G*power calculation [25], we required 200 participants to validate the mobile app questionnaire using these parameters.

Statistical Analyses

Descriptive variables were compared between the 2 experimental groups (ie, group 1: first paper-based EQ-5D-5L questionnaire or group 2: first mobile app questionnaire) to check whether randomization had achieved a good spread of baseline variables across the groups in the study. Participants missing >1 question in the mobile app (5, 1.9%) were removed from the analysis to have as many completed questionnaires as possible for

validation (approximately 200 completed on paper and via the mobile app).

To compare the paper- and app-based questionnaires, polychoric correlation analyses were used for all EQ-5D-5L questions, except for the VAS scale, as the questions were answered using a 5-point Likert scale [23]. For these calculations, the package Lavaan (version 0.6-9) in R (designed by Robert Gentleman and Ross Ihaka and developed by the R Core Team) was used [26]. Pearson correlation was estimated for the VAS. For the main outcome, that is, the correlation between paper and the mobile app, the average score over 2 days in the mobile app was correlated with the observed score from the paper version. The answers given the first time a question appeared in the mobile app were combined at time point 1 (App T1); the answers provided during the second time were combined at time point 2 (App T2). In addition, the correlations between the observed score on paper and App T1, and the observed score on paper and App T2 were calculated, as presented in [Multimedia Appendix 2](#).

To study the longitudinal correlation or test-retest reliability, we examined the test-retest correlation of the 2 time points using the mobile app (App T1 vs App T2) and the validity assessment (paper vs digital [the mobile app]) through the polychoric correlation. With similar correlation coefficients (eg, within a few points of each other), we can assume that both methods measure the same. Furthermore, paired *t* tests (2-tailed) were used to check whether participants consistently scored higher or lower on paper or on the mobile app ([Multimedia Appendix 3](#)).

Data are presented as mean (SD). A *P* value of <.05 was considered statistically significant. Correlation values of 0.0 to 0.3 indicate weak agreement, 0.3 to 0.5 indicate mediocre agreement, 0.5 to 0.7 indicate strong agreement, and >0.7 indicate very strong agreement [27]. Box plots are presented for descriptive analyses of the usability of the mobile app.

Results

Descriptive Results of Study Participants

A final data sample of 255 participants (117 males—group 1: 54, 43%; group 2: 63, 49% and 138 females—group 1: 73, 57%; group 2: 65, 51%), with an age of ≥ 18 years and no more than one observation missing, were included in the analysis. Although there was no maximum age set for inclusion of participants, the maximum age of respondents was 64 years. In total, 56.5% (144/255) of the participants were highly educated and had obtained at least a bachelor's degree. The demographic data of the participants are presented in [Table 1](#). Characteristics are listed in total and per condition (group 1: paper first; group 2: mobile app first). The distribution of the demographic characteristics between the groups was consistent. Group 2 appeared to have slightly more people aged >50 years (52/128, 40.6% vs 35/127, 27.6% in group 1) and people living in the eastern part of the Netherlands (39/128, 30.5% than in group 1 (24/127, 18.9%).

Table 1. Baseline characteristics of the participants (N=255) who completed the study in total and the representation in the group.

Parameter	Participants, n (%)	Group 1 (paper first), n (%)	Group 2 (mobile app first), n (%)
Gender			
Man	117 (45.9)	54 (42.5)	63 (49.2)
Woman	138 (54.1)	73 (57.4)	65 (50.7)
Age (years)			
18-34	88 (34.5)	48 (37.8)	40 (31.3)
35-49	80 (31.4)	44 (34.6)	36 (28.1)
50-64	87 (34.1)	35 (27.6)	52 (40.6)
Education^a			
Low	10 (3.9)	4 (3.1)	6 (4.7)
Middle	101 (39.6)	46 (36.2)	55 (43)
High	144 (56.5)	77 (60.6)	67 (52.3)
Region^b			
Cities	27 (10.6)	15 (11.8)	12 (9.4)
North	25 (9.8)	11 (8.7)	14 (10.9)
East	63 (24.7)	24 (18.9)	39 (30.5)
South	56 (22)	26 (20.5)	30 (23.4)
West	84 (32.9)	51 (40.2)	33 (25.8)

^aParticipants who only attended primary education, prevocational secondary education (VMBO or LBO) were defined as less educated. Participants with a secondary school (preparatory vocational secondary education [mavo], senior general secondary education [havo], or university preparatory education [vwo]) or senior secondary vocational education and training (MBO) degree were defined as middle educated. Participants with at least a bachelor's degree in higher professional or university education were categorized as having a higher education.

^bParticipants were recruited from all over the Netherlands. An overview of participants living near big cities and region of the Netherlands is presented.

Descriptive Results by Domain

The average scores of the different variables on paper, App T1 (first time question in the mobile app) and App T2 (second time question in the mobile app) are presented in [Table 2](#). With the exception of the VAS score (range 0-100), a lower score indicates a better quality of life (range 1-5). As can be seen, the group generally considers themselves healthy and scores between 1 and 2 on the five domains (mobility, self-care, usual activities, pain or discomfort, and anxiety or depression) across

the different media (paper vs the mobile app). The mean VAS score for paper administration was 77.7 (SD 14.3), and the mean VAS score for the mobile app was 78.7 (SD 15.8). The scores and their variability remained similar over the questionnaires, indicating no clear difference in the answer tendency. Within self-care, a very low variance and overall, a low score were observed (paper average 1.1, SD 0.4; mobile app average 1.1, SD 0.3). [Multimedia Appendix 3](#) presents 2-tailed *t* tests pertaining to the difference in responses on the paper and mobile app versions.

Table 2. Average score per EQ-5D-5L question.

Variable	Paper, mean (SD)	App, mean (SD)	App T1 ^a , mean (SD)	App T2 ^b , mean (SD)
Visual analog scale score	77.705 (14.324)	N/A ^c	N/A	78.697 (15.751)
Anxiety or depression	1.596 (0.845)	1.542 (0.782)	1.556 (0.798)	1.522 (0.832)
Pain or discomfort	1.659 (0.831)	1.587 (0.716)	1.616 (0.780)	1.578 (0.767)
Usual activities	1.467 (0.730)	1.437 (0.713)	1.410 (0.747)	1.451 (0.735)
Self-care	1.110 (0.439)	1.086 (0.332)	1.078 (0.335)	1.093 (0.354)
Mobility	1.247 (0.619)	1.247 (0.558)	1.235 (0.579)	1.240 (0.556)

^aApp time point 1 (App T1) was the first time the question was answered.

^bApp time point 2 (App T2) was the second time that the same question was answered.

^cN/A: not applicable (via the mobile app, each question of the EQ-5D-5L, with the exception of the visual analog scale score, was requested twice).

The Mobile App—Retest Results

The EQ-5D-5L questions in the mobile app were answered twice. Correlations between App T1 and App T2 were high (range 0.73-0.9; $P < .001$; Table 3), with the highest correlation observed for self-care and the lowest for anxiety or depression and mobility. This indicates high test-retest reliability across

all domains. Compared with the correlations between methods (Table 4), the differences were small (range 0.19-0.02). The CIs overlapped with a notable correlation with self-care. However, this may be because of the very low variance within self-care (Table 2), causing a small difference in answers and generating a disproportionately large influence.

Table 3. Polychoric correlations between app time point 1 (App T1) and time point 2 (App T2).

App T1 vs App T2	Correlation	SE	z score	P value	Range (lower-upper)
Anxiety or depression	0.729	0.029	24.838	<.001	0.671-0.786
Pain or discomfort	0.744	0.028	26.640	<.001	0.689-0.799
Usual activities	0.786	0.024	32.855	<.001	0.739-0.833
Self-care	0.897	0.012	73.058	<.001	0.873-0.921
Mobility	0.730	0.029	24.906	<.001	0.672-0.787

Table 4. Polychoric correlations between EQ-5D-5L paper and EQ-5D-5L mobile app (average App T1 and App T2) version.

Digital variable versus paper	Correlation	SE	z score	P value	Range (lower-upper)
VAS ^a _digital	0.636	0.030	20.876	<.001	0.576-0.696
Anxiety or depression	0.791	0.122	6.496	<.001	0.553-1.030
Pain or discomfort	0.824	0.121	6.783	<.001	0.586-1.062
Usual activities	0.812	0.122	6.657	<.001	0.573-1.052
Self-care	0.880	0.124	7.083	<.001	0.636-1.123
Mobility	0.915	0.121	7.545	<.001	0.677-1.152

^aVAS: visual analog scale.

Correlations Paper-Based EQ-5D-5L Questionnaire Versus the Mobile App

Table 4 displays the results of the polychoric correlations, showing high relations between the different scores on paper and in the mobile app (average App T1 and App T2) across the 5 domains (>0.79). It is difficult to set a cutoff value based on a variety of assumptions and indicators. However, as all correlations between the paper and digital questions are above 0.79, they indicate a very strong validity for repeated questions about anxiety or depression, pain or discomfort, usual activities, mobility, and self-care. Mobility showed the strongest correlation (0.92; $P < .001$). In addition, the correlations of the EQ-5D domains paper versus app were in the same range as the test-retest reliability results. The estimated correlation of the VAS scores was lower (0.64; $P < .001$) compared with the questions on the 5 domains (>0.79 ; $P < .001$).

The polychoric correlations between paper and App T1 and between paper and App T2 are presented in the Multimedia Appendix 2. Lower correlations were observed between paper and App T1 (>0.64) and paper and App T2 (>0.65), compared with the correlations between paper and the average score of the mobile app (>0.79) and compared with the correlations between App T1 and App T2. Using paired 2-tailed t tests, no

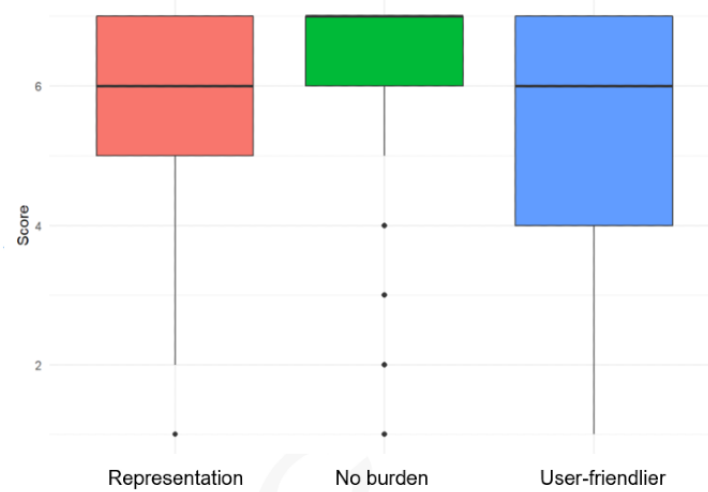
significant differences between the average mobile app score and the observed paper score were found (Multimedia Appendix 3) or between App T1 and App T2 (Multimedia Appendix 4). Consistently higher or lower scoring of paper compared with the mobile app was also not observed. A strong agreement between the paper and the mobile app was observed (>0.64), with no structurally higher scores on paper or the mobile app.

The slight difference in correlation strength between the correlations between App T1 and App T2 (Table 3) and the correlations found between paper and the mobile app (Table 4) may be because of the effect of time (between the 2 moments of answering in the mobile app) and not the difference in media (paper vs the mobile app). This is because the perceived quality of life changes slightly over the course of a day and between days, even in a healthy population [28].

Subjective Evaluation of the Mobile App

A short evaluation questionnaire was requested via the app to gain insight into its usability. Figure 2 shows the usability on three aspects: “the app provides a good representation of how I feel,” “it is no burden to answer this questionnaire quarterly,” and “the app is more user-friendly than the paper-based questionnaire.” The scores ranged from 1 to 7, with a higher score indicating that the participants strongly agreed with the statement.

Figure 2. Usability of the mobile app, where a higher score indicates higher agreement with the question posed, the questions being, “The app provides a good representation of how I feel;” “It is no burden to answer this questionnaire quarterly;” and “The app is more user-friendly than the paper-based questionnaire.”.



Most (197/261, 75.5%) participants indicated that the mobile app provided a good representation of how they felt. Furthermore, the participants perceived no burden to answer this questionnaire quarterly via the mobile app. In addition, the mobile app was perceived as more user-friendly than the paper-based questionnaire. However, some (42/261, 16.1%) participants mentioned in their free-text comments that user-friendliness could be improved in some ways. For example, a couple of participants mentioned that the notification or icon of the mobile app always remained at the top left on their phone screen, which was experienced as unpleasant.

Discussion

Principal Findings

This study aimed to validate an innovative way to measure health-related quality of life using a mobile app based on the EQ-5D-5L questionnaire that may replace the paper version of the questionnaire. The mobile app prompts a participant to answer a single question of the EQ-5D-5L questionnaire twice a day, once in the morning and once in the afternoon. In total, all questions were asked twice, spread over 5 consecutive days. This study was designed to compare the scoring in the mobile app to the gold standard paper-based version of the EQ-5D-5L.

This study showed high correlations, of over 0.79 ($P < .001$), for all 5 questions between the paper-based EQ-5D-5L questionnaire and the mobile app questionnaire (averaged App T1 and App T2). When comparing the paper-based version separately with the 2 time points App T1 and App T2 (Multimedia Appendix 2), the correlations were slightly lower. Depending on the domain (eg, mobility, self-care, usual activities, pain or discomfort, and anxiety or depression), the correlations between the paper-based version and App T1 or App T2 were higher. For all domains, the correlation of the mean of both entries was higher than that for one entry, regardless of whether it is App T1 or App T2. Averaging the 2 scores may have eliminated some variability, potentially increasing the correlation. Nevertheless, because of the high correlations for App T1 (>0.64) and App T2 (>0.65), completing the questionnaire once

via the mobile app seems to be sufficient, considering its high retest reliability. In addition, no significant differences between the paper score and the mobile app were observed, indicating that the scores were not structurally higher for either paper or the mobile app. Regarding test-retest reliability, high correlations were found between the App T1 and App T2 scores (>0.73). Both the high correlation between the paper version and the mobile app questionnaire, along with the high correlation of the in-between comparison of the mobile app time points (App T1 vs App T2), make the new mobile version of the EQ-5D-5L questionnaire a reliable replacement for the paper-based method.

A review [12] demonstrated the equivalence of electronic and paper-based patient-reported outcome measures. Equivalence was observed in 43 studies. However, 2 studies did not find equivalence, and 10 studies had no clear conclusions. Furthermore, Jiang et al [16] criticized the web-based method in comparison with the face-to-face method. Therefore, validation of the new smartphone method compared with the gold standard is important before using the new method in a health care setting.

Belisario et al [7] compared the responses to questionnaires using a mobile app with other methods (eg, paper, laptop, and web based). No major differences in using the app or “other methods” were observed. This study used a threshold correlation of >0.6 , which is in line with our results, and we found correlations of >0.64 .

Mulhern et al [10] executed a comparable study with the EQ-5D-5L questionnaire requested on paper and via a mobile phone app. In this study, a higher response rate was observed for mobile phone questionnaires. However, their study used a parallel design; the participants completed only one administration method. In comparison, in this study, participants completed both the paper-based and mobile app versions of the EQ-5D-5L. This study design is recommended to have confirmative evidence for equivalence [29], because the same participants undergo both methods. In a study by Lundy et al [30], the EQ-5D-5L paper version was examined using different devices (handheld, tablet, interactive voice response, and web).

They found substantial evidence supporting the measurement equivalence of the different modes of data collection (paper format and screen-based and phone-based formats of the EQ-5D-5L provided) [30]. Evidence that this is not the case for the current questionnaire was found in the study by Kim et al [31]. They showed high correlations for the International Prostate Symptom Score questionnaire requested via an app and on paper. Furthermore, Bellamy et al [32] found high correlations between a paper-based and mobile-based scores for osteoarthritis. Different studies [11,33,34] showed a similar response to a questionnaire requested via an app and a paper-based version. These results support the validity of the EQ-5D-5L mobile app questionnaire used in this study in healthy volunteers.

An attribute of the questionnaire itself in a healthy population, such as this, is the low variance. Most people answered that they did not have any daily issues on each of the Likert scale questions. Therefore, polychoric correlation was applied, because this method is more sensitive to ordinal data with low variance. The reliability and validity of the mobile app in unhealthy people should be tested in a follow-up study, because the variance in the domains may be higher, which could affect the correlations between the methods.

We found a lower correlation for the VAS score (0.62; $P < .001$) than for the 5 domain questions between the 2 methods. This may be because of the greater sensitivity to the daily differences in this score, as the scale runs from 0 to 100 instead of from 1 to 5 as the domain questions (continuous vs categorical data). However, most individuals (204/255, 80%) scored >70 , leaving an effective score range of 70 to 100. This means that an individual who scores 74 today and 75 tomorrow has an increase, whereas an individual who scores 74 today and 72 tomorrow has a decrease in score, although both deviations may be a nonnoticeable difference for the individual. When asked about categories, this would be the same category, and no deviations would be depicted.

Earlier studies showed a low yet positive correlation between consecutive measurement moments within persons for the EQ-5D VAS of 0.21 [35], indicating that a lagged correlation of 0.62 seems reasonable for a lagged relationship between individuals. In this study, there were several days between completing the questionnaire on paper and via the mobile app, which might have caused differences in the VAS scores.

Furthermore, the display length of the mobile device could affect the 0 to 100 scores differently compared with the paper length, resulting in more variation. However, other studies showed no effect of differences in device length on VAS scores; they were all similar even if the screen was half the size, meaning that the VAS itself may be a constant measure [36].

Strengths and Limitations

This study has some limitations. In this study, most (144/255, 56.5%) participants were highly educated, and only 4% (10/255) of the participants had a low education level. Therefore, it is not yet known whether this mobile app is usable for lower educated people and whether education level affects the validity of the paper-app comparison. Furthermore, the usability for

older people is not known, because the maximum age in the study was 64 years. In addition, although the app-based questionnaire is relatively simple, it does not test which minimal digital skills are needed for the use of the mobile app. The participants in the study were digitally skilled (as part of the inclusion criteria) and indicated that the questionnaire app was user-friendly (Figure 2). In addition, the mobile app was only tested with people who stated to be healthy at their own discretion, which may have caused low variance in scores.

Most eHealth app studies have nonrepresentative populations [37,38]. This indicates that there may have been a selection bias during the recruitment of people for this type of study. Nicholl et al [37] also reported that participants were predominantly female, White, well educated, and middle aged, and thus the wider applicability of digital self-management interventions remains uncertain. This is important for the usability of the at-home tests. However, this may not be applicable to the general population.

Despite these limitations, a good representation of the population with sufficient spread of age, gender, and people living in the Netherlands was obtained. Furthermore, the number of participants was sufficient for validation (calculated necessary: 200; completed the study: 255). Another strength of this study was the testing period of the mobile app before the start of the study. Before the study began, the mobile app was optimized using feedback from the testers.

Future Studies

Only healthy participants were included in this study. It is recommended to test the app in distinct groups of patients to gain insight into whether the perception of quality of life in diseased people can be measured with the mobile app as well.

An app should be attractive through pictures and should not be textual. Positive feedback and rewarding also play key roles in eHealth interventions [39]. The long-term use of and compliance with mobile apps require special attention. Recommendations for the app can be provided by using an extensive usability questionnaire. AB testing, which allows for the comparison of different variations of the mobile app, may be used to improve mobile app usability. Aesthetics (attractiveness), utility (relevance), and usability play vital roles in eHealth.

In addition, the study population consisted mainly of highly educated individuals. It is recommended that the mobile app be tested in a low socioeconomic group of people too. It is also worthwhile to validate the mobile app for use by older people. Older people are often less comfortable using mobile apps, and information about quality of life may be even more relevant for this group [40]. Another recommendation is to determine the use of the mobile app in long-term monitoring; for example, as a follow-up tool during or after treatment [11,31,34].

In addition, there is another instrument for scoring perceived health, the health monitor. The health monitor is inspired by the self-anchoring scale, also known as Cantril Ladder, which uses 10 steps to stress one's health [41], combined with a short questionnaire. The health monitor is used to measure a person's perceived acceptance and control of their illness or well-being. Future research should investigate whether the health monitor

is comparable with the EQ-5D and could be used as a future quality of life tool. Furthermore, the next level of nonobtrusive measurement of quality of life could be achieved by means of digital phenotyping. Digital phenotyping is the quantification of a particular human behavior using data from personal digital devices or wearables. In the near future, data such as proximity to other devices using Bluetooth, estimation of activity, or detection of voice could be applied as robust, continuous nonintrusive proxies of aspects of quality of life [42].

Conclusions

In this study, high correlations between the questionnaire requested via the mobile app and on paper were observed. This

indicates that the mobile app is valid for use and is as reliable as the paper-based version of the EQ-5D-5L. With the widespread use of mobile phones, the mobile app is potentially valuable for perceiving a patient's health in a simple and valid way, as an alternative to the paper-based EQ-5D-5L questionnaire. The mobile app could reduce the current burden and errors with the use of questionnaires, such as skipping questions, giving more answers than required, and data entry errors. In addition, mobile app data will be immediately available and stored and can easily be compared with previously completed questionnaires. However, more research is required to establish the use of mobile apps for consecutive monitoring of various user groups.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Example (in Dutch) of EQ-5D-5L question (mobility) programmed in the Q1.6 app.

[[PNG File , 124 KB](#) - [formative_v6i8e37303_app1.png](#)]

Multimedia Appendix 2

Polychoric correlations between EQ-5D-5L paper and EQ-5D-5L App T1 and App T2.

[[PNG File , 33 KB](#) - [formative_v6i8e37303_app2.png](#)]

Multimedia Appendix 3

Paired 2-tailed *t* test for mean difference in digital versus paper measurements.

[[PNG File , 14 KB](#) - [formative_v6i8e37303_app3.png](#)]

Multimedia Appendix 4

Paired 2-tailed *t* test for mean difference in App T1 versus App T2.

[[PNG File , 14 KB](#) - [formative_v6i8e37303_app4.png](#)]

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Abbreviations

VAS: visual analog scale

WMA: World Medical Association

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Original Paper

A Comparison Between Clinical Guidelines and Real-World Treatment Data in Examining the Use of Session Summaries: Retrospective Study

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Abstract

Background: Although behavioral interventions have been found to be efficacious and effective in randomized clinical trials for most mental illnesses, the quality and efficacy of mental health care delivery remains inadequate in real-world settings, partly owing to suboptimal treatment fidelity. This “therapist drift” is an ongoing issue that ultimately reduces the effectiveness of treatments; however, until recently, there have been limited opportunities to assess adherence beyond large randomized controlled trials.

Objective: This study explored therapists’ use of a standard component that is pertinent across most behavioral treatments—prompting clients to summarize their treatment session as a means for consolidating and augmenting their understanding of the session and the treatment plan.

Methods: The data set for this study comprised 17,607 behavioral treatment sessions administered by 322 therapists to 3519 patients in 37 behavioral health care programs across the United States. Sessions were captured by a therapy-specific artificial intelligence (AI) platform, and an automatic speech recognition system transcribed the treatment meeting and separated the data to the therapist and client utterances. A search for possible session summary prompts was then conducted, with 2 psychologists validating the text that emerged.

Results: We found that despite clinical recommendations, only 54 (0.30%) sessions included a summary. Exploratory analyses indicated that session summaries mostly addressed relationships (n=27), work (n=20), change (n=6), and alcohol (n=5). Sessions with meeting summaries were also characterized by greater therapist interventions and included greater use of validation, complex reflections, and proactive problem-solving techniques.

Conclusions: To the best of our knowledge, this is the first study to assess a large, diverse data set of real-world treatment practices. Our findings provide evidence that fidelity with the core components of empirically designed psychological interventions is a challenge in real-world settings. The results of this study can inform the development of machine learning and AI algorithms and offer nuanced, timely feedback to providers, thereby improving the delivery of evidence-based practices and quality of mental health care services and facilitating better clinical outcomes in real-world settings.

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KEYWORDS

Empirically based practices; natural language processing; psychotherapy; behavioral therapy; adherence; treatment fidelity; clinical training; real-world data; real-world study

Introduction

Background

Mental health is a major global health concern. Mental illnesses will affect close to half of the world's population at some point in their lives [1]. In addition to the personal toll of these illnesses, they also cost the global economy US \$1 trillion per year in lost productivity alone [2]. Cognitive behavioral interventions have a robust evidence base for their efficacy and effectiveness in treating a variety of mental health issues. However, an ongoing challenge in the field has been how to "bridge the gap" between the laboratory or classroom and the clinic, with the data suggesting that the implementation of these methods in real-world settings is often much more challenging. One hypothesis for this is that therapists in real world settings may not be as adherent to the protocols on which these treatments have been tested and the evidence base established.

Cognitive behavioral treatments are designed to help individuals identify and alter maladaptive cognitions, emotions, interpersonal relationships, and problematic behaviors to reduce symptoms and lead more productive and satisfying lives. At this point, numerous versions of behavioral interventions have been manualized and studied in comparative trials with robust effects versus waitlist and placebo conditions, as well as medications and other forms of psychotherapy and disseminated worldwide. The need for focused behavioral treatments has become stronger following the COVID-19 pandemic, given the global increase in mental health disorders [2,3] and the resulting demand for mental health services, coupled with a dramatic shortage of clinicians [4]. Given this need-service gap, it is imperative that behavioral treatments be delivered in accordance with the empirically based guidelines based on which they were established in order to maximize the potential of replicating the outcomes of the clinical trials with individuals "in the real world" with mental health concerns.

Therapist Adherence to Treatments as Designed

"Therapist drift," or the tendency of clinicians to adhere only partially to established empirically supported practices, has been documented in the literature with respect to many treatment models [5,6]. Therapists' attitudes toward evidence-based practices (EBPs), their licensing status, and organization characteristics combinatorically affect their use of recommended strategies [7,8]. Further, clinical trainings or specialty workshops for EBPs are often not enough to facilitate change of practice and improved client outcomes unless some ongoing follow-up sessions are offered for supervision [9].

Complicating matters further, therapy is often like a "black box" in which little is done to monitor or encourage clinicians to adhere to core active ingredients of empirically supported treatments. As such, it has been proposed that clinical research should utilize observations that are less subject to bias [10,11]. In addition, data from real-world treatments indicate that few empirically based therapeutic techniques are in effect, even when clinicians report that they offered evidence-supported behavioral treatments [12].

Session Summary: An Example of Therapist Adherence

Empirically supported protocols are often built on a basic set of theoretical ideas. Although certain aspects may differ amongst protocols, certain essential concepts remain common to them all [13]. Dryden [14] argues that it is essential for the client to leave the session with what they view as important takeaways. As the session comes to a close, it is best practice for the therapist to invite the client to summarize the session rather than the therapist summarizing what transpired for the client during the session [14]. Indeed, one of the key elements in almost every manualized treatment is encouraging the client to compose a *summary* at the end of each therapy session [15-19]. This form of feedback is described as a means of helping clients review their own understanding of the session and the rationale for the interventions provided [20]. Further, a session summary provides clients an opportunity for feedback, which empowers clients to conceptualize their needs, assess their progress toward their goals, and make their own decisions. It also allows the therapist to ensure that key components of the sessions have been understood and highlighted. Therefore, a session summary could be viewed as a common, transdiagnostic evidence-based component that is one of the key ingredients related to the effectiveness of the session.

The importance of session summary has not been overlooked by researchers, and reports on treatment studies often mention this strategy [21,22]. Perlich and Meinel [23] even developed a tool for collaborative session summary, in which the client and the therapist review the session and their takeaways. However, when asked about their own adaptations of EBPs, 32% of therapists reported removing components of the intervention, with the session summary being the most frequently omitted part from the therapy process [24]. Similarly, one of the most common challenges of community mental health therapists learning cognitive behavioral therapy (CBT) was their limited attempts to solicit the client's feedback [20], and in text-based CBT, very few therapists summarized the session [25].

While the session summary is just one example of possible therapist drift [6], given its importance of reinforcing the therapeutic process and strengthening the learnings obtained during treatment, and that it is a technique that can be delivered quite briefly and has a high face validity across interventions, it may serve as a proxy for how much the clinician is adhering to the full range of tasks that are essential for evidence-based therapies (EBTs) to be effective. Therefore, this study explored how common are session summaries in real-world behavioral treatments.

Methods

Settings and Interventions

This study is based on the retrospective analysis of fully anonymized data from behavioral health treatments provided in 37 behavioral health care programs across the United States. All client participants received either individual, group, or couples therapy in either an outpatient or intensive outpatient

program. Clients sought treatment for a range of mental health concerns, and therapists were free to provide the intervention they believed was most suitable for the client's presenting problem and characteristics. Therapists were either psychologists, social workers, or licensed counselors. The sample comprised 17,607 treatment sessions administered by 322 therapists to 3519 clients.

The Eleos Health Platform

All sessions were processed via an artificial intelligence (AI) therapy-specific platform (Eleos Health). This platform captures the treatment conversations, provides a verbatim session transcript, and summarizes intervention insights to inform treatment-planning and clinical decision-making [26]. The platform collects key metrics from treatment sessions and integrates them with standardized evidence-based self-report measures, leveraging insights developed through machine learning (ML) and natural language processing (NLP) analysis of large treatment data sets [27]. Eleos also uses AI methods to increase adherence with clinical standards and drive operational efficiency.

Ethical Considerations

The platform is Health Insurance Portability and Accountability Act-compliant, and all participants consented to have their sessions processed through it. This study was approved by an external institutional research board, Sterling IRB (9545).

Data Processing

To fully capture and make sense of the speech data, we developed an algorithm to identify the specific interventions carried out in behavioral treatment sessions and consequently determine whether a session summary was recorded. First, the sessions were transcribed using an automatic speech recognition system (ASR) as well as a domain-based text-cleaning algorithm. Second, since the session transcripts are unstructured data, we developed a treatment-oriented, speaker diarization ML model in accordance with their utterances in the treatment session. A team of trained graduate-level clinicians tagged over 2500 therapy conversations and labeled the speakers as either "patient" or "therapist." These data were consequently used in

a model that analyzed the full transcribed session and assigned a speaker label for each participant. Third, we applied the term frequency-inverse document frequency, a commonly used feature generation method, to identify if the speaker is either the therapist or a client. As a classification algorithm, we used a logistic regression model with a binary cross-entropy loss and trained the model using stochastic gradient descent. On a session level, our in-house solution demonstrated 98% accuracy in differentiating between speakers in therapy sessions.

Data Analysis

Eleos's NLP-based engine extracted potential session summary from therapists' utterances, identifying the frequencies of lexical terms, which were said during the latter 20% of the session, and retrieving phrases such as the following: "[I] just want to review what we talked about"; "So what did you learn here today?"; "If it was something that you were going to take away from today's session, what would it be?"; "What's your take home message from today?"; "Alright, let's do our summary for the day"; "kind of [your] two main takeaways"; and so on. For quality assurance, 2 psychologists (SSS and TK) reviewed 682 sessions that included language associated with a session summary and indicated whether the algorithmically identified text did in fact reflect a meeting review prompt. Figure 1 outlines the data analysis approach used in this study. Finally, we compared sessions with and those without a summary on the following variables: most commonly discussed topics, therapist-to-client listening ratio, the most commonly used intervention techniques, and content of the progress note that the therapist had generated for this session in the program's electronic health record (EHR). Further, to assign the sentiment expressed during these specific sessions, we applied Valence Aware Dictionary and sEntiment Reasoner (VADER) [28] on the therapist's and patient's texts, independently. VADER is a lexicon and rule-based sentiment analysis tool that uses a sentiment lexicon and a list of lexical features (eg, words) that are labeled in accordance with their semantic orientation as either positive or negative [29]. VADER not only classifies the data to either positive or negative, but also provides a score to indicate the strength of the sentiment detected [28].

Figure 1. Overview of the classification and data analysis process for real-world session summaries. ASR: automatic speech recognition; ML: machine learning; VADER: Valence Aware Dictionary and sEntiment Reasoner.



Results

Provision of a Session Summary

Our analysis found that only 54 of the 17,607 (0.30%) behavioral treatment sessions included a session summary. Of these 54 treatment meetings, session summaries most commonly addressed interpersonal relationships with family and friends

(n=27), issues related with work (n=20), the word “change” (n=6), and alcohol (n=5).

Characteristics of Sessions Including Summaries

Data were further analyzed to review descriptive differences between therapy sessions with and those without a summary. Sessions that included a prompt to help the client summarize the meeting had a lower therapist listening ratio (33% vs 49%),

indicating that therapists were less verbally active throughout the meetings that included feedback. The number of therapeutic interventions detected was greater in sessions that included a session summary; on average, therapists used 17% more interventions in meetings with a summary. Sessions with meeting summaries also included greater therapist use of validation, complex reflections, and proactive problem-solving techniques. Moreover, therapists who prompted their client to summarize their session were 83.3% more likely to assign treatment homework and report it on their EHR progress note. Therapists who encouraged a summary also had a 12% greater likelihood of completing their progress note within 48 hours of the session's date: 69% of those who had asked for a summary

also completed their progress note within this time frame, compared to 61% of therapists who did prompt a summary. [Table 1](#) provides an overview of the differences between sessions including and not including summaries.

Applying the VADER algorithm in sessions that included summaries revealed that the clients expressed, on average, slightly more positive and negative emotions (0.6% and 4%, respectively) than those with no summary. However, the therapists tended to express less emotion in the sessions including a summary, expressing 9% less positive statements and 7% less negative statements. [Table 2](#) provides an overview of the differences between sessions including and those not including summaries around statements' sentiments.

Table 1. Differences in therapists' behaviors between sessions including and those not including a meeting summary.

Sessions	Listening ratio, %	Progress note completion rate, %	Type of interventions detected
Without a summary	33	61	1.04
With a summary	49	69	1.26

Table 2. Sentiment differences between sessions including and those not including a meeting summary.

Sessions	Patients' positive statements, %	Patients' negative statements, %	Therapists' positive statements, %	Therapists' negative statements, %
Without a summary	7.70	4.50	8.90	4.20
With a summary	7.40	4.50	8.20	3.90

Discussion

Principal Findings

While the evidence base is strong and robust for behavioral interventions, their efficacy is tied to maintaining a structure and including certain key components in each session. Therapist drift from the key active ingredients of validated treatment protocols could compromise the efficacy and effectiveness of the treatments, thus limiting the impact of treatment on the individual [30]. This study examined the practice guidelines versus practice in real-world behavioral health care settings as they pertain to a key component found in most behavioral interventions: encouraging clients to review and summarize their treatment session [20]. Session summaries are important because they allow the client an opportunity to reflect back on the treatment meeting, their developing understanding of the maladaptive processes underlying their symptoms, as well as some effective coping strategies they could employ. They also allow the therapist to ensure that key components of the sessions have been understood and highlighted. In controlled and case-series studies reported in the literature, the technique of requesting feedback is stated explicitly [31]. This study found that very few therapists provide feedback to their clients in the form of a session summary. Our findings suggest that providers who encouraged their clients to reflect on their treatment demonstrated a more active therapy style—their sessions were characterized with more back-and-forth exchanges between the therapist and the client, they provided more interventions during the meeting, and they even tended to complete their progress note faster. These results suggest that therapist adherence to at

least one of the key components of most empirically supported behavioral treatments was absent in most of the real-world sessions we reviewed.

Comparison With Prior Work

The findings of this study indicate that in contrast to guidance in treatment protocols, therapists delivering behavioral treatments in real-world settings rarely encourage their clients to reflect on the session during their meeting. To the best of our knowledge, this study is the first to evaluate a large and diverse data set of actual therapy sessions. These findings extend the results of previous studies that have exclusively relied on practitioner self-report and provide insight on how therapists practice in real-world treatment settings [32]. Therapists may overestimate their adherence to practice guidelines, as 32% reported not providing all parts of treatments [32], while this study suggests that adherence rates are much smaller. Session summary, or feedback, can be perceived as a method for prompting clients to form implementation intentions, thereby likely facilitating greater treatment impact; however, prior research has found that therapists do not often explicitly discuss with their clients to plan actions as a result of the treatment session [33]. Further, higher-caseload therapists reported feeling that learning about new EBTs would be time-consuming, which consequently could serve as a barrier to implementing these techniques [30]. In light of this research, it may not be surprising that therapists do not adhere to EBT recommendations despite realizing their potential benefits to service users. Of note, it has been proposed in the literature that treatment protocols are difficult to administer in the field as originally designed in controlled studies, and that "flexibility within fidelity" should

be practiced in order to maximize the effects of these programs [13]. Hence, a systematic understanding of the context affecting variations from prescribed practice and omissions of specific techniques is warranted.

Limitations

This study utilized data from 17,607 sessions taking place in behavioral health clinics across the United States. The data are likely more representative of the therapist behaviors occurring in real-world settings than are the findings of controlled studies. Nonetheless, this study has limitations. The anonymized database did not include demographic and clinical information of the clients and therapists, which could have enriched our analysis. Future studies should also collect explicit data on the treatment that was provided and how it maps on to the client's treatment plan. Further, the low number of sessions with summary statements limited our ability to utilize the sentiment and content analyses. Additionally, the analysis did not include outcome data such as symptom reduction or client satisfaction,

which are important to assess in the context of the treatment process. From a theoretical and practical standpoint, interviewing therapists about their considerations of using strategies will help better define underlying processes affecting behavioral treatment implementation.

Conclusions

Given the importance of following treatment protocols as initially intended, there is much potential in automating timely feedback for therapists. This study is the first to our knowledge that provides real-time, observational data on clinical practice in real-world settings. As such, it provides a new perspective to how clinicians provide therapy that can enrich that data captured by therapist self-reports. Empirically supported ML and AI algorithms can offer clinicians, trainers, supervisors, and stakeholders nuanced observations on treatment adherence, thereby improving the quality of implementation, dissemination, and ultimately, effectiveness of mental health treatments.

Data Sharing Statement

The data that support the findings of this study are not publicly available owing to privacy and ethical restrictions.

Conflicts of Interest

SSS, SJ, GP, and TK are employees of Eleos Health Inc, which created the platform providing the data for this study. SAR is an unpaid advisor to Eleos Health Inc.

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Abbreviations

AI: artificial intelligence

CBT: cognitive behavioral therapy
EBP: evidence-based practice
EBT: evidence-based therapy
EHR: electronic health record
ML: machine learning
NLP: natural language processing
VADER: Valence Aware Dictionary and sEntiment Reasoner

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Original Paper

A “No-Code” App Design Platform for Mobile Health Research: Development and Usability Study

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Abstract

Background: A challenge facing researchers conducting mobile health (mHealth) research is the amount of resources required to develop mobile apps. This can be a barrier to generating relevant knowledge in a timely manner. The recent rise of “no-code” software development platforms may overcome this challenge and enable researchers to decrease the cost and time required to develop mHealth research apps.

Objective: We aimed to describe the development process and the lessons learned to build Pathverse, a no-code mHealth app design platform.

Methods: The study took place between November 2019 and December 2021. We used a participatory research framework to develop the mHealth app design platform. In phase 1, we worked with researchers to gather key platform feature requirements and conducted an exploratory literature search to determine needs related to this platform. In phase 2, we used an agile software framework (Scrum) to develop the platform. Each development sprint cycle was 4 weeks in length. We created a minimum viable product at the end of 7 sprint cycles. In phase 3, we used a convenience sample of adults (n=5) to gather user feedback through usability and acceptability testing. In phase 4, we further developed the platform based on user feedback, following the V-model software development process.

Results: Our team consulted end users (ie, researchers) and utilized behavior change technique taxonomy and behavior change models (ie, the multi-process action control framework) to guide the development of features. The first version of the Pathverse platform included features that allowed researchers to (1) design customized multimedia app content (eg, interactive lessons), (2) set content delivery logic (eg, only show new lessons when completing the previous lesson), (3) implement customized participant surveys, (4) provide self-monitoring tools, (5) set personalized goals, and (6) customize app notifications. Usability and acceptability testing revealed that researchers found the platform easy to navigate and that the features were intuitive to use. Potential improvements include the ability to deliver adaptive interventions and add features such as community group chat.

Conclusions: To our knowledge, Pathverse is the first no-code mHealth app design platform for developing mHealth interventions for behavior. We successfully used behavior change models and the behavior change technique taxonomy to inform the feature requirements of Pathverse. Overall, the use of a participatory framework, combined with the agile and hybrid-agile software development process, enabled our team to successfully develop the Pathverse platform.

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KEYWORDS

app development; behavior change technique; health promotion; mobile health; mobile application; application development; design platform; platform development; no-code mHealth app; no-code app; no-code; end user; participatory research; Pathverse; agile; hybrid-agile; software design; software development; software developer; computer science; BCT; behavior change; research tool; research instrument; digital platform; mHealth; mobile app

Introduction

Advancements in internet-enabled digital devices (eg, smartphones and wearables) and improved access to these devices have led to the rapid growth of mobile health (mHealth) research [1]. Due to the flexibility and scalability of mHealth technology, there has been tremendous interest among researchers and public health agencies in leveraging mHealth for promoting a healthy lifestyle and preventing chronic diseases [1-4]. Previous studies have shown that mHealth interventions can be efficacious in improving physical activity and healthy eating behaviors and reducing sedentary behavior [1,2,5]. However, research on the optimal ways to design these mHealth interventions to maximize effectiveness for different health conditions and population groups is still in its infancy. A recent meta-analysis found that efficacious mHealth apps that aimed to improve diet and physical activity and reduce sedentary behavior used a variety of behavior change theories and behavior change techniques (BCTs). BCTs are strategies that help individuals change their behavior; thus, these strategies are critical to creating effective and replicable behavior interventions [6]. Some efficacious apps incorporated BCTs such as motivational messages, rewards, gamification in the form of exergames, social support through interaction with peers, and friendly team challenges [7]. Meanwhile, other effective interventions have shown that using tailored health advice, goal setting, self-monitoring, and performance feedback in an app's design can lead to greater intervention effects [7-10]. Overall, more research is needed to realize the full potential of mHealth technology.

One of the challenges facing researchers conducting mHealth intervention research is the cost and time required to develop and maintain mobile apps [11]. The cost to develop these customized mobile apps (eg, behavior health counselling interventions, daily diary survey studies, and self-monitoring apps) can range broadly. Even an app with few features can cost between US \$70,000 and \$100,000 and take 3 to 6 months to develop [12]. Furthermore, the app development cost often does not fit into the budget of government research grants (eg, those provided by the National Institute of Health Research or the Canadian Institute of Health Research). Existing mobile app development kits, such as Apple's ResearchKit and Android's ResearchStack, have attempted to improve the app development process for researchers [13,14]. However, these frameworks

still require significant software programming to develop apps and often require researchers to hire specialized software developers to develop iOS and Android apps. Due to the rapidly evolving digital technology space, these challenges can be a significant barrier to developing relevant mHealth knowledge in a timely manner [15]. The need for research tools to help generate rapid and relevant research knowledge has been a long-noted issue in health research and a solution is desperately needed [16].

An innovative solution to overcome these mHealth app development challenges facing researchers has recently arisen: "no-code" development platforms [17]. A no-code mHealth research app development platform could enable researchers with no previous software programming skills to create apps through a graphical user interface (UI). Similarly to using no-code tools such as Squarespace to create websites [18], researchers could use a no-code mHealth design platform to create multiple versions of an app to evaluate their effectiveness in various conditions. Researchers could use drag and drop tools to select the required BCTs (eg, self-monitoring and goal setting tools) needed for a behavior change framework. We believe a no-code app design platform could significantly expedite the mHealth app development process and reduce the time and cost required. Currently, there is a lack of a no-code app design platform explicitly designed for researchers to develop mHealth behavior interventions. Thus, the purpose of this paper is to describe the development process and the lessons learned in building a no-code mHealth app design platform, Pathverse.

Methods

We used a participatory research framework to develop a no-code mHealth app design platform called Pathverse [19]. A participatory framework is a method that involves active collaboration between end users (ie, researchers) and software developers at various stages of development to ensure that the final product is relevant and useful [20,21]. This study was divided into four phases: (1) determination of features required for a no-code mHealth design platform; (2) development of the platform; (3) gathering of user feedback; and (4) implementation of user feedback to further refine the platform. The entire development process took place between November 2019 and December 2021. A summary of the development timeline and activities is shown in [Table 1](#).

Table 1. Development phases of the web-based program.

Phases	Activities	Dates
(1) Determine feature requirements	Determine features required for the "no-code" mHealth design platform, Pathverse	Nov 2019-Mar 2020
(2) Develop the platform	Use the Scrum development framework to design the Pathverse platform	May 2020-Dec 2020
(3) Gather user feedback	Usability and acceptability testing	Feb 2021-May 2021
(4) Implement user feedback	Revise the Pathverse platform based on usability and acceptability testing	Sep 2021-Dec 2021

Phase 1: Determine Feature Requirements (November 2019-March 2020)

mHealth researchers (n=13) with various levels of research experience (eg, students, early career researchers, and senior

researchers) and software developers (n=4) were involved in identifying key software features for the no-code app design platform, Pathverse. The team members' demographics are presented in [Multimedia Appendix 1](#), Table S1. The mHealth research team's expertise included mHealth app development

and evaluation, behavior science, psychology, health promotion, and usability testing. The software development team expertise included Python, JavaScript, Dart, and the Scrum development process. We performed an exploratory web search using Google with the search term *no-code mHealth app builders* to determine whether such mHealth app builders existed. In addition, we performed a literature search to determine mHealth apps features that were associated with intervention effectiveness. Specifically, MEDLINE, PubMed, EMBASE, and PsycINFO were searched for articles published from January 2009 to December 2019 with the following key words: (*mobile health OR mHealth OR internet intervention OR web-based interventions*) AND (*effectiveness OR efficacy*) AND (*features OR characteristics OR behaviour change techniques OR theories*) AND (*systematic review OR literature review OR meta-analysis*). Our interdisciplinary team met regularly throughout this phase to brainstorm features (eg, self-monitoring tools and goal setting) required to build mHealth apps. In order to ensure that these features met the researchers' requirements for building mHealth apps, our team used the multi-process action control framework (M-PAC) as a theoretical template model and used physical activity change as the template outcome behavior. The M-PAC framework has been shown to be effective in promoting physical activity [22-24]. M-PAC emphasizes a social cognition approach to intention formation, the adoption of action control through self-regulation, and an action control maintenance phase once a behavior becomes habitual and self-identified [23]. One advantage of the M-PAC model is its ability to address the "intention to behavior" gap, which poses a particular challenge for individuals adopting a new lifestyle, because almost all individuals joining mHealth app interventions have already formed an intention to adopt a healthy lifestyle [23,25,26]. Finally, we matched the proposed BCTs to the M-PAC mechanisms of action [22], which guided the features for the Pathverse app development platform. A list of key features and a mock-up design of the Pathverse platform were developed by the end of this phase.

Phase 2: Develop the Platform (May-December 2020)

We used the Scrum framework to develop the Pathverse platform [27]. This agile software framework uses an iterative approach that allows for valuable input from end users throughout the software development cycle. Scrum uses predefined short-sprint cycles that usually last from 2 to 4 weeks. Each sprint cycle consists of design, implementation, evaluation, and planning for the next sprint. The Scrum framework enables the development team to create the first version of the software at the earliest stage of the development process. Furthermore, regular meetings throughout the development cycles enable end users to provide valuable feedback and make rapid adjustments throughout the development cycles.

We used a 4-week sprint cycle in this project. We aimed to produce a working version of the platform in about 7 months (ie, 7 sprint cycles). The key members in the Scrum team were an mHealth researcher (the product owner, SL), the Scrum master (HL), and the software development team. End users with various levels of mHealth research experience (researchers, research assistants, and students) were involved during each sprint. The Scrum team presented the completed platform

features and discussed goals for the next sprint with the team at the end of each sprint.

Phase 3: Gather User Feedback (February-May 2021)

Similarly to our previous studies [28,29], we gathered user feedback by assessing the usability and acceptability of the Pathverse platform. Usability and acceptability assessments are part of a technique in user-centered interaction design to evaluate how researchers interact with the platform; we used this approach to evaluate whether Pathverse met its intended requirements. We used a convenience sample of health researchers (n=5) who were interested in using or had used mHealth applications in their research. Participants were required to have not previously used the Pathverse platform. Due to the COVID-19 pandemic, the assessments were conducted using video calls. A week prior to the video call, participants were given access to the platform and were asked to use it to build a mobile app program aimed at promoting a healthy lifestyle. During the video call, we conducted a structured interview to gather feedback on what the user liked and disliked about the platform and to determine areas needing improvement. The qualitative interview data were summarized using thematic analysis to identify areas for improvement. Participants were also asked to complete a questionnaire evaluating the likeability and usefulness of the platform. The questionnaires were adapted from an mHealth app usability questionnaire that assesses the likability and usefulness of the platform [30]. The score had a scale ranging from 0 to 10, with 10 indicating "strongly agree," and 0 indicating "strongly disagree."

Phase 4: Implement User Feedback (September-December 2021)

Based on user feedback, our team planned for an additional phase of development. During this phase, we used the V-model software development process. This method combines traditional sequential development methodology (eg, the waterfall method) with feedback mechanisms in the agile development process (eg, Scrum) to ensure that the new features added work appropriately [31]. The V-model software development process was chosen instead of the Scrum method due to the well-defined project requirements and the smaller project size [31]. Our team used the following development stages: (1) requirement analysis (ie, gathering project requirements from researchers), (2) system and architectural design (ie, determining the critical software components required for the final product), (3) module design (ie, determining the critical modules for the software components identified), and (4) coding (ie, starting to program the modules). We also conducted validation testing for each development stage to ensure that the platform worked appropriately. The validation testing consisted of the following: (1) unit testing (performed by the software team to eliminate system bugs during the coding phase), (2) integration testing (performed by the software team to ensure the new features developed worked appropriately with the existing platform), (3) system testing (conducted by the researchers to ensure the development met the build requirement), (4) user acceptance testing (performed by the research team to ensure the platform was ready for use in the real world).

Ethical Considerations

Informed consent was obtained from participants completing the usability and acceptability testing. This study was approved (17361) by the Human Research Ethics Board at the University of Victoria.

Results

Phase 1: Determining Feature Requirements

Our multidisciplinary team of researchers and software developers met regularly to determine requirements and features for the Pathverse platform. A summary of the activities conducted at each meeting is shown in [Table 2](#). Our exploratory Google web search revealed that there was a lack of no-code mHealth app development tools designed for researchers. A literature review suggested that an mHealth app platform would need a variety of software features in order to deliver a wide range of BCTs [3,7,32-34]. For example, a review of BCTs in 40 exercise and dietary apps showed that the apps included an average of 8.1 (range 2-18) techniques [35]. Commonly included BCTs were “provide instruction” (33/40 of apps, 83%), “set graded tasks” (28/40, 70%), “prompt self-monitoring” (24/40, 60%), and “model/demonstrate the behavior” (24/40, 53%). At least one of the following 3 BCTs was also included in 55% (22/40) of the apps: “provide opportunities for social comparison,” “plan social support/social change,” and “prompt identification as a role model” [35]. A more recent systematic review suggested that prompts and cues, personalization, goal setting, and action planning were the most common BCTs used in effective mHealth trials to improve lifestyle behaviors and

chronic condition management [36]. However, the optimal number and combinations of BCTs needed for effective mHealth interventions would most likely depend on the underlying theoretical approach and the proposed mechanisms of action. Thus, this reinforces the need for the Pathverse platform to provide researchers with the flexibility of building mHealth apps with various BCTs for a chosen theoretical framework (eg, M-PAC, self-determination theory, or theory of planned behavior).

Our team generated a list of potential Pathverse features by building a mock-up app using the M-PAC framework as a template theoretical framework and physical activity as the behavior change outcome. Similarly to our previous study, our team then matched the BCTs required to implement the physical activity app using the M-PAC framework [28].

The final platform features included the ability to (1) design customized and interactive multimedia content in the app; (2) set flexible content delivery logic (eg, delay the time release or only show new lessons when completing the previous lesson); (3) deploy customized surveys to the participants; (4) provide personalized self-monitoring trackers (ie, daily steps); (5) enable participants to set goals; (6) implement customized app notifications to remind participants of any new mHealth intervention content; (7) provide gamified points and badges; and (8) enable participants to share progress made on their social media accounts (eg, Instagram and Facebook). [Table 3](#) shows how these Pathverse features could potentially be used to deliver the BCTs listed in the Coventry, Aberdeen & London—Refined (CALO-RE) taxonomy [37].

Table 2. A summary of the activities conducted during the meetings.

Date	Activities
November 8, 2019	<ul style="list-style-type: none"> Discussed common features used in current popular mHealth lifestyle promotion apps
December 12, 2019	<ul style="list-style-type: none"> Brainstormed potential mHealth content and features required for the platform based on an example physical activity promotion app that used the multi-process action control framework Received feedback from researchers on app mock-ups and discussed the user journey for researchers to create apps Provided feedback on potential app logic needed to deliver multimedia content in an app
January 10, 2020	<ul style="list-style-type: none"> Compiled a wish list of features for an mHealth app builder platform, which included multimedia content delivery, messaging, online community, self-monitoring tools, wearable integration, adaptive intervention delivery logic, gamification features (eg, awards, points, and competitions), diaries, virtual lockers to store memories of accomplishments, surveys, reminders and notifications, goal setting, team challenges, quizzes, the ability to customize the app UI^a (eg, color, fonts, and layout), a means of tracking app usage, and a mechanism for online consent
January 30, 2020	<ul style="list-style-type: none"> Created several UI designs of a “no-code” app design platform Received design feedback from end users
February 14, 2020	<ul style="list-style-type: none"> Further refined UI designs and discussed the user journey and potential ways researchers could interact with the no-code app design platform to create mHealth apps Discussed potential privacy and security measures that the platform needed to consider Brainstormed and finalized the name of the no-code app design platform: Pathverse
March 12, 2020	<ul style="list-style-type: none"> Finalized a list of features that our team would attempt to include for the first version of the no-code app design platform Estimated software development timeline and the number of software developers required

^aUser interface.

Table 3. Behavior change techniques that can be implemented using the identified Pathverse features.

Pathverse features	Potential behavior change techniques that could be implemented using the proposed Pathverse features. The numbers in parentheses refer to behavior change techniques in the Coventry, Aberdeen & London—Refined taxonomy [37].
(1) Ability to design customized multimedia content (eg, text, pictures, video, and interactive quizzes) on various app pages; the content can be organized into “lessons” depending on the intervention curriculum (for example, lesson 1 might discuss the benefits of physical activity and lesson 2 might provide information on setting graded goals)	<ul style="list-style-type: none"> • Provide information on consequences of behaviour in general (1) • Provide information on the consequences of behaviour to the individual (2) • Provide information about others’ approval (3) • Provide normative information about others’ behaviour (4) • Barrier identification/problem solving (8) • Set graded tasks (9) • Prompt review of behavioural goals (10) • Prompt review of outcome goals (11) • Prompt rewards contingent on effort or progress towards behaviour (12) • Shaping (14) • Prompting focus on past success (18) • Prompting generalization of a target behaviour (15) • Prompt self-monitoring of behavioural outcome (16) • Provide information on where and when to perform the behaviour (20) • Provide instruction on how to perform the behaviour (21) • Model/demonstrate the behaviour (22) • Teach to use prompts/cues (23) • Environmental restructuring (24) • Fear arousal (32) • Prompt self talk (33) • Prompt use of imagery (34) • Relapse prevention/coping planning (35) • Stress management/emotional control training (36) • Motivational interviewing (37) • Time management (38) • General communication skills training (39) • Prompt identification as role model/position advocate (30) • Facilitate social comparison (28)
(2) Set program delivery logic for the content created (for example, a new program lesson can be delivered every week)	<ul style="list-style-type: none"> • Provide feedback on performance (19) • Use of follow-up prompts (27)
(3) Deploy customized surveys to the participants; the surveys can include multiple choice answers, Likert scales, and drop-down or open-ended questions	<ul style="list-style-type: none"> • Barrier identification/problem solving (8) • Prompt self-monitoring of behavioural outcome (16) • Facilitate social comparison (28)
(4) Track physical activity–related outcomes from participants’ fitness trackers; data will be automatically synchronized from trackers connected to Apple or Google Health	<ul style="list-style-type: none"> • Prompt self-monitoring of behaviour (16)
(5) Enable participants to set personal goals; participants can also receive reminders about the goal due date	<ul style="list-style-type: none"> • Goal setting (behaviour) (5) • Goal setting (outcome) (6) • Action planning (7) • Set graded tasks (9) • Prompt review of behavioural goals (10) • Prompt review of outcome goals (11)
(6) Implement customized app notifications to remind participants of any new mHealth intervention content	<ul style="list-style-type: none"> • Prompt review of behavioural goals (10) • Prompt review of outcome goals (11) • Prompt practice (26)
(7) Provide gamified points and badges ^a	<ul style="list-style-type: none"> • Prompt rewards contingent on effort or progress toward behaviour (12) • Provide rewards contingent on successful behaviour (13) • Shaping (14) • Stimulate anticipation of future rewards (40)
(8) Enable participants to share progress made on their social media accounts (eg, Instagram and Facebook) ^a	<ul style="list-style-type: none"> • Provide information about others’ approval (3) • Facilitate social comparison (28) • Plan social support/social change (29) • Prompt identification as role model/position advocate (30)

^aThese features were not developed in the Pathverse app (version 1.5).

Phase 2: Platform Development

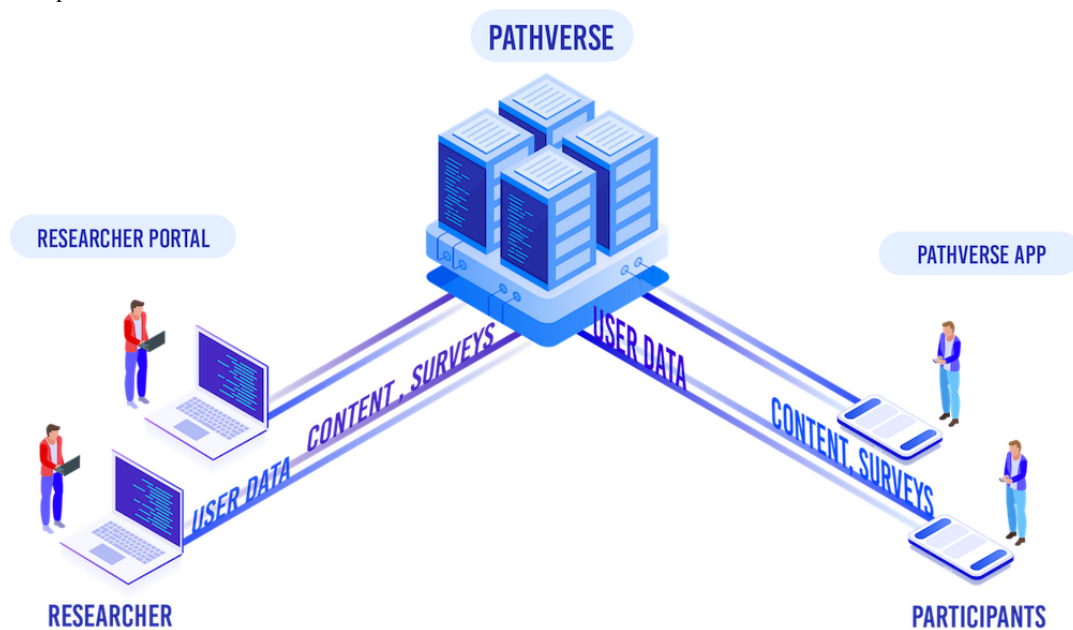
The Scrum team met with researchers throughout the sprint cycles to gather user feedback and plan the tasks to be completed by the end of the next phase. A summary of the activities completed in each Scrum phase is described below. The commit history of the software development process can be found in [Multimedia Appendix 2](#).

Sprint 1

The first sprint started with determining the Pathverse platform architecture required to implement the key features identified in phase 1. The platform consisted of 3 main components: the Pathverse researcher web portal, the Pathverse participant app (available in both the iOS and Android app stores), and the

backend application program interface (API) server and databases ([Figure 1](#)). The researcher portal enabled a researcher to create mHealth apps. The research participants could then download the Pathverse app to access the intervention. The API server acted as an intermediary between the database and the frontend interfaces by relaying information back and forth between storage and users. In this stage of the sprint, our team planned and designed the foundations of the 3 components. This started with determining all the types of data that were going to be used within these components. With the data structure decided, our team worked on user flow and UI for each of the components. Finally, our team finalized platform security. At the end of this phase, researchers and our programming team met to finalize the platform architecture to start development.

Figure 1. Pathverse platform architecture.



Sprint 2

The programming team simultaneously coded the components of the Pathverse platform. At the end of this sprint, the programming team developed a prototype version of the dashboard of the Pathverse researcher web portal using React.js, a JavaScript library licensed from the Massachusetts Institute of Technology [38]. The login and home screen of the participant app used Flutter [39], and the Pathverse API server used Django, an open-source Python web framework (Django Software Foundation). Along with the visuals, the team also completed designing the platform's database, optimized relationships within the database, and added data serializers and authentication functions. Researchers and the programming team met at the end of the phase to review the preliminary UI designs of the web portal and the participant app.

Sprint 3

The main priorities for this sprint were to finish developing the feature that enabled researchers to upload customized multimedia content for an mHealth intervention and set the delivery logic for the intervention. This was the first time the integrated platform was tested collectively. After sharing a

working prototype at the end of this phase, researchers tested the prototype and provided feedback on system bugs and design issues, and they also suggested other features that would improve their experience. The top-priority suggestions included the need to optimize multimedia content (eg, font size and color) for various screen sizes, organize the order of the intervention content delivery using drag and drop, and provide real-time visualization of the multimedia content added to the Pathverse participant app in the research portal.

Sprint 4

The programming team attempted to implement the suggestions made by the end users from the previous sprint. Additionally, the programming team completed the customized survey feature. This feature enabled the researchers to collect various types of survey responses (eg, multiple choice, ratings or Likert scales, drop-down questions, and open-ended questions). These features were tested, and various system bugs, UI design issues, and additional features were discussed. Specific main feature modification requests included providing options to enable participants to complete the survey multiple times and randomize the order of the questions. Due to the large quantity of feedback received (for UI and feature requests) and the slower

than expected feedback implementation, our team decided not to develop 2 features: gamified points and social sharing. This was to ensure that a working prototype of the Pathverse platform could be delivered on time.

Sprint 5

The programming team developed and implemented the self-monitoring tool for step tracking in the participant app. This allowed the Pathverse app to connect to Apple or Google Health wearable devices and display a user's daily step data. The end users worked with the development team to provide feedback on how the wearable data were displayed in the app. The end users provided the feedback that participants should also be able to display other health metrics, including blood pressure, weight, and daily active minutes.

Sprint 6

The programming team completed the development of goal setting and customized app notification features during this sprint. The goal-setting features enabled the participants to set customized personal goals and customized reminders for goal due dates. The customized app notification enabled researchers to set personalized app reminders whenever new app content

became available to the participants. At the end of this phase, the programming team presented the first beta version of the platform to the end users. Due to time constraints, the programming team could not implement the feature that allowed the participant app to display all the health metrics requested, such as blood pressure and weight. A prototype of the daily active minutes feature was added. Our team decided that the next sprint would focus on conducting quality assurance (QA) testing.

Sprint 7

The primary goal of this sprint was to conduct QA testing prior to launching the Pathverse platform and submitting the app to the Apple App Store and Google Play Store. The end users and programming team generated a list of system bugs while testing the various features that were developed (eg, multimedia tools, survey tools, and self-monitoring tools). The programming team and the end users met weekly during this sprint to discuss solutions to resolve known system bugs. The app (version 1.0) was officially submitted to the iOS and Android app stores at the end of this sprint. [Figure 2](#) shows screenshots of the Pathverse research portal for creating mHealth app interventions and [Figure 3](#) shows the Pathverse participant app.

Figure 2. Pathverse researcher portal for creating mHealth app content.

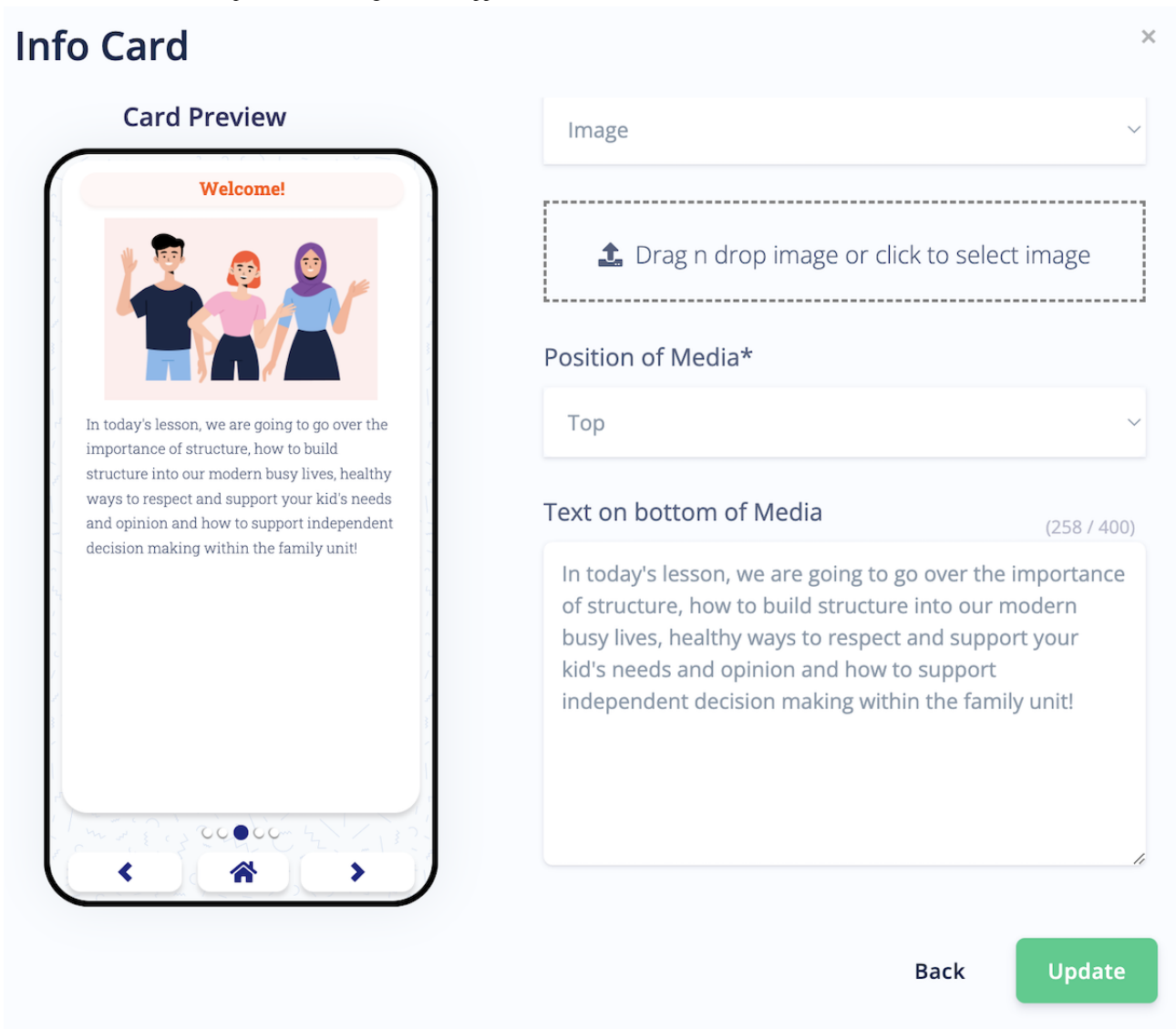
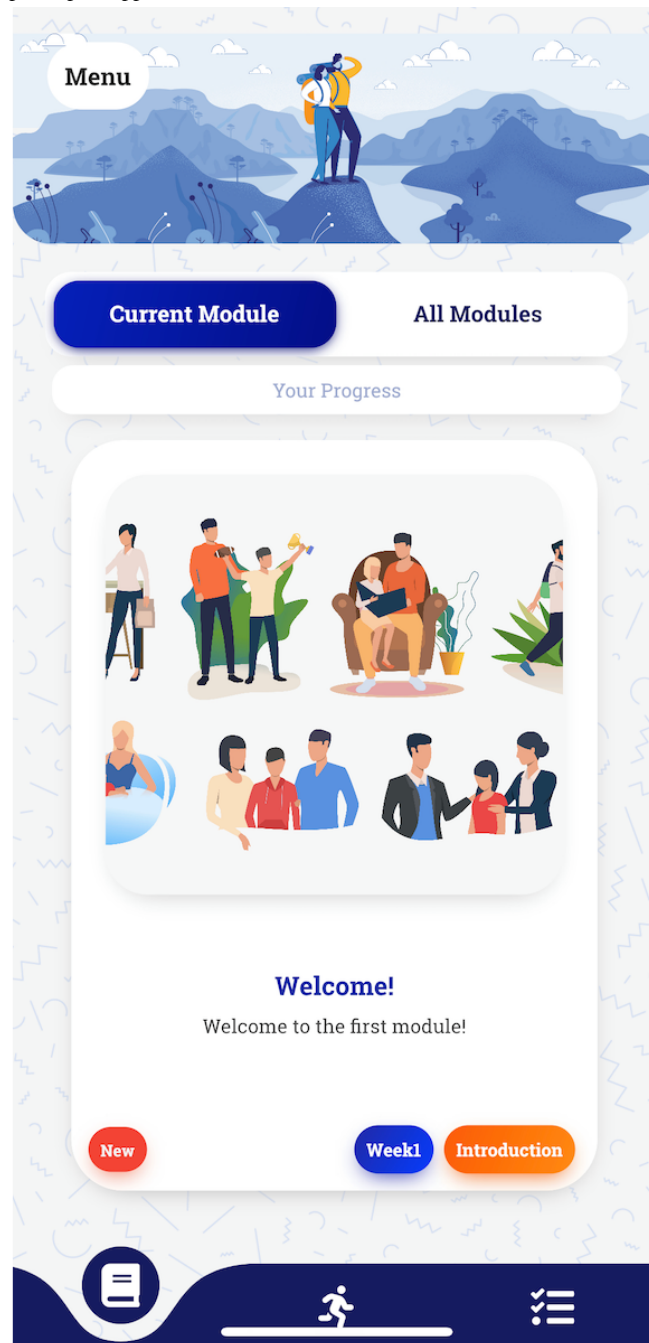


Figure 3. Screenshot of the Pathverse participant app.



Phase 3: Gathering User Feedback

We invited 5 participants to provide feedback on the Pathverse platform. The demographic characteristics of the researchers are shown in [Multimedia Appendix 1](#), Table S2. Overall, all participants had previous experience with mHealth research; 3 of 5 were from a different research institution from the platform development team. Overall, the platform received high scores for likeability (mean score 8.2, SD 2.2, range 4-10) and usefulness (mean score 8.3, SD 1.5, range 6-10). See [Multimedia](#)

[Appendix 1](#), Table S3 for a descriptive summary (with the mean, SD, range) of the questionnaire items used to evaluate platform likeability and usefulness.

The most helpful features identified by the users included easy navigation for both the research portal and participant app and the ability to download app usage and survey data. Potential improvements included the ability to deliver multiple surveys throughout the day, add the ability to deliver adaptive interventions, and add features such as community group chat. A summary of the feedback received is shown in [Table 4](#).

Table 4. Summary of feedback received in phase 3.

Questions	Summary of feedback (illustrative quotes)
What did you like about the app?	<ul style="list-style-type: none"> • <i>The participant's app layout was easy to navigate.</i> • <i>The self-monitoring tools for physical activity were useful and it was great that can be integrated with Apple and Google Health.</i> • <i>The user-interface design is clean and logical.</i> • <i>It is available on both IOS and Android.</i>
What did you dislike about the app?	<ul style="list-style-type: none"> • <i>Slow load time when multiple modules were added.</i> • <i>Text font size was too small on some pages.</i> • <i>There is limited character space per page. Some text/title are cut off in the app.</i> • <i>There are some spacing/formatting issues. Not sure if this can be fixed on the admin portal or a display issue.</i>
What changes do you think can help improve the app?	<ul style="list-style-type: none"> • <i>Greater ability to customize app layout, color, font.</i> • <i>Add community chat features, gamification.</i> • <i>Current goals can only be marked as complete. The ability to mark current goals as incomplete and need time to revisit can be helpful.</i> • <i>Zoom/video chat integration.</i> • <i>More self-monitoring tools can be helpful (e.g. weight training log, diet log).</i>
What did you like about the research web portal?	<ul style="list-style-type: none"> • <i>Good research portal navigation. It was easy to use the multimedia content, quizzes, surveys to the mHealth app.</i> • <i>Easy to use research portal console to enrol research participants</i> • <i>It was great to see the updates made to the app is reflected in real-time.</i> • <i>The ability to download app usage and survey data.</i>
What did you dislike about the research web portal?	<ul style="list-style-type: none"> • <i>The self-monitoring tools are pretty limited. It will be great to add more monitoring tools and integrate with other wearables.</i> • <i>Sometimes the web portal will not be able to save the order of the modules. Autosave will be helpful.</i> • <i>Finding the right image size for the app graphics is challenging.</i> • <i>Not knowing how long the title or text should be before it gets cut off in the app.</i> • <i>Can't change the font size or color.</i> • <i>Not sure the function of the "tags". Need better instructions.</i>
What changes do you think can help improve the research web portal?	<ul style="list-style-type: none"> • <i>The ability to deliver multiple surveys throughout the day. This can greatly expand the survey feature to be used for a daily diary or ecological momentary assessment study.</i> • <i>The ability to choose whether to display self-monitoring tools in the participant app. Not all mHealth studies (e.g., daily diary/EMA studies) need to show participants their daily steps.</i> • <i>The app usage data download can be formatted in a way that is easier for analysis (e.g. long vs wide format).</i> • <i>The ability to download third party wearable data from the platform.</i> • <i>Should consider adding adaptive intervention delivery logic.</i> • <i>Add rich text card will be helpful.</i> • <i>Change the app preview to look like a phone can enhance the preview experience.</i>

Phase 4: Implementing User Feedback

We applied the V-method of software development. The requirement analysis phase occurred in September 2021. Based on the user feedback from the previous phase, our team determined three main requirements that we would implement given the availability of resources: (1) expand survey functionalities so that multiple surveys could be delivered throughout the day, (2) improve the data download format (eg, allow a longer data structure format) for easier analysis and postprocessing, and (3) provide the ability to customize whether to use the self-monitoring features, as not all mHealth studies require this feature. The system and architecture design and the module design phase took place during the last week of September 2021. The programming team determined the main modules to be developed to meet the program requirements. These modules included customized survey release times in the researcher web portal, a display of the various surveys in the

participant Pathverse app, the ability to download survey data in .csv format, the ability for researchers to choose whether to collect wearable and survey data in the researcher web portal, and revision of the UI design for the participant app to not display self-monitoring tools. Based on these module designs, the software team initiated the coding phases from October to November 2021. The validation testing to resolve system bugs took place in December 2021. Pathverse (version 1.5) was released to the app stores at the end of this phase. Video demonstrations of the functionality of the platform were made available online [40].

Discussion

Principal Findings

This study describes the development process of a no-code mHealth app design platform for researchers. To our knowledge, this platform (Pathverse) is the first no-code mHealth app design

platform for developing mHealth behavior interventions. This platform has the potential to enable researchers with no previous software programming skills to design mHealth intervention apps. Consequently, this should help reduce the time and cost required to develop mHealth interventions. Our team used a behavior theory framework (M-PAC) and the BCT taxonomy to inform the design of the various software features in the first version of the Pathverse platform. These features can offer researchers the flexibility to design mHealth interventions with various BCTs, depending on the behavior theory or the mechanisms of action. The participatory development methods used in this project allowed our team to ensure that feedback from end users (researchers) was incorporated throughout the development phases. Despite receiving helpful feedback (eg, the social wall, gamification, and app color and font customization) from the researchers, our team could only address the most important issues given resource availability. However, we plan to address all the feedback received in future development.

Comparison With Prior Work

Similarly to previous mHealth software development studies [28,29], our team learned several lessons throughout the development process. First, the use of M-PAC and matching the proposed BCTs to the M-PAC mechanisms of action was effective in gathering feature requirements for the Pathverse platform. This process enabled our team to determine various BCT use cases and ways to implement them using the features developed (eg, multimedia content delivery, program logic, and self-monitoring tools). We believe that future platform development could use a similar process and could benefit from the use of other behavior theories as templates. This may help our team discover new use cases for the features developed.

The software development methods (eg, Scrum and the V-model) used in this study were effective in delivering the product on time. However, our team found that the Scrum method easily led to scope creep, resulting in a buildup of backlog tasks and feature cancellation. For example, after completing the customized survey feature, the research team requested additional survey functionality (eg, randomization of survey choices) in sprint 4. Similarly, they requested additional self-monitoring trackers (eg, for weight and blood sugar) in sprint 6. We also spent a significant amount of time optimizing and making changes to the app UI throughout the Scrum cycles. Future development should set a limit on the number of UI changes that can be made after the initial designs have been approved. Scope creep is a known challenge in agile development environments [16]. There are several contributing factors to scope creep, which include unclear communication,

project complexity, quality issues, time constraints, over-optimism, and unwillingness to say “no” to the client [41]. Several strategies have been proposed to prevent scope creep in software development [42]. For example, mapping the impact of a change as a percentage of the time, cost, and quality of the product could help an agile project manager decide whether to accept or reject the change. Future development may consider using similar techniques to control scope creep.

Finally, we learned the need to implement QA protocols throughout the software development phases. We did not designate a specific QA analyst role during the rapid sprint cycles. Thus, some QA issues were not discovered until the product was launched. Adopting QA testing early in the development cycle could help avoid users experiencing software bugs following deployment. An advantage of using the V-model was the systematic approach to QA testing throughout the development stages. Thus, future Scrum software development might consider incorporating a dedicated QA analyst as part of the team.

Strengths and Limitations

The end users identified several useful features (eg, the online community, adaptive intervention features, and gamification features) that could be implemented in the future to further expand the capabilities of the no-code mHealth app builder tool for researchers. A strength of the study was using the participatory framework throughout the development of the Pathverse platform. This process enabled our team to gather valuable insights into ways to improve the platform. A limitation of the study is that the end users who were involved in designing and testing the platform were mHealth researchers; this may limit the generalizability of our findings beyond this population. Furthermore, the end users provided feedback about platform feature development throughout the development phases. Due to our limited sample size during usability testing, it remains unclear how these features would be used in a larger group of users. Future studies are warranted.

Conclusion

In summary, this study describes the development process of Pathverse, a no-code mHealth app design platform. The process reinforced the importance of involving end users (eg, researchers) and demonstrated the use of agile and hybrid-agile software development methods to develop mHealth research tools. Our participatory research approach enabled our team to clarify the feature requirements of the Pathverse platform. Overall, we believe that our no-code mHealth app design platform will help researchers decrease the resources required to leverage mHealth technology.

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Conflicts of Interest

After the development of the Pathverse platform, SL and HL cofounded Pathverse Inc to commercialize the platform described in this paper.

Multimedia Appendix 1

Supplementary Tables S1 S2 S3.

[[DOCX File , 19 KB - formative_v6i8e38737_app1.docx](#)]

Multimedia Appendix 2

Platform Commit History.

[[XLSX File \(Microsoft Excel File\), 17 KB - formative_v6i8e38737_app2.xlsx](#)]

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Abbreviations

API: application program interface

BCT: behavior change technique
M-PAC: multi-process action control
mHealth: mobile health
QA: quality assurance
UI: user interface

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Original Paper

Designing Studies to Inform Tobacco Harm Reduction: Learnings From an Oral Nicotine Pouch Actual Use Pilot Study

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Abstract

Background: Introduction of new tobacco products in the United States, including those that may be lower on the risk continuum than traditional combustible cigarettes, requires premarket authorization by the US Food and Drug Administration and information on the potential impact of the products on consumer behaviors. Efficient recruitment and data capture processes are needed to collect relevant information in a near-to-real-world environment.

Objective: The aim of this pilot study was to develop and test a protocol for an actual use study of a new tobacco product. The product included in this study was a commercially available oral nicotine pouch. Through the process of study design and execution, learnings were garnered to inform the design, execution, analysis, and report writing of future full-scale actual use studies with tobacco products.

Methods: A small sample (n=100) of healthy adult daily smokers of 7 or more cigarettes per day were recruited to participate in an 8-week prospective observational study conducted at 4 geographically dispersed sites in the United States. A smartphone-based customized electronic diary (eDiary) was employed to capture daily tobacco product use, including 1 week of baseline smoking and 6 weeks during which participants were provided with oral nicotine pouches for use as desired.

Results: Online screening procedures with follow-up telephone interviews and on-site enrollment were successfully implemented. Of 100 participants, 97 completed the study, with more than half (59/99, 60%) identifying as dual- or poly-users of cigarettes and other types of tobacco products at baseline. There was more than 90% (91-93/99, 92%-94%) compliance with daily eDiary reporting, and the majority (92/99, 93%) of participants expressed satisfaction with the study processes. Product use data from the eDiary indicated that after an initial period of trial use, pouches per day increased among those continuing to use the products, while per day average cigarette consumption decreased for 82% (79/97) of all study participants. At the end of the week 6, 16% (15/97) of participants had reduced their cigarette consumption by more than half.

Conclusions: The design of this study, including recruiting, enrollment, eDiary use, and oversight, was successfully implemented through the application of a detailed protocol, a user-friendly eDiary, electronically administered questionnaires, and remote monitoring procedures. High-resolution information was obtained on prospective changes in tobacco product use patterns in the context of availability of a new tobacco product. Future, larger actual use studies will provide important evidence supporting the role that alternatives to combustible cigarettes may play in smoking reduction and/or cessation and lowering the population health burden of tobacco and nicotine-containing products.

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KEYWORDS

harm reduction; pilot; nicotine pouch; actual use; electronic diary; smartphone; survey; combustible cigarette; smoking reduction; remote monitoring

Introduction

Combustion-related toxicants drive the adverse health effects associated with cigarette smoking, including cardiovascular disease, respiratory disease, and cancer, among others [1]. The American Cancer Society indicates that “smoking is by far the leading risk factor for lung cancer. About 80% of lung cancer deaths are thought to result from smoking” [2]. To reduce the harm associated with smoking, alternatives to combustible cigarettes that fall lower on the toxicant exposure and health risk continuum are increasingly available [3,4]. These can include heated tobacco products, electronic nicotine delivery systems, smokeless tobacco products, and oral nicotine pouches (ONPs). Similar to smokeless products, ONPs are placed in the mouth for use. ONPs contain nicotine and flavorants but no tobacco leaf, resulting in much lower toxicant levels compared to other combusted and noncombusted tobacco products. Thus, ONPs are anticipated to present fewer potential health risks to users [5,6].

Tobacco products such as ONPs are regulated by the US Food and Drug Administration (FDA) and require authorization from the Center for Tobacco Products before they can be sold in the United States [7]. Manufacturers must submit premarket tobacco applications with sufficient information for the FDA to determine whether their marketing is appropriate for the protection of public health [8]. The Center for Tobacco Products requires information to assess the potential impact of a new product on current tobacco user behaviors, including who uses the product, how the product is used, and the effects of its use on the use of other tobacco products. Various study designs can be employed to provide this information, including randomized clinical trials, longitudinal cohort studies, and actual use studies (AUS) [3,9-15].

Unlike in a randomized clinical trial with managed interventional arms, in the prevailing model of tobacco AUS, smokers (the intended user) are sufficiently supplied with study products and remain free to use or not use the product at their discretion. Research participants are followed over varying time periods to capture daily product use patterns, including use of the new product and any consequent changes from their baseline tobacco consumption patterns. An AUS can also provide

information on whether tobacco users revert to using their usual tobacco products after initiating use of the new product, subjective experiences to inform use transition patterns, and whether users engage in product misuse. To date, few AUS findings are in the published literature. Two industry-sponsored studies have been published that assess the use of novel tobacco products [10,11]. In the first, over 1000 US smokers were provided a nonmarketed heated tobacco product for use over a 6-week period and recorded their tobacco product use using a daily electronic diary (eDiary) [10]. A similarly sized AUS was conducted to assess the use of a marketed ONP among adult US smokers and smokeless tobacco product users [11]. End points included complete substitution of combustible cigarette by the new products and reductions in levels of combustible cigarette use.

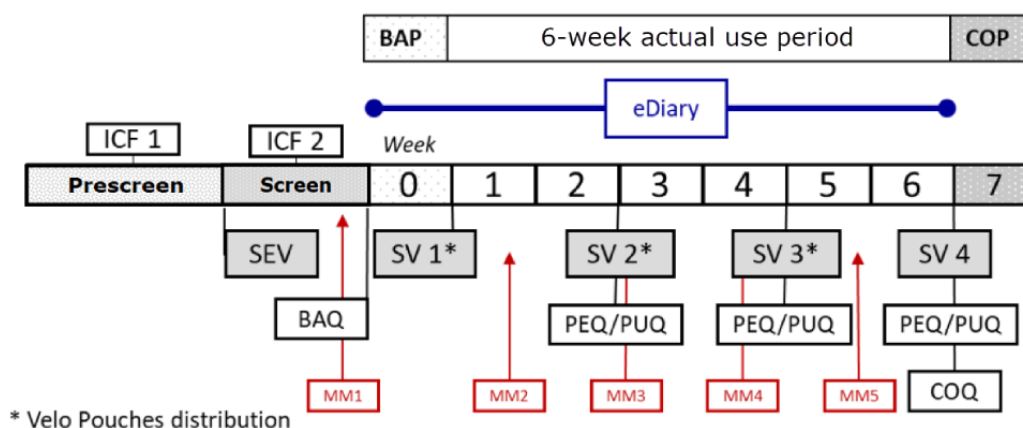
Collecting the required information on nonmarketed products is challenging due to the requirement of obtaining authorization for research use of new tobacco and nicotine-containing products (TNP), determining the appropriate sample population of who to include in studies (ie, current smokers or dual users of cigarettes and other tobacco products), and the cost of studies with large numbers of participants. In designing appropriate studies with large samples, it is beneficial to trial and test procedures to maximize efficiency around factors such as recruiting, optimizing the logistics around distributing study products (accommodating regulatory restrictions), and the establishing procedures to ensure capture of reliable use data on a frequent (at least daily) basis. Therefore, we conducted a pilot study with 100 adult smokers to inform the design, execution, analysis, and report writing of future full-scale AUSs.

Methods

Study Design

This was a pilot multisite, open-label, 8-week, prospective observational study (Figure 1), conducted between September 25 and December 31, 2020, at 4 sites geographically dispersed across the United States. The primary objective was to describe the patterns of use for the ONPs and combustible cigarette over a 6-week actual use period (AUP) using a self-reported daily eDiary.

Figure 1. Overall study design. BAP: baseline assessment period; COP: close out period; ICF: informed consent form; SEV: screening and enrollment visit; SV: site visit; BAQ: baseline assessment questionnaire; PEQ: product experience questionnaires; PUQ: product use questionnaires; MM: marketing material; COQ: close out questionnaire.



Study Products

The study products were 2 oral nicotine pouches: Velo Pouch Mint (4 mg nicotine) and Velo Pouch Citrus (4 mg nicotine, Modoral Brands Inc). Participants could select which flavors they received and could move between flavors as desired. Originally supplied at site visit 1, the product was resupplied at follow-up site visits. Detailed product accountability logs were kept by site staff.

Study Population

A total of 100 generally healthy US adults (aged 21 years or older) who were daily menthol and/or nonmenthol cigarette smokers of 7+ cigarettes per day (CPD) were recruited from nationally representative consumer databases of individuals agreeing to be contacted for market research studies.

The sample for this pilot study of 100 was considered adequate to develop and test procedures across multiple sites, with a reasonable number of participants per site ($n=25$) to allow for monitoring of the staff training, recruitment, and product distribution processes, across geographies. The sample size was not determined by any a priori formal sample size calculation.

Inclusion criteria included no intention of quitting tobacco use during the next 8 weeks, no participation in tobacco research studies in the past 3 months, and ability to complete all surveys in English. Anyone who used Velo Pouches currently or in the past; was pregnant, breastfeeding, or planning to become pregnant; or did not agree to restrict Velo Pouch use to only the products supplied in the study was excluded from participating.

Procedures

The overall study design and notable events are provided [Figure 1](#). Candidate participants were identified using a 2-stage screening and informed consent process. During the first stage (prescreening), a computer-assisted telephone interview identified interested and eligible candidate participants. These candidates gave verbal consent for further screening at the on-site screening and enrollment visit, where eligibility was reconfirmed and age was verified with a photo identification. Prior to signing the second informed consent form, eligible candidates reviewed product information and physical examples of the study products. Those who indicated an intention to use

the products at least once during the 6-week study underwent the second informed consent process before any protocol-specific procedures were carried out.

The second informed consent form explained the full nature of the study, including the optional use of study products, use of a daily eDiary, frequency of repeat visits to the sites for interviews and questionnaire completion, description of the study products, and expected experiences of their use. In addition to having the participants read the informed consent forms themselves, trained site staff explained the research study to the research participants and answered any questions that arose. A verbal explanation was provided in terms suited to their comprehension of the purposes, procedures, and potential risks of the study and of their rights as research participants. Restrictions and requirements of the study were also explained to the participants. Participants were informed that participation was voluntary and they could withdraw from the study at any time, without prejudice. Participants confirmed their willingness to be in the study using via electronic signature, were enrolled in the study, and completed the baseline assessment questionnaire ([Multimedia Appendix 1](#)) prior to leaving the site and beginning the baseline assessment period. The baseline assessment questionnaire captured additional demographic information (eg, education, occupational status, income), past 30-day TNP use, and supplemental questions related to cigarette dependence.

During the baseline assessment period (week 0), participants recorded their daily tobacco product use in the eDiary as described below. Following the baseline assessment period, participants participated in a 6-week AUP in which they were allowed to use the nicotine pouch study products and all TNP use was recorded daily. Participants were scheduled for in-person site visits 5 times during the study as noted in [Figure 1](#) (screening and enrollment visit and site visits 1 to 4). Participants received reminders prior to the day of each follow-up visit by email (1-3 days prior) and by telephone (1 day prior).

At site visits 1 through 3, study products were provided at no cost for use as desired. At site visits 2 through 4, participants were interviewed to review their prior period's eDiary compliance and share their experience with and use of the ONPs

via a product experience questionnaire ([Multimedia Appendix 2](#)) and product use questionnaire ([Multimedia Appendix 3](#)). Given the study was fielded during the COVID-19 pandemic, appropriate mitigation procedures were in place (temperature testing, social distancing, masking, etc) to ensure participant and staff safety. At the close of the AUP on site visit 4, participants returned all unused product and were asked about their satisfaction with study participation via a closeout questionnaire ([Multimedia Appendix 4](#)). The 1-week closeout period allowed participants to communicate any adverse events (AEs) or ask additional study questions.

eDiary

Due to the high frequency of daily use over an extended period of time, participants used an eDiary installed on their personal smart devices to record their daily combustible cigarette and other TNP use rather than a paper diary. This practice decreased the overall study burden on participants, reduced potential sources of error when transferring data from a paper diary to a study database, and allowed for familiarity and ease of use of the device by participants. Those who did not own smartphones or whose own devices were incompatible with the eDiary app were provided provisioned devices and limited data plans for the duration of the study. This ensured that barriers to enrollment were not created for those of limited means or lower socioeconomic status. The eDiary was an easy-to-use third-party app slightly modified by its developers for use in this study and previously used in other published health-related studies [16-18].

The app was programmed to capture daily TNP use during a set 6-hour time window every evening. Four unique electronic marketing executions were delivered via the eDiary app, one approximately every 7 to 9 days, to simulate advertising exposure as in the real world. Participants received daily notifications that their eDiary was open for completion and compliance was monitored by site staff through an online portal including sites sending additional reminders or phone calls for any data missing for the prior 2 days.

Electronic patient-reported outcome best practices were followed in its design [19]. All information collected via the app was held by the developer on a restricted access secure database in compliance with the appropriate data protection regulations in the United States. Any personal information such as email addresses and IP addresses were kept separately and securely and not linked to any other data. Participants were assigned a unique identification number to link the data with the questionnaire data in the EDC and only pseudoanonymized, individual-level data were processed for the purposes of the study.

Data Management and Analysis

All eDiary and questionnaire data were collected by an FDA 21 Code of Federal Regulations Part 11 compliant electronic data capture system [20].

Data sets were created and exported for analysis according to FDA standards. Although the small number of participants in this pilot study precluded detailed substantive analyses, a comprehensive statistical analysis plan and study report were prepared according to International Council for Harmonisation

of Technical Requirements for Pharmaceuticals for Human Use guidelines to prepare for and identify additional requirements that would be used for planning larger studies [21]. All analysis were descriptive by design, with no a priori statistical hypotheses and no statistical testing or multivariate modeling. The statistical evaluation was performed with the software package SAS (release 9.4, SAS Institute Inc).

Ethics Approval

Oversight

The final protocol, informed consent forms, and all pertinent study documents were reviewed and approved by the Sterling Institutional Review Board (reference number: 8229) prior to participant recruitment and any study procedures. The study was conducted using standard operating procedures adopted by Cerner Enviza, an Oracle company, and was conducted under the rubric of good epidemiological practice [22].

Monitoring and AEs

A telephone hotline was available throughout the study for participants to report any pregnancies, product complaints, or AEs associated with the study products. A separate monitoring team ensured adherence to the protocol and a detailed procedures manual which included interview and product accountability guidelines. In-person monitoring was intended to be conducted on-site but due to COVID-19 was converted to a remote monitoring process which used streaming technology to observe participant interviews and confirm site compliance. As an observational study with commercially available tobacco products and no clinical end points, this study was not submitted to any publicly available trial registry.

Compensation

Participants received industry-standard prorated compensation at each site visit for time spent on completing the daily eDiary and attending the site visits. The compensation schedule was designed to maximize return to sites for periodic visits and completion of the study, so honoraria were distributed at key milestones. The compensation did not depend upon the use of any tobacco or nicotine-containing products, including their own combustible cigarettes or study-provided nicotine pouches.

Results

Recruitment

This pilot study was successful in terms of designing and evaluating all the procedures and processes necessary for a full-scale AUS. A total of 3690 candidate participants were screened online, 223 were interviewed by telephone, and 137 met all criteria, including preliminary interest in the study product, and were scheduled for a screening and enrollment visit. There was a 20% no show rate for the screening and enrollment visit, and a screen fail rate of 7% at the screening and enrollment visit.

Once the target sample size of 100 was achieved, screening was discontinued. The predominant reasons for not qualifying for the study were not being a daily smoker of the minimum of 7 CPD, having previously used Velo Pouches, no interest in using

the study product, and currently quitting or planning to quit all TNP use in the next 8 weeks.

Participant Demographics

Participant demographic characteristics at enrollment are presented in [Table 1](#) (n=100). All participants in the final analysis set (n=99 after exclusion of 1 participant who did not fulfill criteria of using at least 1 pouch) started regular smoking more than 12 months prior to study entry. Participants' self-reported CPD mean was 14.6 (SD 5.72) during the 6 months prior to study entry, and just over half (59/99, 60%) of

participants reported also using other types of tobacco products (eg, electronic nicotine delivery systems, smokeless tobacco) within the past 30 days. Approximately half (49/99, 50%) were classified as having low nicotine dependence based on a total score of 4 or less on the Fagerström Test for Nicotine Dependence [23].

Over the study period there was very low attrition (3%: 1 withdrawal, 2 lost to follow-up). Attendance at each site visit was high, with only 3 participants missing a scheduled site visit 2 or 3.

Table 1. Participant demographic characteristics at enrollment (n=100).

Characteristic	Value
Age (years), mean (SD)	48.1 (11.03)
Age category (years), n (%)	
21-48	48 (48.0)
>49	52 (52.0)
Gender, n (%)	
Male	56 (56.0)
Female	44 (44.0)
Nonbinary	0 (0.00)
Race, n (%)	
White	61 (61.0)
Black or African American	35 (35.0)
All other	4 (4.0)
Ethnicity, n (%)	
Hispanic or Latino	6 (6.0)
Not Hispanic or Latino	94 (94.0)
Education, n (%)	
Some high school	2 (2.0)
High school degree or equivalent	58 (58.0)
College graduate	40 (40.0)
Income (\$), n (%)	
<39,999	31 (31.0)
40,000-79,999	50 (50.0)
>80,000	19 (19.0)
Employment, n (%)	
Working now	70 (70.0)
Not working	30 (30.0)

eDiary Experience and Compliance

The eDiary was well received with very high participant compliance. More than 90% (91-93/99, 92%-94%) of participants were fully compliant with daily eDiary entries, and 97% (95-98/99, 96%-99%) reported their product use at least 5 days during each week of the AUP.

Only a small number of participants (15/99, 15%) required reminder calls (a total of 19 calls) if they had not completed the diary at the end of the day.

In addition to the functional success of study procedures and processes, the study was viewed positively by participants with 93% (92/99) satisfied with the experience and 95% (94/99) were being likely to recommend the study to others (87/99, 88% very likely; 7/99, 7% likely).

Some participants suggested improvements for future studies such as providing more flexibility around time frames to complete the eDiary (9 mentions). Others indicated a preference for a broader range of product options (flavors/nicotine levels; 5 mentions), and for remote interviewing (3 mentions).

The product use questionnaire showed that the majority of use was as described on the product packaging and communicated to participants during the informed consent process. In total, only 4 participants reported using Velo Pouches in any way other than instructed and none were associated with any AE report. One participant sucked the pouch, one moistened the pouch with water, one moistened the pouch on the tongue, and one participant used two pouches at the same time. Further, 15 participants used the product at the same time as another TNP, two accidentally swallowed the pouch, and 38 reported spitting out saliva while using the product. No safety issues emerged during the study, and no AE reports required adjudication.

Product Use

In the first week of the AUS (following the baseline assessment period), all participants tried the study ONPs (Figure 2). Over time, the proportion of participants using ONPs decreased (from 0% reporting no use in week 1 to 15.5% [15/97] in week 6). Among those who continued using the ONPs, the average pouches per day increased (Figure 2, darker bars). Whereas the proportion of participants using between 1 and 6 pouches per day decreased between week 1 and week 6 (71/99, 72%, to 40/97, 41%), the proportion using 7 or more pouches per day increased from 27% (27/99) in week 1 to 42% (41/97) in week 6.

Of interest for potential tobacco harm reduction, combustible cigarette use decreased over the study period for 82% (79/97) of the study participants (see Figure 3). At week 6, approximately 16% (15/97) of participants reduced their cigarette consumption by more than 50%, 18% (17/97) reduced their CPD between 30% and 50%, and almost half (47/97, 49%) reduced their CPD between 1% and 30%.

Figure 2. Changes in frequency of pouch use/day over 6-week actual use study.

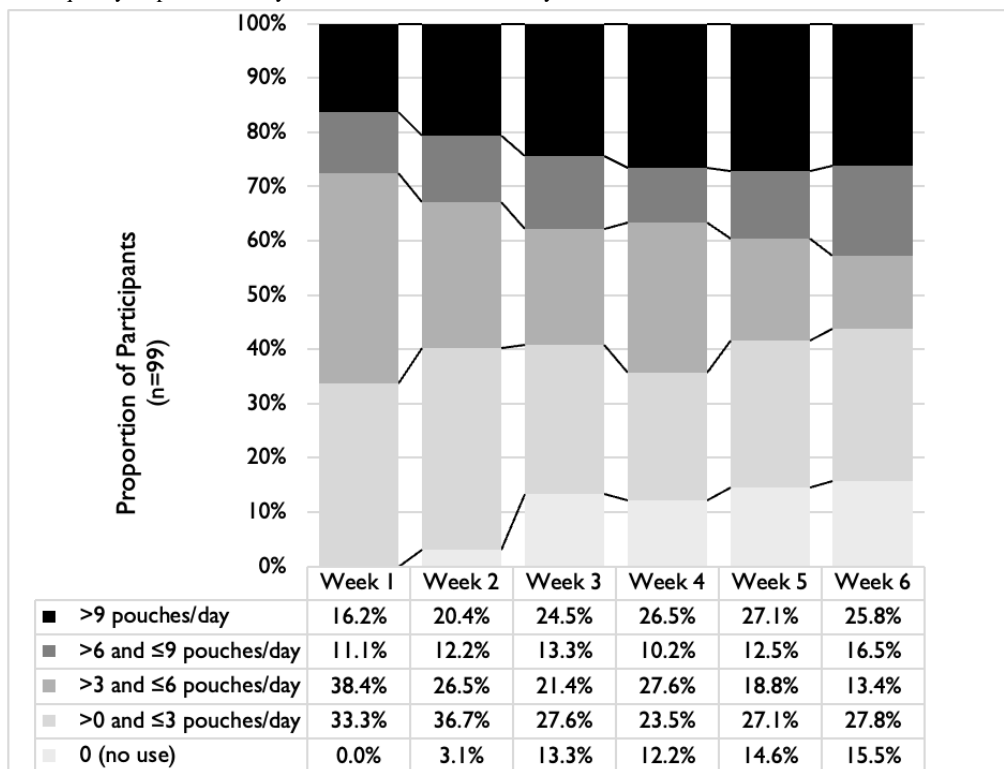
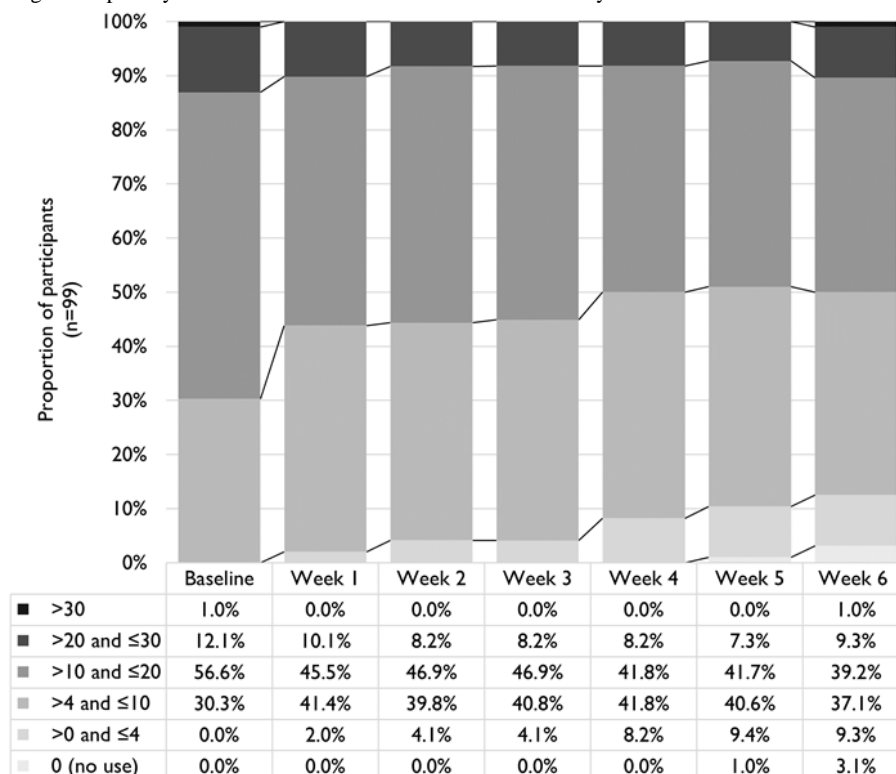


Figure 3. Changes in cigarettes per day use from baseline over 6-week actual use study.



Discussion

Principal Findings

The success of this pilot study in terms of methods and procedures relied on a detailed protocol, user friendly eDiary, and electronically administered questionnaires to capture study product and TNP use and other information about product use patterns. Experience during the pilot study execution highlighted some considerations to be incorporated in future AUS designs.

Selection Criteria

Because of the high level of dual use, particularly with electronic nicotine delivery systems, at baseline, future studies should consider maintaining a broad definition of eligible participants to encompass a real-world demography. Traditional studies on tobacco harm reduction have tended to use only daily combustible cigarette use as an entry criterion [24-26]. A definition of regular use may be more appropriate as product use behaviors are changing with increasing availability and acceptance of other forms of TNP [27,28].

Similarly, many daily smokers in the candidate pool did not meet the 7 CPD threshold. With the rise of combustible cigarette alternatives and an overall decline in combustible cigarette use, lower thresholds for study entry may be warranted to reflect the real-world behaviors of those likely to use the new products in the future, including for those looking to completely supplant combustible cigarette use [29]. Optimally, participants should have sufficient combustible cigarette daily use to detect a change in combustible cigarette use behaviors over the time of the study.

Candidate participants were excluded if they were quitting or intending to quit all TNP use. Future AUS may relax this criterion and allow the inclusion of those intending to quit

combustible cigarette but continue use of other TNP. This would allow for an investigation of differences in product use and changes in cigarette smoking among smokers who were not immediately interested in quitting all TNP [30].

Recruitment

Recruitment of the 100 planned pilot study participants via market research sites was successful. A larger AUS powered to achieve narrow confidence intervals around product adoption or CPD reductions may necessitate using additional recruitment strategies to boost or augment the number of combustible cigarette smokers in their databases and to increase diversity of enrollees. For example, a multimodal recruiting strategy may be needed to increase representation of younger adult smokers [31,32]. This pilot was conducted in only 4 sites and recruited a relatively large proportion of African American participants, while the number of those of other races and ethnicities was low. Identifying sites with higher populations of other important subgroups will also be helpful in expanding demographic diversity for future studies.

Product Use

Since there was no sampling of the product during the enrollment or baseline period, participants first opportunity to try the product was during week 1 of the AUP. Nearly all participants used pouches in the first 2 weeks. The majority rated their liking of the product as in between. By week 6, the number with strong positive reactions to the product increased, and the data suggest that those who did not like the product after trial discontinued use whereas those who liked the product increased their use. Furthermore, product use other than as directed was infrequent and did not suggest any significant modifications to procedures or participant instructions in future studies.

Although the number of enrolled participants was small and precludes a detailed statistical analysis and interpretation, the results of ONP uptake and CPD reduction provide a directional indication of potential product use in a real-world setting that can be tested in follow-up studies with larger sample sizes.

Comparison With Prior Work

The pilot results were in a positive direction for the potential of ONP to supplant combustible cigarette use, in line with preliminary trends seen in a recent ONP AUS with a larger sample size [11]. The study attrition was low, and eDiary compliance in our study was high as compared to other reported studies with shorter time frames [33]. Low attrition may be attributable to the compensation level and in-person payments being spread over the entire 8-week study. High eDiary compliance could have resulted from reinforced attention to the eDiary via intermittent marketing material delivery, regular reminders to complete the eDiary, and the close monitoring of the eDiary data by site staff. Once per day eDiary entries, rather than multiple entries throughout a given day, also helped to reduce the protocol burden on participants and improve compliance [34]. Given the eDiary success, one key learning from this study was to expand the technology used to manage the study. In this study, 2 systems were used for data capture—a central database for eDiary data and individual site spreadsheets for product dispensation and return. Integrating these data streams into a single portal-based system will improve efficiency in managing products, reconciling product use data, and requesting product-specific feedback so that item responses can be captured for only the products that have been distributed to a particular participant.

Consistent with moves toward more decentralized clinical trials [35,36], the pivot to remote monitoring due to COVID-19 was successful for this study and will be incorporated in future studies. Videoconferencing tools, electronic data capture, and electronic signatures allowed for more efficient and timely communication, expanded sponsor participation in on-site activities, and reduced travel-related costs and off-site supervision of participant interviews by monitoring staff.

Limitations

The main limitation of this actual use pilot study is its small size. However, the purpose of the study was to determine the logistic feasibility of conducting a full-scale study. Future studies with much larger sample sizes will have the power to test for explicit associations between combustible cigarette use and study product use and the variation by subgroups of interest (eg, by demographics or smoking history). As with all AUSs, general limitations exist. Participants were all incentivized to participate and received study product at no charge, both of which can limit generalizability.

All data collected were via participants' self-report in a real-world setting. Future AUSs could consider including measurement of change in any proximal biomarkers that could reflect more distal health outcomes. Collecting relevant biosamples (blood, urine, respiratory output) at the start and end of an AUP (especially if longer than a 6-week duration) could provide early indicators of improved health function

among those who reduce their cigarette consumption though use of study products. Since participants returned to each site for product fulfillment, a degree of social desirability bias is possible if participants believed the interviewers expected to see high levels of study product use. The informed consent form at enrollment explained the optional nature of using study product, which was reinforced in staff training and ongoing monitoring interviews. The eDiary data were consistently captured, regardless of the level of study product use.

All questionnaires and the eDiary relied on participants' recall of their TNP use, which can be affected by time since use, environmental considerations, and other factors outside the control of the investigators. With this in mind, participants were given a short, 2-day grace period to enter product use information. Including this small window around diary entries limited recall errors while improving participant compliance. Other research has demonstrated high degree of congruity between eDiary logs and actual combustible cigarette use [37]. Since all TNP uses were captured, the risk of differential recall for cigarettes versus pouches would be minimal and unlikely to be biasing. The small number of participants who required reminders to complete the diary the study would preclude meaningful analyses to gauge the potential impact of any delayed data entry bias, which could certainly be examined in a full larger AUS.

In the closeout questionnaire, a small number of participants made suggestions for future studies. These suggestions can be considered in the design of future studies, although there are limitations to their applicability. Participants suggested more product choices, which will be determined by future research needs and market changes. Some suggested expanding the time frame of eDiary completion, which would necessitate a trade-off between satisfying individual preference flexibility against the minimization of programming and analytic complexity. Finally, a few suggested the preference for being interviewed remotely. This practice is now much more common in accommodation of the COVID-19 pandemic and would be very helpful for several reasons. It could greatly expand the geographical and demographic diversity of participants, who could be interviewed at time convenient to them without needing transportation, childcare, or time away from work, and would allow for increased efficiency and consistency across all sites with the use of remote interviewers. The challenge remains that any AUS would still require close product accountability and means to get products into the hands of age-verified respondents (and return of unused products), in a regulatory environment where there can be significant legal and logistical restrictions to remote distribution of study products.

Conclusions

This pilot (and other research studies) provides an opportunity to assess the impact of product introduction on existing product use patterns. The initial trends from this work provide evidence that the availability and use of this alternative TNP may be associated with combustible cigarette reduction or smoking cessation use and thus has the potential to positively impact public health. The execution of this pilot study with very low participant attrition, successful daily eDiary data collection, and

strong participant satisfaction indicate a high likelihood of success for future fuller AUS with much larger samples and broader geographical distribution. If regulatory and legal challenges can be overcome and alternative study product distribution methods become available (eliminating attendance at sites in person), such studies will be able to attract a broader demographic mix, especially among groups of participants with

barriers to study participation because of logistical difficulties. Finally, as we look to the future and the ultimate public health goal of reducing the deleterious impact of cigarette smoking on the public health, incorporating biomarkers of exposure/biological effect and biomarkers of potential harm in AUSs could provide early indicators of ultimate improved health outcomes.

Acknowledgments

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Authors' Contributions

All authors contributed to study design, execution, and preparation of the manuscript.

Conflicts of Interest

The study was sponsored by RAI Services Company and managed by Kantar Health LLC (now Cerner Enviza, an Oracle company). CC, PSM, and SAB are full-time employees of RAI Services Company. RAI Services Company is a wholly owned subsidiary of Reynolds American Inc, which is an indirect wholly owned subsidiary of British American Tobacco plc. MF, CK, and JC are full-time employees of Cerner Enviza.

Multimedia Appendix 1

Baseline Assessment Questionnaire items.

[[DOCX File, 47 KB - formative_v6i8e37573_app1.docx](#)]

Multimedia Appendix 2

Product Experience Questionnaire.

[[DOCX File, 21 KB - formative_v6i8e37573_app2.docx](#)]

Multimedia Appendix 3

Product Use Questionnaire.

[[DOCX File, 22 KB - formative_v6i8e37573_app3.docx](#)]

Multimedia Appendix 4

Closeout Questionnaire.

[[DOCX File, 22 KB - formative_v6i8e37573_app4.docx](#)]

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Abbreviations

- AE:** adverse event
- AUP:** actual use period
- AUS:** actual use study
- CPD:** cigarettes per day
- eDiary:** electronic diary
- FDA:** US Food and Drug Administration
- ONP:** oral nicotine pouch
- TNP:** tobacco or nicotine-containing product

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Original Paper

Assessing the Feasibility of Studying Awareness of a Digital Health Campaign on Facebook: Pilot Study Comparing Young Adult Subsamples

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Abstract

Background: Mass media campaigns for preventive health messaging have been shown to be effective through years of research. However, few studies have assessed the effectiveness of campaigns on digital media, which is currently how youths and young adults are primarily consuming media. In particular, a platform that can accurately assess exposure to digital messaging in a real-life setting has yet to be developed.

Objective: This study examines the feasibility of a unique survey platform, Virtual Lab, to conduct a study on exposure to a media campaign within Facebook using a chatbot-style survey administration technique.

Methods: Virtual Lab is a survey platform that was used to recruit and survey participants within Facebook and Facebook Messenger, respectively. We created a Facebook business account with 2 Facebook pages: one for recruitment and disseminating the survey and the other one for serving the target advertisements. Pre- and postexposure surveys were administered via Facebook Messenger using a chatbot-style questionnaire 1 week apart. During this time, the target advertisements were shown to participants who completed the pre-exposure survey. The total time from recruitment to completion of the postexposure survey was 13 days, and incentive costs were US \$10 per participant. Survey data were compared between those who completed both pre- and postexposure surveys and those who only completed the pre-exposure survey; that is, those who were lost to follow-up. The demographics of the complete cases were also compared to the US census data.

Results: A total of 375 Facebook users aged between 18 and 24 years met eligibility requirements and consented to the study, which consisted of complete cases (n=234) and participants lost to follow-up (n=141). A few differences between complete cases and participants lost to follow-up were observed. Regarding gender, complete cases comprised 40.2% males and 59.4% females, and among participants lost to follow-up, 44.0% were male and 50.4% were female ($P=.003$). Differences were also observed for e-cigarette use status, where a greater number of current users and fewer past and never users were lost to follow-up than complete cases ($P=.01$).

Conclusions: The use of Virtual Lab yielded a diverse sample quickly and cost-effectively. Demographic characteristics of participants who completed the study and those who were lost to follow-up were similar, indicating that no biases were caused by the platform during recruitment or testing. This study suggests the feasibility of the Virtual Lab survey platform for studies of media campaign exposure within Facebook. This platform can advance health campaign research by providing more accurate data to inform digital messaging.

KEYWORDS

campaign evaluation; outcome evaluation; young adults; social marketing; health communications; tobacco control and policy; health campaign; youth; Facebook; digital media

Introduction

Mass media campaigns have been shown to be effective in preventive public health efforts, such as tobacco countermarketing [1,2]. Media campaigns have adapted to using digital media to disseminate health messages, particularly among target audiences that include youth and young adults. Having sufficient exposure of media campaigns is important to measuring their effectiveness [3]. However, a feasible platform to accurately assess exposure, awareness, and outcomes of digital messaging in a real-life setting is yet to be developed, which would ultimately help health communication researchers execute more accurate methodology for campaign evaluation and inform audience segmentation.

In recent years, the transition from a traditional media landscape (TV, newspaper, etc) to consuming digital media via social platforms and streaming services has been largely driven by youths and young adults [4]. With 81% of teens now using social media and more than 33% using social media sites multiple times in an hour, digital media has undoubtedly become a large part of youths' and young adults' lives [5,6]. A majority of 18-29-year-olds use social media platforms such as TikTok, Instagram, and YouTube, and 70% of 18-29-year-olds use Facebook [7]. This transition has occurred at a faster pace than research on how to measure campaign exposure in a digital landscape.

While TV uses standardized gross rating points, the fragmentation of digital media and the way in which people experience digital media have made it complex to determine a standardized encompassing metric. In digital media, advertising is often skippable and perceived as more of a disturbance [8,9], and the obstacles of data privacy make it complicated to obtain or create metrics that are standardized across platforms and parsimonious. There is little research on exposure of media campaigns in a real-life digital setting, likely owing to limited options of viable platforms [10,11]. An increasing number of studies are being conducted within social media, specifically Facebook, to recruit participants [12-14], as well as to assess the feasibility of using Facebook to reach and survey youths and young adults about the use of tobacco and other substances [15,16].

Our pilot study utilized Virtual Lab, a platform that enables research studies to be conducted on Facebook. Recruitment of

participants and exposure to target advertisements occur on Facebook. The surveys are disseminated within Facebook Messenger using a chatbot questionnaire, which has been shown to increase user engagement, user satisfaction, and data quality over traditional web surveys [17-19]. The feasibility of Virtual Lab would allow for quick recruitment of participants and delivery of results, as well as easy navigation of a dashboard during data collection, while remaining cost-effective. The ability to conduct research within the same platform on which campaigns are actively being conducted is important to the progress of campaign evaluation research. The objective of this study was to determine the feasibility of the Virtual Lab platform to recruit participants and assess awareness of an anti-e-cigarette health campaign on Facebook.

Methods

Recruitment

Virtual Lab is a survey platform used to recruit and survey participants within a social media platform, and is owned and run independently of social media companies [20]. To utilize what Virtual Lab has to offer, specifically within Facebook, the first step was to create a Facebook business account. To prevent potential biases, the account was given a general name, "Digital Health Research." Under this account, we created a Facebook page, "Digital Media Experiment," to host advertisements for recruitment purposes. In order to demonstrate the credibility of the page, we posted relevant content and acquired likes. We used this Facebook Page to run recruitment advertisements during August 5-12, 2021. The recruitment advertisements were shown to our target population of people aged 18-24 years and located in the United States. The two recruitment advertisements used in this feasibility study (Figure 1) were designed using the 99designs website. The advertisements used the text "Take a 15 minute survey, get paid \$10." After participants clicked on the study's advertisement, they were sent a message via Facebook Messenger inviting them to participate in the study.

Under the same business account, we created another Facebook page named "Consumer Consciousness," which was solely used to run the target advertisements on the enrolled participants' Facebook Newsfeeds during August 20-26, 2021. We created this second Facebook Page with a different name to prevent biases.

Figure 1. Recruitment advertisements shown on potential participants' Facebook pages.



Ethical Considerations

Privacy measures include encryption of data that are stored and in transmission. Before beginning the pre-exposure survey, participants were sent messages regarding the topic of the survey, compensation, privacy measures, and contact information if they had any questions. Following those messages, the participants were sent a message asking for consent for their participation in the study and if they would like to continue. All studies were reviewed and approved by the institutional review board at George Washington University (NCR202837).

Survey Implementation

The pre- and postexposure surveys were completed using a survey platform called Typeform, which is supported by Virtual Lab. After designing the surveys in Typeform, they were linked to our Facebook business account and pages using the Virtual Lab interface. Typeform used our “Digital Media Experiment” page to send automated messages through Facebook Messenger, similar to a chatbot, to participants who clicked on the recruitment advertisements. Through Typeform, we were able to create logic jumps based off participants’ responses and confirm that they met the recruitment criteria. If participants did not meet the eligibility criteria, they were thanked for their participation and the survey ended. If the participants met the eligibility criteria, they were allowed to continue the survey.

After participating in the pre-exposure survey administered by the “Digital Media Experiment” page, respondents randomized to be exposed were shown the target advertisement via the “Consumer Consciousness” page in their Facebook Newsfeeds. All participants were invited to take the postexposure survey a

week after completion of the pre-exposure survey. The postexposure survey was also administered by the “Digital Media Experiment” page via Facebook Messenger.

Measures

The pre-exposure survey consisted of questions to determine demographic characteristics and e-cigarette status. Questions determining demographics included age, gender, sexual orientation, combined race and ethnicity, and perceived financial status. e-Cigarette use status was determined through 2 questions: an ever-use question, “Have you ever tried using any e-cigarette/vape (even 1 or 2 puffs)?” with response of “yes” or “no.” For those who responded with “yes,” there was a current-use question, “During the past 30 days, on how many days did you use an e-cigarette (even 1 or 2 puffs)?” where they could respond with 0-30 days. Respondents were classified as never users if they responded with “no” to the ever-use question, as past users if they responded with “yes” to the ever-use question and 0 to the current-use question, and as current users if they responded with “yes” to the ever-use question and >1 days to the current-use question.

Intentions to use e-cigarettes was determined by asking the question, “Do you think you will use an e-cigarette (even 1 or 2 puffs) in the next year?” Answer choices were “definitely not,” “probably not,” “probably yes,” and “definitely yes,” where “definitely not” was coded as no intentions to use and all other choices were coded as having intentions to use. Intentions to quit using e-cigarettes was only asked of current users: “Are you seriously thinking about quitting e-cigarettes/vapes for good?” The responses were dichotomized where “No, I am not thinking about quitting” was coded as no quitting intentions and the following were coded as having

intentions to quit: “Yes, but not within the year,” “Yes, within the year,” “Yes, within the next 6 months,” “Yes, within the next 30 days,” and “I’ve already quit.”

The post-survey included questions for e-cigarette use status and intentions to use and quit, as listed above, as well as questions about the target advertisement they were exposed to between taking the pre- and postexposure surveys. These questions were asked in the pilot study to ensure feasibility for the proceeding full study. Participants were first shown an advertisement they were exposed to and asked if they can see and hear the video. If they responded with “no,” they were directed to the end of the survey. Those who responded with “yes” were asked how many times they have seen the advertisement, receptivity questions on what they thought of the advertisement, and about actions they would take after seeing the advertisement. This series of questions on the target advertisement were then repeated for the second target advertisement.

Statistical Analysis

A series of descriptive analyses were conducted to examine the feasibility of recruitment methods and the diversity of samples. Survey data were compared between complete cases and participants lost to follow-up and among different e-cigarette use status groups. Complete cases were defined as participants who completed the survey through the last question in the postexposure survey. Loss to follow-up was defined as participants having been lost at any point before the last question in the postexposure survey.

In analysis 1, we compared sample demographics and use status between complete cases and participants lost to follow-up. For continuous measures, means and SDs were obtained and *t* tests were conducted to compare differences between groups. For categorical measures, frequencies and proportions were obtained and Pearson chi-square tests were conducted. The analysis included the number of missing participants to observe the difference between complete cases and participants lost to follow-up.

In analysis 2, we compared sample demographics with the US national survey data. Race and ethnicity were compared by sex between the US population and complete cases collected in this study. The US national demographics for the population aged 18-24 years were retrieved from the US Census Bureau as of 2019 (the most recently available year). We conducted chi-square tests to evaluate the difference of proportions of these demographics between the US population and the study sample. Analyses were conducted using Stata SE 15 (StataCorp) and Excel (Microsoft Inc).

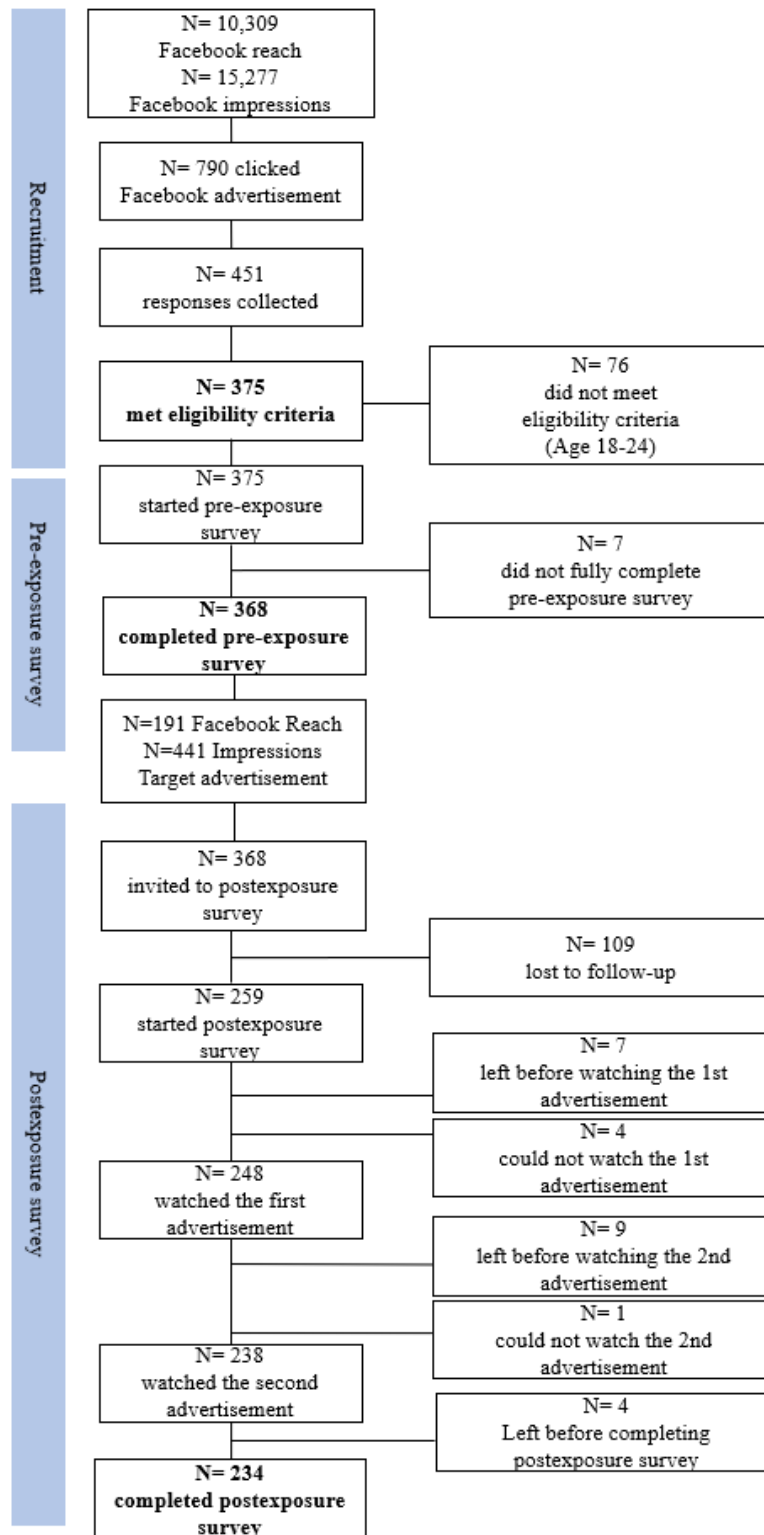
Results

Recruitment and Target Advertisements

The study’s Facebook recruitment advertisements had a reach of 10,309, which is defined as the number of unique individuals who saw the advertisement at least once. The recruitment advertisement generated 15,718 impressions—that is, the number of times the advertisement was displayed on a person’s screen—and was clicked a total of 790 times. The percentage of times a person saw the recruitment advertisement and clicked on it, or the Link-Click-Through Rate, was 4.77%. The study’s Facebook target advertisements had a reach of 191 unique individuals and generated 441 impressions. The target advertisements were played a total of 353 times and were played to 100% of their length only 11 times. The largest drop after any play time to 25% of the total advertisement length was from 25% to 50% of their length (70 and 29 times, respectively). The advertisements were played to 75% of their length 19 times. A visual representation of the in-platform recruitment data is shown in [Figure 2](#).

The subsample of participants lost to follow-up consisted of participants who began the pre-exposure survey but did not finish ($n=7$), completed the pre-exposure survey but did not begin the postexposure survey ($n=109$), started the postexposure survey but did not watch the first or second advertisement ($n=21$), and watched both advertisements but did not complete the postexposure survey ($n=4$). If they did not watch either advertisement in the postexposure survey, it could have been because they left the survey or responded that they could not see or hear the advertisement.

Figure 2. Flowchart of sample recruitment and retention.



Sample Characteristics

Sample demographics are summarized in Table 1 and organized by the total sample (n=375) and subsamples of those who completed both surveys (n=234) and those lost to follow up (n=141). Participants included 375 Facebook users aged 18 to

24 years. They were on average 21 (SD 2.0) years old, 56.0% female, and racially and ethnically diverse (45.6% non-Hispanic White, 12.0% Hispanic, 10.1% non-Hispanic Black or African American, or 23.7% non-Hispanic Asian). Of them, 45.6% were never users, 20.5% were past users, and 33.3% were current users.

Table 1. Demographics and e-cigarette use status between complete cases and participants lost to follow-up (N=375).

Variables	Total participants	Complete cases (n=234)	Participants lost to follow-up (n=141)	P value
Age (years), mean (SD)	21.0 (2.0)	21.1 (2.0)	20.8 (2.0)	.14
Gender, n (%)				.003
Male	156 (41.6)	94 (40.2)	62 (44.0)	
Female	210 (56.0)	139 (59.4)	71 (50.4)	
Other or missing	9 (2.4)	1 (0.4)	8 (5.7)	
Sexual orientation, n (%)				.69
Heterosexual	240 (64.0)	155 (66.2)	85 (60.3)	
Homosexual	29 (7.7)	17 (7.3)	12 (8.5)	
Bisexual	63 (16.8)	36 (15.4)	27 (19.1)	
Other or missing	43 (11.5)	26 (11.1)	17 (12.1)	
Race and ethnicity, n (%)				.28
Non-Hispanic White	171 (45.6)	102 (43.6)	69 (48.9)	
Hispanic	45 (12.0)	30 (12.8)	15 (10.6)	
Non-Hispanic Black or African American	38 (10.1)	22 (9.4)	16 (11.3)	
Non-Hispanic Asian	89 (23.7)	63 (26.9)	26 (18.4)	
Other/missing	32 (8.5)	17 (7.3)	15 (10.6)	
Financial status, n (%)				.11
Live comfortably	119 (31.7)	75 (32.1)	44 (31.2)	
Meet needs with a little left over	135 (36.0)	94 (40.2)	41 (29.1)	
Just meet basic expenses	69 (18.4)	39 (16.7)	30 (21.3)	
Do not meet basic needs	21 (5.6)	11 (4.7)	10 (7.1)	
Decline to answer/missing	31 (8.3)	15 (6.4)	16 (11.3)	
e-Cigarette use status, n (%)				.01
Never user	171 (45.6)	112 (47.9)	59 (41.8)	
Past user	77 (20.5)	56 (23.9)	21 (14.9)	
Current user	125 (33.3)	66 (28.2)	59 (41.8)	
Missing	2 (0.5)	0 (0.0)	2 (1.4)	

Analysis 1

The proportions for gender and use status differed between complete cases and participants lost to follow-up. Complete cases comprised 40.2% males and 59.4% females, whereas participants lost to follow-up comprised 44.0% males and 50.4% females ($P=.003$). Based on chi-square analysis, the statistical difference found for gender was driven by the “other/missing” category. Complete cases comprised 47.9% never users, 23.9% past users, and 28.2% current users, whereas participants lost to follow-up comprised 41.8% never users, 14.9% past users, and 41.8% current users ($P=.01$); the largest difference was observed among current users. Age, sexual orientation, race and ethnicity, and financial status did not significantly differ between groups.

Analysis 2

The proportions of gender and race and ethnicity in complete cases in the study sample were significantly different from the US census data, as shown in Table 2. The sample comprised 40.3% males and 59.7% females, whereas the US census data set comprised 51.3% males and 48.7% females ($\chi^2_{1,233}=11.2$, $P<.001$). The sample included 43.4% Non-Hispanic White, 12.9% Hispanic, 9.4% Non-Hispanic Black or African American, and 27.0% Non-Hispanic Asian participants. This was significantly different from the US census data set that comprised 53.7% Non-Hispanic White, 22.1% Hispanic, 14.3% Non-Hispanic Black or African American, and 5.5% Non-Hispanic Asian participants ($\chi^2_{4,233}=218.4$, $P<.001$).

Table 2. Demographics between US national survey and complete cases among 18–24-year-olds.

Race and ethnicity	US national survey ^a			Complete cases		
	Total sample, %	Males, %	Females, %	Total sample, %	Males, %	Females, %
Non-Hispanic White	53.7	51.4	48.6	43.4	43.6	56.4
Hispanic ^b	22.1	51.5	48.5	12.9	43.3	56.7
Non-Hispanic Black or African American	14.3	50.7	49.3	9.4	9.1	90.9
Non-Hispanic Asian	5.5	50.8	49.2	27.0	49.2	50.8
Other/missing	4.4	50.5	49.5	7.3	23.5	76.5
Total	100	51.3	48.7	100	40.3	59.7

^aSource: American Community Survey 5-Year Estimates–Public Use Microdata Sample 2019.

^bDerived as the difference between total and non-Hispanic counts from the US Census Bureau.

Discussion

Principal Findings

To our knowledge, this is the first study to examine the utility of Virtual Lab within the real-life setting of Facebook as a viable platform for media campaign awareness studies. The results of this pilot study provide support for continued use of the Virtual Lab platform to recruit participants and obtain data from a nationwide sample.

We found that recruitment yielded a diverse sample, consistent with other convenience samples [10,21], and it was carried out cost-effectively and quickly. Within 1 week of recruitment and 1 week of conducting the study, 375 respondents participated in the study with a total of 234 to complete the study. Including the US \$5 Amazon e-gift cards for each survey, the total cost for incentives per respondent was approximately US \$10 [22]. There were additional costs for executing the study and recruitment, which vary on the basis of project goals and sample size; expenses remained lower than those on other survey platforms. Overall, this is a low-cost data collection option with great potential for high reach and customized sampling by respondent characteristics via longitudinal panel research on a social media platform.

Most demographic characteristics were similar between those who completed the study and those who were lost to follow-up, indicating that the platform is not causing biases in recruitment or testing to result in certain groups dropping out of the study at greater rates than others. Chi-square analysis showed a difference in gender between complete cases and participants lost to follow-up. This was also observed when comparing the samples to the US census data. However, a resulting sample with a greater proportion of females than males is commonly seen in surveys using a convenience sample [10,21]. Although the sample lost to follow-up shows a higher rate of current use status than that of the complete cases sample, the latter consists of a significant amount of past and current e-cigarette users, comprising over 50% of the sample. e-Cigarette use status in the completion sample is also similar to nationwide prevalence numbers, deeming the sample to still be valuable and representative.

Limitations

Although the results support the feasibility of the Virtual Lab platform, there are some limitations to this study. First, a large proportion (37.6%) of the eligible starting sample of the pilot study was lost to follow-up. Efforts to bolster retention are being made for the proceeding study, including increasing compensation for participation and speed of distribution of compensation. Second, this study only examined the feasibility of Virtual Lab on Facebook. Thus, the feasibility of Virtual Lab on other social media platforms, such as Instagram, will require future research once it becomes available. Third, there were limitations in the ways to ask questions within Facebook Messenger using the Typeform platform. One of these limitations includes the inability to select more than one response for a question, such as identification of race and ethnicity. In order to address this limitation, we programmed the survey to repeat questions where multiple-choice responses would normally be available until the participant indicated that they had selected all relevant responses. Another limitation we encountered when converting the Typeform survey to Facebook Messenger was the inability to boldface words.

Digital health is a growing field, but there has been relatively little research using social media platforms to recruit participants, deliver interventions, and collect data. The ability to follow up with participants over time and collect data in a low-cost, rapid, and relatively low-burden manner offers tremendous potential for social media health research and interventions. It can lead to more effective campaign interventions that aim to improve youth and young adults' health behaviors, such as substance use prevention. This study suggests that such intervention studies are feasible and may be a valuable tool for researchers. Future studies should include randomized controlled trials in real-world settings on Facebook and other social media, provide social media stimuli aimed at health behavior change, and follow participants over time to evaluate outcomes.

Conclusions

The development and use of a platform that allows for experimentation within social media platforms is essential for the progress of mass media campaign evaluation research. Virtual Lab, a new cost-effective platform that allows for

customized recruitment and longitudinal follow-up of participants and execution of survey research on Facebook, has shown to be feasible for media campaign awareness studies.

Importantly, with the use of Virtual Lab, research can result in more accurate data to inform health campaigns and their dissemination.

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Conflicts of Interest

None declared.

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Original Paper

Digital Content-Free Speech Analysis Tool to Measure Affective Distress in Mental Health: Evaluation Study

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Abstract

Background: Mood disorders and depression are pervasive and significant problems worldwide. These represent severe health and emotional impairments for individuals and a considerable economic and social burden. Therefore, fast and reliable diagnosis and appropriate treatment are of great importance. Verbal communication can clarify the speaker's mental state—regardless of the content, via speech melody, intonation, and so on. In both everyday life and clinical conditions, a listener with appropriate previous knowledge or a trained specialist can grasp helpful knowledge about the speaker's psychological state. Using automated speech analysis for the assessment and tracking of patients with mental health issues opens up the possibility of remote, automatic, and ongoing evaluation when used with patients' smartphones, as part of the current trends toward the increasing use of digital and mobile health tools.

Objective: The primary aim of this study is to evaluate the measurements of the presence or absence of depressive mood in participants by comparing the analysis of noncontentual speech parameters with the results of the Patient Health Questionnaire-9.

Methods: This proof-of-concept study included participants in different affective phases (with and without depression). The inclusion criteria included a neurological or psychiatric diagnosis made by a specialist and fluent use of the German language. The measuring instrument was the VoiceSense digital voice analysis tool, which enables the analysis of 200 specific speech parameters based on machine learning and the assessment of the findings using Patient Health Questionnaire-9.

Results: A total of 292 psychiatric and voice assessments were performed with 163 participants (males: $n=47$, 28.8%) aged 15 to 82 years. Of the 163 participants, 87 (53.3%) were not depressed at the time of assessment, and 88 (53.9%) participants had clinically mild to moderate depressive phases. Of the 163 participants, 98 (32.5%) showed subsyndromal symptoms, and 19 (11.7%) participants were severely depressed. In the speech analysis, a clear differentiation between the individual depressive levels, as seen in the Patient Health Questionnaire-9, was also shown, especially the clear differentiation between nondepressed and depressed participants. The study showed a Pearson correlation of 0.41 between clinical assessment and noncontentual speech analysis ($P<.001$).

Conclusions: The use of speech analysis shows a high level of accuracy, not only in terms of the general recognition of a clinically relevant depressive state in the participants. Instead, there is a high degree of agreement regarding the extent of depressive impairment with the assessment of experienced clinical practitioners. From our point of view, the application of the noncontentual analysis system in everyday clinical practice makes sense, especially with the idea of a quick and unproblematic assessment of the state of mind, which can even be carried out without personal contact.

Trial Registration: ClinicalTrials.gov NCT03700008; <https://clinicaltrials.gov/ct2/show/NCT03700008>

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KEYWORDS

mobile health; mHealth; depression; assessment; voice analysis; evaluation; speech; speech analysis; tool; distress; mental health; mood; diagnosis; measurement; questionnaire; mobile phone

Introduction

Background

Mental illnesses are highly important worldwide [1]. In particular, affective disorders such as depression or anxiety lead to considerable distress in individuals who are affected [2]. In addition, these disorders are an economic and social burden to society [3]. To recognize the need for care and the effects of ongoing treatment or treatment that may need to be adapted quickly, contact with mental health professionals (physicians, trained nursing staff, or psychologists) is essential [4]. Still, many of the patients were in primary care treatment without mental health specialization, only with short-time contact with a physician and did not reach complete remission [5]. In addition to the difficulty of getting an appointment with a professional, there is a problem of fluctuations in the symptoms [4], which makes it challenging to determine clinical symptoms. The calls to implement measurement-based treatment in psychiatry are increasing; however, clinician-rated assessments and patient-reported outcomes may be complex [6]. Therefore, the necessity for new assessment methods is undisputed, with which more frequent or even regular progress control is possible.

For several years, such assessments have been known as ecological momentary assessment (EMA) [7,8]. With the development of digital technologies, particularly smartphones, they have been extensively studied [9]. Conventional measurement methods are either digitized or mobilized. Diverse approaches have also been undertaken to develop and evaluate new measurement methods that were previously not feasible; for example, use of wearables measuring biological and behavioral indices such as temperature, movement, or heart rate [10]. Such procedures result in 2 advantages from the point of view of the practitioner: on the one hand, it is possible to collect findings from real life in a close-meshed manner [11]; on the other hand, the application of the technology enables the person concerned to do part of the recovery process himself and control what increases compliance [12]. The application of EMA allows a short assessment to be performed frequently and under conditions of everyday life [7].

The importance of language and voice in conveying feelings, emotions, and moods is undisputed, and impairments in speech production are well known in mood disorders [13-15]. The content of the spoken word (the "text") [16] and nonverbal aspects (speaking style, flow of language, speech melody, etc) are both relevant and relatively independent [17-19]. Even without social interaction, inner speech is essential for the development of self-worth and self-efficacy, as well as for reflecting on experience and relational framing [20]. Human language as a form of expression, with human listening on the other side, has been the basis of professional therapeutic support for mental disorders for more than 100 years [21]. Recent developments in linguistic and psychological research in

relational frame theory have been acceptance-based treatments, such as acceptance and commitment therapy [22,23].

In the last few decades, advances in digital technology to diagnose or treat mood disorders have been enormous and have enabled a wide range of applications [24]. The worldwide spread of smartphones is so pronounced that an overwhelming proportion of people have access to this technology [25]. This also allows a better acquisition of voice recordings over a distance than was possible a few years ago, and the development of calculation power to push forward machine learning in different ways allows more intensive and detailed analysis of speech and voice [26,27]. By developing and applying unique algorithms, attempts can now be made to map the performance of active human listening and the associated assignment of emotions and moods [26]. This technique using machine learning should then be applied in the sense of an EMA in everyday life to record depressive moods and, ideally, observe the therapeutic effect and course [28].

It is well known that human speech is not simply the process of opening and closing the mouth but a more complex process involving more than 100 muscles, powered by many different brain regions, especially the auditory cortex, somatosensory cortex, and other brain parts and networks working in language perception and speech production [29]. There are many different acoustic features, such as pitch, speed, sound intensity, jitter, tremor, and vowel space, which are different in depressed patients compared with nondepressed persons. Research has been conducted to improve the knowledge of single-person aspects [30]. Thus, we have learned in the past that experienced clinicians or close friends can realize altered acoustic features in the case of depression, but it should be an essential perspective to implement accurate algorithms to analyze these parameters correctly without human supervision.

This study uses a noncontent linguistic analysis algorithm developed by VoiceSense, a company specializing in prosodic speech analysis, which links speech patterns to behavioral tendencies. Using machine learning technology to analyze data obtained from the speech or voice of patients with mental health complaints could be helpful to (1) complement the assessments of experienced psychiatrists or not-so-experienced physicians in primary care and (2) monitor the symptomatology of patients between consultations. This technology could optimize treatment procedures by learning the success rates of different individual treatments [31]. However, it is essential to train and check the machine learning algorithms and prove the algorithms repeatedly using samples with English or non-English native speakers, different mental states, or defined mental disorders in a longitudinal study [32].

This study provides a structured setting for the differentiated evaluation of psychopathological factors (effects, personality aspects, psychomotor factors, etc) using speech pattern analysis.

Research Objectives

The primary objective of this study was to examine the depression severity state of patients with depression, as measured by the Patient Health Questionnaire-9 (PHQ-9), compared with their acoustic vocal patterns.

We hypothesized that the vocal analysis system could confirm depression severity classification performed by an experienced psychiatrist consultant.

Methods

Setup

Participants

Participants were recruited in an outpatient neuropsychiatric treatment center.

The inclusion criteria were neurological or psychiatric diagnosis made by a psychiatric consultant who was not part of the study team and fluent use of the German language. The diagnostics were based on the International Classification of Diseases, 10th Revision criteria because they are binding in the German public health care system and the psychiatric consultant's experience.

Exclusion criteria included psychosis, dementia, speech or language disorders in neurological diseases, terminal or life-threatening illnesses, addiction history, a suicide attempt recently or in the last 12 months, or insufficient language skills.

Data collection took place between November 2018 and September 2019.

After removing participants who did not complete either the psychiatric assessment or audio collection, a total of 163 participants were included in the study, 47 (28.8%) of whom were men. We established a G-power calculation before starting

the study and calculated the necessity of 152 participants to reach the required power.

Assessment Sessions

Each participant participated in at least one assessment session (psychiatric and voice). In contrast, a part of the participants (100/163, 61.3%) took part in 2 assessment sessions, and a part of the participants took part in 3 (29/163, 17.8%) assessment sessions. Because of our proof-of-concept study setting, we set a relatively open frame for the participants and assessments. The number of assessments carried out was determined by the follow-up appointments of the attending physicians; participants who had one or more outpatient appointments with the therapist within a short period were asked to participate in the next assessment more frequently.

The time intervals between the first, second, and third sessions for the same participant were at least one week, ranging up to 3 months, so that the psychiatric state and the voice patterns could be different in the session, even for the same patients. Therefore, each participant session was treated as a separate data point in the sample and included an independent psychiatric assessment and voice analysis.

Number of Assessments

Overall, there were 292 psychiatric assessments and 292 recorded audio sessions for the 163 participants. These 292 sessions (psychiatric and voice) consisted of the data set sample to compare the psychiatric state and vocal patterns.

Demographic Characteristics

The participants were aged between 15 to 82 years. The participants were categorized into 6 age groups to examine age-related differences. [Table 1](#) shows the distribution of the participants and sessions across the demographic scales.

Table 1. Participants' distribution across demographic scales (N=163) and sessions (n=292).

Demographic category	Participants, n (%)	Sessions, n (%)
Gender		
Male	47 (28.8)	73 (25.0)
Female	116 (71.2)	219 (75.0)
Age group (years)		
15 to 20	8 (13.0)	17 (5.8)
21 to 30	57 (35.0)	112 (38.4)
31 to 40	46 (28.2)	81 (27.7)
41 to 50	24 (14.7)	39 (13.4)
51 to 60	21 (12.9)	32 (11.0)
61 to 82	7 (4.3)	11 (3.9)
Education level		
No completed education	38 (23.3)	70 (24.0)
Apprenticeship	53 (32.5)	93 (31.8)
Master craftsman certificate	7 (4.3)	16 (5.5)
University degree	60 (36.8)	102 (34.9)
Others	5 (3.1)	11 (3.9)
Marital status		
Single	77 (47.2)	148 (50.7)
Married or in a relationship	73 (44.8)	129 (44.2)
Living apart or divorced	12 (7.4)	14 (4.8)
Widowed	1 (0.6)	1 (0.3)
Current psychological treatment		
No	60 (36.8)	124 (42.5)
Yes	103 (63.2)	168 (57.5)

Tools

Psychiatric and Behavioral Assessments

To differentiate and compare depressive states, we used PHQ-9 with 9 questions, developed and published in 1999 [33]. This assessment was initially created for the screening and measurement of severity. The PHQ-9 score ranges from 0 to 27, because each of the 9 items can be scored from 0 to 3. A score of 3 indicates severe symptoms, and 0 indicates an absence of symptoms. The authors of the PHQ-9 described a model that

shows a high correlation between the 5 states of depression and between clinicians' diagnosis and severity classification, whereas other authors replicated the quality of the tool [34]. Validation of the tool included 3890 patients. We used the PHQ-9 for both the diagnosis and the severity classification.

The PHQ-9 scale consists of 5 depression categories. [Textbox 1](#) lists these 5 categories.

We also performed other measurements to compare vocational state with other mental problems or disorders, but the results will be published elsewhere.

Textbox 1. Patient Health Questionnaire-9 (PHQ-9) depression categories.

PHQ-9 scale and depression category
<ul style="list-style-type: none"> • 0 to 4: absence of depressive disorder • 5 to 10: subsyndromal symptoms • 10 to 14: mild symptoms • 15 to 19: moderate symptoms • 20 to 27: severe symptoms

Audio Collection Software

The participants' voices were recorded using the VoiceSense mobile audio collection app. VoiceSense mobile apps collect patients' audio for health care monitoring. The app required a log-in based on the coded ID of the participant to prevent personal identification. After log-in, the participant was presented with general questions (eg, "Please say in a few sentences on your social life. How often do you meet with friends? Do you spend quality time with your family?"). There are 9 such general questions, and the appl displayed 1 out of the 9 questions every time. The participant was requested to press *record*, answer vocally to the presented question, and press *stop recording* when completed. If required, additional questions were raised until at least 2 minutes of the participant's voice were collected. Once completed, the audio was uploaded to VoiceSense's cloud server for analysis using a special algorithm. During audio collection, the participants were alone in one of our testing rooms.

Vocal Analysis

The VoiceSense behavioral vocal analysis software analyzed the recorded voices of the patients based on previous work to code and train a machine learning analyzer.

VoiceSense behavioral vocal analysis software applies acoustic analysis, focusing on the prosodic features of speech. The analysis was language independent. The analysis does not use speech recognition, so there is no understanding of what has been said; hence, it is entirely content-free. To help the participants speak freely and noncontentually, they were presented with a set of questions ([Multimedia Appendix 1](#)). They had the option of either answering these questions or expressing their ideas and opinions.

According to the rules of the European Union regulations or the Defense Advanced Research Projects Agency of the US-Military (DARPA), we describe the process of analytics a little bit more in the next sentences not as a *black box* but as a process with 3 steps:

1. VoiceSense vocal analysis first calculated over 200 raw voice parameters from the samples of each audio recording. These basic parameters consist of a wide range of acoustic feature segmentation, including lengths, ranges, slopes, frequencies, values, and shapes of pitch-extracted parameters, amplitude-extracted parameters, and silence-extracted parameters within the speech recording. Thousands of data points are calculated and averaged per recording to form a data set of over 200 parameters that

reflects the individual's speech patterns in the given recording.

2. The basic parameters were then calibrated and normalized to overcome possible biasing effects within the specific recording owing to amplitude differences, pitch differences, speech type differences (conversation or monologue), gender differences, and age differences. The calibration process was performed against large natural-speech vocal reference data sets with over 14,500 recordings collected by VoiceSense over the years, covering different speech types, genders, ages, and languages.
3. The calibrated and normalized parameters were then analyzed using machine learning techniques to select and weight the vocal parameters that best correlated with the searched phenomena. The process uses the standard repeated random subsampling cross-validation method, which randomly splits the data set into training and test subsamples and repeats the process for multiple iterations to obtain a stable and reliable predictive model equation. Therefore, this model provides a unified speech-based score with normalized continuous scores as well as categorized (1-10) scores, which are associated with the phenomena, in this case, with depression. The statistical fit of the model to the reference scale (in this case, depression) was evaluated using Pearson correlation, ANOVA, and positive and negative predictive values (confusion matrix).

Procedures

Participant Recruitment

Participants were recruited from August 2018 to August 2019 at the Neuropsychiatric Center of Hamburg, one of Germany's largest outpatient only treatment centers, focused on neurology and psychiatry.

All participants were patients treated at the Neuropsychiatric Center with a diagnosis of depression. During the recruitment period, the patients were informed of the possibility of their physicians' participation in the study.

In all, 2 study supervisors (PT and NS) recruited the participants. The supervisors did not have any contact with the participants.

Baseline Assessment

After participants recruitment, a baseline assessment was taken, which include the items listed in [Textbox 2](#).

The results of the Big-5 personality questionnaire and the attention deficit hyperactivity disorder-related diagnostics will be published later.

Textbox 2. List of items in baseline assessment.

Baseline assessment

- Demographics (gender, age, psychological treatment, educational level, and marital status)
- Big-5 personality questionnaire for assessment of behavioral tendencies. The Big-5 questionnaires were administered only once, as unlike the psychiatric state, it was not expected to change from one session to the other.
- Attention deficit hyperactivity disorder (ADHD): some of the participants had already undergone ADHD assessment in the past. The ADHD diagnosis (yes or no) was added to the data set of the participants.

Psychiatric Assessment Session

In each assessment session, the participants completed the following psychiatric evaluation tools as listed in [Textbox 3](#).

Textbox 3. Psychiatric evaluation tools.

Evaluation tools
<ul style="list-style-type: none"> • Patient Health Questionnaire-9 for depression • General Anxiety Disorder-7 scale • Patient Health Questionnaire-15 for somatic symptom severity, somatization, and somatoform disorders • Symptom Checklist-90-R

Audio Collection Session

VoiceSense audio collection apps were installed on the tablets of the mental health professionals who participated in the research.

During each assessment session, the research assistant activated the VoiceSense app installed on the tablet. The app was logged in with the participant's experiment ID in each session. However, the participant's ID was only a serial number given to each participant by the research administrator. In this way, the recording could be associated with a specific participant but could not be associated with the actual identification of the participant. The conversion table between the actual participant's ID and the ID of the experiment was kept secure by the research administrator.

After log-in, the app presented to the participant selected general questions (as described in the audio collections section). The participant was requested to answer the question, and the app recorded the participant's voice while responding to the questions. The mental health professionals ensured that the recording was performed in a quiet environment (the session room), and only the participant's voice was recorded. At least two minutes of audio was collected per participant in each session. If the recording length after the first question did not reach 2 minutes, the app presented another question or questions until at least two minutes of audio were collected.

Central Audio Analysis

Once the recording session was completed, the app sent the recorded audio to the VoiceSense cloud server. The VoiceSense cloud server is a highly secure server running under Microsoft Azure cloud facilities (in the United States) and is recognized by the German authorities as safe for keeping medical data.

VoiceSense software processes are certified by the ISO's (International Organization for Standardization) highest information security standards, ISO 27001 and ISO 27799.

The audio data for each session were analyzed as described in the *Vocal Analysis* section, and over 200 raw speech parameters were generated for each recorded session.

These raw data parameters were calibrated and normalized to overcome possible biasing effects. The calibrated parameters

The participants completed the questionnaires. The assessments were performed after the session. The results of the General Anxiety Disorder-7 scale, Patient Health Questionnaire-15, and Symptom Checklist-90-R will be published in a separate publication.

of the 292 sessions were used as the input data set for statistical analysis.

Calculating the Vocal Depression Score

As described in the *Vocal Analysis* section of the *Methods* section, more than 200 raw voice parameters were calculated per audio recording. The parameters were calibrated and normalized by audio analysis and then passed as input data to the machine learning models for the vocal depression score calculation.

As described, a *repeated random subsampling cross-validation method*, using training and test subsamples, was used to select and weight the vocal parameters that best correlated with the searched phenomena (in this case, depression) to generate the articulated predictive model for depression.

Given the relatively small sample size of the study (N=292) compared with typical machine learning data sets, 5-fold cross-validation was chosen. The method randomly split the sample into a training subsample of 192 scores and a test subsample of 100 scores, and the process repeated itself for 10 iterations.

The method generated a predictive model (equation) consisting of a selected feature set of 13 weighted vocal parameters (out of over 200 input parameters). The outcome scores were normalized to generate a continuous vocal depression score (mean 5, SD 1). The score was also calculated on a categorical 1 to 10 scale (10=high depression).

Ethics Approval

The study protocol was approved by the ethics committee of the Neuropsychiatric Center of Hamburg, Germany (No. 2017-002) under the Declaration of Helsinki. Written informed consent was obtained from all participants before inclusion in the study.

Results

Overall, 163 participants completed both psychiatric assessments and audio collection, and 292 sessions had both psychiatric and vocal analysis scores.

Psychiatric Scales Scores

The state of psychiatric severity could change between sessions and was, therefore, measured separately in every session. Hence, all 292 scores were used for psychiatric score comparisons, although there were only 163 participants in the study.

Vocal Analysis Scores

The vocal analysis patterns could change between sessions and were, therefore, measured separately in every session. Hence,

all 292 session scores were used for verbal and psychiatric score comparisons, although there were only 163 participants in the study.

Correlation Between the Vocal Depression Score and the Psychiatric Depression Score (PHQ-9)

The overall Pearson correlations between the vocal depression score and the PHQ-9 depression score were highly significant, as presented in [Textbox 4](#).

Textbox 4. Pearson correlations between the vocal depression score and Patient Health Questionnaire-9 for depression.

Pearson correlations

- Overall sample (N=292): $r=0.41$; $P<.001$
- Training sample (N=192): $r=0.46$; $P<.001$
- Test sample (N=100): $r=0.30$; $P=.001$

PHQ-9 (Depression)

Overview

[Table 2](#) shows the PHQ-9 depression scores distributed by the 5 depression severity categories and the vocal analysis scores.

As can be seen, the average vocal depression score increases by the PHQ-9 depression severity category.

A single-factor ANOVA test was performed on the vocal depression scores and different PHQ-9 categories to determine whether the differentiation between the categories was

significant. This result was highly significant ($F_{291}=14.5672$; $P<.001$).

Specific 2-tailed t test comparisons were performed to determine the significance of the differences in vocal depression scores between each PHQ-9 depression severity category.

[Table 3](#) shows the t test probability matrix of all the specific comparisons between the vocal depression scores of the different PHQ-9 severity categories. As can be seen, the vocal scores of all severity categories are significantly different from each other, except for the difference between categories 2 (subsyndromal symptoms) and 3 (mild symptoms) and between categories 4 (moderate symptoms) and 5 (severe symptoms).

Table 2. Depression (Patient Health Questionnaire-9 [PHQ-9]) scores by severity categories and vocal depression scores.

Overall sample (N=292)	Severity category				
	Absence of depressive disorder (1)	Subsyndromal symptoms (2)	Mild symptoms (3)	Moderate symptoms (4)	Severe symptoms (5)
Assessments, n	87	98	49	39	19
Vocal depression score, mean (SD)	4.521 (1.0929)	4.933 (0.841)	5.179 (0.829)	5.626 (0.913)	5.792 (0.963)

Table 3. *t* test probability matrix of vocal depression scores by Patient Health Questionnaire-9 (PHQ-9) severity category.

Depression (PHQ-9) score	Severity category				
	Absence of depressive disorder (1)	Subsyndromal symptoms (2)	Mild symptoms (3)	Moderate symptoms (4)	Severe symptoms (5)
Absence of depressive disorder (1)	1	0.0032 ^a	9.89×10^{-5b}	8.41×10^{-9b}	1.6×10^{-6b}
Subsyndromal symptoms (2)	— ^c	1	0.1155	7.26×10^{-5b}	0.0004 ^b
Mild symptoms (3)	—	—	1	0.0145 ^d	0.0149 ^d
Moderate symptoms (4)	—	—	—	1	0.5238
Severe symptoms (5)	—	—	—	—	1

^a $P < .01$.^b $P < .001$.^cNot applicable.^d $P < .05$.

Comparison of PHQ-9 (Depression) Score and Vocal Depression Score Across Demographic Scales.

Table 4 shows the average PHQ-9 depression and the average vocal depression scores across the demographic scales.

Single-factor ANOVA tests were performed for each demographic scale to determine whether the differences between the scale categories were significant for both the PHQ-9 depression scores and vocal depression scores.

Table 4. Patient Health Questionnaire-9 (PHQ-9) and vocal depression scores by demographic scales (N=163 Participants, n=292 sessions).

Demographic category	Participants, n (%)	Sessions, n (%)	Depression (PHQ-9) score, mean (SD)	Vocal depression score, mean (SD)
Gender				
Male	47 (28.8)	73 (25.0)	2.47 (1.281)	5.18 (1.050)
Female	116 (71.2)	219 (75.0)	2.29 (1.194)	4.94 (0.978)
Age group (years)				
15 to 20	8 (4.9)	17 (5.8)	1.765 (0.970)	4.580 (0.711)
21 to 30	57 (35.0)	112 (38.2)	2.027 (1.102)	4.881 (1.053)
31 to 40	46 (28.2)	81 (27.7)	2.432 (1.060)	4.991 (0.964)
41 to 50	24 (14.7)	39 (13.4)	2.949 (1.503)	5.245 (0.908)
51 to 60	21 (12.9)	32 (11.0)	2.844 (1.370)	5.547 (0.917)
61 to 82	7 (4.3)	11 (3.8)	1.909 (0.701)	4.471 (0.925)
Educational level				
No completed education	38 (23.3)	70 (24.0)	2.086 (1.176)	5.054 (0.951)
Apprenticeship	53 (32.5)	93 (31.8)	2.753 (1.282)	5.231 (0.943)
Master craftsman certificate	7 (4.3)	16 (5.5)	1.563 (0.629)	4.419 (0.904)
University degree	60 (36.8)	102 (34.9)	2.216 (1.087)	4.890 (1.034)
Others	5 (3.1)	11 (3.9)	2.545 (1.635)	4.567 (1.129)
Marital status				
Single	77 (47.2)	148 (50.7)	2.446 (1.203)	5.024 (1.032)
Married or in a relationship	73 (44.8)	129 (44.2)	2.225 (1.270)	4.967 (0.972)
Living apart or divorced	12 (7.4)	14 (4.8)	2.071 (0.730)	4.977 (0.962)
Widowed	1 (0.6)	1 (0.3)	3.000 (-)	6.039 (-)
Current psychological treatment				
No	60 (36.8)	124 (42.5)	1.653 (0.817)	4.652 (0.865)
Yes	103 (63.2)	168 (57.5)	2.833 (1.222)	5.257 (1.017)

Gender Differences

No significant differences were found between men and women for either the PHQ-9 scores (ANOVA test: $F_{291}=1.173611$; $P=.28$) or vocal depression scores (ANOVA test: $F_{291}=3.175943$; $P=.08$).

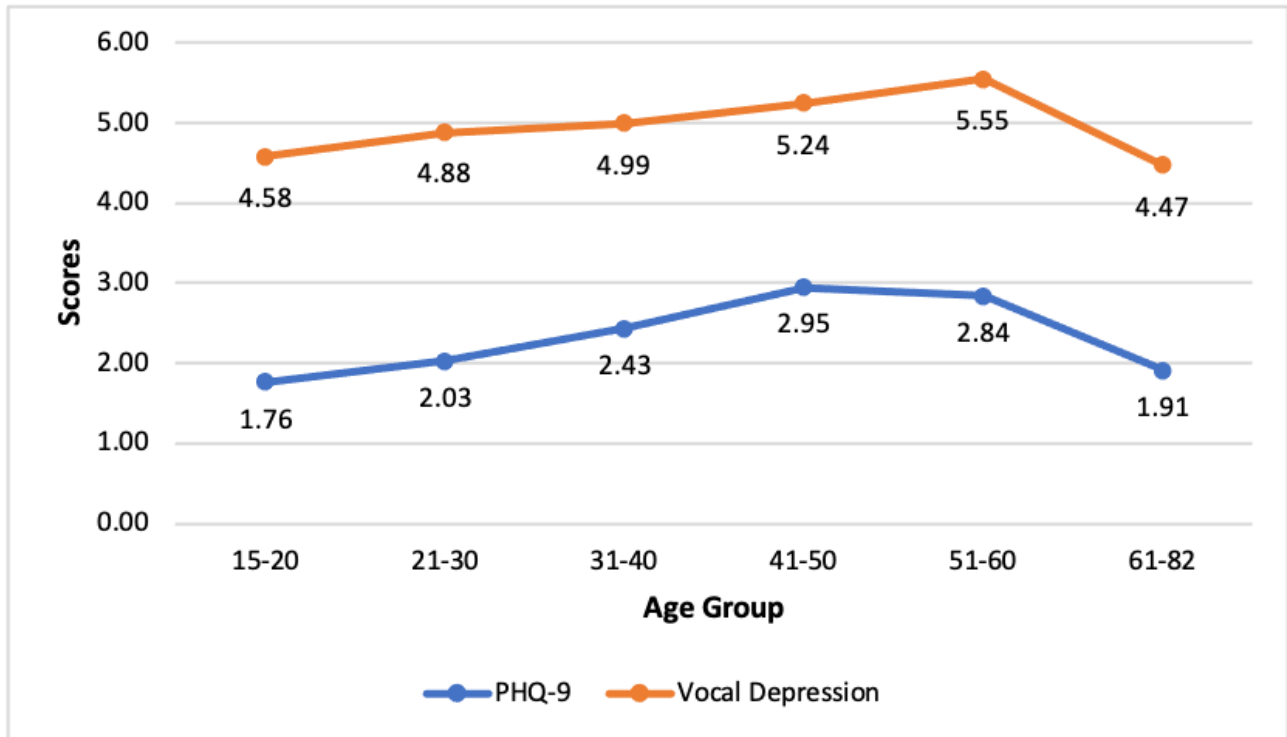
Age Group Differences

Significant differences in depression scores were found between age groups for both the PHQ-9 (ANOVA test:

$F_{291}=6.162602798$; $P<.001$) and vocal depression ($F_{291}=4.125516$; $P<.001$) Depression scores were generally higher in older age groups for both PHQ-9 and vocal depression, except for the oldest age group.

As seen in [Figure 1](#), the average score changes between age groups were very similar for PHQ-9 and vocal depression scores (the average scores are different owing to the different scales).

Figure 1. Patient Health Questionnaire-9 (PHQ-9) and vocal depression scores by age group.

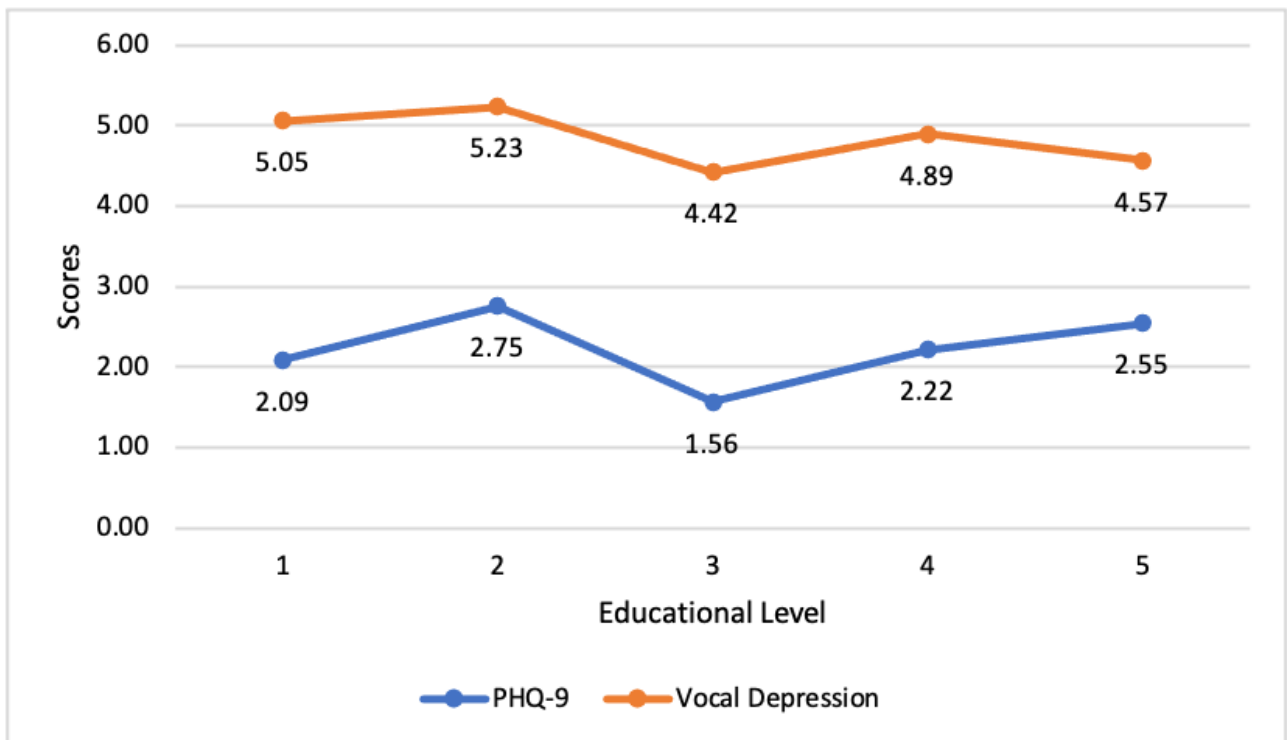


Educational Level Differences

Significant differences in depression scores were found between educational level groups for both PHQ-9 (ANOVA test: $F_{291}=5.769297$; $P<.001$) and vocal depression ($F_{291}=3.593119$; $P=.007$).

As seen in Figure 2, the average score changes for education levels were very similar for the PHQ-9 and vocal depression scores (the average scores are different owing to the different scales).

Figure 2. Patient Health Questionnaire-9 (PHQ-9) and vocal depression scores by educational level.



Marital Status Differences

No significant differences were found in depression scores between the marital status groups, neither for the PHQ-9 (ANOVA test: $F_{291}=1.081893$; $P=.52$) nor for vocal depression scores (ANOVA test: $F_{291}=0.434517$; $P=.73$).

Psychological Treatment Differences

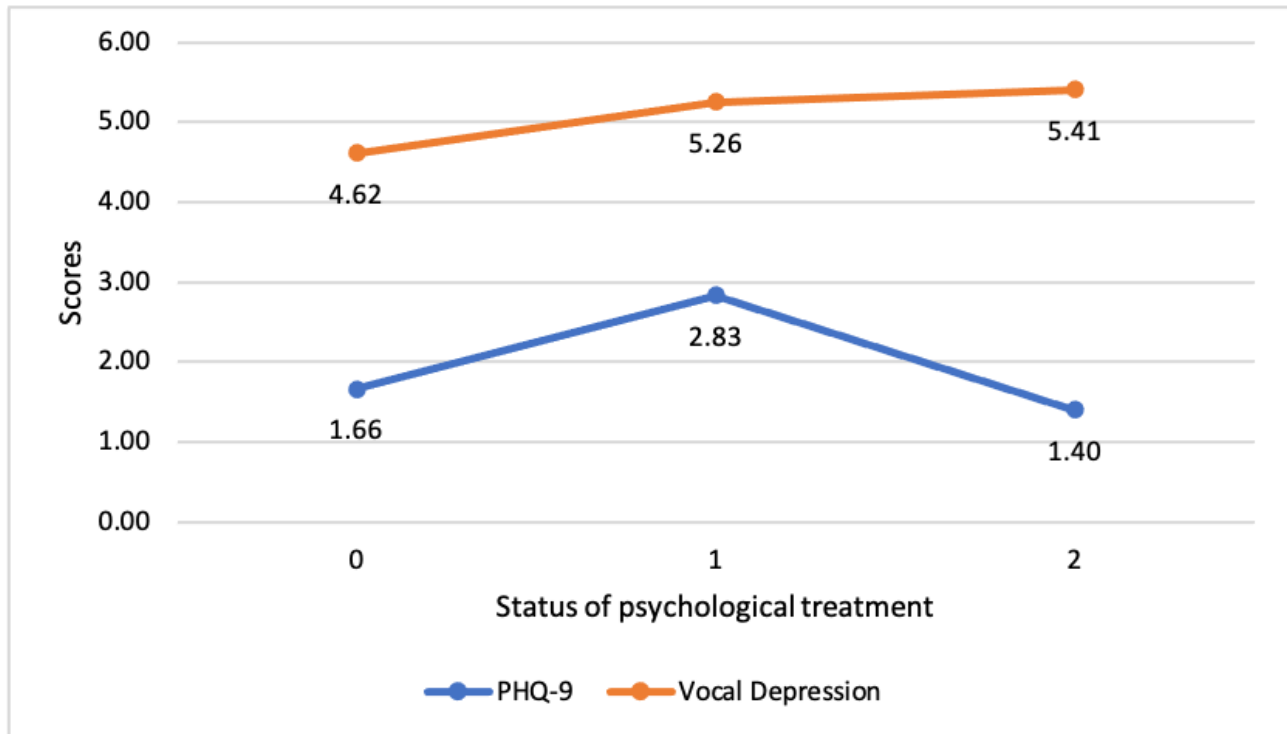
Overview

Significant differences in depression scores were found between psychological treatment status for both the PHQ-9 (ANOVA

test: $F_{291}=86.937647$; $P<.001$) and vocal depression (ANOVA test: $F_{291}=28.66407$; $P<.001$).

As seen in Figure 3, the average score changes for current psychological treatment status *no* in every sessions (0) and *yes* in every session (1) are similar for the PHQ-9 and the vocal depression scores (the average scores themselves are different due to the different scale), the average score changes are not clear similar in *no* in one session (2), but this group is too small with $N=5$ to allow a clear explanation.

Figure 3. Patient Health Questionnaire-9 (PHQ-9) and vocal depression scores by psychological treatment status.



Statistical Fit (Predictive Power) of the Vocal Depression Scores to the PHQ-9 Depression Scores

As shown by the aforementioned results, strong and significant relationships were found between the vocal depression scores and PHQ-9 depression scores.

However, what is the practical accuracy that can be expected from using vocal analysis for tracking and screening for depression? In statistical terms, this question relates to the predictive power of the vocal model or its statistical fit to PHQ-9 depression reference scores.

A common way to evaluate a model's strength is by labeling the model's scores as positive and negative predictive values and performing a confusion matrix analysis.

The PHQ-9 scores were labeled as follows: scores 1, 2, and 3 were labeled as *Low Depression* and scores 4 and 5 were labeled as *High Depression*. A total of 63.4% (185/292) of participants were labeled as *Low Depression*, and 36.6% (107/292) of participants were labeled as *High Depression*.

The vocal depression scores were labeled as follows: scores 1 to 6 (within the 1-10 scale) were labeled as *Low depression risk*

and scores 7 to 10 were labeled as *High depression risk*. A total of 59.9% (175/292) of participants were labeled *Low depression risk*, and 40.1% (117/292) of participants were labeled as *High depression risk*.

Table 5 shows the confusion matrix of the number of participants classified according to these 4 labels for the entire sample and training and test subgroups.

Of the 107 participants that were labeled as *High Depression* according to the PHQ-9, 68 (63.6%) were classified as *High depression risk* by the vocal depression analysis (true positive) and 39 (36.4%) were classified as *Low depression risk* (false negative).

Out of the 185 participants that were labeled *Low Depression* according to the PHQ-9, 136 (73.5%) were classified as *Low depression risk* by the vocal depression analysis (true negative) and 49 (26.5%) were classified as *High depression risk* by the vocal depression analysis (false positive).

Overall, out of the 292 participants, 204 (136+68) were classified as consistent with the PHQ-9 depression (accuracy=69.9%).

Table 6 provides the confusion matrix attributes for the entire sample and training and test subgroups.

As explained in the *Methods* section, the vocal depression model was developed using a training subsample (on which the model was trained) and a test subsample (on which the model was tested).

Hence, the model's predictive power is best evaluated using the confusion matrix results for the test subsample. It is also

interesting to observe the differences between the training and test subsamples to assess the expected stability of the model.

As can be seen, the confusion matrix results for the test subsample were similar to the results of the training subsample. The overall accuracy of the model was 70.8% in the training subsample and 68% in the test subsample. This means that the vocal depression model is relatively stable and is expected to provide an overall accuracy of close to 70% when used for depression screening and tracking.

Table 5. Patient Health Questionnaire-9 (PHQ-9) depression and vocal depression labeled matrixa.

Confusion matrix (vocal depression)	PHQ-9 depression (N=292)			Training subgroup (N=192)			Test subgroup (N=100)		
	Low	High	Total	Low	High	Total	Low	High	Total
Low risk	136	39	175	89.2	24.7	113.9	46.8	14.3	61.1
High risk	49	68	117	31.3	46.8	78.1	17.7	21.2	38.9
Total	185	107	292	120.5	71.5	192	64.5	35.5	100

^aThe values are participants and virtual parts of participants predicted and classified from the algorithm.

Table 6. Confusion matrix attributes.

	Entire sample (%)	Training subgroup (%)	Test subgroup (%)
Accuracy: correct classifications	69.9	70.8	68.0
Sensitivity (recall): true positive rate	63.6	65.5	59.7
Specificity: true negative rate	73.5	74.0	72.6
Precision: positive predictive value	58.1	59.9	54.5
False positive rate	26.5	26.0	27.4
False negative rate	36.4	34.5	40.3

Discussion

Principal Findings

In this study, consisting of 163 participants affected by different degrees of depressive states, it was shown that there is a high correlation between the depression severity classification as measured by the PHQ-9 self-filled questionnaires and between the depressive vocal scores as measured by the VoiceSense analysis system.

Compared with other studies that used biomarkers or wearables for detecting depressive states [35], we only used noncontent speech analysis. No participant had to buy or wear an additional digital tool or some hardware; no participant had to be aware of some unexpected action of an unusual wearable device. To start the analysis, it was only necessary to perform one short call with the VoiceSense system. The implementation of the VoiceSense speech analysis was unproblematic; the connection via Wireless Local Area Network showed adequate sending and receiving performance for the tablets used for recording. The sound quality was good and enabled a fair vocal analysis evaluation.

Each depressive vocal score was calculated based on only one voice recording in the evaluation. It is expected that the accuracy will increase with multiple recordings. Corresponding

calculations will be performed for participants who have made several sound recordings.

As the basis for speech analysis, we used a machine learning algorithm that had already been applied to various personality aspects and affective states in English-speaking participants. Here, we tested whether and to what extent it is possible to let this system *learn further* to change the language and to what time the recognition of affective states can succeed in comparison with clinical tests. We achieved a high level of agreement with at least 384 training minutes after running the algorithm 10 times. The results of the confusion matrix showed that fairly good accuracy was achievable. The accuracy of the test sample was maintained at 68%. Specificity and sensitivity also correspond to high values of 59% and 72%, respectively. Even in everyday clinical practice, no better agreements are achieved by different therapists in cursory examinations.

We were able to achieve stable results with the voice analysis system, which largely corresponded to the results of testing in the PHQ-9. The effects were long-lasting; after training on the first 192 data sets, the following data sets could be detected with high accuracy. No restrictions due to the course of time or abnormalities in the intervals between individual tests were recognizable. Thus, the use of the speech analysis system alone could accurately discriminate individuals with a high risk of depressive phases or could monitor the course of treatment and

recovery of patients without direct contact with an experienced psychiatrist.

Comparison With Previous Research

We compared our study to other studies that investigated the approach to analyzing speech in patients affected by depression. Some actual research studies noncontent aspects of speech compared with low or severe depressive symptoms [36]. The results confirm a relationship between acoustic parameters of speech not only in the case of severe depressive disorder but also in nonsevere cases. This study used humans' interpretation of audio recordings; we used digital techniques for a similar task. However, some research has been conducted to develop machine learning settings to identify if someone is depressed. In the various conferences of Audio Visual Emotion Challenge and Workshop in recent years, based on different data sets of depressed people, some researchers have shown that automatized techniques to identify this subgroup could reach a good recognition level [37,38].

In a group of older adults with depression, voice pattern and speech activity could be shown in an automated deep learning–based analysis as essential parameters to detect late-life depression [39].

The results that we were able to find here correspond to the descriptions of the specified studies. The main strength of our study is that data from an average outpatient group were available from an outpatient care center. None of the test participants were first made aware of the study or the problem of depressive disorders and how external stimuli could measure them. Therefore, the results can be regarded as reliable.

Nevertheless, the experimental results of the researchers cited are confirmed. With a training effort of only 192 candidates, we achieved almost congruent results for the remaining 100 measurements in the test run. Therefore, the use of the technical approach described here for easier and faster diagnosis of depressive disorders can be considered helpful in clinical practice, especially in detecting depressive disorders at an early stage or monitoring close-meshed treatment.

An interesting study showed that a measurement-driven therapy approach for patients with depression (as part of a telemedicine platform) can achieve far better treatment results than the previous approach, with occasional live contact with the treating physician. Suppose you transfer the core idea here—the regular

and low-threshold recording of treatment effects and progressions—to implementation in everyday therapy, independent of a telemedicine treatment platform. There should also be exciting improvements in the treatment quality if changes in findings can be applied promptly [40].

Such an automated analysis with a shallow threshold to commit will make it possible to provide a more intensive and individual, person-centered treatment if the measurement results show a highly negative mood or other problematic stages of depressive disorder. It can assist in regulating treatment and medication dosage more accurately according to the patient's state at the time of vocal assessment.

Conclusions

The PHQ-9 is a well-established and appropriate tool for screening and assessing depressive disorders and depressive phases. However, the PHQ-9, similar to other assessment tools, is problematic for some patients and time consuming for both physicians and patients.

Using a tool with machine learning algorithms, such as VoiceSense, to capture the affective phase of a patient can work not only much faster but also over distance because the patient and physician do not need to see and sit together. VoiceSense could be installed on the patient's smartphone so that only the scores are transmitted to the physician's database. Treatment flexibility is possible, and distance diagnostics can be used.

The importance of such an assessment is not a considerable question—both to improve individual therapy planning and to distinguish threatening phases of depression of an individual from harmless ones with significantly reduced effort. The value of such a remote monitoring approach has recently been emphasized during the COVID-19 pandemic.

In a further step, possible changes in the course of therapy must be recorded more precisely. The extent to which the result of the speech analysis changes if the condition of the test participant changes, and of course, it must ultimately be confirmed whether the good correlation is also confirmed if the recording of the test participant's condition is not only proved by a self-rating similar to the PHQ-9 but also through a suitable third-party rating. That is now reserved for future studies; we will conduct this in collaboration with one of the largest German public health insurance companies.

Conflicts of Interest

YD works in a company called VoiceSense. VoiceSense has developed the vocal analysis system used in this study and it also funded this study.

Multimedia Appendix 1

List of the general questions presented in the VoiceSense mobile audio collection app.

[DOCX File, 13 KB - [formative_v6i8e37061_app1.docx](#)]

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Abbreviations

- EMA:** ecological momentary assessment
ISO: International Organization for Standardization
PHQ-9: Patient Health Questionnaire-9

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Original Paper

Assessment and Prediction of Depression and Anxiety Risk Factors in Schoolchildren: Machine Learning Techniques Performance Analysis

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Abstract

Background: Depression and anxiety symptoms in early childhood have a major effect on children's mental health growth and cognitive development. The effect of mental health problems on cognitive development has been studied by researchers for the last 2 decades.

Objective: In this paper, we sought to use machine learning techniques to predict the risk factors associated with schoolchildren's depression and anxiety.

Methods: The study sample consisted of 3984 students in fifth to ninth grades, aged 10-15 years, studying at public and refugee schools in the West Bank. The data were collected using the health behaviors schoolchildren questionnaire in the 2013-2014 academic year and analyzed using machine learning to predict the risk factors associated with student mental health symptoms. We used 5 machine learning techniques (random forest [RF], neural network, decision tree, support vector machine [SVM], and naive Bayes) for prediction.

Results: The results indicated that the SVM and RF models had the highest accuracy levels for depression (SVM: 92.5%; RF: 76.4%) and anxiety (SVM: 92.4%; RF: 78.6%). Thus, the SVM and RF models had the best performance in classifying and predicting the students' depression and anxiety. The results showed that school violence and bullying, home violence, academic performance, and family income were the most important factors affecting the depression and anxiety scales.

Conclusions: Overall, machine learning proved to be an efficient tool for identifying and predicting the associated factors that influence student depression and anxiety. The machine learning techniques seem to be a good model for predicting abnormal depression and anxiety symptoms among schoolchildren, so the deployment of machine learning within the school information systems might facilitate the development of health prevention and intervention programs that will enhance students' mental health and cognitive development.

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KEYWORDS

machine learning; depression; anxiety; schoolchildren; school-age children; children; youth; young adult; transition-aged youth; early childhood education; prediction; random forest

Introduction

Background

Mental health conditions are emerging as health priorities around the globe, with depression being the main cause of illness among adolescents [1], as all other aspects of life in the early adolescent years are greatly affected by poor mental health. The majority of mental health disorders appear by the age of 14 years, yet they may go untreated and thus present severe consequences for the child's mental, physical, and social health in the long term [2]. The early detection and treatment of mental health conditions in childhood and adolescence not only enhance the child's quality of life, academic performance, physical health, and social life but also helps them cope with external risk factors as adults [3,4].

With over 300 million official diagnoses worldwide, depression is the most prevalent mental health condition [5]. Although ordinarily and mistakenly interchanged, as well as with a major overlap within their symptoms and treatment, depression and anxiety are 2 distinct diagnoses with different consequences for the patient [6]. The main symptoms of depression include memory loss, lack of concentration, inability to make decisions, loss of interest in daily life activities, feelings of guilt, irritation, and in some cases, suicidal thoughts [6,7]. Anxiety, on the other hand, is an "aversive emotional and motivational state occurring in threatening circumstances" [5], whereby an individual is unable to make decisions or identify the best behavior to remove or instigate the threat. Furthermore, the overlapping depression and anxiety symptoms might affect several of the students' life areas, including school and family life, friendship, and academic performance. Studies found that depression and anxiety could lead to a lack of attention or motivation, which could influence schoolchildren's performance [8-11].

Although both anxiety and depression are conditions that severely affect schoolchildren and adolescents and have been shown to predict future mental health problems, interventions are focused on prevention or treatment instead of prediction and risk factors [12].

Prior Work

Schoolchildren's mental health problems including depression and anxiety have been studied by many researchers [12-16]. Research studies have reported that depression and anxiety lead to several negative consequences on children's health development, such as functional impairment and poor cognitive development, social development, and educational and academic performance. It has been found that depression and anxiety symptoms are associated with many risk factors, including poor lifestyle and eating habits, violent behavior, negative social and family support, and socioeconomic factors [13-16].

Data mining and machine learning (ML) techniques have previously been used for mental health prediction, yet most researchers have focused on target populations besides schoolchildren [4,6,17]. Several ML algorithms were used in predicting anxiety- and depression-associated risk factors, such as support vector machine (SVM), convolutional neural network, random forest (RF) tree, and naive Bayes (NB). For instance,

Seah and Shim [7] used data mining techniques on social media users, particularly the Reddit platform, to understand the risk factors associated with suicide. Wang et al [18] studied the change of anxiety severity and prevalence among undergraduate students undergoing web-based learning during the COVID-19 pandemic using the XGBoost ML model. Priya et al [4] aimed to predict anxiety, depression, and stress among employed and unemployed individuals through the use of 5 different ML algorithms. Richter et al [6] used ML for differentiating the symptoms of anxiety and depression among adult patients. In 2 studies [4,19], RF and NB algorithms reported an average accuracy rate of 71% and 73% for anxiety and depression symptoms, respectively. Rois et al [20] assessed the performance of different ML algorithms in predicting depression, anxiety, and stress among Bangladeshi university students and found that the RF model had the highest accuracy level of 89.7% and the logistic regression model had the lowest accuracy level of 74.5%. Furthermore, in Priya et al [4], decision tree (DT), NB, SVM, RF, and k-nearest neighbor algorithms were used in predicting anxiety and depression among adults aged 20-60 years, and the study found that the RF algorithm had the highest performance accuracies of 79.8%, 71.4%, and 72.3% for depression, anxiety, and stress, respectively.

Overall, ML techniques have been successfully used as predictors for childhood obesity [21,22], academic performance [23,24], children's personalities [25], and cognitive performance [1,5,26,27], among others. Thus, the literature has proven that ML is an effective methodology for the prediction of risk factors in several fields—one of which is mental health. The RF classifier and ensemble techniques have been shown to have the highest accuracy rates [4].

Aim

The role of ML in predicting mental health conditions among schoolchildren specifically has seldom been explored. Therefore, this study aimed to assess the accuracy of 5 ML techniques in predicting depression and anxiety and its associated risk factors (mental health, physical health, social support, and violence, among others) among schoolchildren in Palestine.

Methods

Data Collection

The data were collected from the multidisciplinary research project on the Determinates of Students' Health (physical, mental, and social) in the West Bank and East Jerusalem, conducted in collaboration between the Ministry of Education and Al-Quds University in the 2013-2014 academic year. The study sample included students in fifth to ninth grades (aged 10-15 years) in public schools (administered by the Palestinian Authority) and United Nations Relief and Works Agency schools. A representative sample of 3984 students selected from 100 schools was used in this study.

Ethics Approval

The study received ethical approval from the Ministry of Education and Al-Quds University Institutional Review Board (05-Aug-2013-12/10).

Variables

The data set included the associated risk factor variables related

to depression, anxiety, physical, and social health, in addition to the sociodemographic variables evidenced in [Table 1](#).

Table 1. Machine learning models' variables.

Variable name	Description	Value
Gender	Gender	Boy or girl
Age	Age	10-15 years
FAS ^a	Economic status	Low, medium, or high
ST	School type	Public or refugee
LP	Living place	Urban or nonurban
FatherEdu	Father's education	≤Secondary or >secondary
MotherEdu	Mother's education	≤Secondary or >secondary
HealthyIntake	Healthy food intake	Low or high
UnhealthyIntake	Unhealthy food intake	Low or high
BMI	Body mass index	Normal, overweight, or obese
Smoking	Tobacco risk	Yes or no
PAL	Physical activity	Low active or active
FAL	Free-time activity	Low active or active
FSL	Family support level	Low, moderate, or high
PSL	Peer support level	Low, moderate, or high
SSL	School support level	Low, moderate, or high
PTSD ^b	Posttraumatic stress symptoms level	Low, moderate, or severe
Depression	Depression symptoms	Normal or abnormal
Psychosomatic_SympL	Psychosomatic symptoms	Low, moderate, or severe
Health_Perception	Positive health perceptions	Low, medium, or high
LSL	Life satisfaction level	Low, medium, or high
Academic_Score	Average grades score	Excellent/very good, good, or weak/fail
Violence	Home violence	Never, sometimes, or often true
Bullying	Bullying behaviors	Never, bullied, or bully/victim
Anxiety	Anxiety symptoms level	Normal or abnormal

^aFAS: family affluence scale.

^bPTSD: posttraumatic stress disorder.

Sociodemographic Variables

The variables considered were gender, age, degree level, place of residence, household income, school category (public or United Nations Relief and Works Agency), and parents' education.

Depression

The depression data were collected using the 18-item Depression Self-Reported Scale (DSRS) [28] for children aged 8 to 14 years. The DSRS items were composed of 3 answer categories (never=0, sometimes=1, and always=2), with the highest score indicating higher depression. The item "I like to play outside my home" was excluded given that, in Palestinian culture, girls do not go outside for play. The total score was calculated through the addition of the scale items' answers. The DSRS total score was classified into the following groups:

- Normal: between 0 and 9 points.
- Mild or moderate depression: between 10 and 20 points.
- Severe depression: higher than 20 points.

To improve the performance of ML prediction, the mild or moderate and severe depression categories were grouped into 1 category (called the abnormal category). The final scale was classified into the normal and abnormal categories.

Anxiety

The 7-item General Anxiety Disorder [29] scale was used for measuring anxiety. The anxiety score was estimated by assigning the scores of 0, 1, 2, and 3 to the response categories of "not at all," "about every week," "more than once a week," and "every day," respectively. The scores of 5, 10, and 15 were taken as the cutoff points for mild, moderate, and severe anxiety, respectively. To improve the performance of ML prediction,

the mild, moderate, and severe anxiety categories were grouped into 1 category (called the abnormal category). The final scale was classified into the normal and abnormal categories.

Physical Activity

The students were asked 3 questions to collect the following data on the levels of physical activity: (1) the number of days the students were physically active for more than 1 hour in the last week, (2) the frequency of the number of hours of playing sports outside of school, and (3) the total number of hours of physical exercise per week.

Free-Time Activity

The following data on students' free-time activities were collected from the students through questions: (1) the daily number of television-watching hours, (2) the number of hours spent on using the internet per week, and (3) the daily number of hours spent on playing video games.

The physical and free-time questions considered the weekdays only (excluding weekends). The activities categorization used the quartiles analysis. For physical activity, the active level of students was identified by the upper quartiles range, whereas the inactive level was identified by the lower quartiles range. For free-time activities, the inactive students were identified by the upper quartiles range, whereas the active ones were identified by the lower quartiles range.

Food Intake

The students' food intake information used the 7-item food frequency scale. The scale items were classified into 7 categories based on intake profile similarity: (1) legumes and vegetables; (2) fruits; (3) milk, yogurt, cheese, and alternatives; (4) sugar; (5) soft drinks; (6) juices and beverages; and (7) energy drinks. The response categories were (1) never, (2) one to two times/week, (3) three to four times/week, and (4) five to seven times/week (almost daily). Students were categorized into 2 groups, healthy and unhealthy intake, based on the item scale sum. The healthy intake group included participants who reported that they did not consume unhealthy food groups (soft drinks, sugar, or energy drinks), and the unhealthy group included participants who did not report to consume healthy food items (vegetables, fruits, milk, and dairy products).

Social Support

The variable considered 3 aspects of support: (1) family, (2) schoolteachers, and (3) peers. Each survey section included 2 items related to the students' communication frequency with the above aspects of social support.

Health Perceptions

The perception of health and life was assessed using the 6-item perception scale. The scale items included questions about the students' self-perception of health and life quality.

Life Satisfaction

Students were asked to evaluate their life satisfaction by ranking it from 0 to 10, with 0 indicating the worst life satisfaction and 10 indicating highly satisfied.

Posttraumatic Stress Disorder

A 20-item posttraumatic stress symptoms measurement scale was used. The scale measured the anxiety disorder caused by an intensely stressful event. The items were ranked on a 5-point scale from 0, indicating "never," to 4, indicating "very much."

Academic Performance

This variable was obtained from the students' academic records. The average performance score was calculated for 6 school subjects: Arabic language, English language, Religion, Social Studies, Science, and Mathematics. The total score was identified by the following categories: excellent/very good, good, or weak/fail.

Home Violence

The home violence variable was assessed through 5 items rated on a 3-point scale; the answer options were (1) never, (2) sometimes, or (3) often true. Higher scores point to a higher occurrence of home violence.

School Violence and Bullying

These variables were assessed by asking questions related to the frequency of bullying either experienced or witnessed at school. There were 4 violence and bullying categories identified: 0 for not engaged in bullying behavior; 1 for bullying others only; 2 for bullied only; and 3 for bully-victim (those who were both bullies and victims).

Psychological Attributes

The parent version of the Strengths and Difficulties Questionnaire was used to assess students' psychological attributes [30]. The scale was composed of 25 items covering negative and positive attributes; each item was answered with either "not true=0," "somewhat true=1," and "certainly true=2." The scale included emotional symptoms, behavior problems, hyperactivity or inattention, peer relationship problems, and pro-social behavior. In all, 3 categories were identified from this scale: 0 for "normal" (0-13 points), 1 for "borderline" (14-16 points), and 2 for "abnormal difficulties" (≥ 17 points).

ML Algorithms

In this study, 5 ML predictive models (artificial neural network [ANN], RF, SVM, NB, and DT) were built and compared to each other to consider their predictive accuracy on the given data set. This predicted the depression and anxiety symptoms among schoolchildren according to the severity level. The data set was divided into the ratio of 70:20:10, representing training, testing, and validation, respectively. The cross-validation approach with grid search method was used for parameters optimizations. The parameters for different algorithms were set as follows:

- In the ANN model, the hidden layer had 500 neurons, with 500 as the maximum number of iterations based on logistic activation function.
- The RF model had 1000 trees and 5 maximum depth trees. The maximum number of samples for splitting the internal nodes was set to 2, and the leaf node minimum number was set to 1.

- The SVM regularization parameter was set to 20, the Radical Basis Function kernel was set to 0.001, and the bias error control factor was set to 1.
- Based on the optimization results, the algorithms were used in predicting the depression and anxiety symptoms. The ML algorithms used are described in [Table 2](#).

Table 2. Description of machine learning techniques.

Machine learning algorithm	Description
Artificial neural network	Neural networks are a series of algorithms that recognizes relationships between sets of data. The algorithm is built of many small, classified aggregators that feed-forward from the input data to the target prediction [31,32].
Random forest	Random forest is an ensemble learning technique that is used for classification along with regression through decision trees and outputs the plurality of votes from the trees [33]. Each tree is exposed to a data subset and independently evaluates the features available to arrive at a conclusion [34,35].
Support vector machine	The support vector machine is an algorithm used for classification in addition to regression analysis. Support vector machine creates a decision surface for the prediction of variables starting from a small number of similar cases across the support vector and then classifying the remaining cases based on how they fall on the side of the support vector [34,35].
Decision tree	A decision tree is an algorithm that builds a tree-like structure for classifying features with multiple levels of observations [32]. The substructures, “leaves,” represent the objects’ class, whereas the “branches” represent the features [34-36].
Naive Bayes classification	Naive Bayes is the easiest and most powerful algorithm to predict features within a data set. This machine learning algorithm analyzes the training sets across the variables to find how likely the variables’ ability is for predicting the target [34,35].

Data Analysis

The data variables were cleaned and normalized before analysis. The data set consisted of 3984 student records. The ML algorithms were applied to predict the students’ mental health depression and anxiety symptoms by using the Orange data mining software [37] for testing and validating the ML models.

Different performance measures were used to evaluate whether the ML models can predict schoolchildren’s depression and anxiety symptoms, such as accuracy, specificity, precision, recall, and F-measure. The calculating equations for performance measure are as follows:

$$\text{Specificity} = \text{True Negative} / (\text{False Positive} + \text{True Negative}) \text{ (1)}$$

$$\text{Precision} = \text{True Positive} / (\text{True Positive} + \text{False Positive}) \text{ (2)}$$

$$\text{Recall} = \text{True Positive} / (\text{True Positive} + \text{False Negative}) \text{ (3)}$$

$$\text{F-measure} = (2 \times \text{Precision} \times \text{Recall}) / (\text{Precision} + \text{Recall}) \text{ (4)}$$

$$\text{Accuracy} = (\text{True Positive} + \text{True Negative}) / (\text{True Positive} + \text{True Negative} + \text{False Positive} + \text{False Negative}) \text{ (5)}$$

Results

A brief descriptive analysis was performed to present the depression and anxiety levels among the Palestinian schoolchildren and understand the data distribution before the evaluation of ML techniques. The data set was composed of 3984 students with a mean age of 13 (SD 1.5) years, ranging from ages 10-15 years. Among these students, approximately 29.8% (n=1188) were boys and 70.2% (n=2796) were girls. Data in [Table 3](#) show the depression levels distributed by grade levels. The eighth and ninth grades students reported the highest moderate depression levels (eighth: 61%, 469/769; ninth: 61.5%, 494/803). The seventh and ninth grades students reported the highest severe depression levels (seventh: 6.6%, 54/824; ninth: 7.3%, 59/803). The results show that more than half (57.3%, 2283/3984) of the students reported a moderate level of depression in all ages.

Table 3. Students' depression and anxiety levels by grade.

Mental health condition, grade	Normal, n (%)	Moderate, n (%)	Severe, n (%)
Depression			
Fifth grade (N=797)	362 (45.4)	404 (50.7)	31 (3.9)
Sixth grade (N=791)	288 (36.4)	460 (58.2)	43 (5.4)
Seventh grade (N=824)	314 (38.1)	456 (55.3)	54 (6.6)
Eighth grade (N=769)	256 (33.3)	469 (61)	44 (5.7)
Ninth grade (N=803)	250 (31.1)	494 (61.5)	59 (7.3)
Anxiety			
Fifth grade (N=797)	452 (56.7)	147 (18.4)	198 (24.8)
Sixth grade (N=791)	426 (53.9)	164 (20.7)	201 (25.4)
Seventh grade (N=824)	432 (52.4)	203 (24.6)	189 (22.9)
Eighth grade (N=769)	438 (57)	172 (22.4)	159 (20.7)
Ninth grade (N=803)	479 (59.7)	192 (23.8)	133 (16.6)

The results in [Table 3](#) show the percentage distribution of anxiety levels by grade levels. The participants reported a decrease in anxiety severity levels as grade levels increased. Students in the fifth and sixth grades had the highest anxiety levels (24.8%, 198/797 and 25.4%, 201/791, respectively). Overall, more than half (55.9%, 2227/3984) of the students reported normal anxiety levels at all ages. However, the minimum anxiety level found in ninth graders (16.6%, 133/803) might still affect the students' growth and development. We observed significant differences between the depression and anxiety scores, grades, and genders. The results also indicated that girls reported higher depression (6.4%, 180/2796) and anxiety (22.9%, 640/2796) levels than boys (4.3%, 51/1188 and 20.2%, 240/1188, respectively). Furthermore, the results in [Table 4](#) show that the univariate analysis of depression symptoms indicated a high significant association with posttraumatic stress disorder (PTSD), life satisfaction, health

perception, gender, physical activity, family support, smoking, home violence, and grade; whereas for anxiety, the results show a significant association with PTSD, family support, school support, friend support, grade, home violence, gender, and bullying behaviors.

[Table 5](#) demonstrates the comparison between ML algorithms' accuracy rates for the models used in predicting students' depression and anxiety. Besides the SVM and RF models, which had the highest accuracy rates (depression: 92.6% and 92.4%, respectively; anxiety: 76.5% and 78.4%, respectively), the other ML algorithms had acceptable performance accuracies. The 2 classes of depression and anxiety resulted in the confusion matrix depicted in [Table 6](#); the columns show the predicted classes, whereas the rows show the actual classes. To further present prediction accuracy, the instances classification accuracy of the 5 models is shown in [Table 7](#).

Table 4. The univariate analysis of depression and anxiety symptoms by study variables.

Mental health condition, variable	<i>F</i> test (<i>df</i>)	<i>P</i> value
Depression		
PTSD ^a	643.5 (1,3983)	<.001
Life satisfaction	83.6 (1,3983)	<.001
Positive health perception	34.6 (1,3983)	<.001
Gender	12.5 (1,3983)	<.001
Physical activity	11.1 (1,3983)	<.001
Family support	9.4 (1,3983)	<.001
Smoking	7.5 (1,3983)	.006
Grade	5.7 (1,3983)	<.001
Anxiety		
PTSD	105.2 (1,3983)	<.001
Family support	59.5 (1,3983)	<.001
School support	46.0 (1,3983)	<.001
Friend support	24.4 (1,3983)	<.001
Grade	6.1 (1,3983)	<.001
Home violence	6.0 (1,3983)	.002
Gender	5.5 (1,3983)	.02
Bullying behaviors	5.0 (1,3983)	.001

^aPTSD: posttraumatic stress disorder.

Table 5. Comparison of prediction accuracy among the 5 machine learning models.

Model	Depression, %	Anxiety, %
Decision tree	88.5	74.1
Support vector machine	92.6	76.5
Random forest	92.4	78.4
Artificial neural network	91.9	75.7
Naive Bayes	87.1	72.7

Table 6. Confusion matrix of the machine learning models' performance.

Machine learning algorithm, actual	Depression, predicted		Anxiety, predicted	
	Normal	Abnormal	Normal	Abnormal
Decision tree				
Normal	3200	293	2752	590
Abnormal	360	1832	864	1479
Random forest				
Normal	3096	397	2856	486
Abnormal	37	2155	730	1613
Naive Bayes				
Normal	2766	727	2713	629
Abnormal	18	2174	905	1438
Support vector machine				
Normal	3068	425	2570	772
Abnormal	2	2190	570	1773
Neural network				
Normal	3141	352	2746	596
Abnormal	111	2081	775	1568

Table 7. Performance measures analysis for the different machine learning models.

Model, mental Health condition	AUC ^a , %	CA ^b , %	Error rate, %	F1-score ^c , %	Precision, %	Recall, %
Decision tree						
Depression	86.7	88.5	88.5	88.5	88.5	86.7
Anxiety	73.7	74.4	74.1	74.2	74.4	73.7
Support vector machine						
Depression	96.8	92.5	92.6	93.7	92.5	96.8
Anxiety	82.1	76.4	76.5	76.8	76.4	82.1
Random forest						
Depression	97.2	92.4	92.4	93.3	92.4	97.2
Anxiety	86.8	78.6	78.4	78.5	78.6	86.8
Artificial neural network						
Depression	96.8	91.9	91.9	92.3	91.9	96.8
Anxiety	84	75.9	75.7	75.7	75.9	84
Naive Bayes						
Depression	95.5	86.9	87.1	89.9	86.9	95.5
Anxiety	82.3	73	72.7	72.8	73	82.3

^aAUC: area under curve.

^bCA: correspondence analysis.

^cF1-score: harmonic mean between precision and recall.

Table 7 shows the different performance measures (area under curve [AUC], accuracy, error rate, F1-score, precision, and recall) calculated for the 5 ML models. The results in Table 7 indicated that the highest accuracy rates for both variables, depression and anxiety, was achieved by the SVM and RF algorithms. Nevertheless, the results of the confusion matrix in

Table 6 show imbalanced classes of depression and anxiety classifications by the ML algorithms, which means that accuracy measure will not provide sufficient performance measure. Therefore, we used the harmonic mean of recall and precision (F1-score) as an additional performance measure for the selected ML algorithms. The F1-scores obtained by the SVM and RF

models were the highest for both depression and anxiety, whereas the NB model reported the lowest accuracy and F1-scores for both depression and anxiety. The classification results show that the RF, SVM, and ANN models presented the highest accuracy levels for predicting students' depression and anxiety. However, all algorithms used in this study produced an acceptable performance measure for depression and anxiety symptoms.

The RF receiver operating characteristics for the 2 depression and anxiety classes are presented in Figures 1 and 2 and Table 8. There were 2 numerical categories of student depression and anxiety used: normal and abnormal. The receiver operating characteristics resides in the upper left corner; thus, the RF algorithm has a better prediction of positive value than the other studied algorithms (AUC of 82% and 81% for depression and anxiety, respectively).

Figure 1. SVM and random forest receiver operating characteristics curve for abnormal depression (TP rate of sensitivity against FP rate of specificity). FP: false positive; SVM: support vector machine; TP: true positive.

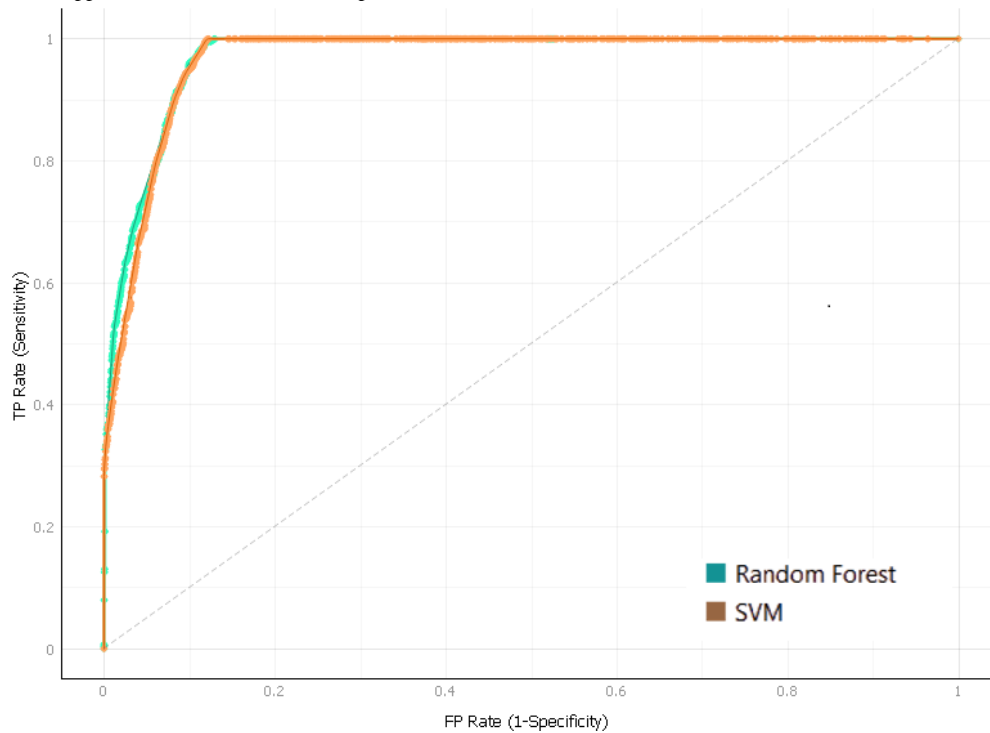
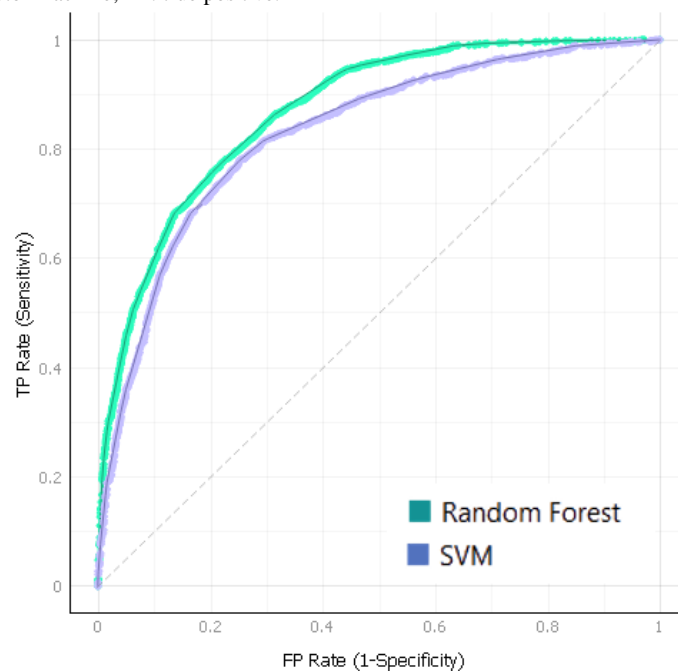


Figure 2. SVM and random forest receiver operating characteristics curve for abnormal anxiety (TP rate of sensitivity against FP rate of specificity). FP: false positive; SVM: support vector machine; TP: true positive.



The features importance ranking for depression and anxiety symptoms were analyzed using the RF ranking method. The features importance was scaled from 0% to 100%. The features with importance greater than 60% were selected and presented in Table 8. The most important features that affected depression symptoms were age, bullying behaviors, PTSD, life satisfaction, anxiety symptoms, health perception, friend support, academic score, school support, home violence, and family income.

Psychosomatic symptoms, age, bullying behaviors, family support, PTSD, depression symptoms, friend support, school support, home violence, academic score, family income, and physical activity were the most important features that affected the schoolchildren's anxiety symptoms.

Other variables were found to be less important for depression and anxiety among schoolchildren and therefore were not presented in Table 8.

Table 8. Depression and anxiety symptoms predictors importance ranking.

Mental health condition, symptom	Importance, %
Depression	
Family income	60
Home violence	66
School support	71
Family support	75
Academic score	78
Friend support	80
Health perception	83
Anxiety symptoms	84
Life satisfaction	85
PTSD ^a	90
Bullying behaviors	94
Age	95
Anxiety	
Physical activity	60
Family income	64
Academic score	70
Home violence	77
School support	78
Friend support	79
PTSD	83
Depression symptoms	84
Family support	88
Bullying behaviors	90
Age	93
Psychosomatic symptoms	96

^aPTSD: posttraumatic stress disorder.

Discussion

Principal Findings and Comparisons With Previous Work

In this study, we used ML models in predicting depression and anxiety symptoms among schoolchildren. The study found that two-thirds of students reported moderate depression symptoms and about 7% had severe depression, whereas around 22% of students reported moderate and severe anxiety symptoms. The

data showed that students in the sixth, eighth, and ninth grades had higher depression symptoms, whereas students in the fifth and sixth grades reported higher anxiety symptoms. These results are consistent with similar studies that found high depression and anxiety rates among adolescents [4,15,38-40]. The severe depression level of our study was close to those reported among schoolchildren in Germany, Canada, and Jordan [14,39,41]. The severe anxiety level was consistent with the results reported among adolescents living in Jordan, Spain, Canada, and Saudi Arabia [38,39,41,42].

The performance of the ML algorithms in predicting schoolchildren's depression and anxiety was assessed using the AUC, accuracy, precision, recall, and F1-score performance measures. In total, 23 relevant features were used after performing feature selection using ML algorithms. The features were used as input variables, whereas the average depression and anxiety scores were considered as the target variables independently. Among the tested models, SVM and RF showed the best performance results for depression (SVM: 92.5%; RF: 76.4%) and anxiety (SVM: 92.4%; RF: 78.6%). Furthermore, the specificity for the SVM and RF models were 87.8% and 88.6% for depression, respectively, and 76.9% and 85.5% for anxiety, respectively. Of the 23 features selected, 16 features were correlated to instances of depression and anxiety, including physical, mental, and social health indicators. However, the other models showed acceptable performance scores in predicting depression and anxiety. Thus, the findings of our study are consistent with other studies that assessed ML models in predicting depression and anxiety among adolescents and adults [4,6,17,43-48]. In Priya et al [4], the NB model had the highest accuracy levels for anxiety, depression, and stress, whereas the F1-score showed that the RF model had the highest performance measure for stress symptoms. Furthermore, the results are consistent with other studies that assessed the ML models in predicting depression and anxiety among adults [44-46]. The studies showed that the ML models are efficient in predicting depression and anxiety symptoms.

Significant risk factors for schoolchildren's depression and anxiety were found. Poor family and school conditions, such as low levels of school and family support, home and school violence (bullying behaviors), and low levels of positive health perception were highly significant to the risk of suffering from severe and moderate depression and anxiety, mainly among boys. This has been observed through the implementation of ML models. Additionally, the same results were obtained when controlling and not controlling for school type, age, and place of residence.

Furthermore, the data have shown that health-associated factors also had a significant effect on students' growth, cognitive development, and academic performance [49]. Moreover, it has been found that negative health conditions, such as obesity and PTSD, had a direct negative impact on student's mental health and cognitive development. Conversely, mother's education, gender, age, locality, physical activity, and good nutrition had less significant effects on mental health issues than the abovementioned variables.

These findings are consistent with other related studies that have found a strong association between mental health problems and risk factors such as school and home violence or negative health conditions [3,43,50,51]. Similar to previous studies, the research has shown that specific conditions such as obesity and PTSD are significantly correlated to depression and anxiety [5,26,52]. Furthermore, the prediction accuracy results obtained from the implemented ML algorithms are equivalent to the prediction accuracy rates obtained from related studies in the fields of mental health, as the RF model proved to be the most significantly accurate model [4,53].

Moreover, this study shows that several ML algorithms can predict depression and anxiety and their associated risk factors. The used algorithms successfully managed to predict the target variables, and the NB algorithm had the lowest accuracy rate for both anxiety and depression. However, it could be considered for the prediction of mental health conditions among schoolchildren with the presented variables. The RF ML model, on the other hand, proved the most effective in predicting depression and anxiety when students' health (physical and social) and related risk factors are considered. Overall, the classification accuracies were all at a favorable level. These findings show the importance of integrating ML techniques in the fields of mental health. These findings are consistent with other studies that indicated the importance of using ML in psychiatric and mental health diagnosis [4,54,55]. In the study of Haque et al [56], the RF model reported the highest accuracy among other ML algorithms (RF, XGBoost, and DT) in detecting depression among children aged 4-17 years. Furthermore, Sau et al [57] assessed 5 ML algorithms (logistic regression, NB, RF, SVM, and CatBoost) in identifying risk factors associated with anxiety symptoms, with the CatBoost model reporting the highest accuracy among the other ML models.

In this study, the risk features importance rating for anxiety and depression was estimated, which showed that age, bullying behaviors, PTSD, life satisfaction, and anxiety are the 5 most important features in predicting depression symptoms, whereas psychosomatic symptoms, age, bullying behaviors, and depression symptoms are the most important features in predicting anxiety symptoms. The study findings are consistent with other studies that found that the children's age, academic score, family income, social and family support, school and home violence, and physical activities are significant and important factors in predicting schoolchildren's depression and anxiety [13,15]. An important contribution of this study is the classification of schoolchildren at high risk to develop anxiety and depression symptoms. The most important features in our model are consistent with previous studies, which found that the population with high risks of anxiety and depression has a higher rate of tobacco use, increased BMI, and decreased academic performance [21,58-60].

Strengths and Limitations

Currently, the standard mental assessment scales are used in detecting schoolchildren's depression and anxiety, and it is mainly based on the health care system screening programs, which are mainly used when abnormal symptoms are witnessed. Furthermore, the current practices might fail in detecting the main associated factors with a subsequent delay in detection and intervention. Our prediction model combined the different levels of risk factors, including physical, mental, and sociodemographic factors. Our model is less dependent on the schoolchildren's subjective awareness of health status and health care screening behaviors; thus, the model improved the automatic and early detection of schoolchildren's depression and anxiety.

Overall, our study strengthens the need for the implementation and deployment of ML in addressing mental health problems.

The early detection and prediction of risk factors associated with mental health symptoms (depression and anxiety) can enhance the development of intervention and prevention programs that improve children's growth and cognitive development. Thus, this research study not only introduces the ML techniques in predicting depression and anxiety but also provides the policy makers with the power of ML in the early prediction and diagnosis of schoolchildren's mental health problems.

The study is limited by the number of variables. Based on the findings presented in this paper, future research will benefit from expanding the study by adding additional associated factors, including cognitive development skills, in-school student behavior, social activities, and digital media activities. Furthermore, variables related to external factors, such as the incidence of violence in the community, presence of soldiers, checkpoints, and mobility restrictions are not present in this study, yet these variables would be very relevant to further investigate the risk factors associated with anxiety and depression among schoolchildren in the Palestinian context.

The presence of these variables would further enhance the accuracy of the ML prediction models for anxiety and depression.

Conclusions

The study assessed the accuracy and performance of 5 ML models in predicting the associated health factors on Palestinian schoolchildren's depression and anxiety. Based on the results presented, this research concludes that ML algorithms, particularly (but not exclusively) RF and neural network, are effective predictive models for students' mental health status. These models could be integrated into schools' information systems for the automatic prediction of students' depression and anxiety based on key features. In this manner, students, families, school staff, and administration will be able to tackle issues that might affect students' mental health using the obtained prediction results. Likewise, by making use of accurate ML techniques, such as RF, public health professionals, health care providers, and decision makers will be able to predict rising issues and implement relevant intervention programs to enhance students' health, education, and well-being.

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Data Availability

The data sets generated and/or analyzed during the current study are available from the corresponding author on reasonable request.

Conflicts of Interest

None declared.

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Abbreviations

ANN: artificial neural networks
AUC: area under curve
DSRS: 18-item Depression Self-Reported Scale
DT: decision tree
ML: machine learning
PTSD: posttraumatic stress disorder
RF: random forest
SVM: support vector machine

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Original Paper

Translation and Validation Study of the French Version of the eHealth Literacy Scale: Web-Based Survey on a Student Population

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Abstract

Background: eHealth literacy is emerging as a crucial concept for promoting patient self-management in an overloaded hospital system. However, to the best of our knowledge, no tool currently exists to measure the level of eHealth literacy among French-speaking people. The eHealth Literacy Scale (eHEALS) is an easy-to-administer 8-item questionnaire (5-point Likert scale, ranging from strongly disagree to strongly agree) that has already been translated into many languages. Currently, it is the most cited questionnaire in the literature.

Objective: The aim of this study was to translate eHEALS to French and validate the French version of eHEALS (F-eHEALS).

Methods: The validation of the F-eHEALS scale followed the 5 steps of the transcultural validation method: double reverse translation, validation by a committee of experts (n=4), pretest measurement to check the clarity of the items (n=22), administration of the scale in French via a web-based quantitative study combined with two other questionnaires (Health Literacy Survey-Europe-16 and Patient Activation Measure-13; N=328 students), and finally test-retest (n=78) to check the temporal stability of the measurements obtained from the scale.

Results: The results obtained for the measurement of factor structure, internal consistency, and temporal stability (intraclass correlation coefficient=0.84; 95% CI 0.76-0.9; $F_{77,77}=6.416$; $P<.001$) prove the validity and fidelity of the proposed scale. The internal consistency of F-eHEALS was estimated by Cronbach α of .89. The factor analysis with varimax rotation used to validate the construct showed a 2-factor scale. The effect of the construct was analyzed using 3 hypotheses related to the theory. The F-eHEALS score was correlated with the Health Literacy Survey-Europe-16 score ($r=0.34$; $P<.001$) and the Patient Activation Measure-13 score ($r=0.31$; $P<.001$).

Conclusions: F-eHEALS is consistent with the original version. It presents adequate levels of validity and fidelity. This 2D scale will need to be generalized to other populations in a French-speaking context. Finally, a version taking into account collaborative applications (ie, Health 2.0; eg, Digital Health Literacy Instrument scale) should be considered on the basis of this study.

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KEYWORDS

eHealth Literacy Scale; eHEALS; eHealth literacy; transcultural validation process; Health Literacy Survey-Europe; HLS-EU

Introduction

Background

eHealth (or connected health) is an emerging field that incorporates various stakeholders, for instance, in the fields of medical informatics, public health, and companies [1]. This field can be an interesting opportunity to overcome the weaknesses of the current health systems and help health professionals and patients by making them active in their own health [1,2]. To benefit from this emerging field, connected medical devices available to the general public have to be accessible to all user profiles [3,4], regardless of the environment in which they are used. This means that patients must be able to use these tools correctly [5]. Using health information technology requires a specific set of knowledge and skills such as the ability to read, use computers, search for information, understand health information, and contextualize it [6]. All these skills relate to *eHealth literacy* [6]. In other words, assessing individuals' skills in using eHealth is equivalent to assessing their level of eHealth literacy. eHealth literacy scales have been developed to address this need [7].

eHealth Literacy: Definition and Theoretical Models

According to the *Institute of Medicine*, eHealth literacy refers to a person's skills "to search for, find, understand and evaluate health information from electronic sources and to apply the knowledge gained to treat or solve a health problem" [8]. This definition highlights the importance of contextual factors, including the media through which health information is disseminated and the level of health literacy in relation to these media [6]. Current media for the diffusion of health information include interactive tools for behavior change, such as applications, websites, and phone support services [9,10]. However, there is significant difference between the use of technology and the use of web-based health information (ie, digital literacy or eHealth literacy) [11], even if both the use of technology and the use of web-based health information are activities associated with eHealth literacy. Therefore, Norman and Skinner [6] aimed to identify the skills required to use this information.

Early studies in this field focused on *general literacy* (ie, "the ability to understand and use written information...to achieve personal goals and expand one's knowledge and abilities" (p12) [12]. Research has expanded into areas such as health literacy and eHealth literacy in relation to patient health [13]. The fundamental theories of eHealth literacy are, in part, based on social cognitive theories [14] and self-efficacy theories [15-17]. These theories consider self-confidence as a precursor of the behavior changes and skills needed to acquire high level of eHealth literacy. On the basis of these theories, Norman and Skinner [6] proposed a model of eHealth literacy (*lily model*) based on six different skills (or *literacies*) applied to health: (1) *traditional literacy* and numeracy, (2) health literacy, (3) information literacy, (4) scientific literacy, (5) media literacy, and (6) computer literacy. According to Norman and Skinner [6], eHealth literacy consists of a combination of all these 6 *core literacies*. These authors developed the *eHealth Literacy Scale* (eHEALS), an eHealth literacy rating scale to promote

eHealth and identify strategies to help patients use digital media in health. The eHEALS does not measure skills directly, but "measures consumers' *perceived* skills and comfort with eHealth" (p24) [6].

eHealth Literacy Scales and Cross-cultural Validations

Currently, several tools are available to assess eHealth literacy. In a systematic review of health literacy instruments [18], the authors identified 8 instruments including the eHEALS [7], *eHealth Literacy Questionnaire* [19], *eHealth Literacy Framework* [20], *Digital Health Literacy Instrument* (DHLI) [21], *eHealth Literacy Assessment Toolkit* [22], eHEALS-Extended [23], *Electronic Health Literacy Scale* [24], and *Transactional eHealth Literacy Instrument* [25]. To the best of our knowledge, none of these scales have been validated in French.

Several reasons led us to choose to validate eHEALS in French [7]. First, the eHEALS is a relatively short tool (8 items), making it easy to administer and combine with other scales. Second, currently, it is the most widely used scale for measuring eHealth literacy in international scientific literature [26]. This tool has been translated into different languages over the past 10 years [27-39]. This shows that it can be used in various languages and cultural contexts. However, currently, its French translation does not exist. Furthermore, one of the advantages of eHEALS is that it can be adapted to different populations and different contexts. The scale was administered to different categories of individuals, such as older people [40], young adults [41], nursing students [42], and teenagers [43].

The eHEALS Original Version

The original version of eHEALS, created by Norman and Skinner [7], is composed of 10 items relating to the 6 literacy types of the *lily* model mentioned previously. A total of 8 items assess users' knowledge; comfort; and perceived skills in finding, assessing, and applying digital health information to answer health questions. The scale also includes 2 additional items that focus on participants' perception of the use of the internet as a decision-making tool and its usefulness in collecting health information (these items are not included in the total score).

The psychometric characteristics of the original scale were assessed on a sample of teenagers (N=664; mean age 14.95, SD 1.24 years). Cronbach α was .88, and the test-retest reliability was 0.68 [7]. The authors used factor analysis and highlighted a single-factor solution (eigenvalue=4.479; 56% of the variance explained).

Factors Affecting eHealth Literacy

Several factors are associated with eHealth literacy: sociodemographic characteristics, health literacy, and commitment to health. Studies do not agree on the association with sociodemographic characteristics (gender, education level, and health outcomes) [38,44-46]. As some studies show differences in eHealth literacy according to these sociodemographic characteristics and others do not, obtaining an overview of the eHealth literacy level of a population is complex. Chesser et al [47] showed in a systematic review that

eHealth literacy was associated with the level of education and advanced age, even if there is some variability among the older population.

Contrary to the association with sociodemographic characteristics, there seems to be a consensus on the relationship between health literacy and eHealth literacy [38,45,48,49], health literacy being one of the components of eHealth literacy in the model suggested by Norman and Skinner [6]. Neter et al [49] found a positive, moderate, and significant correlation between the scores on Health Literacy Survey-Europe-16 (HLS-EU-Q16) and eHEALS ($r=0.36$; $P<.05$) in a sample of 199 adults. Similar results ($r=0.43$; $P<.001$) were obtained by Duplaga et al [48] on a sample of 199 young adults (aged 18-29 years). Wängdahl et al [38] also found a moderate positive correlation ($r=0.47$; $P<.05$) between the HLS-EU-Q16 and the Swedish version of eHEALS in a sample of 323 adults.

Furthermore, there seems to be a link between patient commitment to health and the level of eHealth literacy. Patient commitment to health, also known as *patient activation*, is commonly measured by the *Patient Activation Measure-13* (PAM-13) scale [50]. For instance, Lee et al [51] assessed the level of activation among 399 adults who were chronically ill, using PAM-13 and their eHealth literacy level using eHEALS. The authors showed a positive, moderate, and significant correlation between these 2 variables ($r=0.50$; $P<.001$).

In summary, previous studies agree on the link between health literacy and eHealth literacy and the link between patient health activation and eHealth literacy. However, the links between the sociodemographic characteristics of individuals and eHealth literacy seem to be less convergent.

Objective

The objective of this study was to translate eHEALS, which is already developed by Norman and Skinner [7], into French and validate it with a student population.

Methods

Procedure

To conduct the translation, adaptation, and validation of eHEALS [7], we followed the American Psychological Association guidelines [52] and the 5 steps recommended by Vallerand [53]: translation, validation with experts, pretest measurement, administration of the tool, and test-retesting. Figure S1 in [Multimedia Appendix 1](#), translated from Vallerand [53], shows these steps.

These 5 steps were conducted between December 2019 and March 2020.

Ethics Approval

This study complied with the principles set out in the Declaration of Helsinki of 1964 and its subsequent amendments. Before the experiment, the participants signed a web-based consent form, and the questionnaire was validated by the research ethics committee of the university Picardie Jules Verne. The participants did not receive any financial compensation for their participation, and they agreed to participate in the study.

The anonymity, confidentiality, and secure storage of the data were guaranteed to the participants and respected.

Step 1: Translation of eHEALS Into French by a Process of Double Reverse Translation—Preparation of a Preliminary Version

We have been authorized to translate the original eHEALS scale by its authors [7]. After authorization, we performed a double reverse translation of the eHEALS by 2 professional translators who had French as their native language, independently of each other. This method is considered “ideal for drafting the psychological instrument” (our translation; p665) [53]. Then, the 2 French versions obtained were retranslated into English by 2 professional translators who had English as their native language and had not seen the original version, again independently of each other. In total, 2 French versions and 2 preliminary English versions were produced at the end of this phase.

Step 2: Validation by a Committee of Experts

A committee of 4 experts, 3 (75%) of whom are authors of the manuscript, consisting of 1 (25%) expert in neuropsychology, 1 (25%) expert in cognitive psychology, and 2 (50%) other experts in ergonomics, met to examine the quality of the translations and agree on the best version. To do so, they compared the different translated versions with the original English version, taking into account the French cultural context and checking the clarity of the language. This committee made some minor changes to the selected items. A French version of eHEALS (F-eHEALS) was established after the committee’s intervention. The committee members discussed in detail the translation of the term *health resources*. The suggestions for translation were as follows: “ressources en santé,” “ressources sur la santé,” or “ressources de santé.” Members agreed on “ressources sur la santé” as being more inclusive and easy to understand. The committee was also unsure whether to propose the term “information” instead of “resources.” Finally, the term “resources” (“ressources” in French) was retained to not differ from the original version.

Step 3: Pretest Measurement for Clarity of Items

We performed a pretest measurement to check the clarity of the items (ie, unambiguous wording of the translated items). A total of 22 participants were asked to evaluate the items (including the instructions) using a web-based questionnaire. To do so, participants had to read each item and judge its clarity on a scale from 1 (*not at all clear*) to 7 (*very clear*). Items that were scored ≤ 4 needed to be reviewed. For each item, participants could also leave comments on potential ambiguities and justify their scores for each item. The results of this pretest measurement were used to create a final version of F-eHEALS.

Step 4: Administration

A total of 344 students aged 16 to 33 years responded to F-eHEALS, two additional scales (HLS-EU-Q16 and the PAM-13), and questions on their sociodemographic characteristics.

This population was relevant because the suitability of the tool for a population of young adults has already been demonstrated

[32,33,35,37,41,42]. To target this population, the scales were shared on Facebook groups of students from several French universities. All respondents had to be students and have French as their native language.

The instructions given to the participants explained the main objective of the study regarding the translation of the eHEALS scale and provided some explanations to justify the presence of the other questionnaires (ie, HLS-EU-Q16 and PAM-13): “It concerns your perceptions of your ability to search, find and process health-related information on the Internet, your involvement in your health.” As there appears to be a relationship among patient commitment, health literacy, and eHealth literacy, we chose to add PAM-13 and HLS-EU-Q16 to the questionnaires to measure concurrent validity.

Each participant had to consent to the study by means of electronic validation to be able to access the questionnaires. First, the participants completed information about their age, gender, level of education, and field of education and a question related to their health conditions. Then, they were asked to complete F-eHEALS, HLS-EU-Q16 [54], and finally, PAM-13 [50]. After completing the questionnaires, participants were asked if they wanted to be contacted again for the test-retest by providing an email address.

Step 5: Test-Retest

Test-retest stability is the best indicator of the metric quality of a scale relative to other fidelity indices [55]. This evaluation has the specificity of measuring the temporal stability of the measurements [53]. A total of 170 participants agreed to be contacted on a later date. The same questionnaires with the same format (instructions, consent, and questionnaires) were sent to the participants 1 month after their initial enrollment. Of the 170 participants, 84 (49.4%) participants responded to the questionnaires.

Measures: Questionnaires and Data Analysis

F-eHEALS Questionnaire

F-eHEALS, similar to the original version of eHEALS developed by Norman and Skinner [7], consists of 8 items measuring eHealth literacy on a 5-point Likert scale (ranging from 1=*strongly disagree* to 5=*strongly agree*). A total of 2 other items, related to the importance and usefulness that individuals attach to the internet for making decisions about their health, are included, but are not to be counted in the final rating. The eHEALS score depends on the points obtained for each item (*strongly disagree* scores 1 point and *strongly agree* scores 5 points). The eHEALS score ranges from 8 to 40 points. The higher the score, the higher the level of eHealth literacy. The analysis of the items was conducted on the 8 items that make up eHEALS [7].

HLS-EU-Q16 Scale

The *HLS-EU-Q16* [54] is the short version of *HLS* developed by Sørensen et al [56]. It has been translated into French [57]. This version consists of 16 items, 13 (81%) of which assess the 4 types of health literacy skills: the ability to access, understand, evaluate, and apply health information [56]. The respondent has to assess their own ability to access the information (eg,

“Please indicate on a scale from very easy to very difficult, how easy it is for you to understand your doctor’s or pharmacist’s instructions on how to take your medication?”). Overall, 4 categories of answers were proposed on a 4-point Likert scale. *Difficult* or *very difficult* responses do not score any points, whereas *easy* and *very easy* responses score 1 point. Then, the total score is calculated: the higher the score, the higher the level of health literacy.

French Version of PAM

PAM-13 [50], translated into French [58], is a 13-item scale that assesses a patient’s knowledge, skills, and confidence in self-managing their health or chronic illness. The respondent has to assess their ability to self-manage their health (eg, “All things considered, I am the person who is responsible for taking care of my health”). Respondents provide their answers on a 5-point Likert scale (from 1=*strongly disagree* to 5=*strongly agree*). Then, the total score is calculated based on the participants’ response to each item. The total score for the items ranges from 13 to 65 points; the higher the score, the higher the level of commitment to health.

Data Analysis

Overview

The results were analyzed using SPSS (version 22; IBM Corp). All the data of this study are in open access [59]. The fidelity assessment was performed by analyzing the internal consistency of the tool, as assessed by Cronbach α . Cronbach α was $>.7$, which indicates that the items in the study are consistent [60]. Construct validity was measured by means of three statistical analyses: (1) exploratory factor analysis (principal component analysis with varimax rotation), (2) analysis of interitem correlations, and (3) analysis of construct effects using Pearson correlations among HLS-EU-Q16, PAM-13, and F-eHEALS.

Exploratory Factor Analysis

To verify whether the measures are suitable for factor analysis, we used the Kaiser-Meyer-Olkin (KMO) and Bartlett sphericity tests. KMO values close to 1 are considered to be ideal, and statistically significant result in the Bartlett sphericity test shows that the correlation matrix is not an identity matrix. The multivariate normality test (distance of Mahalanobis) was used to ensure the normality of the data. If the Mahalanobis maximum value is less than the critical value, multivariate normality is existing. Then, we used principal component analysis (varimax rotation; Kaiser criterion >1), which is a multivariate interdependence technique that allows the associated variables and the measurement of latent constructs to be determined. To conduct this analysis, a minimum statistical power is required. Hair et al [61] consider it necessary to have a ratio of 10 participants per variable in the analysis, which will correspond to a minimum of 80 participants for our scale. Factor scores >0.71 were considered to be excellent, those >0.63 to be very good, those >0.55 to be good, those >0.45 to be acceptable, those close to 0.32 to be poor, and those <0.32 to be very poor [62].

Analysis of Interitem Correlations

The analysis of interitem correlations allows the internal coherence of the scale to be assessed. To measure this construct, the elements must be sufficiently correlated ($r > 0.4$).

Analysis of the Effects of Constructions

The construct effect makes it possible to verify the links between the construct and the variables identified in the literature [53]. We formulated 3 hypotheses about the links between health literacy and other variables that have previously been shown to be related to eHealth literacy. The measurement of the effect of the construction is based on 3 hypotheses: (1) the level of eHealth literacy is not correlated with sociodemographic characteristics (gender and health outcomes), (2) the level of eHealth literacy will be positively and moderately correlated with the level of health literacy, and (3) the level of eHealth literacy will be positively and moderately correlated with the level of patient activation. We used Pearson correlations to validate (or invalidate) the hypotheses.

Results

Translation and Equivalence Verification With the Original Version (Steps 1, 2, and 3)

During the pretest measurement to assess item clarity ($n=22$; mean age 38.47, SD 8.44 years; range 26-63 years), none of the F-eHEALS items were rated < 4 (Multimedia Appendix 2). All items had been rated a mean score of 6.27 (SD 1.15) and, therefore, were considered to be understandable and clear. Only items 5 and 6 were modified in a minor way by changing the term “ressources” to “informations,” the first term being considered to be very confusing by the respondents. This term had already been discussed by the expert committee.

Validation (Steps 4 and 5)

Sociodemographic Characteristics of the Sample

Of the 344 participants who responded to this scale, we excluded 15 (4.4%) participants: 7 (47%) participants were not students, 8 (53%) were aged > 35 years and thus considered to cause risk of age bias, and 1 (7%) did not give their consent. Thus, 95.3% (328/344) of the participants (mean age 21.22, SD 2.7 years; 274/328, 83.5% were women; 52/328, 15.9% were men; and 2/328, 0.6% were nonbinary) were eligible for step 4. Details of respondent characteristics are presented in Multimedia Appendix 3.

Internal Consistency and Temporal Stability

Of the 344 participants who responded to the questionnaires, 170 (49.4%) participants agreed to be recontacted for the retest. Of these 170 participants, 84 (49.4%) responded to the

questionnaire. Of the 84 participants, 6 (7%) participants had to be excluded because their identification did not allow a link to be made with the database of contacts from the first test. Thus, 93% (78/84) of the participants were included in the retest. The temporal stability of our sample was (intraclass correlation coefficient=0.84; 95% CI 0.76-0.9; $F_{77,77}=6.416$; $P < .001$). We also observed a strong and positive correlation between the 2 sessions ($r=0.72$; $P < .001$). The internal consistency of F-eHEALS was estimated by a Cronbach α of .89.

Assessment of Construct Validity

Exploratory Factor Analysis by Principal Component Analysis

The Bartlett sphericity test was significant ($N=328$; $\chi^2_{28}=1616.3$; $P < .001$), and the KMO index was 0.85. The multivariate normality test was performed (distance of Mahalanobis: dof=8; mean 7.976, SD 5.317; minimum=0.876; maximum=30.146). None of the outliers were removed.

The analysis of the main factor produced an eigenvalue of 4479. The first 2 factors were extracted on the basis of Kaiser criteria, because they have an eigenvalue > 1 . The first factor (item) alone explained 57.72% of the total variance of the 8 items analyzed. Thus, the first 2 factors (items) explained 71.54% of the total eigenvalue variance. In Multimedia Appendix 4, we can see that the Cattell scree test validates Kaiser criteria because it is located between item 2 and item 3.

Examination of the factor structure of the initial scale revealed 2 factor axes (Table 1). When analyzing components 1 and 2 in relation to the 8 items before rotation, we observed a loading of all items for the first factor. We also observed 2 similar correlations between the 2 factors and item 7. We proceeded to a varimax rotation to obtain a simple factorial representation. After varimax rotation, we observed that items 1, 2, 3, 4, and 5 loaded on the first factor.

Item 1 corresponds to “I know how to find helpful health resources on the Internet,” item 2 corresponds to “I know how to use the Internet to answer my health questions,” item 3 refers to “I know what health resources are available on the Internet,” item 4 refers to “I know where to find helpful health resources on the Internet,” and item 5 corresponds to “I know how to use the health information I find on the Internet to help me.” For factor 2, items 6 and 7 were loaded. Item 6 corresponds to “I have the skills I need to evaluate the health resources I find on the Internet” and item 7 refers to “I can tell high quality from low quality health resources on the Internet.” Item 8, corresponding to “I feel confident in using information from the Internet to make health decisions,” seems to straddle the 2 factors after varimax rotation.

Table 1. Principal component factor analysis before and after varimax rotation^{a,b}.

Item	Principal component analysis before varimax rotation		Principal component analysis after varimax rotation	
	Factor 1	Factor 2	Factor 1	Factor 2
1	<i>0.79</i> ^c	-0.36	<i>0.86</i>	0.12
2	<i>0.86</i>	-0.31	<i>0.89</i>	0.21
3	<i>0.86</i>	-0.27	<i>0.87</i>	0.23
4	<i>0.80</i>	-0.13	<i>0.74</i>	0.32
5	<i>0.79</i>	0.03	0.65	0.45
6	0.66	0.58	0.24	<i>0.85</i>
7	0.61	0.66	0.16	<i>0.88</i>
8	0.66	0.13	0.48	0.46

^aVariance accounted for=71.54%.

^bCronbach α =.89.

^cScores >0.7 have been italicized.

Patterns of Interitem Correlation

After analysis of the correlation matrix ([Multimedia Appendix 5](#)), we found that the 8 items in F-eHEALS are positively correlated with each other. The values were in the range of 0.30 to 0.86. The lowest correlation recorded was between item 1 and item 7 ($r=0.3$). In contrast, the highest correlation observed

was between item 2 and item 3 ($r=0.86$). Item 7 appeared to have the lowest correlation with the other items. The average interitem correlations ranged from 0.53 to 0.78 ([Table 2](#)). The means of the interitem correlations of the original eHEALS scale ranged from $r=0.51$ to 0.76 [7], which is close to the F-eHEALS results.

Table 2. Descriptive statistics by items (N=328).

Item	n (%)	Mean (SD) ^a	Range	Interitem correlation	Original interitem correlation, (Norman and Skinner [7])
1	328 (100)	3.31 (1.06)	1-5	0.69	0.68
2	328 (100)	3.25 (1.14)	1-5	0.78	0.70
3	328 (100)	3.32 (1.11)	1-5	0.78	0.68
4	328 (100)	3.53 (1.06)	1-5	0.71	0.76
5	328 (100)	3.48 (1.07)	1-5	0.71	0.73
6	328 (100)	3.22 (1.19)	1-5	0.59	0.63
7	328 (100)	3.72 (1.08)	1-5	0.53	0.55
8	328 (100)	2.34 (1.03)	1-5	0.57	0.51

^aOverall mean (SD)=26.16 (6.61).

Concurrent Validity of the Scale

The F-eHEALS score correlated positively and significantly with the HLS-EU-Q16 score ($r=0.34$; $P<.001$) and the PAM-13 score ($r=0.31$; $P<.001$). We did not observe significant difference between gender ($F_{3,324}=1.56$; $P=.20$), health outcomes (chronic disease; $F_{1,326}=0.017$; $P=.89$), and F-eHEALS score.

Discussion

Principal Findings

The objective of the study was to translate eHEALS to French and validate F-eHEALS in a student population. The results of this study validated its translation and adaptation, allowing us to propose a French version of the validated eHEALS scale ([Multimedia Appendix 6](#)).

Comparison With Previous Studies

Translation

The translation process highlighted the complexity of translating from English to French. Although the translated content must remain the same as the original version, reflecting the real meaning of the items, it also has to be adapted to the language and culture of the target population. During the double reverse translation, terms were discussed by the expert committee—specifically, *health resources*, having been mentioned in other translations [38,45], illustrates the universal complexity of translating from English to other languages. After conducting the pretest measurement to check the clarity of the items, the scale was presented to a sample of 328 students.

Validation

Fidelity

The fidelity of F-eHEALS was measured using internal consistency and temporal stability. Internal consistency was evaluated using Cronbach α , and temporal stability was evaluated by confidence index. In our study, internal consistency (Cronbach α =.89) was judged to be excellent according to recommendations of Nunnally [60]. Regarding temporal stability, we observed good fidelity [63] of our sample. These results are congruent with those of the original study [7], which obtained a similar result (Cronbach α =.88). Moreover, our results regarding fidelity are consistent with those of several studies that have shown a higher Cronbach α than the original (ie, >.88) [27-29,38-41].

Construct Validity

The Bartlett sphericity test was significant, and the KMO sampling precision index can be described as excellent. These results indicate that the correlations between the items are of good quality and thus legitimize the factor analysis. In addition, as the current sample includes 328 participants, this was correct and the statistical power was considered to be sufficient [61].

Construct validity highlighted a 2-factor (or 2D) structure. Although this contradicts some studies [27,28,33,35,40,41,64], other studies have also revealed a 2-factor structure [30,37,39,49,65-67]. This 2-dimensionality is fully consistent with the multidimensional property of eHealth literacy, which is composed of different literacies [6]. These results are consistent with 3 studies [65,67,68] that found the item structure similar to ours (ie, information seeking: items 1, 2, 3, 4, 5, and 8 and information appraisal: items 6 and 7). Nevertheless, in the systematic analyses, Lee et al [18] demonstrated the lack of high-quality evidence for structural validity and internal consistency for 2-factor scales in the 3 studies, which shows the instability of 2-factor scales. Therefore, it is important to remain cautious about this structure.

We observed a problematic load factor for item 8. In the item loading analysis, item 8 was in the first factor before rotation; however, item 8 straddles the 2 factors after varimax rotation. This analysis is consistent with the Italian translation and validation before rotation [65]. It is likely that if the authors had rotated, they would probably have found similar results. Many other similarities were observed between this study and the Italian validation study (eg, Cronbach α , variance accounted, and 2D scale). This is probably owing to the common Latin roots of French and Italian languages. However, these similarities are not observed in other Latin translations (eg, Portuguese and Spanish). Moreover, in an Italian validation with a population of nurses, De Caro et al [33] observed a unidimensionality. This shows the instability of eHEALS according to the population. Item 8 also seemed problematic in other validations observing a 2D scale [39]. This is likely owing to the fact that in the original article, the loading of item 8 was not excellent. Item 8 loads at 0.6 without rotation, which does not seem to be *good* [62]. However, to the best of our knowledge, no study on the validation of eHEALS has removed item 8 from the questionnaire, despite its weakness. Therefore,

despite the difficulties of discrimination and the ambiguous load factor of item 8, consistent with Dale et al [39], Gazibara et al [37], Richtering et al [66], and Shiferaw [30], we decided to retain it.

Depending on the language, item 8 can switch between the first [37] and second factors [65]. Items 1 to 5 begin with "I know," whereas items 6 and 7 refer to the notion of self-evaluation, such as "I have the skills" or "I can." Item 8 seems to be close to the notion of reliability and trust ("I feel confident") and, therefore, to the notion of self-evaluation including items 6 and 7. Thus, this double factor divides the items into two dimensions: those measuring information-seeking skills (items 1-5) and those measuring the evaluation of health information (items 6-8).

It would seem appropriate to measure a mean score for each underlying factor, rather than an overall score. However, considering the instability of some items, it seems more relevant to measure an overall score. Moreover, a score for each factor can compromise comparisons and standardization, with most studies using an overall score. Considering these indications, we suggest calculating scores for each factor and an overall score in future uses of F-eHEALS.

The variance explained by the 2-factor model in this study is also relatively high compared with that in other similar validation studies in other languages [27,32,35].

The quality of representation of the items (ie, whether the items are well represented by the dimensions of the construct) was judged to be excellent because all the items showed a score >0.45. Thus, we have decided to retain all items in the translation and validation of eHEALS. The means of the interitem correlations of the original eHEALS scale [7] are consistent with the F-eHEALS results. The effect of the F-eHEALS scale construction was acceptable. To validate its content, we formulated 3 hypotheses, which have proved to be correct. The first hypothesis, according to which there was no link between user characteristics (age, gender, and health status) and the level of eHealth literacy, was validated. We found no significant correlations between the F-eHEALS scores and the sociodemographic characteristics of our sample. These results are consistent with the results of other studies regarding gender [44,47] and health outcomes [44]. Our second hypothesis, according to which there was a link between health literacy and eHealth literacy, was validated. In addition, the health literacy score, measured using HLS-EU-Q16, was positively and moderately correlated with the F-eHEALS score. These results are consistent with those of other studies [38,45,48,49]. Our third hypothesis, expecting a link between the level of patients' health activation and the level of eHealth literacy, was validated. The patient health activation score, measured using the PAM-13, was positively and moderately correlated with the F-eHEALS score, which is consistent with the study by Lee et al [51].

Limitations

This study has some limitations. First, our sample was very homogenous in terms of important factors influencing eHealth literacy, as it was composed exclusively of young adult students for a practical reason. Moreover, this scale was administered to

different categories of individuals, such as older adults [40], young adults [41], nursing students [42], and teenagers [43]. Therefore, this scale should be validated in a more representative sample of French-speaking populations in a subsequent study. Second, the PAM-13 scale has only been partially validated. Only the analysis of internal consistency and temporal stability was conducted [58]. A more complete validation is necessary. Similarly, confirmatory factor analysis should be performed. Third, as F-eHEALS is a 2D scale, we recommend scoring the 2 subscales separately and measuring the overall score, as done in this study. Fourth, French scientific literature is relatively scarce in the area of health literacy. Our comparisons were made on the basis of a wide variety of cultures and languages. We hope that translations of scales, such as F-eHEALS, will promote studies in the field. Fifth, eHEALS, HLS-EU-Q16, and PAM-13 are subjective assessments [38], as the level of eHealth literacy is self-reported by respondents and may be overestimated or underestimated. Therefore, it will be interesting to clarify the links between subjective and objective assessments to better understand the margins of error in these tests.

Recently, since the development of interactive applications—social networks, forums, and so on (Health 2.0)—that help people communicate about their health, eHealth literacy is required to be considered as a broader skill [35]. To

bridge the *digital divide*, it will be important to use instruments that measure all varieties of eHealth literacy. Even if eHEALS is strongly correlated with DHLI [21], considering these aspects of interaction, we encourage French-speaking researchers to integrate new items related to these new forms of interaction into eHEALS or to translate and validate DHLI [21] to measure the variability of eHealth literacy encompassing the competencies from Health 2.0 and to allow the French-speaking community to catch up in this field.

Conclusions

This study was conducted with a population of young adult students for a practical reason, which allowed us to propose the first eHealth literacy scale that is validated in terms of fidelity and the validity of F-eHEALS to the French-speaking community. This 2D scale will need to be generalized to other populations in a French-speaking context. Finally, a version considering interactive applications (ie, Health 2.0 and DHLI scale) should be considered on the basis of this study. The value of such a scale seems to be even more relevant as eHealth has never been as much in demand as in recent years and will probably be even more so in the future, particularly owing to the increasing use of eHealth technologies. We hope that this study will enable other authors to initiate studies in the field of eHealth literacy in the French context.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Steps described by Vallerand [54].

[PNG File , 223 KB - [formative_v6i8e36777_app1.png](#)]

Multimedia Appendix 2

Presentation of the clarity of the items (and instructions) of the French version of eHealth Literacy Scale, judged by 22 volunteer laypeople.

[DOCX File , 15 KB - [formative_v6i8e36777_app2.docx](#)]

Multimedia Appendix 3

Details of respondent characteristics (N=328)—sociodemographic characteristics, health status, health literacy level, and eHealth literacy level.

[DOCX File , 16 KB - [formative_v6i8e36777_app3.docx](#)]

Multimedia Appendix 4

Explanation of variance using Cattell scree test on item-specific score values.

[PNG File , 15 KB - [formative_v6i8e36777_app4.png](#)]

Multimedia Appendix 5

Interitem correlation matrix for the French version of eHealth Literacy Scale.

[[DOCX File , 15 KB - formative_v6i8e36777_app5.docx](#)]

Multimedia Appendix 6

The French version of eHealth Literacy Scale.

[[DOCX File , 19 KB - formative_v6i8e36777_app6.docx](#)]

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Abbreviations

DHLI: Digital Health Literacy Instrument
eHEALS: eHealth Literacy Scale

F-eHEALS: French version of eHealth Literacy Scale

HLS-EU-Q16: Health Literacy Survey-Europe-16

KMO: Kaiser-Meyer-Olkin

PAM-13: Patient Activation Measure-13

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Original Paper

Just-in-Time Prompts for Running, Walking, and Performing Strength Exercises in the Built Environment: 4-Week Randomized Feasibility Study

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Abstract

Background: App-based mobile health exercise interventions can motivate individuals to engage in more physical activity (PA). According to the Fogg Behavior Model, it is important that the individual receive prompts at the *right* time to be successfully persuaded into PA. These are referred to as *just-in-time* (JIT) *interventions*. The Playful Active Urban Living (PAUL) app is among the first to include 2 types of JIT prompts: JIT adaptive reminder messages to initiate a run or walk and JIT strength exercise prompts during a walk or run (containing location-based instruction videos). This paper reports on the feasibility of the PAUL app and its JIT prompts.

Objective: The main objective of this study was to examine user experience, app engagement, and users' perceptions and opinions regarding the PAUL app and its JIT prompts and to explore changes in the PA behavior, intrinsic motivation, and the perceived capability of the PA behavior of the participants.

Methods: In total, 2 versions of the closed-beta version of the PAUL app were evaluated: a basic version (Basic PAUL) and a JIT adaptive version (Smart PAUL). Both apps send JIT exercise prompts, but the versions differ in that the Smart PAUL app sends JIT adaptive reminder messages to initiate running or walking behavior, whereas the Basic PAUL app sends reminder messages at randomized times. A total of 23 participants were randomized into 1 of the 2 intervention arms. PA behavior (accelerometer-measured), intrinsic motivation, and the perceived capability of PA behavior were measured before and after the intervention. After the intervention, participants were also asked to complete a questionnaire on user experience, and they were invited for an exit interview to assess user perceptions and opinions of the app in depth.

Results: No differences in PA behavior were observed ($Z=-1.433$; $P=.08$), but intrinsic motivation for running and walking and for performing strength exercises significantly increased ($Z=-3.342$; $P<.001$ and $Z=-1.821$; $P=.04$, respectively). Furthermore, participants increased their perceived capability to perform strength exercises ($Z=2.231$; $P=.01$) but not to walk or run ($Z=-1.221$; $P=.12$). The interviews indicated that the participants were enthusiastic about the strength exercise prompts. These were perceived as personal, fun, and relevant to their health. The reminders were perceived as important initiators for PA, but participants from both app groups explained that the reminder messages were often not sent at times they could exercise. Although the participants were enthusiastic about the functionalities of the app, technical issues resulted in a low user experience.

Conclusions: The preliminary findings suggest that the PAUL apps are promising and innovative interventions for promoting PA. Users perceived the strength exercise prompts as a valuable addition to exercise apps. However, to be a feasible intervention, the app must be more stable.

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KEYWORDS

just-in-time interventions; context-based; prompts; reminders; physical activity; mobile health; mHealth; exercise application; Fogg Behavior Model; user experience; engagement; feasibility study; mobile phone

Introduction

Background

Motivating individuals to engage in regular physical activity (PA) is a global interest as physical inactivity can lead to numerous serious health issues such as cardiovascular diseases, cancer, and diabetes [1]. Therefore, individuals are recommended to engage in at least 150 minutes of moderate to vigorous PA (MVPA) every week. In addition, it is recommended to perform bone- and muscle-strengthening exercises at least 2 times a week [2] as they provide additional health benefits next to aerobic exercise [3,4]. However, many individuals do not meet these guidelines [5]. Recent data show that 58.3% of adults (aged >18 years) engage in sufficient moderate PA, and 82.2% engage in sufficient muscle and bone strength exercises, but only 52.9% engage in both [5].

A promising method to increase PA are mobile health (mHealth) PA apps [6,7] such as mobile phone apps. Mobile phones are well integrated into our daily lives [8]; they can continuously track PA behaviors with limited effort from the individual and provide real-time feedback on their behavior. In addition, by continuously tracking the behavior and context of the individual, it is now possible to develop highly personalized and context-based interventions that can offer the right support at the right time [9].

Previous studies have indicated that mHealth PA interventions are more likely to be effective when they are grounded in theory and, as such, contain adequate persuasive strategies [10,11]. Persuasive strategies (or behavior change techniques [12]) are theoretically underpinned elements of interventions intended to facilitate a positive behavior change (eg, rewards and goal setting). It is theorized that persuasive strategies can change the determinants of behavior, such as motivation and capability [13], which in turn influences the targeted behavior. Several studies have demonstrated that self-regulatory persuasive strategies such as goal setting, feedback, monitoring, and prompts are effective in changing PA behavior [7,10,14,15].

In addition, the research fields of human-computer interaction and design thinking emphasize the importance of the quality of the user experience for the success of the intervention [16,17]. *User experience* is an umbrella term that encapsulates concepts such as user satisfaction, perceived usefulness, esthetics, and user-friendliness [18]. Previous studies have demonstrated that apps that have a low subjective user experience are more likely to face low acceptance rates and the problem of nonadherence [19,20]. This is problematic as participants do not engage (sufficiently) with the behavior change components of the

intervention [17,21,22] and nonadherence has been shown to negatively influence intervention effectiveness [23,24]. Thus, both the selection of persuasive strategies and their design and implementation are of importance for the success of the intervention [25,26].

A likely effective persuasive strategy is to provide a prompt to engage in a certain behavior [27]. According to the Fogg Behavior Model (FBM) [28,29], the prompt also has to be sent at *the right time* to effectively change behavior. The right time, or *the moment of opportunity*, to send a message is when the individual is motivated enough and when they can perform the exercise. If the motivation and ability are high enough, the individual has crossed the *activation threshold* and can therefore be triggered to perform a behavior. In addition, a well-designed prompt can also increase the motivation (referred to as *spark prompts* [27]) or ability (referred to as *facilitator prompts* [27]) of an individual.

Interventions that aim to send messages at the right time are often referred to as *just-in-time (JIT) interventions* or *JIT adaptive interventions (JITAI)* [9,30,31]. With JIT interventions, the content and timing of the prompt supports the need of the user in real time and is triggered by the system based on predetermined factors. JITAI are similar except that they also have the ability to adapt the timing or content of the prompt over time to an individual's changing needs and wishes [9,30,32]. Although prompts are commonly included strategies in PA apps [33], only a few studies have examined the effect of timing on persuasiveness [34,35].

Objectives

Therefore, we set out to investigate 2 novel ways of JIT prompting for PA behaviors with an mHealth app, the Playful Active Urban Living (PAUL) app. First, to initiate running or walking behavior, the app sends JITAI reminder messages based on a reinforcement learning algorithm [36]. Second, during a PA session (outdoor running or walking), the individual receives JIT location-based strength exercise prompts containing instructional videos for performing strength exercises. These prompts are triggered by either beacons or preprogrammed GPS coordinates, allowing the app to send the right instruction video at the right location and time. For this study, 2 parks in Amsterdam (Sloterpark and Oosterpark) and 1 park in Utrecht (Park Transwijk) were selected as exercise locations. We will refer to these two prompts as *reminder messages* and *strength exercise prompts*, respectively, for the remainder of this paper.

To determine the proof of concept for the design and implementation of the 2 types of prompts, we conducted a feasibility study [37]. Examining the feasibility of a digital

intervention before a large-scale effectiveness study is an important step in the development phase. This offers insights into the subjective user experience and engagement with the app and can be used to establish if it is likely that the app will be effective in changing behavior [37,38].

The feasibility of the PAUL app was examined by exploring 4 factors [38]. First, we explored the perceptions and opinions of the users regarding the included persuasive strategies within the PAUL app, with a focus on the 2 novel ways of prompting. Second, the user experience with the PAUL app was examined. Third, we examined the users' behavioral engagement with the app and, finally, we explored whether the PAUL app has the potential to change the motivation and perceived capabilities of the users. In total, 2 versions of the app were examined: the Basic PAUL app and the Smart PAUL app. Both versions of the app are identical except that the Basic PAUL app sends reminder messages at randomized times, whereas the Smart PAUL app sends JITAI reminder messages based on the context and previous PA behavior of the user.

Methods

Participants

Participants were recruited by distributing promotional materials around Sloterpark, Oosterpark, and Park Transwijk. Facebook advertisements were issued targeting individuals aged between 18 and 55 years and living close (<3.5 km) to the parks. In addition, advertisement messages were posted on Facebook resident groups close to the parks (ie, residential groups of apartment buildings). Recruitment materials were also distributed at various universities in the Netherlands and on the social networks of the researchers. The recruitment phase lasted from October 1, 2019, to November 14, 2019.

Initially, we targeted participants aged between 18 and 55 years who lived close (≤ 1 km; 10-minute walk) to one of the parks used with the beacons (ie, Park Transwijk [Utrecht, Netherlands], Oosterpark [Amsterdam, Netherlands], or Sloterpark [Amsterdam, Netherlands]) and did not meet the PA

guidelines of 150 minutes per week (measured using the stages of change questionnaire) [39]. This resulted in too few individuals meeting these criteria; therefore, we changed the eligibility criteria by also including individuals who lived within a 20-minute bicycle ride of the parks (<5 km) and individuals who would like to become more active even if they met the PA guidelines. The exclusion criteria were having a medical condition that made it unsafe to engage in unsupervised PA (defined by the Physical Activity Readiness Questionnaire [40]), not owning an Android smartphone, currently participating in another PA or health-related intervention, or no proficient knowledge of the Dutch language.

The PAUL Apps

During this study, 2 closed-beta versions of the app were evaluated: Basic PAUL and Smart PAUL. The PAUL apps were developed by a multidisciplinary research team over a 2-year period [41]. The design of PAUL is based on theories of behavior change [13,28], technical implementations and design characteristics [33,42], user studies [43], and data mining studies [44,45]. In short, the PAUL apps are designed to function as a coach to help the user increase recreational walking or running behavior and motivate users to perform additional strength exercises during this walk or run. The apps apply 5 theory-based persuasive strategies: monitoring, feedback, goal setting, reminder messages, and instruction videos (Figure 1).

These persuasive strategies were selected as they are theorized to increase the perceived capability and motivation of the participants based on the Capability, Opportunity, and Motivation Behavior model [13] and the FBM [28]. The theoretical assumptions have been described in detail in an earlier paper on the development of the PAUL apps [41]. Table 1 provides a description of the persuasive strategies that are included in the app, the behavior change techniques [27], and the strategies of the persuasive design model [46]. A detailed description of the app and its development process is provided in the study by Sporrel et al [41] and in Multimedia Appendix 1 [41].

Figure 1. Screenshots of the five functionalities of the Playful Active Urban Living app.

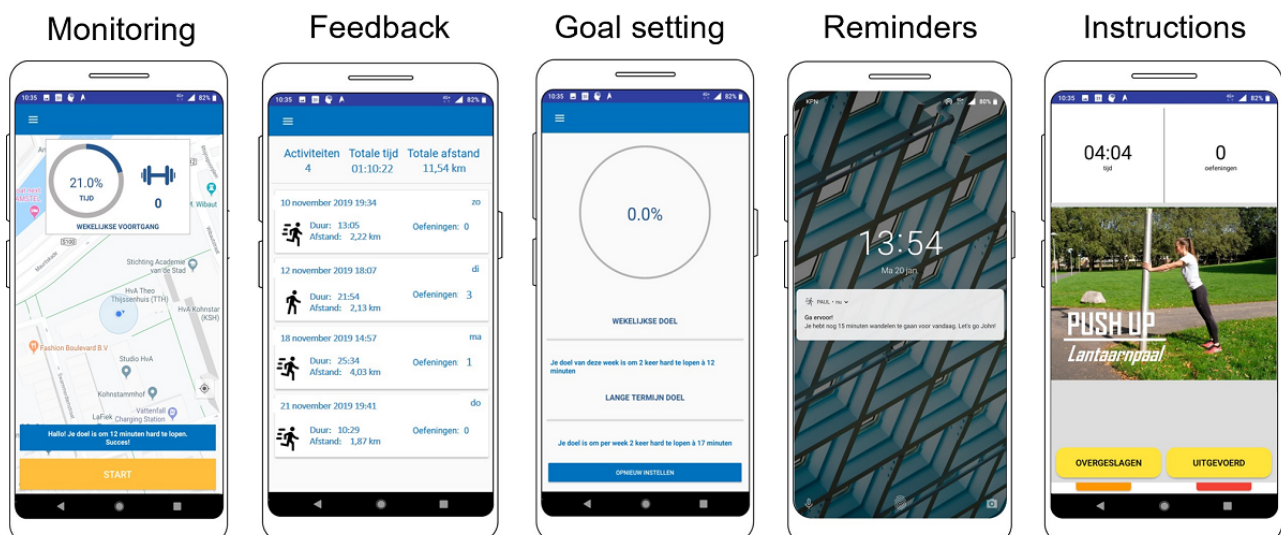


Table 1. A description of the modules in the Playful Active Urban Living (PAUL) app, including the implemented behavior change techniques (BCTs) and persuasive system design (PSD) principles.

PAUL functionality, subcategory, and description	BCTs [27]	PSD principles [46]
<ul style="list-style-type: none"> Strength exercise prompts: The user receives location-based strength exercise prompts (audio and pop-up messages) on predetermined GPS locations. The prompt contains an instruction video of the exercise (squat or push-up) in the direct environment of the user. Amenities in the park (eg, trees, benches, or lantern posts) are used for the exercises. Reminder messages: <ul style="list-style-type: none"> The user receives up to 14 short reminder messages each week containing a motivational suggestion and either information on the progress toward their goal or (affective) information on performing PA^a. The timing of the reminder messages depends on the group allocation (Basic vs Smart PAUL). 	<ul style="list-style-type: none"> Information on when and where to perform the behavior Information on how to perform the behavior Demonstrate the behavior Prompt practice Information provision (general) Provide feedback on performance Prompt practice 	<ul style="list-style-type: none"> Primary task support: <ul style="list-style-type: none"> Reduction Tunneling Rehearsal Normative influence Primary task support: <ul style="list-style-type: none"> Tunneling Tailoring Personalization Dialogue support: <ul style="list-style-type: none"> Reminders Suggestions
Monitoring		
<ul style="list-style-type: none"> PA behavior: The app records and stores PA metrics during app use (frequency, duration, speed, and distance). The user must press “start” to initiate behavior tracking. The app also records and stores situational characteristics during each session and when sending a reminder (weather type, calendar availability, time, and date). After receiving a strength exercise prompt, the user must log if they performed the exercise. Behavior outcome: The user can report notes on the training session and report on a 1-to-5 scale how they are feeling and how intense the workout was. To monitor how many strength exercises the participant has done, they must log whether they performed or skipped the exercises (during the walking or running activity). 	<ul style="list-style-type: none"> Automatic monitoring of behavior Self-monitoring of behavior Self-monitoring of behavior outcome 	<ul style="list-style-type: none"> Primary task support: <ul style="list-style-type: none"> Reduction Self-monitoring Primary task support: <ul style="list-style-type: none"> Self-monitoring
Feedback		
<ul style="list-style-type: none"> Sustained feedback: During running or walking, the user can view simple metrics on their screen (time, distance, current speed, average speed, and number of strength exercises), and the user receives audio feedback every 5 minutes on the duration of the activity. Cumulative feedback: After performing PA with the app, the user can view a summary of their activities (ie, a PA report) with the time, distance, and average speed and a map with their route. The user can access a history view that contains all PA reports. On the home screen, users can view their progress toward their goal. Praise: The user receives a pop-up praise message and a message on the landing page when the weekly goal is reached. Goal setting: To set a goal, the user must perform a short questionnaire. With this questionnaire, the user can set their own long-term walking or running goal (for frequency and duration). Furthermore, a tailored start goal (frequency and duration of activity) is given based on the current fitness level of the participant. The goal increases roughly 10% every week until the long-term goal is reached. 	<ul style="list-style-type: none"> Provide feedback on performance Provide feedback on performance Rewards contingent on successful behavior Goal setting (behavior) Setting graded tasks Review of behavior goals 	<ul style="list-style-type: none"> Primary task support: <ul style="list-style-type: none"> Personalization Self-monitoring Primary task support: <ul style="list-style-type: none"> Personalization Self-monitoring Dialogue support: <ul style="list-style-type: none"> Praise Primary task support: <ul style="list-style-type: none"> Tailoring Dialogue support: <ul style="list-style-type: none"> Suggestions

^aPA: physical activity.

The Smart PAUL app differs from the Basic PAUL app in that it can optimize the timing of reminders with a self-learning module [36]. The self-learning algorithm has the opportunity to learn *right* times (ie, JITAI) to send reminders based on the time of the day, the day of the week, previous PA behavior, and agenda availability [36]. Although the timing differed between the Basic and Smart PAUL apps, the content of the reminders was equal.

Both apps were programmed to send up to 14 reminders per week. However, during the intervention period, there were technical issues that prevented the app from sending the reminders (ie, the notifications were not activated in the app because of a processing error in the sent format). For Basic PAUL, this issue was resolved within the first week, whereas, for Smart PAUL, the issue was resolved after 3 weeks. Therefore, the Smart PAUL group only received the JITAI reminders in the last week of the intervention.

Study Design and Procedures

To determine the feasibility of the PAUL apps, a mixed methods pre-post intervention was performed. This study is part of a larger study that aimed to determine the feasibility of the PAUL apps and examine the user-app interactions with the JITAI reminders. In this paper, we describe the feasibility of the PAUL apps as a whole, whereas we have described the user-app interactions with the JITAI reminder messages in more detail in another paper [47].

Individuals were screened for eligibility using a web-based enrollment questionnaire on the participants' characteristics. Eligible participants were contacted by the main researcher (KS), and a face-to-face meeting was arranged. During this meeting, the participants were informed about the main objective of the study, the study requirements, and the data handling. When an individual had no further questions, they were asked to sign the informed consent form. The participant then received an accelerometer and an information pamphlet that summarized the most important study information.

All participants started with the baseline measurement either on November 11, 2019, or November 17, 2019. On the day before the start of the baseline measurement, the participants received the baseline questionnaire to assess the determinants of PA and self-reported PA as well as a reminder to wear the accelerometer for 7 consecutive days. A reminder to fill in the web-based questionnaire was sent when needed after 2 days.

After successful completion of the baseline period, the participants were manually randomized into the Smart and Basic PAUL groups by an independent researcher with a 1:1 ratio stratified by the 3 parks (ie, Park Transwijk, Sloterpark, and Oosterpark). The group allocation was double-blinded. In the following 4 weeks, the participants could use the PAUL app. The user was asked but not obligated to not turn off the reminder function (ie, push notifications) of the app and to give access to their digital calendar. The participants were informed that this would improve the function of the app without explaining any details of the differences between the 2 groups. During the

intervention, the participant received a visit from a researcher to download the accelerometer data.

At the start of the fourth intervention week, the user was reminded to wear the accelerometer again for 1 week. After 5 weeks, the individual received a link to the final questionnaire on the usability of the PAUL app, the determinants of PA, and the self-reported PA. After the intervention, all the participants were invited for an interview at a location of their liking. As a token of appreciation for participating in this study, the participants received a voucher for a cinema visit or a sports activity with a value of €30 (US \$31.32).

Measurements

Perceptions and Opinions of the PAUL App

To gain a better understanding of the users' perception of the PAUL app and its functionalities, all participants were invited for semistructured exit interviews of 20 to 40 minutes at a location of the participants' choice. The topics in the interview guide covered the perceptions of the included strategies, the design and implementation of the strategies, and the user experience of the strategies. During the interviews, the researchers and participants were still blinded to their group allocation.

User Experience

In addition, a web-based, 20-item, 7-point scale questionnaire on the user experience with the PAUL app was administered at the end of the intervention (acquired from the study by Mollie et al [18]). The questionnaire contained 4 subtopics—perceived effectiveness, usability, satisfaction, and esthetics. The participants could state how much they agreed with the subtopics, from 1 (not at all) to 7 (completely). An item was added to the questionnaire on how many technical problems they encountered.

Behavioral Engagement With the PAUL App

To determine how often the participants used the app during the intervention and, thus, were exposed to the intervention strategies (referred to as *behavioral engagement* [17] or *sustained use* [48]), we examined the number of times the users opened the apps on each intervention day. This was registered automatically by the apps.

Intrinsic Motivation and Perceived Capability

Perceived capability and intrinsic motivation were measured independently for the 3 behaviors of the app (running, walking, and strength exercise). The 6-item perceived competence subscale of the Intrinsic Motivation Inventory [49] was used to measure capability, and the 7-item interest and enjoyment subscale was used to measure intrinsic motivation. The subscales of the Intrinsic Motivation Inventory were back translated into Dutch. Each item could be scored from 1 to 7, with a score of 1 indicating *not at all true* and a score of 7 indicating *very true*. Subscale scores were calculated by reversing 3 items and subsequently averaging the items of the subscales.

PA Measurement

The PA behavior of the participants was measured using a hip-worn accelerometer, the ActiGraph GT3X+ (ActiGraph LLC), 1 week before the intervention (baseline) and in the last week of the intervention (after the intervention). Accelerometer measurements were considered sufficient if the participants wore the accelerometers for a minimum of 8 hours a day and for at least 3 weekdays and 1 weekend day. A total of 35% (8/23) of the participants did not meet these requirements for either the pre- or posttest measurement and were therefore excluded from the analysis.

Analysis

Perception of the PAUL App

The interviews were audio-recorded on the researchers' phones and transcribed verbatim. After transcribing the interviews, the text was imported into MAXQDA Plus (version 20.2.2; VERBI GmbH). Qualitative research cycle was used to code and analyze the data [50]. Before the analysis, a first version of the codebook was developed based on the topic list. Therefore, most codes were developed deductively. The transcripts were then coded. When new topics emerged from the interviews, they were added to the codebook. To ensure that the same coding system was used for all interviews, they were coded again after new codes were derived from the data. Memos were used and served as reminders to explore links between certain codes or to compare conflicting statements.

After coding all the data, the codes were analyzed by a researcher according to a cyclic process [50]. This included regrouping the codes into larger categories (such as *general perceptions of reminders* or *personal support*), exploring links between codes and categories (such as *weather constraints*, *goal setting*, and *reminders*), and comparing between participants. Codes were sometimes also uploaded to Microsoft Excel and subdivided into smaller categories (eg, positive and negative perceptions). The findings for each of the codes and categories were summarized. As this was a cyclic process, the codes were regrouped several times, sometimes into larger categories, and sometimes the codes were divided into subcodes.

User Experience

In addition to the interview data, the questionnaire responses were used to gain an overall perspective on the technical problems, perceived effectiveness, usability, satisfaction, and esthetics of the app. To this end, the questionnaire responses were uploaded to SPSS (version 25; IBM Corporation), and the item on technical issues was inverted. To determine the differences between the Smart and Basic PAUL apps, a Mann-Whitney *U* test was performed (1-tailed exact test with significance at $P < .05$). A participant did not complete this questionnaire and was therefore not included in the analysis.

Behavioral Engagement With the PAUL App

The behavioral engagement with the PAUL app data was uploaded from the servers of the PAUL app and subsequently cleaned by removing duplicate data. The data were validated by cross-checking the data sets of the PAUL app. For some participants (3/20, 15%), no data were recorded by the app. This

was likely due to a connection error with the back end of the app, which could be caused by several factors such as battery failure. Participants whose data were not recorded could not be included in the analysis. Descriptive statistics were calculated for the participants in the Basic and Smart conditions. Differences between the Smart and Basic PAUL apps were calculated using a Mann-Whitney *U* test with an exact test (1-tailed significance at $P < .05$).

Intrinsic Motivation and Perceived Capability

To analyze the changes in intrinsic motivation and perceived capability, we only included the measures for behavior that the participants wanted to change. That is, if the participants had set a goal with the PAUL app to increase their walking activity, we only used their scores for walking. If they had a running and walking goal, the scores were averaged. This also included changes that the participants made during the intervention. The scores for motivation and perceived capability to perform strength exercises were calculated for all participants. The scores were then uploaded to SPSS, and a descriptive analysis was performed. To determine if there were differences between the groups, the differential scores between the pre- and postintervention measurements were calculated, and Mann-Whitney *U* tests were performed (1-tailed exact test with significance at $P < .05$). To determine differences between pre- and postintervention measurements, Wilcoxon signed-rank tests were performed (1-tailed exact test with significance at $P < .05$). Nonparametric tests were used because of kurtosis in the data.

PA Analysis

To process the accelerometer data, they were downloaded using ActiLife (version 6.13.4, firmware 2.2.1; ActiGraph LLC), and the triaxial counts were summed as counts per minute (cpm). Episodes of at least 90 minutes were defined as nonwear episodes. Short interruption periods of a maximum of 2 minutes of 1 to 100 cpm were allowed as nonwear time to account for the possibility of accidental accelerometer movement. Only days with at least 8 hours of wear time were included in the analysis. Freedson Adult (1998) cutoff sets were used to define the time that the participants spent on MVPA (>1951 cpm). The average MVPA time was calculated while excluding nonwear time. To account for the differences in wearing time, the average time spent performing MVPA was calculated. The PA measurements were imported into SPSS, and a Mann-Whitney *U* test with the differential scores was used to determine the differences between Smart and Basic PAUL. A Wilcoxon signed-rank test was used to establish differences between pre- and postintervention measurements (both 1-tailed exact tests with significance set at $P < .05$).

Ethics Approval

The study method was approved by the local ethical committee (GEO S-19253), and the trial was registered in the Netherlands Trial Register (trial ID: NL8166). The study was conducted and reported according to the CONSORT-eHEALTH (Consolidated Standards of Reporting Trials of Electronic and Mobile Health Applications and Online Telehealth) checklist [51].

Results

Participants

Recruitment resulted in 122 individuals who were interested in participating in the study and completed the enrollment questionnaire. After checking eligibility and provision of informed consent, of the 122 interested individuals, 23 (18.9%) were enrolled in the study. The main reasons for exclusion were that the individuals did not live close enough to the parks equipped with beacons or did not own an Android phone. Of

the 23 participants, 3 (13%) discontinued their participation, leaving a total of 20 (87%) participants who completed the study. The participant flow diagram is shown in Figure 2.

The characteristics of the included 20 participants are shown in Table 2. Most participants were women (17/20, 85%), had an average age of 30.65 (SD 8.4) years and an average BMI of 24.52 (SD 5.23) kg/m², and were highly educated (16/20, 80%) and employed (14/20, 70%). Many participants engaged in regular moderate PAs (14/20, 70%), but most participants did not engage in intensive PAs (15/20, 75%).

Figure 2. CONSORT (Consolidated Standards of Reporting Trials) flow diagram of participants. PAUL: Playful Active Urban Living.

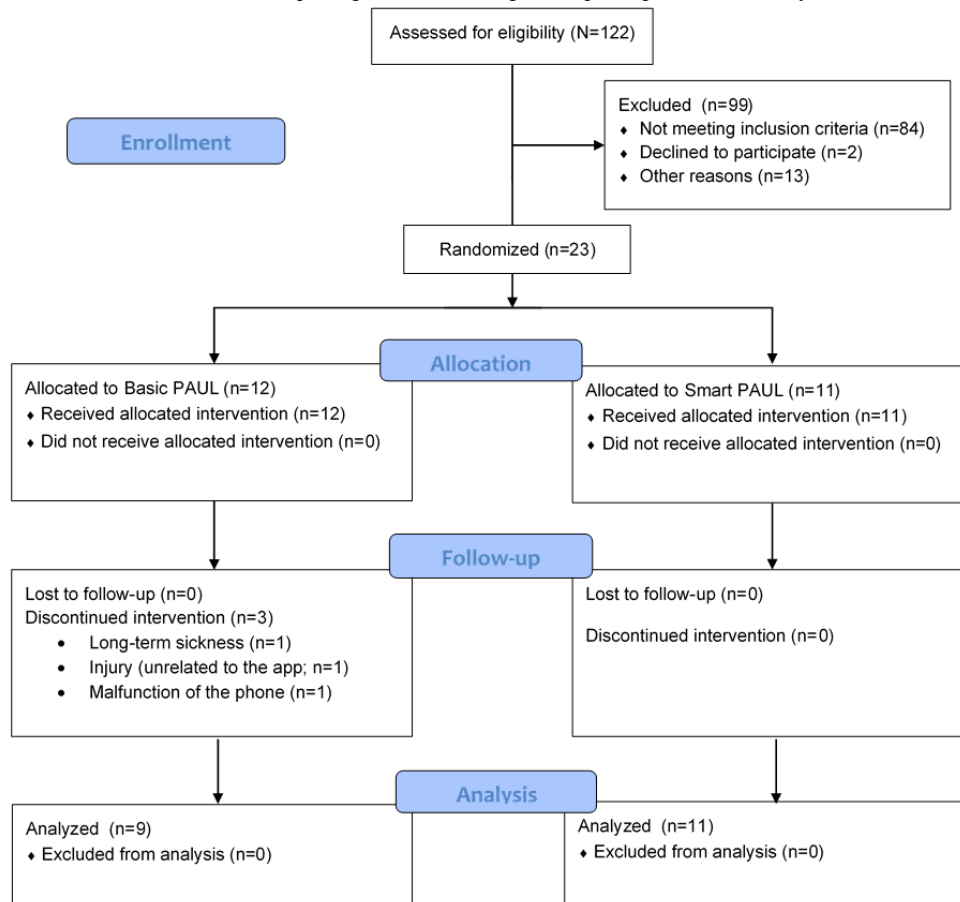


Table 2. Background characteristics of the participants (N=20).

	All (N=20)	Smart PAUL ^a (n=11)	Basic PAUL (n=9)
Gender (female), n (%)	17 (85)	9 (82)	8 (89)
Age (years), mean (SD)	30.65 (8.40)	32.09 (10.73)	28.89 (4.17)
BMI ^b (kg/m ²), mean (SD)	24.52 (5.23)	25.79 (6.49)	22.79 (2.04)
Education level, n (%)			
Secondary school (VWO ^c)	3 (15)	2 (18)	1 (11)
Vocational education	1 (5)	1 (9)	0 (0)
Higher professional education degree	3 (15)	2 (18)	1 (11)
University degree	13 (65)	6 (55)	6 (67)
Housing, n (%)			
Living alone	8 (40)	3 (27)	5 (56)
Living alone with children and others	1 (5)	1 (9)	0 (0)
Living with partner	3 (15)	0 (0)	3 (33)
Living with partner and children	3 (15)	2 (18)	1 (11)
Living with partner, children, and others	1 (5)	1 (9)	0 (0)
Living with more adults (such as student housing)	4 (20)	4 (36)	0 (0)
Employment status, n (%)			
Part-time employment (<34 hours per week)	8 (40)	4 (36)	4 (44)
Full-time employment (≥34 hours per week)	6 (30)	3 (27)	3 (33)
Studying	6 (30)	4 (36)	2 (22)
Stage of change (moderate PA^d), n (%)			
Maintenance phase	13 (65)	6 (55)	7 (78)
Action phase	1 (5)	0 (0)	1 (11)
Preparation	2 (10)	2 (18)	0 (0)
Contemplation	4 (20)	3 (27)	1 (11)
Stage of change (strength exercises), n (%)			
Maintenance phase	5 (25)	3 (27)	2 (22)
Action phase	0 (0)	0 (0)	0 (0)
Preparation	5 (25)	3 (27)	2 (22)
Contemplation	8 (40)	4 (36)	4 (44)
Precontemplation	2 (10)	1 (9)	1 (11)
Running experience, n (%)			
No or little running experience	5 (25)	3 (27)	2 (22)
Experienced runner, not currently running	12 (60)	6 (55)	6 (67)
Experienced runner, currently running	3 (15)	2 (18)	1 (11)

^aPAUL: Playful Active Urban Living.

^bThe weight of 1 participant was entered incorrectly and was therefore not included in this table.

^cVWO: Voorbereidend wetenschappelijk onderwijs (preuniversity education).

^dPA: physical activity.

PA Behavior and Determinants of PA Behavior

To examine to what extent the PA behavior of the participants changed over time, the accelerometer data of the participants were analyzed. A total of 35% (7/20) of the participants were

excluded from the analysis as they did not meet the required wear time. For the remaining 65% (13/20) of the participants, there were no significant differences between the participants in the Smart PAUL group and the Basic PAUL group ($U=16.00$;

$z=-0.714$; $P=.53$) in the differential scores of MVPA time (Figure 3). As there were no differences between the Smart and Basic PAUL apps, the 2 groups were treated as 1 to determine the differences in PA pre- and postintervention measurements. As shown in Figure 3, the percentage of time spent in MVPA slightly decreased over time, but no significant differences were found ($Z=-1.433$; $P=.08$).

Next, intrinsic motivation and perceived capability were examined for running or walking and strength exercises (Figure 4A and Figure 4B, respectively). The Mann-Whitney U test did not show differences between the groups in running and walking behavior motivation ($U=36.000$; $z=-0.736$; $P=.24$) and capability ($U=41.000$; $z=-0.327$; $P=.38$) or in strength exercise

motivation ($U=30.500$; $z=0.158$; $P=.45$) and capability ($U=18.000$; $z=-1.474$; $P=.08$). Thus, the Smart PAUL and Basic PAUL apps appear to influence motivation and capability equally.

To determine the differences in determinants before and after the intervention, a Wilcoxon signed-rank test was performed. As there were no differences between the 2 groups, we analyzed the 2 user groups as 1. Significant differences were found in running and walking motivation ($Z=-3.342$; $P<.001$) but not in capability ($Z=-1.221$; $P=.12$). Regarding the performance of strength exercises, both motivation ($Z=-1.821$; $P=.04$) and capability ($Z=2.231$; $P=.01$) significantly increased.

Figure 3. The pre- and postintervention MVPA time for the Smart and Basic groups. MVPA: moderate to vigorous physical activity; ns: not significant; PAUL: Playful Active Urban Living.

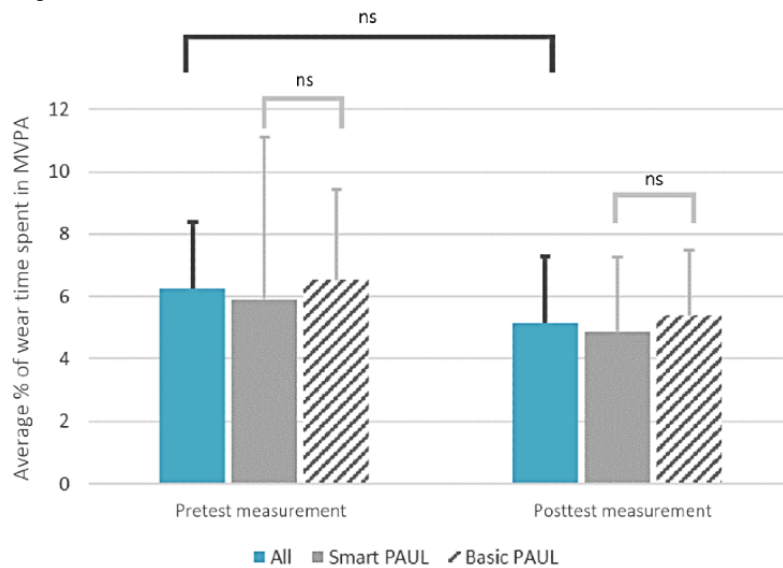
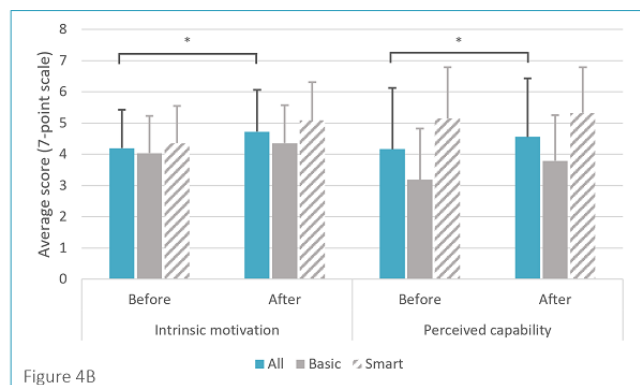
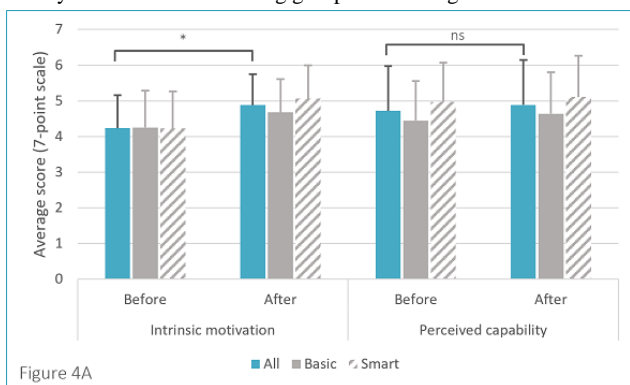


Figure 4. The pre- and postintervention intrinsic motivation (4A) and perceived capability scores (4B) of the participants enrolled in the Basic and Smart Playful Active Urban Living groups. ns: not significant.

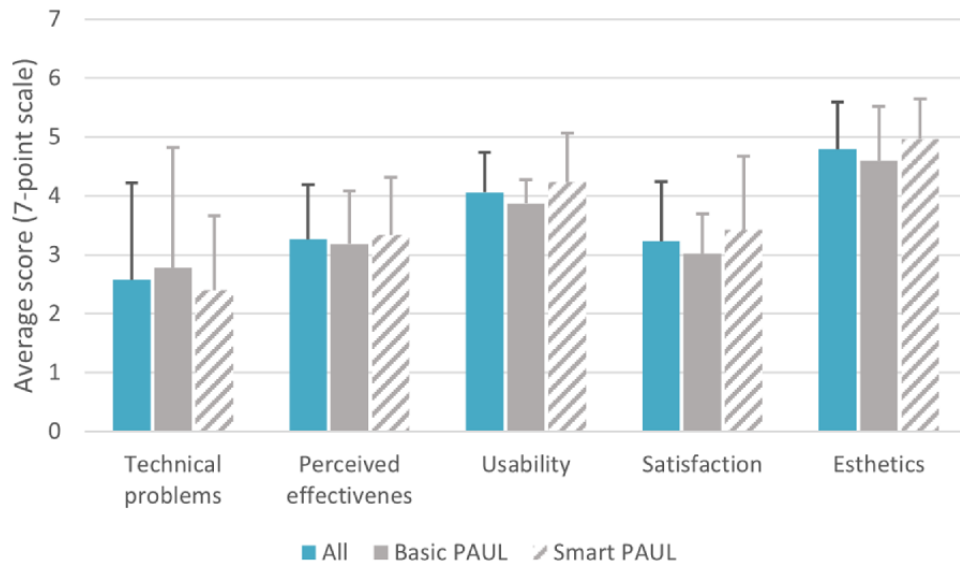


User Experience

The user experience was examined using a questionnaire in which the user was asked to rate the app on a score from 1 (lowest) to 7 (highest). As shown in Figure 5, there were no differences in user experience between the 2 groups in terms of technical problems ($U=41.50$; $z=-0.298$; $P=.41$), perceived effectiveness ($U=40.5$; $z=-0.369$; $P=.37$), usability ($U=27.0$; $z=-1.485$; $P=.07$), satisfaction ($U=31.0$; $z=-1.15$; $P=.13$), and

esthetics ($U=33.5$; $z=-0.948$; $P=.18$). Both groups reported that they experienced many technical issues (mean 2.60, SD 1.64), which likely also resulted in a low perceived effectiveness of the app in changing their PA behavior (mean 3.26, SD 0.91) and a low satisfaction with the app (mean 3.23, SD 1.01). Compared with perceived effectiveness and satisfaction, the participants were more positive in terms of the usability (mean 4.06, SD 0.67) and esthetic appeal of the app (mean 4.79, SD 0.80).

Figure 5. User experience ranging from 1 (low) to 7 (high) of the Smart and Basic PAUL apps. PAUL: Playful Active Urban Living.

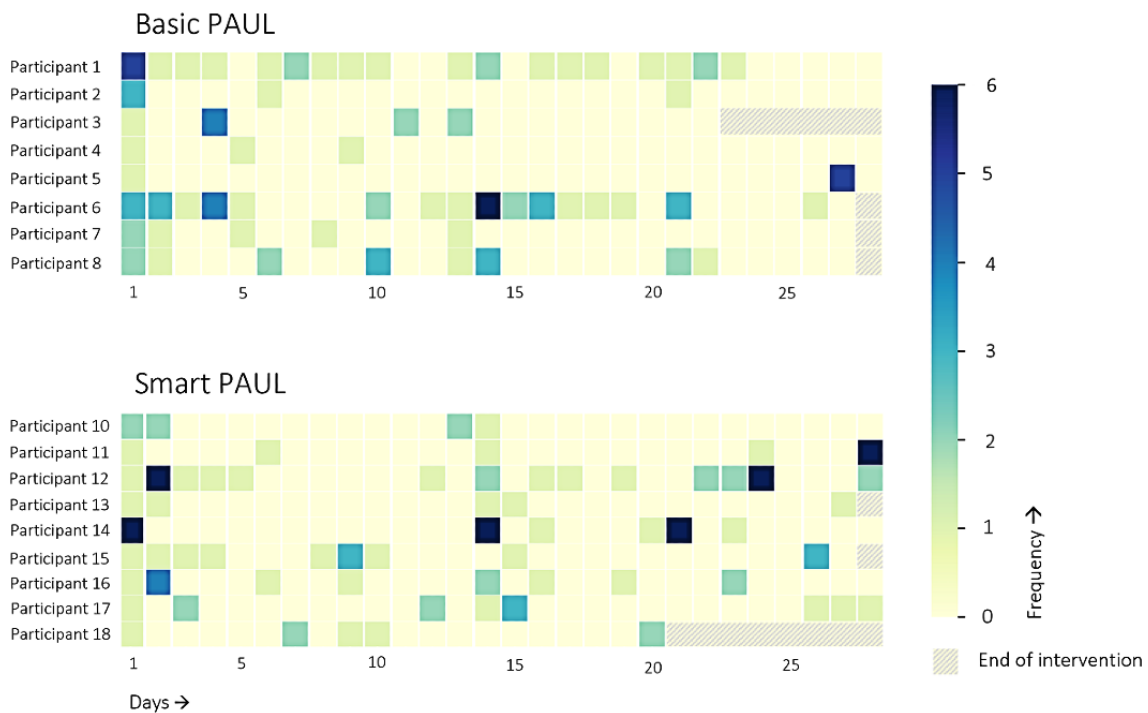


Behavioral Engagement With the PAUL App

To examine whether the participants used the app and, thus, were exposed to the included persuasive strategies, we explored the frequency of opening the app. As can be seen in Figure 6, there were a few frequent users of the PAUL app, and most participants opened it a couple of times a week. On average, the participants opened the app on 7.3 (SD 4.67) days of the 28 intervention days, with the most frequent user opening the app on 19 days and the least frequent user opening it on 2 days.

There were no significant differences between the 2 groups regarding the total frequency of opening the app ($U=28.5$; $z=-0.723$; $P=.48$) or the number of days the apps were open ($U=27.0$; $z=-0.875$; $P=.42$). However, it does seem that the Smart group continued using the app for a longer period as opposed to the Basic group. A likely explanation is that the Smart group started to receive the reminders in the last week, whereas the Basic group received the reminders throughout the intervention.

Figure 6. The daily frequency of opening the PAUL app from the day the Basic and Smart PAUL apps were downloaded. PAUL: Playful Active Urban Living.



Perceptions and Opinions of the PAUL Apps and the JIT Prompts

Overview

In this section, we describe the findings of the exit interviews. The perceptions and experiences of both PAUL apps are reported simultaneously to a large extent as the app functionalities are also largely similar. Only the results regarding the timing of the reminders are reported separately.

Perceptions and Opinions of the PAUL Apps

Overall, the participants thought that the included persuasive strategies were useful and that the most important features were present in the app. The app was perceived by most as “simple” and “basic,” which was liked by some of the participants as it made using the app clear with a simple goal:

And furthermore, it's nice that it's so clear, that you're not lost, or that you're somewhere in 7 steps and think: where am I? And that was nice. He was just clear. [Participant 6, female, aged 35 years]

Other participants indicated that they preferred a more elaborate app:

Um, all right in the general sense. But, um, in many ways, just a little basic. In terms of what you can do with it, of course.... I went running with my girlfriend during this research and she has a Nike running app, and yes, that's super interactive. [Participant 18, female, aged 22 years]

Well, I thought it was, in its essence, a really nice app to use, for instance for running. Here and there, there were some features of which I thought: “Oh those should be further developed.” [Participant 5, male, aged 32 years]

The improvements to the app mainly lay in the development of the implementation of a strategy rather than the addition of another strategy (eg, earning coins or a leaderboard). For instance, participant 18 (female, aged 22 years) would have liked more “interactions” with the app (eg, controlling whether she could perform the strength exercises in a particular exercise session and how many she could perform). By doing so, the users can personalize the apps themselves. Furthermore, the improvements to features that participant 5 (male, aged 32 years) mentioned were to provide more detailed and graphic information about his activities and add more types and locations for the strength exercises. Other participants would have liked “to know the idea behind” the goal setting functionality (participant 8, female, aged 30 years); thus, she would have liked additional information on how the goal was determined.

A frequently mentioned improvement in functionality was to automatically track all the PA activities of the user. Some participants hoped for an app that helped them integrate more PA into their daily activities (eg, cycling slightly further than normal or taking the stairs more often) as this fit better in their life than going for a recreational run or walk. Furthermore, as not all their activities were recorded, they felt as though the app did not give them credit for all their PA behavior:

What I also find unfortunate about it was that you physically had to say that you're going to move now. And a lot of my movements just happen in life, so to speak. So, when I walk to the supermarket, or when I go there or there for a bit. And I'm not gonna enter that. And he won't record that. Whereas for me, those are the moments that I could make a profit, that if he would record it. [Participant 6, female, aged 35 years]

In addition, we asked about the perceptions of 3 frequently used persuasive strategies in apps that were not included in the PAUL apps: rewards (eg, victory points, digital coins, or digital awards), social support, and competition. A few participants indicated that they had nothing against rewards but that they also did not see their added value. More than half of the participants indicated that they would like to be rewarded, but they explained that receiving feedback on their progress or on the number of activities they had done was already enough of a reward. The participants expected that such rewards would strengthen the feeling of having a competition with themselves. For some participants, this was perceived as motivating, whereas others were afraid to disappoint themselves.

Competition with others was disliked by most participants. A total of 10% (2/20) indicated that they would like competition with their friends as this was a fairer comparison and, therefore, more achievable. Sharing exercise outcomes on social media was disliked as this was viewed as a call for attention. A participant indicated that sharing running routes (within the app) would be a good addition to the app. Some participants also suggested other functionalities by themselves. These were to have a selection of running routes, information on why it is important to engage in PA, emails regarding progress, and a game element to motivate users to visit certain exercise locations.

Although the participants in general explained that the app contained the most important strategies, most participants reported that they only used the app a few times. Mostly, they stopped using the app because they encountered technical issues. There were also participants who explained “that's not the apps fault” (participant 6, female, aged 35 years) that they stopped using the app as they encountered barriers such as lack of time or bad weather. For instance, various participants explained that, because of the short winter days, it was already dark when they got home from work. This, together with colder and wetter weather circumstances, made it unpleasant to go outside for a run or walk:

Only I have to say that I used it less than I had hoped, because it was often bad weather, and very dark. And then you're less inclined to go outside. Normally earlier in the summer I would do something more quickly anyway. [Participant 19, female, aged 28 years]

When asking the participants how an app could help them overcome these barriers, they found it difficult to give an answer. After debating the issue, some suggested receiving encouragement to go for walks when there was still daylight; for instance, during lunch. Another participant suggested including a module that enabled them to perform the strength

exercises simply at home in case they were bound to stay there to watch their children or when the weather was bad.

Although some barriers to the uptake of the app lay outside the app, the biggest issue with using it were the technical problems the participants experienced. When encountering a technical problem, this evoked *irritation* and *frustration* in the users or the feeling that their efforts were not recognized by the app or of not being encouraged enough to do more activities. This ultimately resulted in app abandonment. For some participants, it even resulted in thinking that they had done something wrong (participant 5, male, aged 32 years). Various participants explained that, if the app had been more stable, they would have probably used it more often.

Perceptions and Opinions Regarding the Strength Exercise Prompts

Many participants did try out the location-based strength exercises. Of all the strategies that were implemented in the app, the participants were generally the most enthusiastic about the strength exercise prompts:

Well, the best part was that when I just walked through the park, that I always got one, one.... What's that called? That I got a sound [strength exercise prompt], and then I had to do something. I really liked that about it. [Participant 17, male, aged 25 years]

Owing to the novelty of this functionality, the participants became curious and motivated to try it out. Some participants were motivated to perform these strength exercises to increase their strength and fitness. According to these participants, complementing their running activity with strength exercises resulted in a more complete workout in which they trained not only their endurance but also their strength. Furthermore, receiving a strength exercise prompt was perceived as receiving a surprise, some kind of *game* or reward for going outside for a run or walk. The participants explained that it made a running or walking session more diverse and, therefore, more fun. Some participants even referred to the strength exercises as “a moment to catch your breath” for running. In addition, the participants enjoyed that the app gave suggestions on what they could do, similar to a coach, so they did not have to figure everything out themselves:

But I liked the mix, and that it's bound to certain parts of the park, so to speak. That also, when you do an exercise, it can tell you where to do it. So, yeah, I actually really liked that. [Participant 5, male, aged 32 years]

The app could give better suggestions for the strength exercises as it “knew” where the participant was. Some participants explained that it helped them view the park amenities (eg, benches) in a different light, as something they could use during their workout:

Well, what I found very interesting was the part of, uhm, location. That it would indicate those strength exercises at the right places, so to speak. [Participant 8, female, aged 30 years]

To *know* where the user is, the user must share their privacy-sensitive location data with the app. Although most participants did not express any concerns regarding privacy, others explicitly said they preferred not to do this. Several reasons were brought up, including mistrust of who manages these privacy-sensitive data. For instance, some participants were very hesitant to share data with commercial companies, whereas they were willing to share the data with the government or universities:

Well, if it's not commercial, then maybe I would. It depends. Where's it all going, huh? What does that app need to analyze it all? [Participant 16, female, aged 42 years]

In addition, some participants also considered that the privacy-sensitive data that are collected by the app must be of added value to them. In other words, they were willing to share data if they obtained something they wanted from them in return. For instance, one of the participants explained what he liked about the strength exercise prompts:

So, I guess that it shows you: you're here now, so it shows you the [strength exercise] possibilities. Somewhere it's a bit freaky, that he can follow me anywhere, but assuming that privacy is well guaranteed, it delivers a lot. [Participant 10, male, aged 28 years]

Although the app removed some barriers, other barriers remained. Some female participants mentioned that they would not perform the strength exercises as they did not like to do them in such public spaces where other people could “look at you like that” (participant 1, female, aged 27 years and participant 3, female, aged 23 years). Other participants expressed their concern about performing strength exercises without receiving feedback on their posture from a professional. Offered solutions to this problem were to organize a group training, only implement easy exercises, or motivate the participants to practice the exercises at home in front of a mirror. Another improvement that was suggested was offering the strength exercises in more locations so the participants did not have to travel to the location before they could start their run or walk. The participants would also like to have more types of strength exercises and combinations of strength exercises that could be tailored to their capabilities. Some participants indicated that they would like to see where the strength exercises were located so they were motivated to run there, “explore” the neighborhood, and discover new exercise locations.

Perceptions and Opinions Regarding the Reminder Messages

Reminder messages were perceived as important initiators of behavior by almost all participants. The participants said that the reminders “trigger” them (participant 20, female, aged 23 years) and that it “lowers the threshold” to engage in PA (participant 5, male, aged 32 years) and, therefore, increases the chances of engaging in PA. Thus, to some extent, the reminders function as a coach (ie, something that pulls the participants over when they have difficulty in performing the behavior themselves). Unfortunately, not all the participants received the reminder messages. However, these participants

also explained that they thought they would have used the app more if they had received them. As they did not receive the reminder messages, they often forgot the app and their intention to exercise more.

Some participants explained that a reminder message in itself was not enough to motivate PA. Rather, the motivation must come from within, and the reminder message can help overcome barriers or remind them of their plans:

Yes, then it's nice that one of those things reminds you of it, but then you think "yes, but I just don't have time for it right now".... So I'm more like, "yes, I'd like to try," but it doesn't really fit in my schedule. So, then it should be a bigger mind set of "okay, I think this is very important," that you really make that app a part of your daily rhythm, yes. [Participant 10, male, aged 28 years]

The participants highlighted the need for well-timed and highly personalized reminder messages. Although receiving a reminder message at a good time could serve as a trigger, receiving one at a bad time could lead to irritation or feeling like they were failing (participant 20, female, aged 23 years and participant 17, male, aged 25 years). The timing of the reminder message also seemed to influence the perception of its content. For instance, a participant explained that the reminder message was annoying and "preachy." Owing to a busy schedule, she did not have the time to go for a walk even though she had the motivation to exercise. Thus, a motivating message was not appropriate. However, she explained that she would design similar reminder messages herself as, if they were well timed, they entertained her. Furthermore, some participants explained that the content of the reminder message did not really matter at all and that receiving a prompt in itself was already sufficient. In line with these comments, several participants had issues with recalling the content of the reminder messages, indicating that the content indeed was not the most important quality of the reminder.

As the timing of the reminder message was perceived as important, the participants enjoyed the idea that the app knew their schedule by reading their agenda:

I think that's a plus compared to other things. That you can then, that you can link it that way. [Participant 8, female, aged 30 years]

However, some participants did express privacy concerns or did not use a digital agenda that could be integrated into the app.

During the interviews, participants in both groups were generally not positive about the timing of the reminder messages. The perceptions of the timing of the JITAI reminder messages were not more positive than those of the randomly timed reminder messages. A possible explanation for these findings is that the participants in the Smart PAUL group received too few reminder messages as they only received them in the last week of the intervention. Furthermore, owing to the short study duration, the reinforcement learning model could only use a prelearned delivery strategy to determine the timing of the messages. Thus, it was not able to adjust the strategy at an individual level.

As the participants were not satisfied with the timing, we discussed what they would have preferred. It seems that there were roughly 2 groups of participants—one group that liked to set their own times and one group that wanted to receive regular reminder messages throughout the day:

...if I already know that I can't run that day at all, because I must do all kinds of other things, then I think it would only be annoying that I would still get reminders for something.... But I am also someone who then, plans in advance which days she wants to walk, so to speak. [Participant 16, female, aged 42 years]

I'm not a planner, so, um, I get a bit itchy when I'm very tightly planned and know what I'm gonna do on what day. Especially when it's in my spare time. Um, so, I'd rather get [a reminder] every day. That sometimes you think: "oh, yeah, I want to work out." And sometimes I don't. [Participant 18, female, aged 22 years]

Participants who claimed that they always planned their (physical) activities liked to set times at which they wanted to receive the reminder message. In contrast, participants with a more flexible agenda or who did not like to plan liked to receive regular and well-timed reminder messages throughout the day and decide on the spot whether they wanted to exercise.

Discussion

Principal Findings

The feasibility of the Smart PAUL and Basic PAUL apps was examined by exploring the users' perceptions of the app, experiences, behavioral engagement and changes in PA behavior, and determinants of PA behavior. The main findings of the study were that the participants appreciated the included persuasive strategies, especially the strength exercise prompts. The strength exercises were motivating because of their novelty and because they offered variety during a run or walk and a more complete workout. Some participants even perceived the strength exercise prompt as a reward. Furthermore, the reminder messages were perceived as important initiators for PA by most participants, but they were not perceived as well timed.

Another finding was that there were little to no differences between the Smart PAUL and Basic PAUL groups regarding perceptions, opinions, and user experience. This is likely the result of the small difference between the 2 versions of the app, which became even smaller as the reminder messages were not sent during the first part of the study. Owing to this short duration, the Smart PAUL app could only apply a prelearned strategy to determine the timing of the reminders and was not able to adjust the timing to each individual participant. Finally, we found no improvement in the PA behavior of the participants, but we did find an increase in the perceived capability to perform strength exercises, and the intrinsic motivation for walking, running, and performing strength exercises did increase during the intervention. Taken together, we conclude that the PAUL apps are not feasible interventions in their closed-beta state but,

if they were more stable, they could be effective in promoting PA.

The increased motivation for running, walking, and performing strength exercises and capability to perform strength exercises supports the theoretical assumptions on which the PAUL apps were based [41]. However, despite the improvement in the targeted constructs, no increase in the PA behavior of the users was observed. A possible explanation is that PA behavior will only increase if other determinants, such as opportunity [41], increase as well. Another possibility is that the motivation or capability of the user must increase even more to influence PA behavior. Notably, these results must be interpreted with caution because of the small sample size and the lack of a control group. For instance, it is possible that, without the app, PA behavior would have decreased. A randomized controlled trial with a no-treatment control group should be performed to examine this.

By examining the feasibility of the PAUL app, we could explore the perceptions of 2 different types of JIT prompts: one to *initiate* the exercise session and one to initiate a specific behavior *during* exercise. The participants appeared to be especially receptive to the strength exercise prompts during exercise. A likely explanation for this is that, because the participants were exercising, they were already motivated, whereas the prompt itself increased the (perceived) capability of the participant to perform the exercise (ie, it is a facilitating prompt [27]). As explained by the participants, the prompt ensured that they did not have to think about what they should do. At the same time, the prompt nudged the participants to perform the behavior. Consequently, the strength exercise prompt could push the participants over the *activation threshold* while also triggering the behavior [28,29].

By including prompts to initiate a behavior during exercise, the PAUL app is among the first to make a combination of strength exercises and aerobic exercises. Thus far, only 2 other apps have been developed and evaluated: MOPET [52,53] and eCoFit [54,55]. Both MOPET and eCoFit offer exercises at fixed locations to which the participant must travel to exercise. However, based on the interviews in this study, having to travel to a different location could be a barrier to performing PA. Furthermore, the participants expressed a need for variation in terms of going to different locations and choosing different routes to run or walk and different strength exercise types. Thus, to keep an app interesting and surprising, future apps should enable users to use it everywhere. Notably, little is known about which outdoor locations could support the performance of strength exercises and which exercises are suitable. Therefore, future research is needed to examine this to optimize and improve this functionality.

The participants appeared to be less receptive to the second type of prompts, the reminder messages. The reminder messages were often sent when the participants did not have the opportunity or capability to exercise even though they were motivated to do so. Moreover, as the motivation message only aimed to motivate the participants and not to increase their capability, it was not *the right message at the right time*.

The interviews suggested several options to improve the reminder messages that support the FBM [29]. First, to increase the (perceived) capability to exercise, for instance, the exercises can be made easier to achieve by making it possible to do them at home. Second, the timing could be better tailored to the moments of opportunity of the individual (eg, when they do not have other obligations such as childcare or work). To this end, a future system should at least include calendar availability, weather, daylight, amount of PA performed, and the users' (exercise) routines according to the participants. Calendar availability, weather, and the amount of PA performed have been used in earlier studies on JIT reminders [34,56,57], but daylight and routine, to the best of our knowledge, have not been used. In addition, future systems should have longer periods to collect more data to learn the optimal strategy.

The need for a smart and personalized system contrasts with the need for privacy. The participants were very clear on why it is important to have state-of-the-art technology—to provide very personal support that contains the exact types of support they need. This recognizes that every individual is different and has different needs. However, some participants were hesitant to share the data that are needed for this type of support. In line with earlier research [58,59], participants in this study also made a careful trade-off in which the benefits must outweigh the costs (referred to as the *privacy-personalization paradox* [59,60]). Costs that were too high for some participants were the feeling that their information could be misused or that people could make a profit from their data. The participants explained that they would be willing to share data if they had a great added value in their lives or when their curiosity overruled the costs. Thus, careful considerations must be made when working with such technologies in terms of the information that is needed and the potential consequences, such as the exclusion of a part of the target group.

Strengths and Limitations

There are some limitations to this study. A major limitation of this study were the technical issues that overshadowed the results of the feasibility trial. This demonstrates that the beta version of the PAUL app is not stable enough in all devices and Android versions. Nonetheless, the participants could still experience and engage with the apps and their functionalities and, therefore, provide valuable insights into the apps. Second, the participants were mostly highly educated women (13/20, 65%), which limits our understanding of the perceptions of other potential user groups. Finally, as no control group was used, the quantitative analysis should be interpreted with caution [61].

There are also several strengths to our study. For instance, the dropout rate was relatively low, with 87% (20/23) of the participants completing the study. Furthermore, the app was designed based on theories of change and input from potential end users to increase motivation and capability [41], and the study demonstrated favorable effects. The main study strengths are that the Basic and Smart PAUL apps were tested in a real-life setting and the use of a mixed methods approach to gain insights and a deeper understanding of the feasibility of an intervention.

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Authors' Contributions

All authors have read and approved this manuscript. KS performed the study. KS, MS, DDFE, and NN contributed to the study design and methodology. SW developed the reinforcement learning module. RDDdB developed the Playful Active Urban Living apps. SW cleaned the data. KS performed the analysis and prepared the original draft. RDDdB, SW, MS, and DDFE reviewed and edited the manuscript. MD, BJAk, MS, and DDFE contributed to the funding of this research.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Description of the Playful Active Urban Living apps.

[[PDF File \(Adobe PDF File\), 561 KB - formative_v6i8e35268_app1.pdf](#)]

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Abbreviations

CONSORT-eHEALTH: Consolidated Standards of Reporting Trials of Electronic and Mobile Health Applications and Online Telehealth

cpm: counts per minute

FBM: Fogg Behavior Model

JIT: just-in-time

JITAI: just-in-time adaptive intervention

mHealth: mobile health

MVPA: moderate to vigorous physical activity

PA: physical activity

PAUL: Playful Active Urban Living

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Original Paper

The Assessment of a Personalized Nutrition Tool (eNutri) in Germany: Pilot Study on Usability Metrics and Users' Experiences

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Abstract

Background: To address the epidemic burden of diet-related diseases, adequate dietary intake assessments are needed to determine the actual nutrition intake of a population. In this context, the eNutri web app has been developed, providing online automated personalized dietary advice, based on nutritional information recorded via an integrated and validated food frequency questionnaire (FFQ). Originally developed for a British population and their dietary habits, the eNutri tool has specifically been adapted to the German population, taking into account national eating habits and dietary recommendations.

Objective: The primary aim of this study is to evaluate the system usability and users' experience and feedback on the eNutri app in a small-scale preliminary study. The secondary aim is to investigate the efficacy of personalized nutrition (PN) recommendations versus general dietary advice in altering eating habits.

Methods: The app was piloted for 4 weeks by 106 participants from across Germany divided into a PN group and a control group. The groups differed according to the degree of personalization of dietary recommendations obtained.

Results: An overall System Usability Scale (SUS) score of 78.4 (SD 12.2) was yielded, indicating an above average user experience. Mean completion time of the FFQ was 26.7 minutes (SD 10.6 minutes). Across subgroups (age, sex, device screen sizes) no differences in SUS or completion time were found, indicating an equal performance for all users independent of the assigned experimental group. Participants' feedback highlighted the need for more personalized dietary advice for controls, while personalized nutritional recommendations improved the awareness of healthy eating behavior. Further improvements to the eNutri app were suggested by the app users.

Conclusions: In total, the eNutri app has proven to be a suitable instrument to capture the dietary habits of a German population sample. Regarding functionality, system usability, and handling, direct user feedback was quite positive. Nutritional advice given was rated ambivalent, pointing to several weaknesses in the eNutri app, minimizing the system's full potential. A higher level of personalization within nutritional advice subjectively improved the app's usability. The insights gained will be used as a basis to further develop and improve this digital diet assessment tool.

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KEYWORDS

Food Frequency Questionnaire; dietary assessment; Diet Quality Score; web application; digital nutrition; personalized nutrition; system usability; internet; eNutri; EIT Food Quisper

Introduction

Unhealthy diets and their consequences on health are still a matter of high relevance, especially regarding noncommunicable diseases such as diabetes, cardiovascular disorders, or cancer. According to the latest Global Burden of Disease Study [1], dietary risk factors (eg, high sodium intake, low consumption of whole grains and fruits) globally accounted for around 11 million deaths and 255 million disability-adjusted life-years in 2017. With the advent of the internet and computerization, digital applications are increasingly replacing traditional pen/paper methods for collecting nutritional data. Web-based tools were found to collect data of a similar quality compared with their handwritten origins and are preferentially used by younger populations [2].

In this context, *information and communications technologies* (ICTs), such as web-/computer-based services as well as mobile phones, are used to record dietary behavior. Data about nutritional intake can be captured passively through sensing or tracking techniques as well as actively by, for example, manual data entry [3]. Regarding (computerized) instruments, food frequency questionnaires (FFQs) are one of the most commonly used tools to track and assess dietary habits of individuals. Based on a preselected list of foods, individuals report the frequency of their habitual dietary intake. In general, consumption data are collected retrospectively over a recall period of a few weeks up to 1 year [4]. Various types of ICT solutions such as smartphone or tablets and desktops or laptops have been shown to be eligible for the application of digital FFQs [5-7]. The integration of dietary assessment tools into ICTs provides an unobstructive way to offer nutritional advice, which is comparable to nutritional guidance provided by nutrition professionals [8]. Advanced technologies are known to drive healthy changes in dietary intake [9], but to promote long-term use of digital health technologies and behavior change, focus should be placed on user experience and content [3]. Time-consuming data entry and poor overall user interface negatively affect users' experience [10], whereas inclusion of energy and macronutrient content are promoting factors for user system interaction [11].

ICT apps capable of providing personal nutritional advice have attracted considerable attention in recent years [12]. To date, very few apps are equipped with the necessary decision engine for generating automated dietary recommendations in a personalized format that are also valid [13]. To address this need, the eNutri web app has been developed at the University of Reading (Hugh Sinclair Unit of Human Nutrition, United Kingdom) to provide automated personalized nutrition (PN) recommendations with a high degree of personalization [13]. As part of this approach, a validated web-based graphical FFQ illustrating different portion sizes of food items has been integrated into the eNutri app. The app provides personalized dietary recommendations based on retrospectively collected data of users' food consumption habits, considering individual dietary preferences, BMI, sex, and possible dietary restrictions (eg, abstaining from meat consumption). In addition to personalized advice (by nutrition experts) [14], the app can show generic dietary recommendations based on national

guidelines with a low level of personalization [15]. Results of the evaluation of the eNutri app suggest a good usability and acceptance for the online dietary intake assessment [16]. In collaboration with the University of Reading, a German version of the eNutri app was developed, which was adapted to German food consumption habits and underwent some minor modifications (eg, translation into German language, data protection adjustments, replacement of the UK food and nutrient database of McCance and Widdowson [17] by the German Food Code and Nutrient Database or BLS [18]). The dietary recommender system in the app was acquired from the British research partners without modification. In a subsequent 4-week pilot study (eNutri2019 study), the app was field tested in a German population sample [19]. The study was part of the European Institute of Innovation and Technology (EIT) Food Quisper (Quality Information Services and Dietary Advice for Personalized Nutrition in Europe) Project, which aims to create a digital platform for evidence-based PN services and data [20].

In this study, the primary objectives were to assess the eNutri app's suitability for use in a healthy adult population in Germany and to gather user feedback regarding its usability and content. An additional aim was to identify the scope for improvement based on the users' feedback data. Furthermore, this study aimed to evaluate the effectiveness of PN recommendations over generic dietary advice.

Methods

Study (eNutri2019) Design

The German eNutri app was applied within the eNutri2019 pilot study, which was conducted in November and December 2019 in a German population sample. A subsample of the overall study results has been published earlier, comparing specifically the dietary behavior of female vegetarians with omnivores [19]. The analyses contained within this report refer to all study participants (106 participants overall) and are not limited to a selected subset. Participants' dietary intake was assessed retrospectively at 2 different time points, first at baseline (time point 1 [t1]) and second after 4 weeks at the end of the study (time point 2 [t2]). After the baseline survey, study participants were provided with dietary recommendations either in a personalized or in a generic format, according to the group (PN or control) they were assigned to.

Data Collection

Overview

To participate in the eNutri2019 pilot study, individuals had to register online. After passing the inclusion criteria, participants were granted access to the eNutri app via an anonymous alias email address to ensure protection of privacy. Dietary intake, physical activity, anthropometrics, device information, system usability, and feedback were gathered within the eNutri app. Data input was requested at t1 and t2. Participants received reminders via email on dietary recommendations provided after the first survey and to announce the second survey date.

Anthropometric and Sociodemographic Data Collection

For anthropometric measurements, study participants were provided with step-by-step instructions to accurately measure their body height and weight by themselves. Self-reported sex, body height, and weight were gathered within the eNutri app, which automatically calculated the BMI (kg/m^2) as the weight-to-height ratio. Both sex and body height were recorded at t1, whereas only body weight was captured at both time points.

Dietary Assessment

At time points t1 and t2, dietary intake of the previous 564 weeks was assessed retrospectively via a self-administered FFQ integrated in the eNutri app. Before starting the survey, participants received guidance through a tutorial on how to correctly complete the FFQ within the app, which they could return to at any time. The food list and portion sizes used for the FFQ were based on the validated questionnaire of the Food4Me study, a pan-European randomized controlled dietary intervention study [21]. The food list was adapted regarding country-specific popular German food items (eg, pretzels, rusk, fruit nectar, sweet egg dishes). The final FFQ comprised 156 food items. Foods and respective portion sizes were presented as photos, based on representative servings as defined in the BLS [18]. For each food item, a total of 7 different portion sizes were displayed, 3 of which were illustrated with photos, plus arrow buttons on either side of each image to select smaller/larger portion sizes than the ones depicted. Intake frequencies were determined based on 9 different options to choose from (<1/month, 1-3/month, 1/week, 2-4/week, 5-6/week, 1/day, 2-4/day, 5-6/day, or $\geq 7/\text{day}$). An illustrative example of the eNutri input and output visualization module is provided by Fallaize et al [22]. Energy and nutrient intake values were calculated automatically by the system in reference to the BLS.

Diet Quality Score

The nutritional value of the reported dietary habits was quantified using an 11-item Diet Quality Score (DQS) developed for a Western European population [22]. Each individual's DQS was calculated from the eNutri FFQ data at t1 and t2. The scoring system was developed and validated by the University of Reading, based on data from the EPIC (European Prospective Investigation into Cancer) Norfolk cohort study. It is calculated based on 7 food components scoring positively (vegetables; fruit; wholegrain products; healthy fats; oily fish; nuts and seeds; and pulses), and 4 scoring negatively (free sugar, salt, alcohol, and red/processed meat). Scores of all components contributed equally to the overall DQS (interval 0-110). The DQS was reported to be predictive of cardiovascular disease, inflammatory heart disease, acute myocardial infection, and all-cause mortality risk reduction [15].

Dietary Recommendations (System Feedback)

Data collected from study participants were used to generate personalized nutritional feedback. The self-reported data provided by a user (ie, sex, weight, height, food intake, and frequency) are processed to compute an individual's BMI and DQS, and an integrated decision engine (algorithm) calculates

a "healthiness score" for each FFQ item, equivalent to which foods/drinks would have the greatest/worst impact on the DQS if an additional portion per day would be consumed. This score is translated into dietary recommendations within the app, visualized in 5 output sections, namely, "foods to boost," "foods to try," "foods to reduce," "foods to keep eating," and "foods to keep avoiding." A more detailed description of the recommender system of the eNutri app is provided by Fallaize et al [22]. A *tip* section featuring explanations and background information on the specific food recommendation was integrated into the dietary feedback to support users to implement their food-based recommendations into their dietary habits.

Aiming to assess the effectiveness of the personalized dietary advice, participants were randomly assigned to either the control or the PN group, according to their sex, BMI, and age classification, using the method of minimization [23]. After completion of the baseline questionnaires, participants in the control group received generic population-based nutritional recommendations based on national dietary guidelines (German Nutrition Society [DGE]) [24]. The participants assigned to the PN group were provided with personalized dietary feedback, based on their individual FFQ responses and their stated food preferences [22]. After the administration of second questionnaire at t2, both groups received personalized dietary feedback.

System Recording of Time Stamps and Device Screen Size

As a background process, the system automatically recorded time stamps, including the date and the start and end time of FFQ processing. A record was also made of whether a questionnaire was completed in full or only in part. Completion time was calculated based on collected time stamps (for FFQ, system usability and feedback items), which were recorded upon user activity within the app for the first survey (t1). Information on screen sizes was collected as part of the browser details. Device screen sizes were categorized into 3 groups: small <480 pixels, medium 480-1240 pixels, and large >1240 pixels [16].

System Usability Scale and Participants' Feedback

For assessing the efficiency, effectiveness, and satisfaction of app usage [25], the overall System Usability Scale (SUS) score achieved was displayed as a graphical progress bar with corresponding numeric values within the eNutri app after completion of the baseline FFQ. The underlying SUS questionnaire surveyed 10 items in total, addressing the app's usability based on statements such as "I found the system unnecessarily complex" [26]. Each item provides 5 response options ranging from "strongly agree" (equal to 5 points) to "strongly disagree" (equal to 1 point). The qualitative metrics are converted into a numerical scale yielding a total score between 0 and 100 points. Scores higher than 68 points are considered as above average [27,28]. It has been shown that the SUS score is positively correlated with user acceptance [28].

Additional questions were displayed after completing the second eNutri FFQ at t2. Participants were provided with a series of 5-level Likert scale and multiple-choice questions, as well as with a free-text question regarding their subjective feedback on

the eNutri app. Feedback questions were focused on the overall user-friendliness of the eNutri app, the impact of the app on perceptions of a healthy dietary behavior, changes in dietary intake due to the app intervention, and the evaluation of the (dietary) recommendations. Furthermore, participants were asked to rate the user-friendliness of the eNutri app, as well as the app in its entirety, according to a 5-star rating system as commonly applied in app stores (eg, Google Play or iTunes), with 5 stars for the highest and 1 star for the worst rating. Willingness to pay was queried based on several preset pricing options to choose from (€0.00, €0.50 [US \$0.53], €1.00 [US \$1.07], €2.50 [US \$2.67], €5.00 [US \$5.34], and >€5.00 [>US \$5.34]).

Statistical Analysis

The statistical analysis was directed toward usability metrics, where we focused on SUS scores and feedback questions. Furthermore, subgroups were defined by age, sex, and device screen sizes to compare the usability of the eNutri app across different user groups. Feedback questions were analyzed with respect to participant's group assignment (PN and control). Categorical answer options were transformed into numerical answer options with numerical gradation from 1=strongly disagree to 5=strongly agree. Likert-scale coded data and data from the feedback questionnaire at t2 were analyzed by applying nonparametric tests (chi-square test, Fisher exact test, and

Mann–Whitney *U* test). Parametric tests (unpaired *t* test) were applied to check for statistical difference between subgroups and SUS analyses. In addition, written feedback on free-text questions was summarized and then categorized into main topics. Statistical data analysis was performed using Microsoft Excel 2016 (Microsoft Corporation) and R 3.6.0 (R Foundation). *P* values $\leq .05$ were considered statistically significant.

Ethics Approval

Ethical approval was granted by the Research Ethics Committee of the Technical University of Munich (approval no. 328/19S).

Results

Study Population

A total of 792 potential participants registered for the eNutri2019 pilot study ([Multimedia Appendix 1](#)), among which 297 registrants were found eligible. Of these, 167 study participants created an account within the eNutri app and 158 completed the first FFQ; 4 participants actively withdrew from the study and 29 were lost to follow-up. After data cleaning (removing missing, imprecise, or implausible information, such as BMI >60 kg/m² or <15 kg/m²; total energy intakes <600 kcal/day or >4500 kcal/day), a total of 106 participants remained. The sociodemographic characteristics of the study participants included in the data analysis are listed in [Table 1](#).

Table 1. Sociodemographic characteristics of study participants and selected outcome parameters.

Participant characteristics	Total (N=106), n (%)	Total, mean (SD)	PN ^a group (n=53), n (%)	PN group, mean (SD)	Control group (n=53), n (%)	Control group, mean (SD)
Sex						
Female	92 (86.7)	N/A ^b	46 (86.8)	N/A	46 (86.8)	N/A
Male	14 (13.2)	N/A	7 (13.2)	N/A	7 (13.2)	N/A
Age						
Younger (<40 years)	93 (87.7)	23.4 (4.5)	46 (86.8)	23.5 (4.2)	47 (88.7)	23.3 (4.8)
Older (≥40 years)	13 (12.3)	51.2 (5.7)	7 (13.2)	52.1 (6.6)	6 (11.3)	50.0 (4.7)
Level of education						
Less than secondary school	6 (5.7)	N/A	4 (7.5)	N/A	2 (3.8)	N/A
Secondary school	56 (52.8)	N/A	26 (49.1)	N/A	30 (56.6)	N/A
Completed apprenticeship	2 (1.9)	N/A	2 (3.8)	N/A	0 (0)	N/A
University degree	42 (39.6)	N/A	21 (39.6)	N/A	21 (39.6)	N/A
BMI (kg/m²)						
Underweight (<18.5)	5 (4.7)	16.5 (1.0)	2 (3.8)	16.7 (1.6)	3 (5.7)	16.4 (0.8)
Normal weight (18.5–24.9)	79 (74.5)	21.7 (1.8)	40 (75.5)	21.9 (1.8)	39 (73.6)	21.4 (1.7)
Overweight (≥25.0)	22 (20.8)	28.82 (3.58)	11 (20.8)	29.53 (3.84)	11 (20.8)	28.1 (3.3)

^aPN: personalized nutrition.

^bN/A: not applicable.

Evaluation of the Systems Usability

The first survey (FFQ and SUS questionnaire) did not differ between both groups except for the dietary recommendations, which were displayed only at the end of the first survey, after all data were collected from the participants. The mean SUS across all 106 study participants was 78.4 (SD 12.2). PN participants evaluated the eNutri app (mean SUS 79.9, SD 12.5) insignificantly higher than control participants (mean SUS 76.9, SD 11.9; $P=.14$). Female participants had a higher mean SUS score of 78.7 (SD 12.1) compared with male participants, who had a mean score of 76.4 (SD 13.5; $P=.59$). Regarding age groups, younger participants (<40 years) recorded a higher mean SUS of 78.8 (SD 12.0) than older participants (≥ 40 years), who recorded 75.2 (SD 13.5; $P=.39$). Additionally, SUS scores were considered with respect to the screen size of the device participants used to complete the surveys. Participants with small screen sizes (29/106) rated the app best with a mean SUS of 79.4 (SD 12.3), followed by those with medium-size device screen (7/106) with a mean SUS of 78.9 (SD 13.1) and those with large screen size (70/106), who had the lowest mean SUS of 77.9 (SD 12.2; $P=.85$). Across all subgroups, the mean SUS was greater than 68, indicating a good usability.

Analysis of Average Survey Completion Times

Completion time could not be assessed for all participants, due to repeated log-ins by some participants. Thus, completion time was analyzed only for 87 participants, who exhibited an average duration of 26.67 minutes (SD 10.6 minutes). Participants of the control group entered their data (mean completion time of 23.81 minutes, SD 7.8 minutes) faster than those of the PN group (mean completion time of 29.45 minutes, SD 12.3 minutes; $P=.05$). Female participants (75/87, 86%) completed the survey faster, with a mean completion time of 25.37 minutes (SD 9.2 minutes), than male participants (12/87, 14%), with a mean completion time of 34.75 minutes (SD 15.4 minutes;

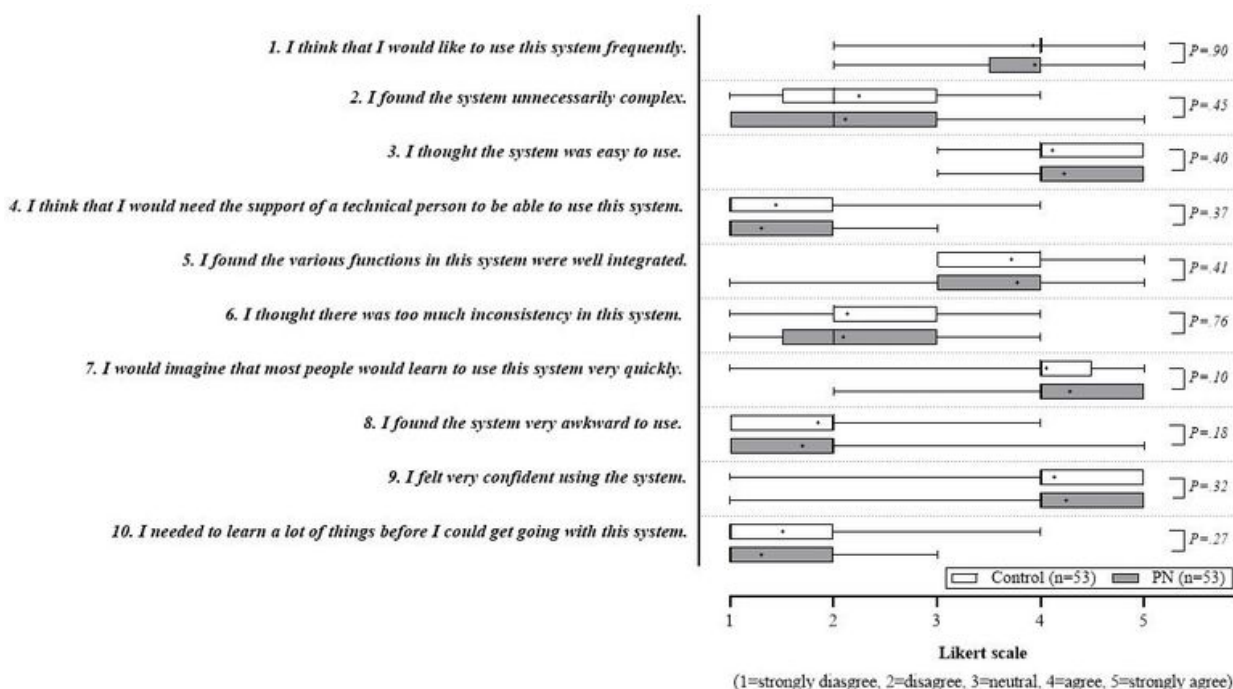
$P=.05$). Younger participants (77/87, 89%) had a mean completion time of 25.84 minutes (SD 10.2 minutes) compared with older participants (10/87, 11%), who had a mean completion time of 33.00 minutes (SD 12.42 minutes; $P=.07$). Regarding screen sizes, participants using a medium device screen size for answering the questions (7/87, 8%) were fastest with a mean completion time of 22.86 minutes (SD 7.4 minutes), followed by participants with small screen sizes (20/87, 23%), who had a mean completion time of 25.65 minutes (SD 8.9 minutes). Participants with large screen sizes (60/87, 69%) took longest, with a mean completion time of 27.45 minutes (SD 11.4 minutes; $P=.76$).

Evaluation of the System’s User-Friendliness

To assess participant’s perception of the user-friendliness of the eNutri app, a series of Likert-scale questions were asked at t1, after completion of the first FFQ and before displaying the first dietary report (Figure 1).

Overall, very high Likert-scale scores (above 4; equivalent to very high agreement rates among the study participants) were recorded for the statements regarding “ease of use of the system,” the “rapid learnability” of the system, and the “confidence in using the system” (all with a median of 4.0 for control/PN). Lowest Likert-scale scores (below 2; equivalent to strong or medium disagreement) were detected for the “need of technical support” to use the system, the “need to learn a lot of things before using the system” (both with a median of 1.0 for control/PN), and the “operation awkwardness” of the app (median of 2.0 for control/PN). Spanning from neutral to agreeing, and at a median of 4.0, feedback on the statements “to use the system frequently” and its “well integration” leveled off. For the statements concerning “system complexity and inconsistency,” the interquartile ranges were between 1 and 3 on the Likert scale with a median of 2.0 each.

Figure 1. Box plot analysis of the Likert-scale ratings.



Participants' Feedback On System Usability

An extended feedback collection conducted after completion of the survey at t2 and after transmission of personalized dietary reports to both PN and control groups (Figure 2) was aimed at providing information about participants' reflections on their own diets or dietary habits.

The distribution of responses to the various survey statements revealed that, with all interquartile ranges spanning between Likert scale scores of 2 and 4, a significantly higher proportion of study participants in the PN group agreed that the eNutri "encouraged them to eat more healthily, even if only for a short period of time" (median control 3.0; median PN 4.0; $P=.02$). Greater deviation in feedback was further observed for the statement "the app changed their perception of what is a 'healthy' diet." With a median of 2.0, most participants in the control group disagreed, while significantly ($P=.02$) more respondents in the PN group (median 3.0) stayed neutral or agreed. A similar tendency was observed for the statements that the app "encouraged me to eat foods that I would normally not eat" (median control 2.0; median PN 3.0), and "It made me feel more confident about making positive changes to my diet" (median control and median PN 3.0). Referring to the statements "It taught me how different foods impact on my health," and "I am still following aspects of the advice and consider my diet to be healthier now," the ratings were quite identical in both groups (median control and median PN 3.0). When asked if participants "plan to continue following aspects of the device though the study has ended," the median was 4.0 for both groups, signaling that the vast majority of study participants agree.

Regarding the question if participants would "recommend the eNutri app to their family and friends," on average 35.8% (38/106) of all participants indicated that would *likely* or *highly likely* recommend the app, with same response frequencies in both PN and control groups. Furthermore, participants were asked "What are the reasons for not following your dietary recommendations?" (Table 2), and the most frequently chosen option was "I did not like the recommended food" (total: 30/106, 28.3%; control: 6/53, 11%; PN: 24/53, 45%; $P<.001$). This was followed by the response "I lacked ideas for including the recommended food into my diet" (total: 29/106, 27.4%; control: 17/53, 32%; PN: 12/53, 23%; $P=.28$) and "recommended foods did not fit into my usual meal plans/recipes" (total: 25/106, 23.6%; control: 10/53, 19%; PN: 15/53, 28%; $P=.25$). In total, 24.5% (26/106) of all participants indicated that "other people shop and cook for me" (control: 11/53, 21%; PN: 15/53, 28%; $P=.37$), while on average 13.2% (14/106) responded that they "will not change certain aspects of their diet, regardless of the advice" (control: 4/53, 8%; PN: 10/53, 19%; $P=.09$). Nearly 10.4% (11/106) of all study participants disagreed with the dietary recommendations provided by the eNutri app because they were incompatible with their dietary restrictions. It is also worth mentioning that on average 13% (14/106; $P=.01$) of the study population indicated that "the recommended foods were expensive," of which almost 21% (11/53) belonged to the PN group. The overall mean star rating of the eNutri app reached 3.3 stars (SD 0.9) out of 5.0. Participants in the PN group rated the eNutri app insignificantly higher (mean stars 3.4, SD 0.9), compared with those in the control group (mean stars 3.2, SD 0.9; $P=.27$).

Figure 2. In-app feedback related to eNutri-induced changes in dietary behaviour.

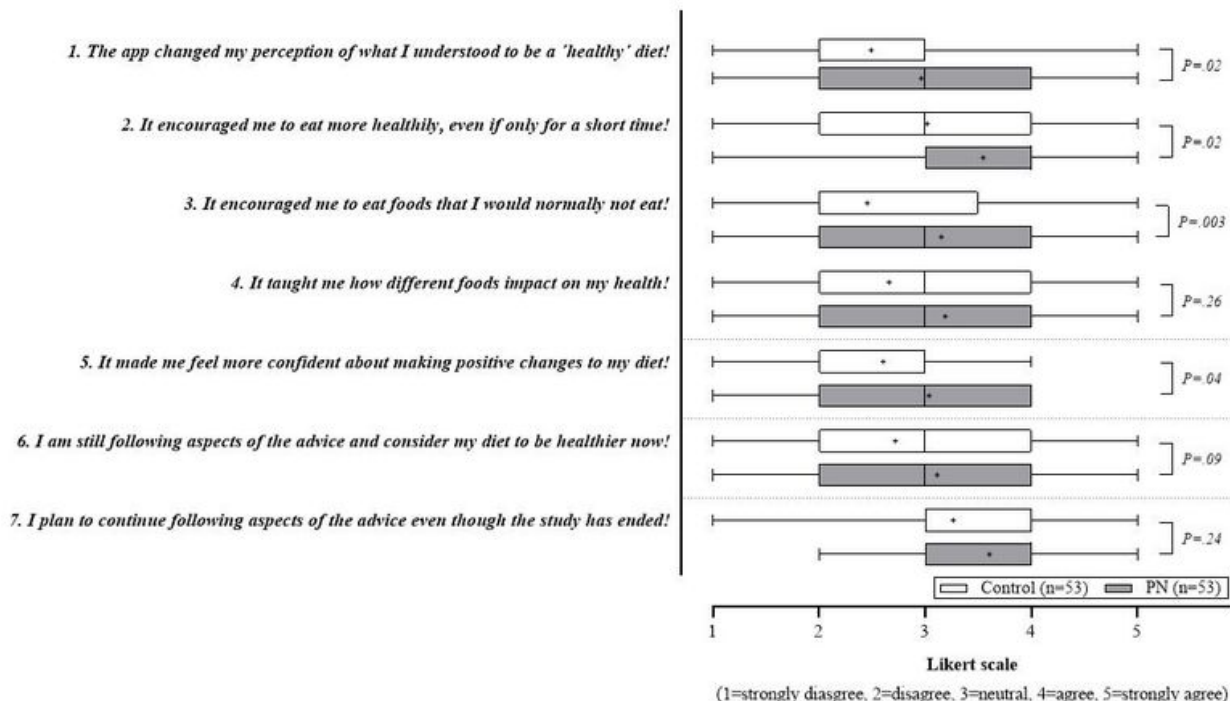


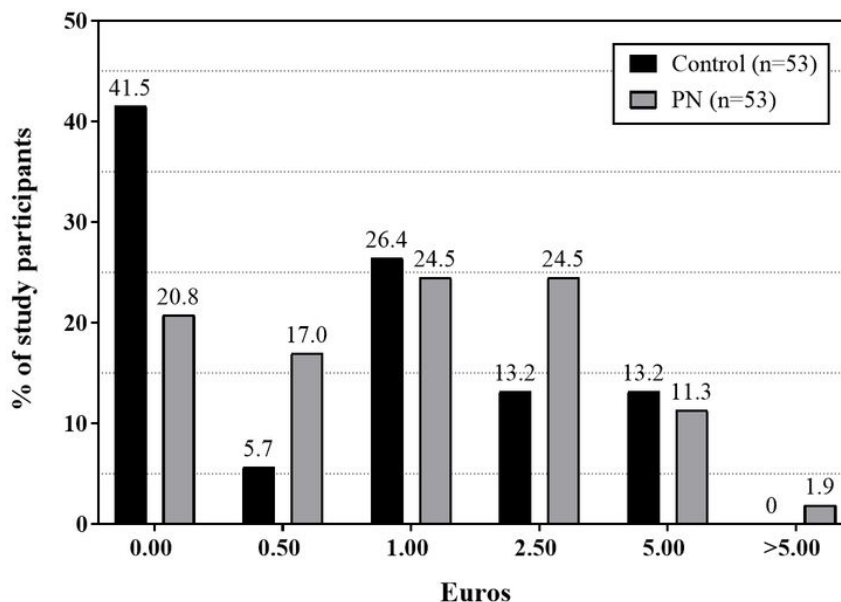
Table 2. Feedback on dietary recommendations provided by eNutri2019 study participants (N=106).

Feedback on nonadherence to dietary recommendations	Control group (n=53), n (%)	PN ^a group (n=53), n (%)	P value
What are the reasons for not following your dietary recommendations?			
I did not like the recommended food	6 (11)	24 (45)	<.001
I lacked ideas for including the recommended food into my diet	17 (32)	12 (23)	.28
The recommended foods did not fit into my usual meal plans	10 (19)	15 (28)	.25
Other people shop and cook for me	11 (21)	15 (28)	.37
I will not change certain aspects of my diet, regardless of the advice	4 (8)	10 (19)	.09
I did not agree that the advice would result in a healthier diet for me	11 (21)	9 (17)	.62
I was not willing to try new foods	1 (2)	1 (2)	.99
The recommended foods were expensive	2 (4)	1 (2)	.01
I did not know what to eat instead when replacing less healthy foods	4 (8)	2 (4)	.68
My dietary restrictions were not considered	3 (6)	2 (4)	.99
The health benefits of making these changes were unclear	2 (4)	2 (4)	.99
I was concerned my weight would change	0 (0)	2 (4)	.50

^aPN: personalized nutrition.

Participants were additionally asked “What is the maximum you would be willing to pay to purchase the eNutri app for unlimited personal use?” (Figure 3). Across subgroups, 31.1% (total: 33/106; control: 22/53, 42%; PN: 11/53, 21%; $P=.04$) would not pay anything at all to purchase the eNutri app,

whereas 55.7% (59/106) would pay between €0.50 (US \$0.53) and €2.50 (US \$2.67). In total, 13.2% (14/106) would pay €5.00 (US \$5.34) or more. Overall willingness to pay did not significantly differ between the PN group and the control group ($P=.3$).

Figure 3. Willingness to pay for the eNutri app across PN and control group.

Open-ended feedback, suggestions, or problems encountered during the eNutri2019 study were collected from 84 participants (control: 45/53, 85%; PN: 39/53, 74%). A categorization was made into 3 main topics: app in general, FFQ, and dietary recommendations.

Respondents positively highlighted the high intuitiveness of the eNutri app in general, coupled with good comprehensibility and ease of use (total: 22/106, 20.8%; control: 10/53, 19%; PN: 12/53, 23%). In terms of the FFQ, the time-consuming process

of data entry was remarked as too long and extensive (total: 12/106, 11.3%; control: 8/53, 15%; PN: 4/53, 8%). Many participants found it difficult to remember the foods and their quantities they had eaten in the previous month and to enter them in the correct section of the FFQ (total: 18/75, 24%; control: 6/40, 15%; PN: 12/35, 34%). At the same time, 12% (9/75) of participants noted positively the photos of the food in different portion sizes included in the FFQ and considered them as very helpful in answering the survey questions. A rather small percentage (7/106, 6.6%) of the responders (control: 3/53, 6%;

PN: 4/53, 8%) suggested a superordinate categorization into food groups (vegetables, meat, etc.), as this would have made it easier to keep track and thus to answer the FFQ. Regarding the dietary recommendations, 45.3% (48/106) of the study participants gave feedback. Nutritional advice in the PN and control groups should be considered in a differentiated manner. In the control group, 58% (31/53) indicated that the nutrition report was rather impersonal, superficial, and too general, yet contained good, easy-to-understand nutrition tips; however, they lacked helpful information for the implementation into everyday life. In the PN group, conversely, 32% (17/53) stated that they would have liked a more detailed nutrition report including more specific information about the amounts of foods to be increased; 16% (17/106) of all respondents (control: 11/53, 21%; PN: 6/53, 11%) reported that the dietary recommendations were not tailored to their individual diet or were incorrect according to the information indicated in the FFQ (eg, no meat consumption as a vegan followed by a recommendation to eat meat).

Discussion

Principal Findings

One of the objectives of the eNutri2019 pilot study as part of the EIT Food Quisper project was to introduce the German eNutri app and evaluate its usability metrics in a real-life setting. From a secondary perspective, this study sought to assess whether the provision of personalized dietary recommendations by the eNutri app provides greater benefits related to nutrition behavior changes than generic dietary advice.

Analysis of the system's usability yielded an overall mean score of 78.4, indicating that using the eNutri app is clearly above an average experience (SUS 68) [29]. As no statistically significant differences between groups could be identified, a good performance across all users can be assumed. Ferrara et al [30] reviewed diet-tracking apps and, inter alia, evaluated the usability of the top 7 diet-tracking apps found within the most popular online app stores in 2017. Across all apps considered, a mean value of 71 (range 46.7-89.2) was obtained. In comparison, the eNutri app achieved a similar usability SUS score, putting it on par. As an indicator for technical and perceived usability performance in terms of effectiveness, efficiency, ease of use, and user satisfaction, the high SUS score of eNutri stands proxy for high user acceptability and great usability.

Within app stores, most nutrition-related apps are free of charge to download but include additional fees to purchase a premium version to get access to more features. The price of an app can be seen as one key criterion for selecting an app within the app stores [31]. One-third of the eNutri2019 study participants stated that they would not pay anything at all to purchase the eNutri app. More than half would pay between €0.50 (US \$0.53) and €2.50 (US \$2.67). These results are in line with qualitative and quantitative research, showing a tendency toward a reluctant willingness to pay for nutrition apps [32,33].

Another aspect showing the value of an app is the common star rating. Overall, participants rated the app with 3.3 out of 5 stars

on average, with no significant differences between the PN and the control group. Among other popular nutrition apps, such as MyFitnessPal, Lifesum, or Freeletics Nutrition, 72% hold an average rating between 4 and 4.5 stars [34], indicating the need to further improve the eNutri app. Ratings are a reflection of user experience that involves a multidimensional interplay of system usability, context of use, expectations, perceived utility, and emotions before and after using an app [35]; thus, a rating of 3.3 stars implies that eNutri exhibits likely shortcomings in these areas that require further investigation and remediation.

A significant factor in this context is also the FFQ. FFQs are commonly integrated within diet-tracking apps to assess dietary behavior. Depending on the number of food items included, the completion time varies between 30 and 60 minutes [36]. The completion time of an FFQ is positively correlated with the potential to create typical biases [37], therefore a shorter completion time is desirable. The mean completion time for the eNutri app was 26.7 minutes, with no significant differences between groups. Franco et al [16] reported a mean completion time of 22.9 minutes in their formative study on the UK version of the eNutri app. Although the completion time of the eNutri FFQ is within a comparable range, its length was burdensome for respondents, as reflected in the open-ended feedback. To decrease the effort for the user, investigations on how to streamline the FFQ without reducing its quality need to be undertaken.

Comparison With Prior Work

Regarding the potential of the eNutri app to change a users' dietary behavior, the majority of the participants stated via open feedback that using the app motivated them to make changes in their diets and improved their awareness of healthy eating behavior. The eNutri app was positively evaluated by users, stating that the process of monitoring their dietary intake initiated a self-reflecting process, rising their awareness about unbalanced and unhealthy dietary habits. This process has also been described in various theories on behavior change, identifying *consciousness raising* as a crucial point in the process of change [38]. Furthermore, studies demonstrated a positive effect of food intake recording on the awareness of food quality and quantity [39]. This is in line with previous research indicating that perceived app utility and personalization positively affect the continuance usage intention [39-41]. Participant's feedback suggests that the personalized dietary recommendations tended to being more effective than the generic recommendations, at least in providing nutrition knowledge and support for targeted dietary adjustments tailored to an individual and his/her FFQ-derived food preferences.

Strengths and Limitations

The purpose of this study was to assess the usability of the German version of the eNutri app. Therefore, the design of a pilot study was applied.

First, the implementation of the validated and well-established graphical FFQ strengthens the design of the study. An FFQ is a commonly used dietary assessment instrument that provides information on the type, frequency, and quantity of foods consumed and allows for population estimates. However, FFQs

are prone to over- and underreporting due to their retrospective character and the time-consuming and demanding nature. By contrast, the application of prospective dietary assessment methods reduces recall bias and shows higher validity and precision, such as a food diary with a higher validity and precision [42]. The application of a prospective instrument such as a food diary should therefore be reconsidered.

Second, participants' open feedback revealed a high burden due to the long completion time. At the same point, participants' responses showed that the more personalized a dietary recommendation was, the better it tended to be accepted by them. This highlights the importance of collecting detailed food intake information via the FFQ, to enable the system to detect individual consumption patterns and preferences to subsequently provide tailored recommendations. Therefore, it was essential that the same foods in different processing stages were repeatedly queried in the FFQ (eg, vegetables in raw or cooked condition), because changes in food texture and consistency can greatly influence personal food preferences. For instance, it does not necessarily mean that if someone likes to eat raw vegetables, which can be quite crunchy in consistency, this person will also like them in cooked form with more smoothness. In return, this also means that if the FFQ was shortened, relevant information about food preferences cannot be obtained. A detailed and comprehensive FFQ, by contrast, improves the dietary recommendations, but the temporary burden to fill in the high number of items poses the risk of dropouts. This results in a certain dichotomy, and thus a balance between information demands and effort for completion needs to be found.

Third, evidence suggests that females tend to underreport in nutritional surveys [43]. Overall, there was a high proportion of women among the eNutri study population. This may be due to several reasons, one of which is the observation that women can be quite successfully recruited via social media (eg, Twitter, Facebook) [44], which was also the primary recruitment channel in the eNutri2019 study. Further, gender differences in health information-seeking behavior are known, just as a higher motivation and interest of females to deal with health-related information, coupled with a higher consciousness of nutrition [45,46]. Therefore, we will redesign our recruitment materials to appeal to a broader spectrum of the population for a follow-up study.

Fourth, an important issue arising from the eNutri pilot study is the focus on a healthy adult population. Thus, dietary recommendations provided by the eNutri app are tailored to this target group, while people with special diets requirements (eg, food intolerances, allergies) or certain nutrition-related diseases are excluded. To make the app more compatible for a broader and heterogeneous target audience, it should be adapted to diverse (nutritional) needs, taking into account not only anthropometric, physical characteristics, and individual food preferences, but also medical and behavioral traits or even genetic factors.

Fifth, the main aim was to assess the usability of the German eNutri app. Results revealed that the tool is appropriate for different user groups. The focus of the differentiation between the PN and control groups was concentrated on the open feedback. To perform an in-depth comparison of advice given to the PN and control groups, further studies with longer study periods are needed.

Further Directions

To effectively adopt positive dietary changes, a long-term implementation of the recommendations into daily habits is essential. Considering that many study participants reported having difficulties in implementing the received dietary recommendations, additional features such as a recipe database or cookbook need to be integrated directly into the app. Further improvements in the usability can be achieved by providing some external links to credible databases or scientific literature references or links to the federal Nutrition Society. This is beneficial to expand the app users' knowledge on food and nutrition, if desired. It has also been shown that coaching sessions as well as web-based coaching classes positively influence the success of dietary interventions [47]. The integration of features enabling more personal guidance (eg, chat or video coaching) within the eNutri app is another suggestion for improvement. Some nutrition apps were already designed integrating chatbot functions to support weight loss interventions [48]. To boost long-term user engagement, more in-app personalization, for example, features enabling personal goal setting and progress tracking [49], or integration of personal avatars, is advisable. Incorporating gamification elements to better communicate nutrition knowledge and raise awareness about healthier food choices is also an option with proven benefits [50].

Conclusions

The eNutri app is a field-tested feasible and usable web tool to assess habitual dietary intake. The eNutri app is unique in that it is specifically tailored to the eating habits of a Western European population, more precisely a German population. It takes country-specific food items and eating habits into account and was developed by nutrition experts. The image-based validated food quantification and the app's ease of use contributed positively to an above average usability experience of the eNutri2019 study participants. Users' experience on the eNutri app's usability was above average across different user groups. A higher level of personalization within nutritional recommendation was seen as more supportive for the implementation of positive dietary changes, in the short as well as in the long term. However, the eNutri app needs to be further adapted and extensions regarding behavioral change features need to be included. In total, the German eNutri app represents a promising tool for assessing habitual dietary intake and could become a valuable instrument to support the accomplishment of healthy dietary habits within a wide spectrum of different user groups. As a time- and cost-effective tool, it has the potential to alleviate the burden of diet-related diseases on the health care system.

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Authors' Contributions

BK, TS, PMF, and KG have made substantial contributions to the conceptualization and design of the eNutri2019 study, as well as to data acquisition, data analysis and interpretation, and writing of the original draft. BK and TS contributed equally to author this manuscript. KG and PMF critically revised the manuscript. All authors approved the final version of the manuscript.

Conflicts of Interest

BK, TS, and KG declare that there are no conflicts of interest. PMF is a member of the European Food Information Council (EUFIC) governance Board of Directors representative.

Multimedia Appendix 1

Flowchart of study participants' recruitment.

[[PNG File , 114 KB - formative_v6i8e34497_app1.png](#)]

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Abbreviations

BLS: German Food Code and Nutrient Database
DGE: German Nutrition Society
DQS: Diet Quality Score
EPIC: European Prospective Investigation into Cancer
FFQ: food frequency questionnaire
ICT: information and communications technology
PN: personalized nutrition
SUS: System Usability Scale
t1: time point 1
t2: time point 2

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Original Paper

Effects of Feedback From Self-Monitoring Devices on Lifestyle Changes in Workers with Diabetes: 3-Month Randomized Controlled Pilot Trial

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Abstract

Background: Although lifestyle interventions are useful in the prevention and management of diabetes, they can be expensive and time-consuming. There is some evidence on the effectiveness of automated mobile technology for health self-monitoring; however, few studies have used such devices in the occupational health field.

Objective: We aimed to examine the effectiveness of a digital self-monitoring device on glucose levels and activity of workers with diabetes in Japan. The primary outcomes were changes in blood glucose levels, and the secondary outcomes were changes in weight and BMI.

Methods: A 2-arm randomized controlled pilot trial was conducted with workers from 23 organizations. The intervention group (n=50) wore an armband activity monitor, a body composition monitor, and a blood pressure monitor for 3 months and received semiautomated weekly email messages tailored to their device data. The control group (n=53) engaged in no self-monitoring. Messages were developed by a physician and a dietician. Postintervention changes in blood glucose levels, weight, and BMI were compared between the intervention and control groups, using blood tests and questionnaires.

Results: At the end of 3 months, the intervention group showed significantly lower blood glucose levels (HbA_{1c}: intervention group mean 6.4% (SD 0.3%) vs control group mean 6.6% (SD 0.3%); Cohen $d=0.7$, 95% CI 0.2-1.1; $P=.009$). There were no significant between-group differences in weight and BMI.

Conclusions: Mobile digital self-monitoring was effective in improving blood glucose levels in workers with diabetes. The use of digital health devices is a cost-effective way of implementing health self-monitoring for large numbers of individuals in the workplace. However, due to the large volume of missing values in this study, we need to be careful in interpreting the results, and well-designed intervention studies need to be conducted.

Trial Registration: University Hospital Medical Information Network UMIN000023651; https://upload.umin.ac.jp/cgi-open-bin/icdr/ctr_view_cb.cgi?recptno=R000027244&flwp_key=1008PYbOcXKmk7CAg4Th1FWS

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KEYWORDS

mobile health; digital health; diabetes; workers; self-monitoring; BMI; daily activity; randomized controlled trial; smartphone; mobile phone

Introduction

The number of people with diabetes is increasing, and it is a global public health challenge [1]. In Japan, 18.7% of men and 9.3% of women are at high risk of diabetes [2]. Type 2 diabetes mellitus (T2DM) is associated with both genetic factors and modifiable risk factors such as obesity [3] and physical inactivity [4]. Early detection and prevention of T2DM using lifestyle interventions is preferable to treatment. Even a small amount of weight loss (3%) can improve metabolic status [5]. Additionally, higher daily step count (6000-8000 steps/day) can reduce morbidity [6] and mortality [7]. Lifestyle interventions can reduce T2DM incidence or improve diabetes outcomes [8-14]. However, such interventions often rely on coaching by health professionals, whose skills can affect results [11]. Additionally, the cost and time burdens of lifestyle interventions may preclude their availability to all patients with diabetes.

Interest is growing in the potential benefits of automated wearable or mobile technology as a cost-effective way of monitoring health in large populations [15-17]. A recent review indicated that web-based health behavior change interventions are often as effective as face-to-face interventions, particularly if they feature some type of person-to-person human support to provide encouragement and feedback [18].

Wearable technology devices and smartphones have been used to monitor health in workers with various conditions. Some recent reviews indicate that digital mental health interventions improve workers' well-being and effectiveness [19] and are also effective in preventing and managing diabetes; such tools may be adopted more widely with the growth of medical device innovations [20]. Two core components of mobile health tools are self-monitoring (eg, of diet, blood glucose levels, activity, and weight) and messaging (eg, educational or motivational comments and self-monitoring data feedback or reminders) [20]. Several randomized controlled or pragmatic trials have examined the use of digital health interventions for diabetes [21-28]. However, these studies show inconsistent results for glycemic improvement, and they were conducted in primary health care settings and not in the workplace. There is a small amount of evidence that message-based interventions can improve diabetes outcomes in workers [29], but more studies are needed.

The aim of this study was to examine the effectiveness of a 3-month, digital, semiautomated behavior improvement program on blood glucose levels, BMI, and health-related behavior of workers with diabetes.

Methods

Study Design

A 3-month, 2-arm randomized controlled pilot trial was conducted on Japanese workers with diabetes between June 2016 and August 2016. This was a parallel study with a 1:1 allocation ratio.

Participants

The aim of this study was explained to companies and health insurance unions, and 23 organizations agreed to participate. In Japan, regular medical examinations are conducted once a year, and most companies obtain employee blood glucose measurements (ie, HbA_{1c}). Workers with blood glucose measurements within 3 months before the baseline, whose HbA_{1c}—as per the National Glycohemoglobin Standardization Program (NGSP)—was 6.5%-7.0%, were invited to participate. The inclusion criteria were having 20-65 years of age at the time of participation and permission for participation by the attending doctor or occupational physician.

We excluded workers (1) who received regular diabetes treatment and used insulin or hypoglycemic drugs, (2) had stage ≥ 4 diabetic nephropathy, (3) were on dialysis or hospitalized, and (4) had been diagnosed with malignant tumors in the last 5 years, as well as (5) pregnant or potentially pregnant women. At the beginning of the study, participants were asked if they wished to seek treatment for diabetes and were informed that they could consult with the company occupational physician if they wished.

Randomization

One of the researchers conducted a block randomization and analyzed the data, but he was not involved in the intervention. Two sets of blocks of four (2 from the intervention and 2 from the control group) random combinations were generated using computer-generated randomization codes. Randomization was performed 7 times (corresponding to 7 recruitment periods).

Intervention

The transtheoretical model was used to develop the intervention. The individualized, transtheoretical model-based intervention was an effective strategy for weight management in the primary health care setting [30]. The intervention comprised self-monitoring and tailored feedback email messages. We distributed an armband activity monitor (Moveband 2 WMB-02C-K, LB, BR; NTT DoCoMo Inc) [31], a body composition monitor (HBF-254C; Omron Healthcare Co, Ltd) [32,33], and a blood pressure monitor (HEM-7270C; Omron Healthcare Co, Ltd) [32,34] to the intervention group. Participants were asked to wear the armband activity monitor throughout the day and night except when bathing. The activity monitor measured daily steps. We encouraged participants to measure their body weight and blood pressure at least once a day. The body composition monitor measured body weight and BMI. The blood pressure monitor measured systolic or diastolic blood pressure. The data recorded by the 3 devices were merged into 1 data set. Participants could check their activity status via the 3 devices and their own smartphones. We checked participants' self-monitoring results once a month. If the rate of wearing the activity monitor or measuring the weight was low, we contacted the participants individually and communicated with them to ask them to measure it.

We conducted biochemical examinations (Sunpre Co, Ltd) using a small amount of blood collected from the fingertip [35] for the intervention and control groups at two time points: baseline and after 3 months. To assess the effect of the intervention, the

same examinations were conducted with just the intervention group after 1 month and after 2 months from the baseline. The examinations assessed HbA_{1c} (as per NGSP), total cholesterol, high-density lipoprotein cholesterol, low-density lipoprotein cholesterol, triglycerides, total protein, albumin, glutamic oxaloacetate transaminase, glutamate pyruvate transaminase, γ -glutamyltransferase, urea nitrogen, creatinine, and uric acid. For blood collection, participants warmed their hands and wiped the finger with a sterilizing cloth. They made a small puncture at the fingertip and drew blood into a collecting tool. They mailed the specimen to the laboratory. A biochemical automated analyzer (JCA-BM6050; JEOL Ltd) was used to measure biochemical data. Participants were able to access their examination results 1 week later via their smartphones, tablets, or personal computers.

We sent a semiautomated, tailored email message to participants once a week. The content of the messages was developed by a medical doctor and registered dietician based on Prochaska's transtheoretical theory of health behavior change [36]. The Japanese Ministry of Health, Labour and Welfare's health check and guidance manual [37] is based on this theory, and we have applied the text of this manual to this study. This theory emphasizes the important role of self-efficacy and tailored interventions to improve health behavior [38,39]. We sent messages according to the number of steps measured by the participants. The messages were designed to motivate participants to walk; for example, if a participant walked more than 10,000 steps a day, they would be praised (eg, "Great! You have focused on your walking. Keep up the good work"). If a participant walked less than 3000 steps, they would get the message "let's first focus on walking! Try walking 3 days a week, not every day. It is also effective to take a small walk or change the way you walk." We also added the message about self-monitoring and how to use the equipment. The overall message structure is provided in [Multimedia Appendix 1](#).

Participants in the intervention group were given the above-mentioned measurement devices free of charge.

Participants in the control group were allowed to seek health guidance from their company's occupational physician or nurse, but we did not record whether such guidance was sought. Participants who had high HbA_{1c} levels after 3 months were advised to seek medical advice.

Outcome Measures

Demographic information was collected at baseline. Blood tests and questionnaires assessing motivation for changing physical activity were administered to both groups at baseline and 3 months post intervention ([Multimedia Appendix 2](#)). The motivation question was related to changes in physical activity. We asked participants the following question: "do you plan to start, or have you already started, lifestyle modifications to increase your physical activity?" There were 3 response options: "I have no plan to change," "I currently have a plan to change," and "I already changed my activity." This question and response options were based on a standard questionnaire used in Specific Health Checkups [40], a detailed manual developed by the Japanese Ministry of Health, Labour and Welfare for medical

checkups required by the National Health Insurance Unions [37], and Prochaska's transtheoretical theory of health behavior change [36]. The primary outcome measure was changes in HbA_{1c} (in mmol/mol or equivalently in % as per NGSP) from baseline to 3 months. The secondary outcomes were changes in weight and BMI.

Sample Size Calculations

Sample size calculations assumed an overall 2-sided 5% significance level to be distributed equally between the intervention and control groups. A sample size of 41 in each group was estimated to have at least 80% power to detect a difference of 5 mmol/mol of HbA_{1c} (as per NGSP) post intervention, assuming an 8 mmol/mol SD of HbA_{1c} (as per NGSP) and a significance level of .05. Sample size calculations were performed using the Power and Sample Size software program (version 3.1.6; WD Dupont and WD Plummer) [41]. We assumed a dropout rate of 5% and calculated an overall minimum sample size for each group of 46.

Process Evaluation

For the purpose of evaluating the intervention process, we calculated the average rate per 30 days of available values from the digital devices (armband activity monitor and body composition monitor) in the intervention group. Especially the mean steps per 30 days by the armband activity monitor was described from the first month to the third month for the purpose of confirming whether the behavior of the intervention group continued over the 3-month period. Additionally, the steps were described, stratified by a BMI with the cutoff point of 25 kg/m² based on Japanese obesity criteria [42] and 27.5 kg/m² based on Asian population obesity criteria [43]. A previous study indicated that participants with a higher BMI had lower average daily steps [44].

Statistical Analysis

All analyses were performed by an intention-to-treat approach. To examine the effect of the intervention, we conducted chi-square tests and 2-tailed *t* tests post intervention. Effect sizes were calculated using Cohen *d* for continuous variables. *P* values <.05 were considered significant. All analyses were conducted using Stata software (version 16.1; StataCorp).

Ethical Considerations

The occupational physicians of the companies in the study determined that there were no problems with the participation in the study. In addition, the participants were not restricted from receiving regular occupational health services from the occupational health staff of their companies. We planned that if blood pressure measurements were persistently excessively high during the study period, the investigator, a physician, would contact the individual directly and recommend that he or she see a doctor. However, in reality, none of the participants were directly recommended to see a doctor.

The medical research ethics committee of the University of Occupational and Environmental Health, Japan, approved the study protocol (H28-056). Written informed consent was obtained from all participants. This study is registered with the

University Hospital Medical Information Network (UMIN000023651). Trial development and reporting was guided by the CONSORT and CONSORT-EHEALTH statements.

Results

Figure 1 shows the flow of study participants. A total of 406 individuals were assessed for eligibility criteria. After exclusions ($n=303$), 103 participants were allocated to 50 intervention and 53 control groups. Table 1 shows demographics and clinical characteristics at baseline. Among intervention and control groups, 10 (20%) and 8 (15%) were women, respectively.

Post intervention, there was a significant between-group difference in HbA_{1c} : the effect size (Cohen d) was 0.7 ($P=.009$), and the mean HbA_{1c} for the intervention group (mean 6.4%, SD 0.3%) was 0.2% (2.2 mmol/mol) lower than the mean HbA_{1c} for the control group (mean 6.6%, SD 0.3%; Table 2). There was no significant effect on weight and BMI at postintervention.

In terms of weight change (kg and %) before and after the intervention, the mean weight change for the intervention group was -1.36 (SD 3.6) kg and -1.35% (SD 4.2%), whereas for the control group, it was -0.53 (SD 2.1) kg and -0.72% (SD 2.6%), with no significant difference between the two groups ($P=.23$ vs $P=.46$).

There was a significant between-group difference in motivation for changing physical activity post intervention ($P<.001$).

Additionally, the average rate per 30 days of available values from the digital devices (armband activity monitor and body composition monitor) in the intervention group was very high compared to the control group (84% and 69%, respectively). The mean number of steps per day for the first, second, and third month in 3 months was 7226, 7431, and 7609, respectively (Table 3). Participants with a higher BMI had a lower mean number of steps. Using a BMI cutoff point of 25 kg/m², the mean number of steps remained high for those with a BMI <25. The intervention group experienced no adverse effects.

Figure 1. Flow chart of study participants.

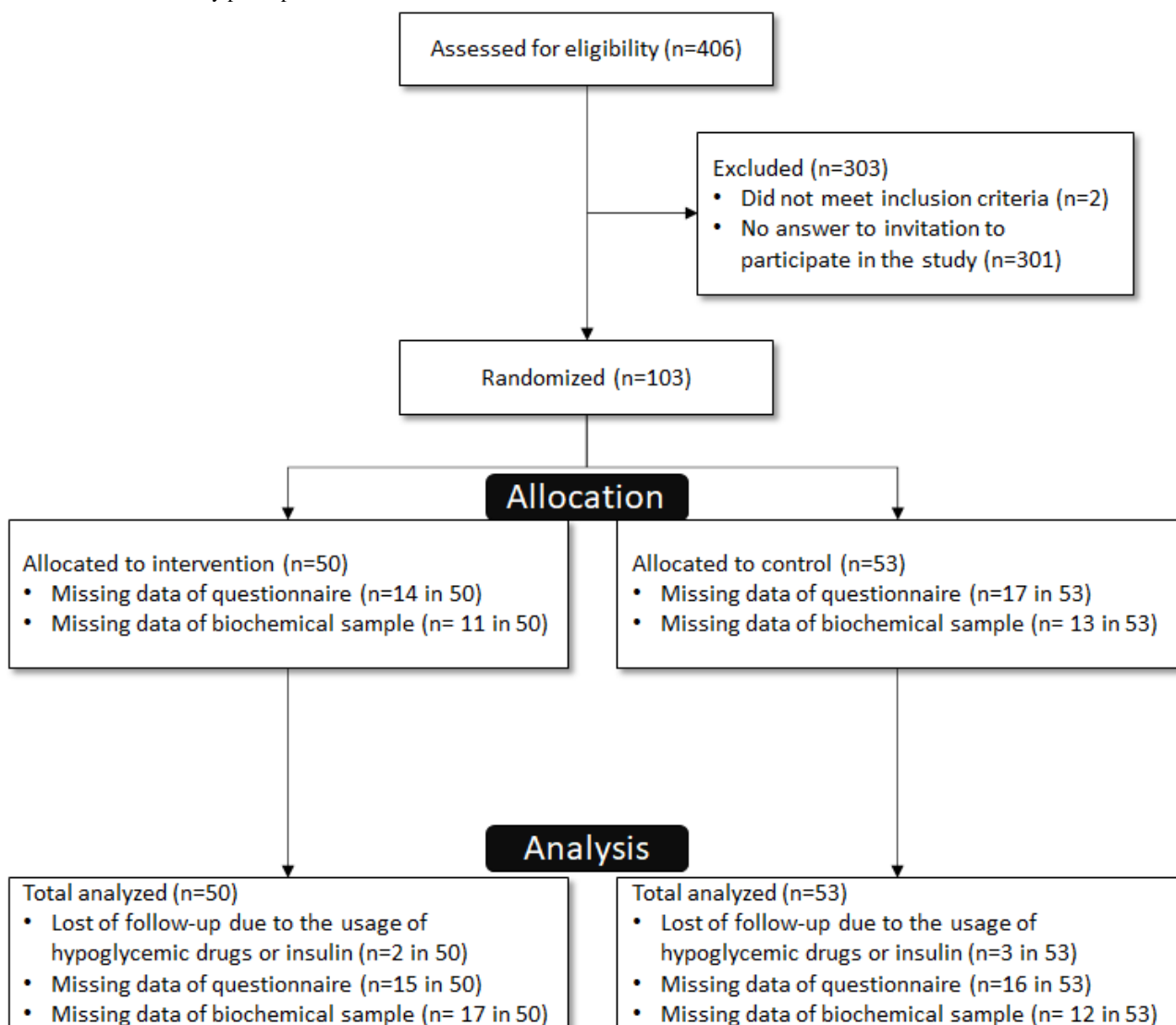


Table 1. Demographics and clinical characteristics at the baseline (N=103).

Characteristics	Participants	
	Control group (n=53)	Intervention group (n=50)
Sex, n (%)		
Women	8 (15)	10 (20)
Men	45 (85)	40 (80)
Age (years), mean (SD)	52.3 (6.6)	51.5 (7.1)
Education, n (%)		
High school graduation	12 (23)	12 (24)
University degree or higher	26 (49)	24 (48)
Missing	15 (28)	14 (28)
Marriage, n (%)		
Yes	33 (62)	28 (56)
No	5 (9)	8 (16)
Missing	15 (28)	14 (28)
Job position, n (%)		
Manager	17 (32)	13 (26)
Staff	21 (40)	23 (46)
Missing	15 (28)	14 (28)
Occupation, n (%)		
Desk work	18 (47)	9 (25)
Service	5 (13)	7 (19)
Research and development	6 (16)	5 (14)
Factory	4 (11)	9 (25)
Others	5 (13)	6 (17)
Missing	15 (28)	14 (28)
Smoking, n (%)		
Everyday	10 (19)	13 (26)
Missing	17 (32)	14 (28)
Alcohol drinking, n (%)		
More than 5 days/week	10 (19)	12 (24)
Missing	17 (32)	14 (28)
Body indices, mean (SD)		
Weight (kg)	77.7 (13.3)	76.5 (13.6)
BMI (kg/m ²)	27.1 (3.7)	27.1 (4.5)
Missing, n (%)	14 (26)	12 (24)
Motivation for changing physical activity, n (%)		
“I have no plan to change.”	4 (8)	5 (10)
“I currently have a plan to change.”	19 (36)	20 (40)
“I already changed my activity.”	13 (25)	11 (22)
Missing	17 (32)	14 (28)
Blood tests, mean (SD)		
HbA _{1c} ^a (%)	6.5 (0.5)	6.6 (0.5)

Characteristics	Participants	
	Control group (n=53)	Intervention group (n=50)
HbA _{1c} (mmol/mol)	47.9 (5.0)	49.1 (5.7)
FBG ^b (mg/dL)	129.7 (34.5)	127.7 (35.6)
Total cholesterol (mg/dL)	203.6 (38.0)	205.0 (36.0)
HDL ^c cholesterol (mg/dL)	54.8 (13.6)	51.7 (10.8)
LDL ^d cholesterol (mg/dL)	119.0 (29.4)	117.6 (29.0)
Total protein (g/dL)	7.5 (0.2)	7.4 (0.3)
Albumin (g/dL)	4.5 (0.1)	4.5 (0.1)
GOT ^e (IU/L)	32.2 (9.1)	33.9 (11.4)
GPT ^f (IU/L)	30.2 (21.5)	30.5 (12.8)
γGT ^g (IU/L)	44.6 (39.3)	53.3 (56.3)
BUN ^h (mg/dL)	13.7 (3.5)	13.8 (3.4)
Creatinine (mg/dL)	0.8 (0.1)	0.7 (0.1)
Urinary uric acid (mg/dL)	5.4 (1.2)	5.4 (1.0)
Missing blood test data, n (%)	13 (24)	11 (22)

^aHbA_{1c}: hemoglobin A_{1c}.

^bFBG: fasting blood glucose.

^cHDL: high-density lipoprotein.

^dLDL: low-density lipoprotein.

^eGOT: glutamic oxaloacetic transaminase.

^fGPT: glutamic pyruvic transaminase.

^gγGT: γ-glutamyl transferase.

^hBUN: blood urea nitrogen.

Table 2. The effect of the intervention compared between the intervention and control groups.

Characteristics	Participants				Effect size, Cohen <i>d</i> (95% CI)	<i>P</i> value
	Control group (n=53)	Missing data	Intervention group (n=50)	Missing data		
HbA _{1c} ^a (%), mean (SD)	6.6 (0.3)	12	6.4 (0.3)	17	0.7 ^b (0.2 to 1.1)	.009
HbA _{1c} (mmol/mol), mean (SD)	48.7 (3.6)	12	46.5 (3.0)	17	0.7 ^b (0.2 to 1.1)	.009
Weight (kg), mean (SD)	76.5 (13.2)	11	74.8 (13.2)	13	0.1 (−0.4 to 0.5)	.58
BMI (kg/m ²), mean (SD)	26.7 (3.7)	11	26.5 (4.4)	13	0.1 (−0.4 to 0.5)	.83
Motivation for changing physical activity, n (%)						<.001
“I have no plan to change.”	7 (13)		5 (10)		N/A	
“I currently have a plan to change.”	18 (34)		4 (8)		N/A	
“I already changed my activity.”	12 (23)		26 (52)		N/A	
Missing data	16 (30)		15 (30)		N/A	

^aHbA_{1c}: hemoglobin A_{1c}.

^b*P*<.01.

Table 3. The trajectory of mean steps per day in the intervention group (N=50).

Characteristics	Participants, n (%)	Mean number of steps per day ^a		
		1-30 days	31-60 days	61-90 days
Total	42 (84)	7226	7431	7609
Missing	8 (16)			
BMI at baseline				
<25	12	9230	9924	9950
≥25	23	7047	7294	767
<27.5	22	8507	9360	9179
≥27.5	13	6602	6391	6330

^aSD was not listed due to variations within the same individual and between individuals.

Discussion

Principal Findings

This is a randomized controlled pilot trial to evaluate the effects of a digital health intervention on blood glucose, BMI, and health behavior in workers with diabetes. After 3 months, HbA_{1c} levels significantly improved in the intervention group, but this was not the case for weight and BMI. The intervention group also showed greater motivation for changing their daily physical activity.

There was a significant improvement in HbA_{1c} values between the intervention and control groups. HbA_{1c} levels reflect the mean blood glucose level over the past 1-2 months and may reflect the effect 1-2 months after the start of the intervention. Few studies have used glycemic markers as an efficacy index in digital health interventions for diabetes prevention and weight loss. According to recent reviews, the median change in fasting glucose is -0.2 mmol/L [45], and the mean change is -0.1 mmol/L [46]; these changes are smaller than those found in this study. Even a relatively small drop of 0.5% in HbA_{1c} values is clinically important in individuals with values of 6.5-7.0, as reducing HbA_{1c} to <6.5 can help prevent microvascular complications such as retinopathy [47,48]. A previous study [28] of tailored behavior support for physical activity, diet, weight loss, stress coping, and sleep compared blood glucose levels after 6 months of weekly email interventions; HbA_{1c} was -0.26% in the intervention group and -0.18% in the control group [28]. However, another study of a mobile health intervention for patients with diabetes showed no difference in HbA_{1c} values between the intervention and control groups one year later [21]; therefore, evidence is inconsistent, perhaps because of between-study differences in populations and intervention programs. Since the number of steps taken before the intervention is unknown, it is difficult to say for sure, but the number of steps taken by the intervention group increased slightly over the 3-month intervention period (Table 3), suggesting that the increase in activity may have led to an improvement in HbA_{1c}. The daily self-monitoring of weight using scales may have boosted self-motivation to increase physical activity [49]. The questionnaire responses after 3 months revealed that motivation to increase physical activity

had increased significantly more in the intervention group. This motivation may lead to the behavior change of walking. Participants with a BMI of 27.5 kg/m² or higher had a decrease in their mean number of steps over the course of 3 months. How to get people with obesity to be active and how to maintain their behavior is an important public health issue.

There was no between-group difference in the secondary outcome—changes in weight and BMI. The weight reduction among the intervention group was 1.4 kg in 3 months, which is lower than previously reported reductions of 2.3 kg (over 12 months) [46] and 2.4 kg (over 3 months) [50] for diabetes lifestyle interventions. One reason for the lack of weight loss may be inadequate subscription to the diet.

Several randomized controlled trials have examined the use of digital health interventions for diabetes when the HbA_{1c} of participants was more than 7.5 [22] or more than 8.0 [21,24]. The new finding of this study was that intervention in subjects with an HbA_{1c} as low as 6.5-7.0 was effective in reducing HbA_{1c} levels. The interventions in this study were via self-monitoring and semiautomated tailored email messages. However, the latter did not elaborate an individualized message, unlike previous studies that individualized them [20,28]. The actual messages are all shown in [Multimedia Appendix 1](#). Although this is a weakness of the study, it shows that self-monitoring may be effective even without individualized messages. Self-monitoring is an intervention method that requires less professional involvement and is more economical. In the workplace, workers may show the results of their self-monitoring to each other and encourage each other. This will increase the motivation for behavior change and will sustain it.

There were some limitations in this study. First, there were a large volume of missing data in the questionnaires and biochemical tests. It is unclear how the bias of the missing data affects the results. Intervention studies need to be designed and conducted in such a way that missing data will be minimal. Second, only 103 (25%) ultimately agreed to participate, although 406 individuals were recruited by being directly approached about participating in this study. Participants in this study received incentives such as blood pressure monitors, but many workers decided not to participate. This suggests that it is difficult to change people's behavior. In addition, participants

in this study were likely to have a high level of awareness of behavior change, so we need to be careful in interpreting the results of this study. Third, the primary outcome of this study, changes in HbA_{1c} levels, reflects blood glucose levels over the past 1-2 months. The effect of the study should be verified by follow-ups for at least 6 months. However, in this study, we were only able to follow up for 3 months after the start of the intervention due to difficulty in securing a budget for the research project. Since there was an improvement in HbA_{1c} in the intervention group within 3 months, it is possible that a longer follow-up would have resulted in a greater effect. It is necessary to verify the results by long-term follow-ups in the future. Fourth, participants were from relatively large companies, and it is unclear whether the findings can be generalized to workers of small companies. Fifth, as body weight was self-measured, the validity and reliability of BMI values were limited. Sixth, it may be possible that occupational stress

may have affected the findings; however, this is unlikely, as there was no difference in occupation and job position between the intervention and control groups.

Conclusions

The 3-month, digital health intervention for self-monitoring and the semiautomated tailored messages were effective in reducing HbA_{1c} levels in workers with diabetes. This study shows that physical activity can be increased, and blood glucose control can be improved without imposing a professional workload. However, we need to take into account the large number of missing values in this study and be careful in interpreting the results; further well-designed intervention studies need to be conducted. Despite the fact that many people were approached to participate in this study, few actually did so. It may be necessary to develop interventions that would encourage a wider range of workers to participate.

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Authors' Contributions

TN played a lead role in the study design and writing of the manuscript. TN and SA contributed to the data interpretation and data analysis. MT carried out all the work, including the coordination of the study. MN and KM reviewed drafts of the manuscript. All authors gave their final approval for the submitted version of the paper.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Example of email messages.

[[XLSX File \(Microsoft Excel File\), 14 KB - formative_v6i8e23261_app1.xlsx](#)]

Multimedia Appendix 2

Timeline that visually represents the timing of intervention for the intervention and control groups.

[[PPTX File , 43 KB - formative_v6i8e23261_app2.pptx](#)]

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Abbreviations

HbA_{1c}: hemoglobin A_{1c}

NGSP: National Glycohemoglobin Standardization Program

T2DM: type 2 diabetes mellitus

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Original Paper

Associations of Maternal and Paternal Parenting Practices With Children's Fruit and Vegetable Intake and Physical Activity: Preliminary Findings From an Ecological Momentary Study

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Abstract

Background: Childhood obesity prevention interventions routinely focus on changing maternal parenting practices. Failure to assess how fathers' weight-related (ie, diet and physical activity) parenting practices contribute to children's energy balance behaviors limits the understanding of their paternal role within the family. Examining the independent and interacting effects of fathers' and mothers' weight-related parenting practices on children's diet and physical activity addresses this important research gap.

Objective: This study used ecological momentary assessment (EMA) to investigate the within-subject and between-subject independent and interactive effects of maternal and paternal encouragement to eat and preparation of fruits and vegetables (F/V) and encouragement of and taking their child to be physically active on their child's self-reported F/V intake and physical activity engagement.

Methods: Participants included mother-father-child triads (n=22 triads, n=205-213 prompts/occasions) in the Mothers and Their Children's Health Study and the University of Southern California Fathers Study. Simultaneously, mothers and fathers (ages_{mean} 44.2 years, SD 5.6, and 45.2 years, SD 8.1, respectively), and their children (age_{mean} 12.0 years, SD 0.7) completed up to 8 randomly prompted EMA surveys per day on separate smartphones for 7 days. At each prompt, mothers and fathers each reported whether they did the following in the past 2 hours: (1) encouraged their child to eat F/V, (2) prepared F/V for their child, (3) encouraged their child to be physically active, or (4) took their child to be physically active. Children self-reported whether they consumed F/V or were physically active in the past 2 hours.

Results: Results from Bayesian multilevel logistic models (all in log-odd units) indicated that at the within-subject level, greater maternal encouragement ($\beta=2.28$, 95% CI 0.08 to 5.68) of eating F/V was associated with greater child report of eating F/V, but paternal encouragement ($\beta=1.50$, 95% CI -0.83 to 4.52) showed no effects above and beyond maternal encouragement. Additionally, greater than usual paternal encouragement ($\beta=2.28$, 95% CI 0.08 to 5.54) and maternal encouragement ($\beta=2.94$, 95% CI 0.36 to 6.69) of physical activity had significant independent effects and were associated with greater child report of physical activity. No other within-subject or between-subject associations nor interactive effects were significant.

Conclusions: Findings from this study suggest that fathers play a role in supporting their children's physical activity but not their intake of F/V. Future EMA studies should recruit larger samples to evaluate the independent and interacting roles of mothers' and fathers' weight-related parenting practices on child's obesogenic behaviors.

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KEYWORDS

parenting; ecological momentary assessment; fruit and vegetable consumption; physical activity; pediatrics; obesity

Introduction

Child obesity prevalence has increased over the past five decades, with 41% of US children classified as overweight, obese, or severely obese [1]. Adverse health outcomes among obese children include hypertension and hypercholesterolemia [2], which track from childhood into adulthood, placing these children at greater risk of early mortality. Parents play a critical role in shaping their children's weight-related behaviors [3]. Thus, childhood obesity prevention interventions have focused on parental behavior change. However, these interventions have demonstrated limited success with preventing increases in children's BMI [4]. One reason may be that the vast majority of these interventions address the practices and behaviors of mothers [5] while excluding the influential role of fathers within the family.

Research informed by family systems theory indicates that behaviors among family members are part of an interrelated system that cannot be examined in isolation [6]. Studies have explored the key role mothers play in providing support for children's healthy eating and physical activity. Cross-sectional between-subjects research examining the relationships between the home environment and children's fruit and vegetable (F/V) consumption showed that parental encouragement of F/V consumption was positively associated with children's F/V consumption [7-10]. Between-subjects results from an ecological momentary study showed that children whose mothers prepared more F/V compared to other mothers had greater odds of eating F/V. Within-subjects results from this study indicated that when mothers expressed greater encouragement and preparation of F/V than usual, their children had greater odds of eating fruits and vegetables at the next prompt [11]. Using the same participants from the aforementioned study, children whose mothers reported taking their children someplace to be physically active engaged in more moderate-to-vigorous physical activity (MVPA). When mothers reported taking their children someplace to be physically active more than usual, their children engaged in more MVPA [12]. These results highlight the influential role mothers have in energy balance behaviors of their children.

Due to limited research conducted among fathers, missing from these analyses are the effects of paternal parenting practices on children's energy balance behaviors [5,13]. This gap is concerning because fathers are parenting and caring more for their children, with a reported increase from 2.5 to 7.3 hours per week over the last 45 years [14], perhaps due to the increased percentage of working mothers, up from 47% in 1975 to 70% in 2014. Furthermore, 2 million US fathers are stay-at-home dads, up from 1.1 million in 1989 [15]. Although the number

of stay-at-home dads in the United States increased 100% in the past 21 years, extant research regarding the role of fathers in children's obesity risk is limited, due in part to the difficulty in recruiting fathers for child health studies [16].

These concerns are further exemplified by a recent review examining fathers' role in children's physical activity that indicated only 1.5% of observational between-subject studies conducted between 2009 to 2015 met study criteria that included the following: included fathers as study participants, presented fathers' data separately from mothers' data, and collected data on fathers' physical activity parenting behaviors and/or fathers' physical activity and children's physical activity. The authors concluded that among the associations examined, more than half were positive, albeit modest, associations between fathers and their children's physical activity [17]. For example, one article reviewed indicated that explicit modeling of physical activity by fathers was positively associated with their sons' accelerometer-measured MVPA and vigorous physical activity [18]. A systematic review of 23 between-subject studies examining fathers' feeding behaviors concluded that paternal modeling of healthy eating, own energy intake, and limit setting of unhealthy eating had a positive effect on children's diet and reinforcement for healthy choices provided by the mother and father were positively associated with children's healthy dietary choices [19]. This emerging evidence warrants further examination to determine how fathers' own diet and physical activity along with their dietary and physical activity parenting practices influence children's diet and physical activity.

Parenting practices may vary within days and across days due to interpersonal interactions, situational encounters, and changing demands and expectations and may negatively affect children's obesogenic behaviors [20,21]. Research is beginning to explore how daily variability in parenting practices contributes to children's obesity risk [22,23]. Participation of fathers in child obesity prevention studies poses challenges including the lack of targeted recruitment specific to fathers, time commitments that overlap with employment schedules, and failure to focus on long-term benefits of fathers' participation [24]. To the best of our knowledge, no studies have examined the effects of within-day variability in fathers' parenting practices on children's energy balance behaviors (ie, diet, physical activity), resulting in a significant gap in childhood obesity research. Failure to assess how fathers' weight-related parenting practices contribute to children's energy balance behaviors limits the understanding of their parental role within the family.

In addition to the lack of research on fathers' influence on their children's energy balance behaviors, prior studies are also limited because they only assess between-subject effects, which

limits our understanding of when parents may have greater influence on children's energy balance behaviors and precludes the tailoring of intervention strategies. Ecological momentary assessment (EMA) is a methodology that uses an intense longitudinal design to collect self-reported data multiple times per day over multiple days. A prompting schedule for participants to respond to mobile phone-based surveys over the course of the day was developed specifically for the individual study. Using EMA allows for real-time data capture of parenting behaviors that increases ecological validity and addresses the lack of examination of within-subject variability. It can capture within-day fluctuations for constructs that change frequently throughout the day (eg, stress). EMA allows for disentangling of within-subjects and between-subjects effects that may ultimately assist in designing effective parenting interventions that can adjust for intra-individual differences. Additionally, EMA helps reduce recall bias found in retrospective studies as reliance on memory to inform on performed behaviors is reduced through the frequent prompting schedule. This exploratory study used EMA to investigate the within-subject and between-subject independent and interactive effects of maternal and paternal encouragement and preparation of F/V and encouragement of and taking their child to be physically active on their child's self-reported F/V intake and physical activity engagement. Based upon cross-sectional studies that examined the role of mothers and fathers on children's physical activity, we hypothesize that there will be a significant positive relationship between fathers' parenting behaviors and their children's F/V intake and physical activity independent of mothers' parenting behaviors. Further, we hypothesize that there will be a significant relationship between mothers' parenting behaviors and their children's F/V intake and physical activity. We hypothesized that there would be a significant interactive effect of maternal and paternal behaviors on children's F/V intake and physical activity.

Methods

Study Design and Participant Characteristics

Participants included a subsample of mother-child dyads and fathers (n=22 mother-father-child triads) enrolled in the Mothers and Their Children's Health Study (MATCH; mother-child dyads) who were also enrolled in the University of Southern California (USC) Fathers Substudy. Participants enrolled in the MATCH study and Fathers Substudy lived in the greater Los Angeles area. Inclusion criteria for the MATCH study comprised mother having at least 50% custody, children aged 8 to 12 years, and the mother and child having the ability to read and write in English or Spanish. Exclusion criteria for the MATCH study included mother currently pregnant, mother works more than 2 weekday evenings or works on weekend days, mother or child taking medications for a psychological condition or oral or inhaled corticosteroids, mother or child experiencing health issues that prevent or limit physical activity, and child enrolled in a special education program. Inclusion criteria for the Fathers Substudy comprised father/father figure with a child currently participating in the MATCH study, having at least 50% custody, and the ability to read and write in English or Spanish. The objective of the larger MATCH study was to examine the

long-term effects of mothers' stress on their children's energy balance behaviors (ie, diet, physical activity, sedentary time). The goal of the USC Fathers Substudy was to examine the role of fathers' weight-related parenting behaviors on their children's energy balance behaviors. MATCH received approval through the USC institutional review board and Northeastern University; the USC Fathers Substudy received approval through the USC institutional review board.

Mothers and their children participated in MATCH over a 3-year period, with 7-day data collection waves occurring every 6 months [25]. During the final 7-day data collection wave of the MATCH study in spring 2018, fathers were contacted via email and phone to determine interest in participating in the USC Fathers Substudy. If fathers expressed interest in participation, they were asked to accompany their spouse/child's mother and child to their upcoming scheduled MATCH data collection appointment at which fathers reviewed and completed informed consent with research staff. Fathers without Android phones were provided moto g (Motorola Mobility LLC) smartphones for collecting EMA data. If participants owned an Android phone, they were instructed to download the appropriate app. Effects of siblings and peers of the enrolled child in the MATCH study were not included in this study.

Mothers, fathers, and their children completed up to 8 randomly prompted EMA surveys per day on their respective smartphones for 7 days. Weekday prompts began between 3 PM to 4 PM, ending between 7 PM to 8 PM for the child (total of 3 prompts) and 9 PM to 10 PM for the mother and father (total of 4 prompts). No prompting occurred during school hours. Weekend prompts started between 7 AM to 8 AM, ending at comparable times for weekday prompts. At each prompt, mothers and fathers independently reported whether they spent time with their child in the past 2 hours by answering the question, "Over the last 2 hours, have you spent time with your child (together in the same location)?" If a yes response was indicated, mothers and fathers subsequently independently reported if they did the following in the past 2 hours: (1) encouraged their child to eat F/V, (2) cooked or prepared F/V for their child, (3) encouraged their child to be physically active, and (4) took their child to be physically active. Response options for each of the 4 questions were yes or no. At each prompt, children reported if they did the following in the past 2 hours: (1) consumed F/V and (2) participated in exercise, sports, or physical activity. Response options for each of the 2 questions were yes or no. In addition to the EMA surveys, fathers completed paper surveys that included sociodemographic information (eg, age, marital status). Mothers previously completed paper surveys that included sociodemographic information (eg, age, marital status, child sex, and ethnicity).

Ethics Approval

MATCH received approval through the USC institutional review board and Northeastern University (HS-12-00446); the USC Fathers Substudy received approval through the USC institutional review board (HS-17-00797). No other approvals were necessary for study completion.

Statistical Analyses

Participant sociodemographics were analyzed using SPSS (version 27, IBM Corp). Means and standard deviations were calculated for mothers, fathers, and children's ages. Percentages were determined for parents' marital status and child sex and ethnicity.

For each child outcome (ie, whether children consumed F/V or were physically active; 1=yes, 0=no), we separately examined whether parental encouragement for eating F/V and physical activity and parental support (ie, cooking or preparing F/V and taking the child to be physically active) had predictive power. The data had a nesting structure with repeated EMA observations (level 1) nested within families (level 2). Given the small number of clusters (ie, families in our data) and the focus on binary outcome variables in our study, we used Bayesian estimation with weakly informative prior distributions to improve the stability of the results [26]. For each child outcome, we fitted 2 two-level Bayesian multilevel logistic models with repeated EMA observations nested within families and the following structure:



where t indicates time and i indicates family, and X^{mo} and X^{fa} are binary predictors for mother and father encouragement or support, respectively. The β s are the fixed effects and the u s are the random effects. To account for the potential time dependence, we also specified an autoregressive error [1] structure for observations within the same day.

For each outcome, we entered the predictors in 3 steps. In step 1, we included the intercept and the main effects of person-mean centered maternal (X^{mo}) and paternal (X^{fa}) encouragement/support at the occasion level as well as mean levels of maternal and paternal encouragement/support for each family. The use of family-mean centering allows us to decouple the between-family and within-family associations [27]. In step 2, we tested the interaction between the father and the mother variables.

For each model, we analyzed only observations where the child answered the EMA prompt and both parents also answered the prompts within the same 2-hour period. Observations were excluded if only one of the parents answered the prompt.

We used the R package (R Foundation for Statistical Computing) brms [28] to perform Markov chain Monte Carlo sampling. For each model, we used 4 chains, each with 2000 iterations. The first half of the samples were used as warmups, resulting in 4000 total Markov chain Monte Carlo samples. All models achieved convergence, as indicated by the potential scale reduction factor being less than 1.01 [29]. Posterior means were used as point estimates, and coefficients were considered significant statistically when the 95% credible interval excluded zero.

Results

The total number of prompts sent was 765 for fathers, 692 for mothers, and 561 for children. The response rates were 80.0%

(612/765) for fathers, 85.0% (588/692) for mothers, and 85.9% (482/561) for the child. The number of prompts where all 3 members in a family answered in the same 2-hour interval was 322, but there were missing data for specific items as reflected below in the model-specific sample sizes.

Mothers and fathers were comparable in age (ages_{mean} 44.2, SD 5.6, and 45.2, SD 8.1, respectively). Children had a mean age of 12.0 (SD 0.7) years. A total of 73% (16/22) of parents indicated being married or living as married. Of the 22 children, 55% (12/22) were female and 41% (9/22) identified as Hispanic/Latino. Child BMI z-scores had a mean value of 0.17 and ranged from -2.5 to 2.0. Table 1 shows the correlations among the parental variables and the child outcomes. We found strong correlations between encouragement and support from the same parent for the same child outcome ($r=.55$ to $r=.83$). In addition, a parent's encouragement/support for physical activity was moderately correlated with the same parent's encouragement/support for eating F/V ($r=.09$ to $r=.53$). There were also moderate correlations between father's and mother's encouragement/support ($r=.13$ to $r=.38$). Child reports of being physically active and eating F/V were moderately associated with parental encouragement and support ($r=.09$ to $r=.26$).

As shown in Table 2, results from Bayesian multilevel logistic models indicated that, at the occasion level, greater than usual maternal encouragement ($\beta=2.28$, 95% CI 0.08 to 5.68, in log-odds units) for eating F/V was significantly associated with greater likelihood of child report of eating F/V, but evidence was not significant for paternal encouragement ($\beta=1.50$, 95% CI -0.83 to 4.52) above and beyond maternal encouragement. Figures 1 and 2 show the model-predicted overall and family-specific probabilities with only mother's or father's encouragement reported in the brms package, computed using the model coefficients (ie, probability = $1 / [1 + \exp(-\eta)]$ where η is the model predicted log-odds). Based on the model, when there was no father encouragement, the predicted probability of eating F/V was 0.39 with mother encouragement, compared to 0.22 without mother encouragement. However, the coefficient for paternal encouragement was not significant, and thus, only predicted probability of eating F/V with mother encouragement is reported. No statistical evidence was found for the between-family level associations, and the interactions between maternal and paternal encouragement for F/V intake were not significant.

When fathers ($\beta=2.28$, 95% CI 0.08 to 5.54) and mothers ($\beta=2.94$, 95% CI 0.36 to 6.69) each have higher levels of encouragement of physical activity than their usual level, children were more likely to report physical activity in the past 2 hours. In other words, holding mothers' encouragement as constant, fathers' encouragement was positively associated with children's physical activity (individual responses shown in Figures 3 and 4). There were also significant differences in the coefficients of maternal and paternal encouragement across families, as indicated by the significant random effect standard deviation (for father, estimate=1.14, 95% CI 0.04 to 3.61; for mother, estimate=2.40, 95% CI 0.15 to 6.62). Specifically, the predicted probability of the child performing physical activity was 0.21 with neither mother nor father encouragement, 0.42

with only mother encouragement, 0.37 with only father encouragement, and 0.59 with both father and mother encouragement. No statistical evidence was found for differential associations at the between-subject and the within-subject levels, and the interaction between maternal and paternal encouragement for physical activity was not significant. The nonsignificant between-level coefficients indicate insufficient evidence for different between-level and within-level coefficients. The random effects were similar in Stage 1 models and were only reported in those final models (Table 2).

F/V: fruits and vegetables.

Table 3 shows the model results when using parental support (preparing F/V for the child and taking the child to be physically active) as predictors of children’s reported health behaviors. Although some of the coefficients were in the positive direction, none of them were significant. The nonsignificant between-level coefficients indicate insufficient evidence for different between-level and within-level coefficients. Parental support refers to mother/father preparing fruits and vegetables or taking the child somewhere to be physically active. The random effects were similar in stage 1 models and were only reported in those final models (Table 3).

Table 1. Pearson correlations among parental encouragement and support and child outcome variables.

	1	2	3	4	5	6	7	8	9
Father encouraging child to play	— ^a	—	—	—	—	—	—	—	—
Father taking the child to play	.67	—	—	—	—	—	—	—	—
Father encouraging child to eat F/V ^b	.20	.15	—	—	—	—	—	—	—
Father preparing F/V	.18	.09	.55	—	—	—	—	—	—
Mother encouraging child to play	.28	.36	-.02	-.14	—	—	—	—	—
Mother taking the child to play	.25	.38	-.03	-.13	.83	—	—	—	—
Mother encouraging child to eat F/V	.14	.14	.22	.13	.53	.44	—	—	—
Mother preparing F/V	-.01	.09	.22	.13	.25	.29	.75	—	—
Child physically active	.12	.19	-.02	-.04	.26	.24	.03	-.03	—
Child F/V consumption	.07	.13	.17	.09	.11	.13	.26	.18	.25

^aNot applicable.

^bF/V: fruits and vegetables.

Table 2. Multilevel model results (in log-odds) of parental encouragement for fruit and vegetable consumption and encouragement to be physically active predicting child outcomes of fruit and vegetable consumption and physical activity (n=205).

	Child F/V ^a consumption	Child physical activity
Fixed effects		
Step 1		
Intercept	-2.88 (-6.63 to -0.01)	-2.31 (-5.62 to -0.05)
Father encouragement (within)	1.50 (-0.83 to 4.52)	2.28 (0.08 to 5.54)
Mother encouragement (within)	2.28 (0.08 to 5.68)	2.94 (0.36 to 6.69)
Father encouragement (between)	0.81 (-4.61 to 7.03)	-0.49 (-5.92 to 4.64)
Mother encouragement (between)	0.94 (-4.01 to 6.56)	-0.49 (-5.92 to 4.64)
Step 2		
Father encouragement × mother encouragement (within)	1.65 (-2.03 to 6.29)	2.56 (-1.66 to 8.35)
Father encouragement × mother encouragement (between)	0.30 (-6.63 to 7.71)	-0.80 (-9.80 to 5.94)
Random effect standard deviations		
Step 1		
Intercept	2.98 (0.96 to 6.56)	1.81 (0.15 to 4.46)
Father encouragement	2.52 (0.14 to 6.78)	1.14 (0.04 to 3.61)
Mother encouragement	1.16 (0.04 to 3.75)	2.40 (0.15 to 6.62)

^aF/V: fruits and vegetables.

Table 3. Multilevel model results (in log-odds) of parental support (preparing fruit and vegetables, taking the child to be physically active) predicting child outcomes of fruit and vegetables consumption and physical activity.

	Child F/V ^a consumption (n=213)	Child physical activity (n=206)
Fixed effects		
Step 1		
Intercept	-3.58 (-7.84 to -0.69)	-2.57 (-5.81 to -0.26)
Father support (within)	1.57 (-0.86 to 4.66)	0.41 (-2.17 to 3.23)
Mother support (within)	0.85 (-1.14 to 3.38)	3.02 (-0.17 to 7.63)
Father support (between)	0.02 (-5.73 to 5.74)	1.17 (-4.28 to 7.82)
Mother support (between)	3.13 (-3.00 to 13.02)	-0.09 (-4.98 to 4.97)
Step 2		
Father support × mother support (within)	3.29 (-0.77 to 9.53)	-1.28 (-6.19 to 3.10)
Father support × mother support (between)	0.44 (-7.33 to 9.08)	-0.04 (-7.81 to 7.66)
Random effect standard deviations		
Step 1		
Intercept	3.49 (1.24 to 7.66)	2.56 (0.47 to 5.88)
Father support	1.46 (0.05 to 4.73)	1.55 (0.05 to 4.97)
Mother support	1.07 (0.04 to 3.48)	2.71 (0.13 to 7.97)

^aF/V: fruits and vegetables.

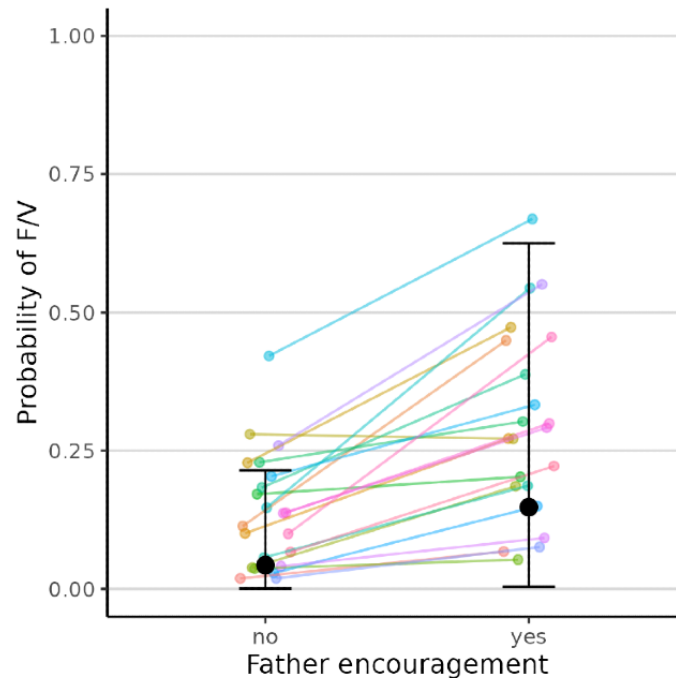
Figure 1. Model-predicted probabilities of a child eating fruits and vegetables as a function of father encouragement when there was no mother encouragement. The black dots and error bars show the overall predicted probabilities and the 95% confidence intervals, whereas the lines show the family-specific predicted probabilities in our sample. F/V: fruits and vegetables.

Figure 2. Model-predicted probabilities of a child eating fruits and vegetables as a function of mother encouragement when there was no father encouragement. The black dots and error bars show the overall predicted probabilities and the 95% confidence intervals, whereas the lines show the family-specific predicted probabilities in our sample. F/V: fruits and vegetable.

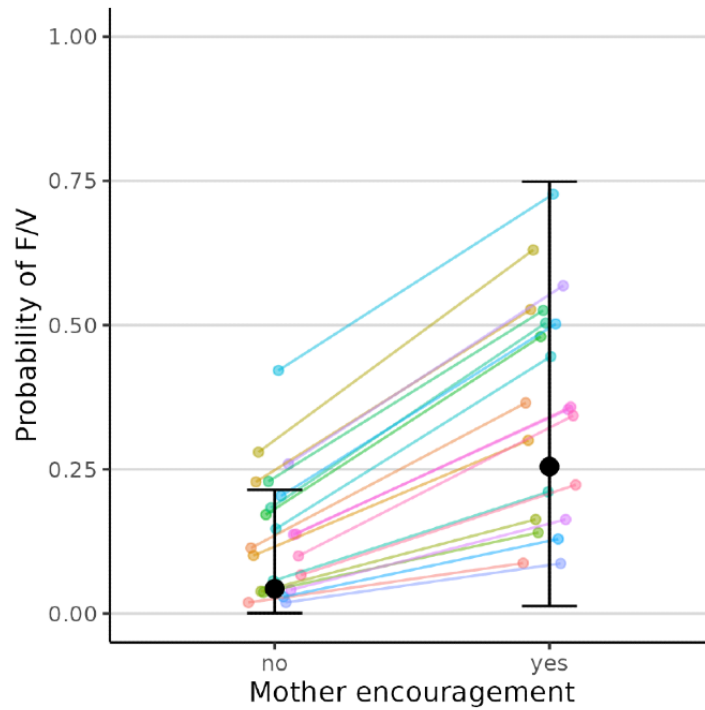


Figure 3. Model-predicted probabilities of a child engaging in physical activity as a function of father encouragement when there was no mother encouragement. The black dots and error bars show the overall predicted probabilities and the 95% confidence intervals, whereas the lines show the family-specific predicted probabilities in our sample.

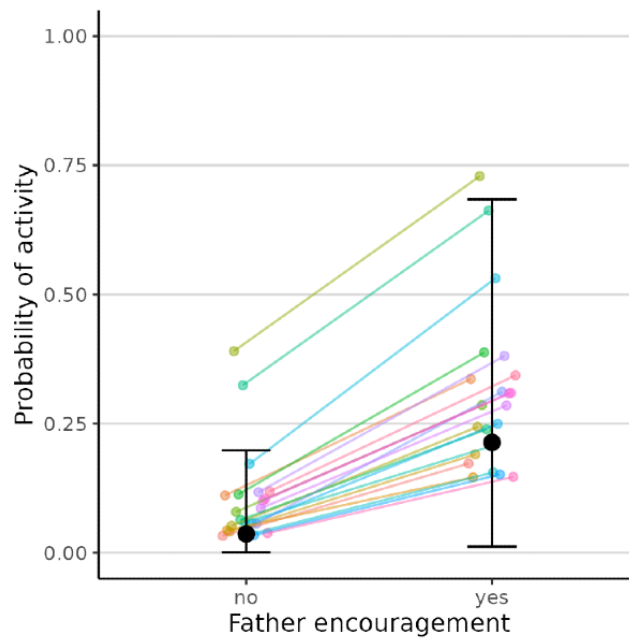
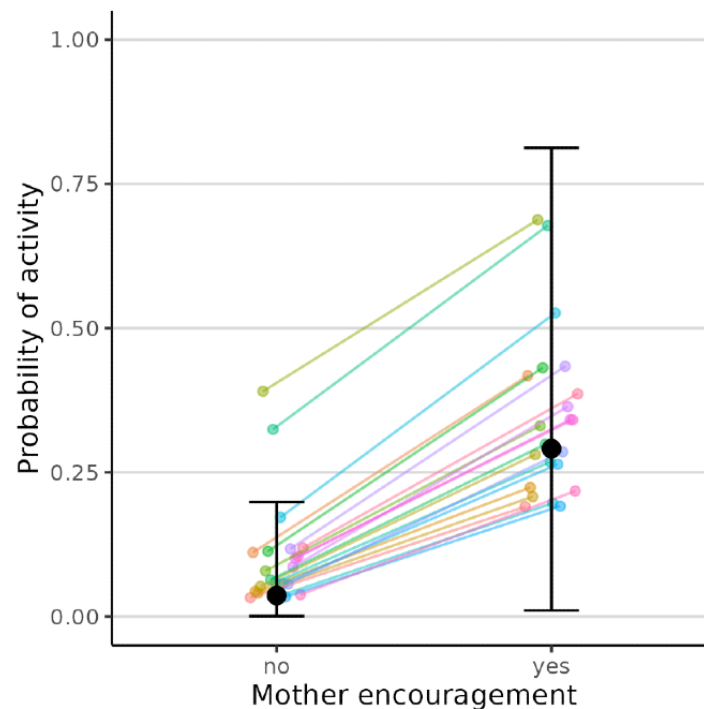


Figure 4. Model-predicted probabilities of a child engaging in physical activity as a function of mother encouragement when there was no father encouragement. The black dots and error bars show the overall predicted probabilities and the 95% confidence intervals, whereas the lines show the family-specific predicted probabilities in our sample.



Discussion

Principal Findings

This exploratory study investigated the within-subject and between-subject independent and interactive effects of maternal and paternal encouragement and preparation of F/V and maternal and paternal encouragement of and taking their child to be physically active on their child's self-reported F/V intake and physical activity engagement. There were no significant between-subject associations for (1) maternal or paternal encouragement of or preparation of F/V on children's consumption or (2) maternal or paternal encouragement of or taking the child to be physically active on children's physical activity. However, given the small number of participants, this study provides insufficient power for between-subject associations. Within-subjects results indicated that greater than usual maternal encouragement was associated with children's greater likelihood of EMA-reported F/V consumption in the past 2 hours; however, paternal encouragement was not associated with children's likelihood of reporting F/V consumption. Additionally, greater than usual maternal encouragement and greater than usual paternal encouragement were independently associated with greater likelihood of children's EMA-reported physical activity in the past 2 hours. No within-subjects results for parental support (ie, taking the child someplace to be physically active, preparing F/V for the child) were significant.

Our previous EMA study using the same MATCH participants without fathers' data showed the positive relationship of maternal encouragement with children's subsequent F/V intake [11], but cross-sectional between-subjects research conducted among Norwegian families (85% mothers, children ages 10 to

11 years) indicated no relationship between parent-reported encouragement of F/V consumption and child-reported F/V intake [30]. In a similar between-subjects study conducted among Icelandic families (85% mothers, children aged 11 years), there was either no relationship between child-reported parental encouragement for F/V consumption and child-reported F/V intake [31] or a negative relationship between maternal-reported encouragement and children's self-reported F/V intake [31]. In our study, mothers and fathers independently reported their encouragement of F/V consumption and children self-reported F/V intake, aligning with the parent-reported cross-sectional results and EMA results. Given the mixed findings in the literature, future research should engage more families and explore within- and between-effects from individual influences provided by mothers and fathers.

Another cross-sectional study that examined differences in children's F/V consumption by race/ethnicity indicated greater child-reported social support for F/V intake among non-Hispanic White children compared to African American and Hispanic children [32]. The authors created a composite parental social support score that included several measures: providing children with prepared F/V, eating F/V, encouraging the child to eat F/V, and wanting the child to eat F/V. Stratified analyses showed that the greater the support provided, the higher reported vegetable consumption among Hispanic children [32]. In this study, we were not able to stratify our analyses by ethnicity due to the small sample size. However, nearly half of the children in our sample identified as Hispanic/Latino, illustrating that maternal encouragement of F/V consumption may be well received by both non-Hispanic White children and Hispanic/Latino children.

This study did not find statistically significant effects of mothers' preparation or fathers' preparation of F/V on children's F/V intake. Previous longitudinal EMA research reported that greater than usual maternal preparation of F/V and greater maternal preparation of F/V when compared to other mothers resulted in increased odds of child-report of F/V consumption [11]. Results from other cross-sectional research indicated a positive association between adolescent-reported F/V consumption and fathers' parenting practices that included preparation of F/V [33]. The lack of a relationship between F/V preparation and child F/V consumption may be due to the proximity of children's ages to adolescence (age_{mean} 12.0 years, SD 0.7) in this study. As children age, they gain more independence for preparing their own snacks and thus, their parents may not spend as much time preparing F/V for them [34]. Additionally, the provision of F/V as snacks may not require extensive preparation, and thus parents may not view this as a considerable amount of time.

In this study, paternal encouragement of physical activity was associated with greater child-reported physical activity. Thus, fathers may play a larger role in supporting children's physical activity than their intake of F/V. One study examined sports participation among low socioeconomic status youth and reported that strong paternal influence may be salient to encouraging children's participation [35]. Previous qualitative research conducted among mothers indicates that they perceive fathers to play an active role in their children's physical activity including encouraging the child to perform physical activity [36]. Additionally, in our study, maternal encouragement of physical activity was also associated with children's physical activity. Our findings are also supported by previous longitudinal EMA research using the same MATCH participants (without fathers' data) that indicates children's MVPA levels were higher when mothers reported encouraging their child to be physically active within the same 2-hour window [12]. Our results also align with previous research indicating that maternal support for physical activity was positively associated with children's device-measured activity levels [37]. In this study, parental encouragement plays a larger role for physical activity promotion rather than F/V intake. This may reflect differences in these behaviors such as the potential planning required to facilitate children's physical activity, whereas home availability of F/V may not necessitate promotion. Thus, children may make more independent choices related to diet but still rely on parents for physical activity (eg, driving child somewhere to be physically active).

In contrast to parental encouragement, there were no statistically significant effects of the parent providing support by taking a child somewhere to be physically active on child-reported PA. Our previous EMA research using the same MATCH participants (without fathers' data) indicates that children were more physically active when mothers reported taking their child somewhere to be physically active [12]. Cross-sectional research that examined the relationship between activity-related parental logistic support included a measure of taking the child somewhere to be physically active. Findings showed mothers had higher mean levels of support for girls' physical activity compared to fathers, but there was no relationship among

paternal and maternal logistical support and objectively measured child physical activity [18]. These contrasting findings may be due to the lack of separation of support into individual components in previous studies along with variability in reporting children's physical activity [38,39]. For example, a study examining the cross-sectional associations between parenting practices and children's pedometer-assessed physical activity combined measures for instrumental support (eg, taking the child somewhere to be physically active) and emotional support (eg, encouraging the child to be physically active). Results indicated that child-reported parent support was positively significantly associated with both boys' and girls' physical activity [38]. Another study found children's perception of parental support was positively associated with both boys' and girls' questionnaire-assessed physical activity [39]. Future research should consider incorporating both child report of mothers' and fathers' support for physical activity and child perceptions of parental support to inform on children's interpretations of parenting behaviors that may affect their own physical activity and identify areas on which to intervene (eg, just-in-time parenting interventions) at the family level.

Strengths and Limitations

There has been limited research on the role of fathers' parenting practices (ie, encouragement and support) on children's energy balance behaviors. Thus, a major strength of this study includes the triadic design within everyday family contexts that allowed assessment of the independent and interactive influences of maternal and paternal parenting weight-related practices on children's diet and physical activity. Additionally, the use of EMA methods to assess parenting and children's behaviors in real time is an additional strength. However, this study is not without limitations. Due to the small sample size, we are unable to generalize our study findings to a broader population. Additionally, we are unable to stratify our results to assess potential moderators such as child sex or ethnicity. The 2-hour time window used for analysis may not have perfectly overlapped among mother-, father-, and child-reported behaviors. We also cannot establish temporality within the 2-hour period. For example, it is unknown whether the mother and/or father encouraged the child to be physically active or eat F/V before or after the child reported engaging in physical activity or eating F/V. We also did not control for environmental contexts including weather conditions, physical location, and level/type of physical activity, which have been shown to influence activity levels [40]. Mothers and fathers were not provided with a specific definition for the term *encourage* as it pertained to children's physical activity and healthy eating. Thus, answering questions related to encouragement of consumption of F/V and physical activity may have been interpreted in various ways. However, they were given the opportunity to ask clarifying questions during orientation to the study and provided with a contact number to ask any questions that arose. We are unaware whether the mother or father ate or exercised in the presence of their child. It is possible that the child reported eating or being physically active because these behaviors were not only encouraged but also modeled by the parent to their child. Last, parenting practices and support, along with children's outcomes of F/V consumption and physical

activity, were self-reported rather than objectively measured and therefore open to recall bias and social desirability bias [41].

Conclusion

Our results indicate children who are encouraged to eat F/V report greater F/V consumption and children who are encouraged to be physically active report greater physical activity. Furthermore, fathers' encouragement of physical

activity has an independent effect to mothers' encouragement of physical activity on children's EMA-reported physical activity. These findings have implications for future just-in-time parenting interventions to promote children's F/V consumption and physical activity. For example, prompting of parental encouragement from both mothers and fathers during times when children can eat F/V and engage in physical activity may result in greater consumption of F/V and higher levels of physical activity.

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Authors' Contributions

NVL conceptualized the USC Fathers Substudy, and GFD conceptualized the MATCH study. NVL, CHY, and MHCL conceptualized the current analysis. MHCL analyzed the data. NVL and MHCL wrote the first draft of the manuscript. NVL, MHCL, CHY, GFD, and BRB reviewed and revised the manuscript. All authors approved of the final version of the manuscript.

Conflicts of Interest

None declared.

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Abbreviations

- EMA:** ecological momentary assessment
F/V: fruit and vegetable
MATCH: Mothers and Their Children's Health Study
MVPA: moderate-to-vigorous physical activity
USC: University of Southern California

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Original Paper

A Smoking Cessation Mobile App for Persons Living With HIV: Preliminary Efficacy and Feasibility Study

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Abstract

Background: The prevalence of smoking in the United States general population has gradually declined to the lowest rate ever recorded; however, this has not been true for persons with HIV.

Objective: We conducted a pilot test to assess the feasibility and efficacy of the Lumme Quit Smoking mobile app and smartwatch combination with sensing capabilities to improve smoking cessation in persons with HIV.

Methods: A total of 40 participants were enrolled in the study and randomly assigned 1:1 to the control arm, which received an 8-week supply of nicotine replacement therapy, a 30-minute smoking cessation counseling session, and weekly check-in calls with study staff, or to the intervention arm, which additionally received the Lumme Quit Smoking app and smartwatch.

Results: Of the 40 participants enrolled, 37 completed the follow-up study assessments and 16 used the app every day during the 56-day period. During the 6-month recruitment and enrollment period, 122 people were screened for eligibility, with 67.2% (82/122) deemed ineligible. Smoking criteria and incompatible tech were the major reasons for ineligibility. There was no difference in the proportion of 7-day point prevalence abstinence by study arm and no significant decrease in exhaled carbon monoxide for the intervention and control arms separately. However, the average exhaled carbon monoxide decreased over time when analyzing both arms together ($P=.02$).

Conclusions: Results suggest excellent feasibility and acceptability of using a smoking sensor app among this smoking population. The knowledge gained from this research will enable the scientific community, clinicians, and community stakeholders to improve tobacco cessation outcomes for persons with HIV.

Trial Registration: ClinicalTrials.gov NCT04808609; <https://clinicaltrials.gov/ct2/show/NCT04808609>

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KEYWORDS

HIV; mHealth; smoking cessation; intervention; smoking; persons with HIV; pilot; pilot test; mobile app; smartwatch

Introduction

The prevalence of smoking in the general US population has gradually declined to 12.5% in 2020, the lowest rate ever recorded [1]. However, this has not been true for persons with HIV, who have disproportionately high smoking rates (34% to 47%) [2-4]. Across several studies of persons with HIV in New York City, Schnall et al [5] found that 47.1% of study participants were cigarette smokers, providing further evidence of the high prevalence of tobacco use in this population [6,7]. High rates of smoking have grave health implications for persons with HIV, placing them at increased risk for bacterial pneumonias [8], acute bronchitis and tuberculosis [9-16], early development of emphysema [17-22], and lung and cervical cancers at a younger age than the general population [23-28]. These disparities are partly due to a higher prevalence of tobacco use in persons with HIV than the general population and partly attributable to exacerbated comorbidities such as cardiovascular disease, lung cancer, and diabetes in persons with HIV who smoke compared to smokers without HIV [29-31]. For persons with HIV, apart from achieving and maintaining a suppressed viral load, tobacco cessation is the most important health behavior they can undertake to maximize both quality of life and life expectancy [32]. Indeed, persons with HIV who quit smoking upon entering HIV care gain more than 5 years of life expectancy as compared to those who enter HIV care and continue smoking [33,34]. Consequently, persons with HIV experience substantial tobacco-related morbidity and mortality.

Given the high prevalence of cigarette smoking among persons with HIV and the benefit of smoking cessation, there is an urgent need to intervene to reduce tobacco use rates. However, the currently available evidence for improving tobacco cessation among persons with HIV is inadequate. Few tobacco cessation interventions have been tested among persons with HIV, and of those that have, there is very low quality evidence that they were effective in the short term and moderate quality evidence indicating similar outcomes to controls in the long term [35-39].

In recent years, the use of mobile health (mHealth) technologies for tobacco cessation, such as Text2Quit [40] and SmokeFree Text from the National Cancer Institute [41], has gained popularity. While these programs have demonstrated positive effects in some populations [42-45], their functionality is limited because text messaging is unable to automatically capture instances when assistance is required to resist cravings or when smoking relapse occurs. To address this need, our study sought to use more advanced technology, comprising a mobile app and smartwatch, that functioned as a sensor to integrate behavioral assessment and a just-in-time cessation intervention for smokers. The app and watch sensor provided smoking relapse prevention to supplement the cessation intervention of traditional nicotine replacement therapy (NRT). Watch sensor data, in conjunction with the app, functioned to prevent smoking relapse immediately following the initiation of NRT (quit date). The purpose of this pilot study was to determine the feasibility and acceptability of the Lumme Quit Smoking app for improving tobacco cessation outcomes in persons with HIV who smoke.

Methods

Study Design

The study was conducted with 40 persons with HIV who smoke who were randomized to 2 study arms. Participants were randomly assigned to receive the Lumme Quit Smoking app (active) or a control condition (standard smoking cessation counseling session). Participants had in-person study visits at baseline and 12 weeks following their baseline visit. The primary objectives of the study were to assess the feasibility and acceptability of the Lumme Quit Smoking app; the study was not powered to assess efficacy. A secondary goal was to establish the effect size needed to conduct a fully powered intervention trial.

Recruitment

Study participants were recruited by posting flyers at a local HIV clinic and from an existing database of persons living with HIV who had participated in earlier studies and agreed to be recontacted for future studies. Study enrollment took place from September 28, 2020, to April 19, 2021.

Inclusion criteria were (1) persons with HIV, (2) aged 18 years and older, (3) own an Android smartphone, (4) understand and read English, (5) not pregnant or breastfeeding, (6) have permanent contact information, (7) smoke 5 or more cigarettes per day for the past 30 days [46], (8) interested in quitting smoking within 30 days, and (9) have an exhaled carbon monoxide (eCO) level of more than 5 parts per million (ppm) at baseline.

Exclusion criteria were (1) self-report having HIV-negative or unknown status; (2) pregnant, breastfeeding, or planning to become pregnant during the study period; (3) planning to move within 3 months of enrollment; (4) positive history of a medical condition that precludes use of the nicotine patch; (5) current use of NRT or other smoking cessation medications (eg, Chantix or Zyban); (6) current enrollment in another smoking cessation program; or (7) eCO of 5 ppm or less at baseline.

Biochemical verification of abstinence appears to be increasingly important, especially in clinical trials, and increases scientific rigor, as both social norms relating to smoking behavior and an increasing number of personal factors (eg, age, pregnancy, hospitalization status, and socioeconomic status) are related to misreporting of smoking behavior. eCO is a useful assessment tool for measuring recent smoking abstinence [47].

Ethics Approval

The Columbia University institutional review board approved this study before commencement of study activities, and the study was registered with ClinicalTrials.gov [NCT04808609].

Procedures

Potential study participants provided verbal informed consent to complete a phone screening to assess eligibility. Eligible participants were then invited to attend an in-person baseline visit at the Columbia University School of Nursing. Upon arrival to the study site, scheduled participants were asked to provide a breath sample to determine eCO level and confirm study

eligibility. Breath samples were analyzed for eCO levels (in ppm) using a breathalyzer (Micro Basic Smokerlyzer, Bedfont Scientific Ltd). Those identified as ineligible were given a Metrocard to thank them for their time. Those identified as initially eligible were asked to complete a written informed consent form. Study staff guided participants through the form and answered any questions.

After providing written consent, participants completed a baseline questionnaire that included demographic characteristics, tobacco use history, illicit substance use history, alcohol use history, psychosocial characteristics, and pharmacotherapy use (Multimedia Appendix 1). Survey instruments were collected via Qualtrics. Following completion of the baseline study assessments, study participants were randomized (1:1) to the Lumme Quit Smoking app arm or the control arm.

Randomization

We did not stratify the sample by any demographic characteristic (ie, age, sex, gender, race, or ethnicity) since this was a pilot study with a small sample. We concealed randomization status from staff and participants until after completion of the baseline assessment to minimize bias. The study statistician who performed the data analysis was blinded to the treatment groups.

Participants in both arms received a smoking cessation counseling session and were provided with NRT in the form of the NicoDerm CQ Patch (GSK Group of Companies) under the supervision of a nurse. Each participant received an 8-week supply of NRT, which was enough to follow the 3-step program. However, they were encouraged not to begin NRT until 2 weeks after the baseline visit. Participants in both study arms set a quit date for 2 weeks after the baseline visit. Dosing of the NRT was based on standard prescribing guidelines. Participants in both arms also received a 30-minute smoking cessation counseling session and weekly check-in calls from the study staff.

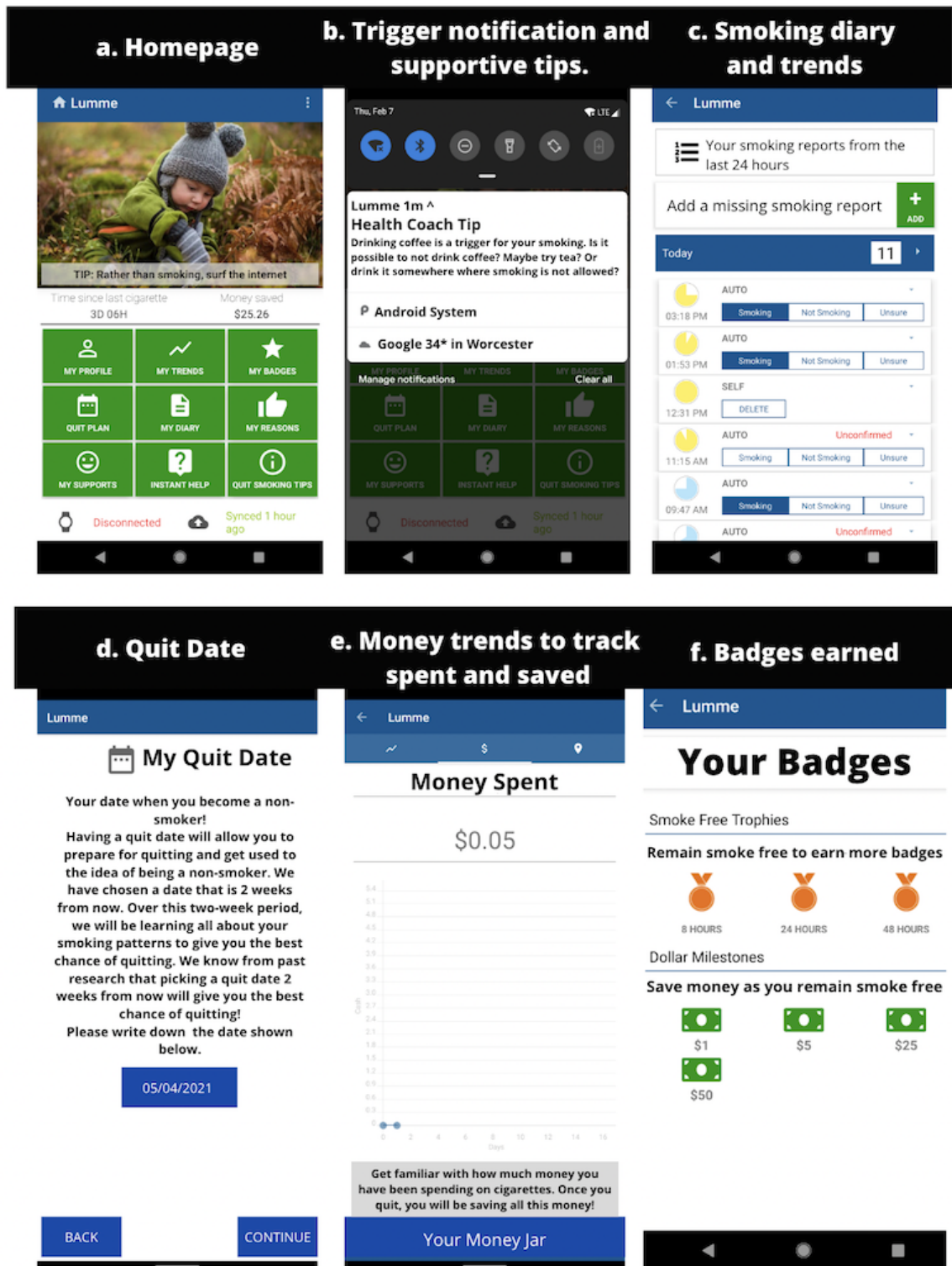
Participants in the intervention arm received a Vapor 2 (Misfit) or Falster 2 (Skagen Denmark) smartwatch (Figure 1). Both smartwatches are compatible with the Lumme Quit Smoking app. The Lumme Quit Smoking app was paired with the smartwatch so that smoking was detected by the smartwatch and the information sent directly to the Lumme Quit Smoking app. The smartwatch detected hand movements indicating a study participant was picking up a cigarette to smoke or a user manually entered a smoking session. The Lumme Quit Smoking app was then able to predict cravings, target users with notifications to prevent individuals from smoking, refine the notifications for each user, and display their change in smoking behavior and money saved in a smoking diary (Figure 2). Users were also able to see their quit plan with their assigned quit date for 2 weeks after baseline, along with smoking trends, supportive tips, and badges earned from the amount of money saved.

Intervention arm participants created an account with the Lumme Quit Smoking app, which passively collected smoking data, such as when the user smoked (time of day, day of week, before/after eating, after waking up/before going to sleep, before driving to/from work, while driving), where the user smoked, and who was nearby when the user smoked (based on repeated detection of the same Bluetooth static address; Lumme does not collect identities), during the first 2 weeks of the study period. At the end of the baseline visit, all enrolled participants were compensated \$40 for their participation in the form of a preloaded debit card. On the day before their quit date, study staff under the supervision of a nurse called participants in both arms to remind them of their quit date and to start using their NRT patches on the morning of their quit date. Additionally, participants in both the control and intervention arm received weekly check-in calls from study staff members. Staff conducted these calls to monitor adherence to NRT, to provide technology assistance to those in the intervention arm who might be experiencing difficulties with the smartwatch or app, and to encourage participant engagement in the study.

Figure 1. Sample picture of smartwatches used by study participants.



Figure 2. Screenshots of the Lumme Quit Smoking app.



Study Measures

To determine feasibility, we examined retentions rates, compliance rates, dosing, eligibility criteria, recruitment and enrollment rates, missing data, and study measures. Retention rates were measured as the number of enrollees who remained in the study; 80% retention was the threshold for feasibility. Compliance rates were calculated as the number of days participants used the Lumme Quit Smoking app divided by the

56 days of the study intervention program with at least 80% of participants having completed at least 75% of the intervention content set as the threshold. Dose was measured as the number of app sessions completed by the participants. Eligibility criteria were assessed to determine if the number of individuals who screened out of the pilot study was too high, indicating criteria that were too stringent. Recruitment and enrollment pace were assessed by dividing the total number of enrolled participants by the number of months in the recruitment period. The study

measures and missing data were evaluated to determine if the survey questions needed adjustment by assessing the extent and patterns of missing data and the length of time needed to complete the study measures.

Primary outcome 7-day point prevalence abstinence was measured by self-report and biochemically verified via eCO at 12 weeks. Baseline nicotine dependence was measured using the Fagerström Test for Nicotine Dependence [48]. Baseline tobacco use was measured through self-reported number of cigarettes smoked per day. Baseline alcohol use was measured using the CAGE (cut, annoyed, guilty, and eye) Alcohol Abuse Screening Tool [49]. Depression was measured using the Center for Epidemiologic Studies–Depression Scale (CES-D) at baseline and 12 weeks [50].

At the 12-week follow-up visit, semistructured in-depth interviews were conducted with study participants. No additional compensation was provided for participation in the interviews. These interviews aim to fill gaps in the literature by taking a qualitative approach to understanding the acceptability of the Lumme app as a smoking cessation tool in the intervention arm and learn more about the perceptions of all participants on the recruitment and enrollment process. Both groups answered the following questions: How would you modify the outreach and recruitment process to improve it or make it easier? How comfortable were you with the recruitment, screening, and enrollment process? How can we improve the current screening process? The intervention group completed a questionnaire (Multimedia Appendix 2-5) that included the following questions, among others: Please describe your general perceptions and expectations of the app. How often did you use the app? How helpful was the app for tobacco cessation?

Data Analysis

Descriptive statistics were used to detail the study sample by condition and as a total sample. Descriptive statistic *P* values were calculated by *t* test, chi-square test, or Fisher exact test. Point estimates and corresponding confidence intervals were calculated for each measure by arm. Because of our small sample sizes, we used Clopper-Pearson exact confidence intervals based on the binomial distribution and reported effect sizes (using relative risk or Cohen *d* depending on the

distribution of the outcome measures) as well as *P* value (calculated by chi-square test for binary outcomes and independent samples *t* test for continuous outcomes) to examine differences in primary outcome (7-day point prevalence abstinence) and secondary outcomes (eCO decrease from baseline to 12-week follow-up, self-reported number of cigarettes smoked per day, and CES-D and CAGE scores) by study arms. The 7-day point prevalence abstinence was calculated as the proportion of participants who reported no smoking/tobacco use in the 7 days prior to their 12-week follow-up visit, biochemically verified by eCO collected at 12 weeks. Participants with eCO levels less than 6 ppm at 12 weeks were classified as abstinent while participants with eCO levels 6 ppm or more at 12 weeks were classified as not abstinent. Participants lost to follow-up were included in the analyses as smokers. We also assessed the time trends of eCO by each study arm and in both arms using paired *t* tests (used to calculate effect size and *P* value) because a total sample size of 37 is sufficient to detect a medium effect size when assessing within-subject effect, the time trend effect. All analyses were performed in SAS (version 9.4, SAS Institute Inc).

All in-depth interviews were transcribed verbatim and then coded using the Fit Between Individuals, Task, and Technology (FITT) framework along 3 dimensions: task-technology fit, individual-technology fit, and individual-task fit [51]. The FITT framework has been successfully used to determine the usability of mHealth technology in prior studies, proving to be a useful framework to guide this analysis [52,53].

Results

Demographic Characteristics

The demographic characteristics of participants are described in Table 1. There was no significant difference in study characteristics between study conditions. The mean age of study participants was 54 years, 50% (20/40) of participants identified as male, 78% (31/40) identified as Black/African American, and 23% (9/40) identified as Hispanic/Latinx. Participants had a mean CES-D score of 15.65 (SD 11.1). CAGE scores indicated that 22% (8/37) of participants had clinical indications of an alcohol use problem.

Table 1. Participant characteristics at baseline (n=40).

Characteristics	Total (n=40) ^a	Intervention (n=20)	Control (n=20)	P value
Age (years), mean (SD)	53.7 (9.2)	53.4 (10.2)	54.0 (8.5)	.84
Gender identity, n (%)	— ^b	—	—	>.99
Male	20 (50)	10 (50)	10 (50)	—
Female	18 (45)	9 (45)	9 (45)	—
Transgender female	1 (3)	0 (0)	1 (5)	—
Genderqueer	1 (3)	1 (5)	0 (0)	—
Sex at birth, n (%)	—	—	—	>.99
Male	22 (55)	11 (55)	11 (55)	—
Female	18 (45)	9 (45)	9 (45)	—
Race, n (%)	—	—	—	.06
Black/African American	31 (78)	13 (65)	18 (90)	—
White	1 (3)	0 (0)	1 (5)	—
Multiracial	1 (3)	1 (5)	0 (0)	—
Unknown	7 (18)	6 (30)	1 (5)	—
Hispanic/Latinx ethnicity, n (%)	—	—	—	.13
Yes	9 (23)	7 (35)	2 (10)	—
No	31 (78)	13 (65)	18 (90)	—
Education, n (%)	—	—	—	.11
None	2 (5)	0 (0)	2 (10)	—
Some high school, no diploma	12 (30)	7 (35)	5 (25)	—
High school diploma or equivalent	14 (35)	8 (40)	6 (30)	—
Some college	8 (20)	2 (10)	6 (30)	—
Associate degree or technical degree	3 (8)	3 (15)	0 (0)	—
Bachelor/college degree	1 (3)	0 (0)	1 (5)	—
Employment, n (%)	—	—	—	.63
Working full-time	1 (3)	1 (5)	0 (0)	—
Working part-time	4 (10)	1 (5)	3 (15)	—
Unemployed	13 (33)	6 (30)	7 (35)	—
Retired	4 (10)	3 (15)	1 (5)	—
Disabled	15 (38)	7 (35)	8 (40)	—
Retired and disabled	1 (3)	1 (5)	0 (0)	—
Unemployed and disabled	1 (3)	0 (0)	1 (5)	—
Working part-time and retired	1 (3)	1 (5)	0 (0)	—
Annual income (US \$), n (%)	—	—	—	.88
<10,000	17 (43)	7 (35)	10 (50)	—
10,000-19,999	12 (30)	7 (35)	5 (25)	—
20,000-39,999	2 (5)	1 (5)	1 (5)	—
40,000-59,999	1 (3)	1 (5)	0 (0)	—
Don't know	8 (20)	4 (20)	4 (20)	—
Health insurance, n (%)	—	—	—	.16
Health exchange	1 (3)	1 (5)	0 (0)	—

Characteristics	Total (n=40) ^a	Intervention (n=20)	Control (n=20)	P value
Medicaid/Medicare	35 (88)	19 (95)	16 (80)	—
AIDS Drug Assistance Program	1 (3)	0 (0)	1 (5)	—
Uninsured	3 (8)	0 (0)	3 (15)	—
Quit attempt in past year, n (%)	—	—	—	.75
Yes	19 (48)	9 (45)	10 (50)	—
No	21 (53)	11 (55)	10 (50)	—
Cigarette type used, n (%)	—	—	—	.61
Menthol	36 (90)	19 (95)	17 (85)	—
Nonmenthol	4 (10)	1 (5)	3 (15)	—
Usual cigarette brand^c, n (%)	—	—	—	.61
Marlboro	3 (8)	1 (5)	2 (11)	—
Newport	36 (92)	19 (95)	17 (90)	—
CAGE^d Substance Abuse Screening Tool^e, n (%)	—	—	—	>.99
Clinically significant alcohol problems indicated	8 (22)	4 (21)	4 (22)	—
Clinically significant alcohol problems not indicated	29 (78)	15 (79)	14 (78)	—
CES-D ^f score, mean (SD)	15.7 (11.1)	16.6 (13.1)	14.8 (8.9)	.61
eCO ^g (ppm ^h), mean (SD)	13.8 (6.4)	14.5 (6.5)	13.1 (6.3)	.48
Number of cigarettes smoked daily in past 30 days, mean (SD)	10.2 (5.3)	11.1 (6.7)	9.3 (3.3)	.31
Number of years smoking, mean (SD)	33.4 (12.1)	34.2 (10.7)	32.7 (13.6)	.70
Fagerström Test for Nicotine Dependence, mean (SD)	6.4 (2.0)	6.7 (1.7)	6.2 (2.3)	.48

^aColumn percentages may not sum to 100% due to rounding.

^bNot applicable.

^cn=1 missing.

^dCAGE: cut, annoyed, guilty, and eye.

^en=3 missing.

^fCES-D: Center for Epidemiologic Studies–Depression Scale.

^geCO: exhaled carbon monoxide.

^hppm: parts per million.

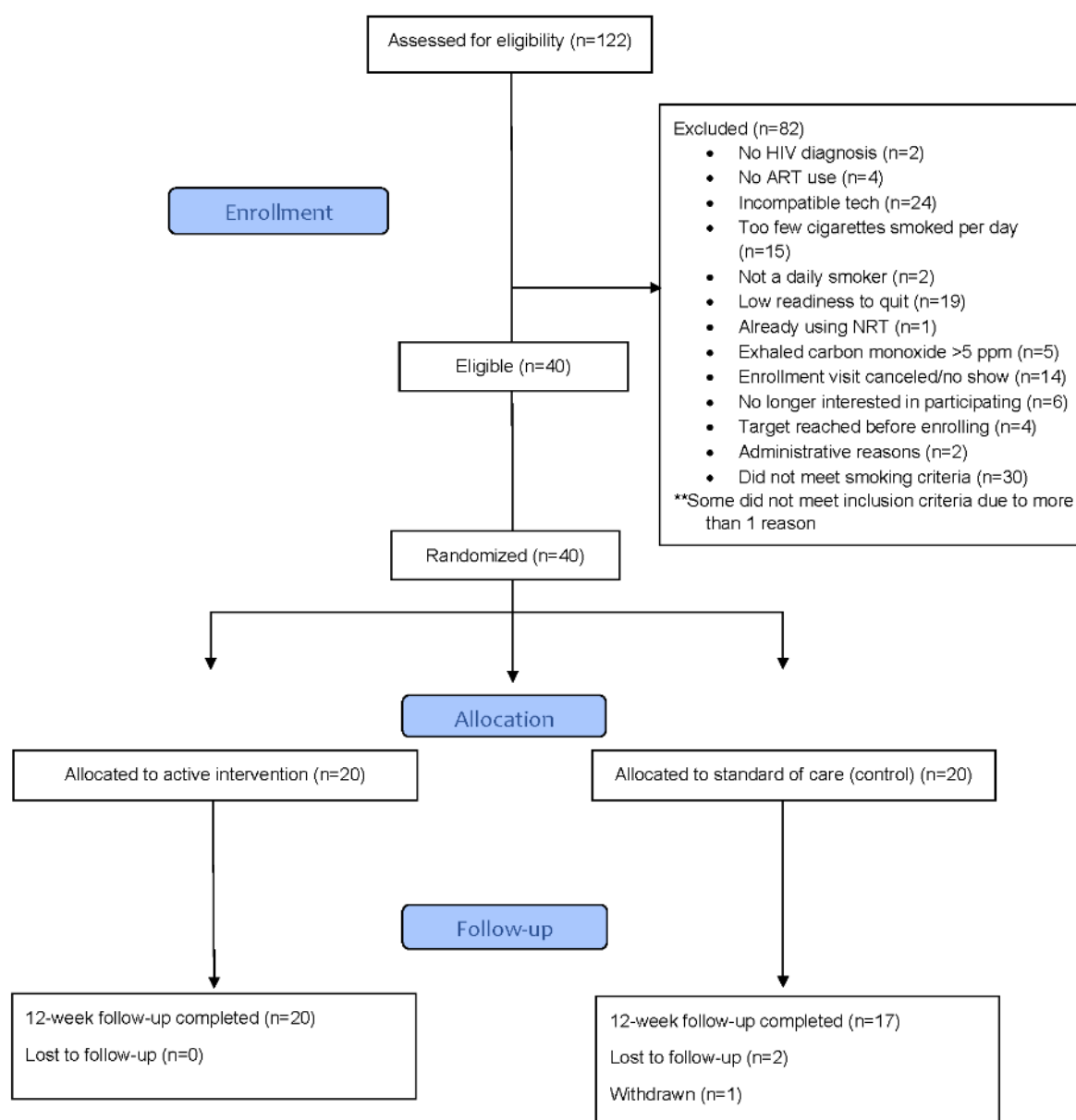
Smoking Characteristics

Participants had a mean eCO at baseline of 13.8 (SD 6.4) and reported smoking an average of 11.5 (SD 4.7) cigarettes daily in the past month. Participants reported smoking for a mean of 33 (SD 12) years. Menthol cigarettes were used by 90% (36/40) of participants and 92% (36/39) reported that Newport was their usual cigarette brand. Per the Fagerström Test for Nicotine Dependence, participants had a mean nicotine dependence level of 6.4 (SD 2.0). Nearly half of participants (19/40, 48%) reported trying to quit smoking in the past year. There were no significant differences in smoking characteristics by study arm.

Feasibility and Retention Rates

Of the 40 participants who enrolled in the study, 37 returned to complete the follow-up study assessment at 12 weeks. Of the 3 participants who did not finish the study, 1 was withdrawn and 2 were lost to follow-up. The 3 participants who failed to complete the study were all assigned to the control arm (Figure 3). Dose was operationalized as the number of app sessions completed by the participant; 80% (16/20) of participants used the app every day during the 56-day period. Of the 16 participants, 14 used the Lumme Quit Smoking app for at least 2 weeks past the official program end date.

Figure 3. Smoking cessation pilot CONSORT (Consolidated Standards of Reporting Trials) flowchart. ART: antiretroviral therapy; NRT: nicotine replacement therapy.



Eligibility Criteria

During the recruitment and enrollment period, 122 people were screened for eligibility with 67.2% (82/122) screening ineligible. Smoking criteria and incompatible tech were the most frequently occurring reasons for ineligibility. During the study's 6-month recruitment and enrollment period, approximately 6 participants were enrolled per month.

Study Measures and Missing Data

All 40 enrolled participants completed the baseline survey, and 37 participants completed the follow-up survey at 12 weeks. Among the 77 completed survey responses, missing data were evenly distributed across study arms. On average, study participants completed the baseline survey in 79 (SD 45) minutes and completed the follow-up survey in 30 (SD 16) minutes.

Acceptability

Table 2 displays descriptive statistics and associated 95% confidence intervals for primary, secondary, and other outcome measures.

The relative risk of 7-day prevalence abstinence was 1.27 between the intervention and control groups, indicating that the 7-day abstinence prevalence was 27% higher in the intervention group than in the control group; the effect size of eCO decrease was small (Cohen $d=0.21$); for other secondary outcomes, the effect sizes were less than small (Cohen $d<0.20$). There was no significant difference in decrease in eCO for the control arm or intervention arm. Average eCO decreased significantly over time (baseline 13.8 [SD 6.4], 12-week follow-up 11.4 [SD 8.2]; $P=.02$) when analyzing both arms together (Table 3).

Table 2. Differences in outcome measures by study arm.

Measure	Control (n=20) ^a		Intervention (n=20)		Total (n=40)		Effect size (95% CI)	P value
	Value	95% CI	Value	95% CI	Value	95% CI		
7-day point prevalence abstinence verified via eCO ^b at 12 weeks, n (%)	2 (12)	1.5 to 36.4	3 (15)	3.2 to 37.9	5 (14)	4.5 to 28.8	1.27 (0.24 to 6.76)	.77
Self-report 7-day point prevalence abstinence at 12 weeks, n (%)	4 (24)	6.8 to 49.9	6 (30)	11.9 to 54.3	10 (27)	13.8 to 44.1	1.27 (0.43 to 3.78)	.66
eCO ppm ^c decrease from baseline to 12 weeks, mean	17 (2.12)	-0.9 to 5.14	20 (3.35)	-0.2 to 6.92	37 (2.78)	0.69 to 4.88	0.21 (-0.44 to 0.86)	.59
CES-D ^d score, mean	20 (14.8)	10.8 to 18.7	20 (16.6)	10.8 to 22.3	40 (15.7)	12.2 to 19.1	0.16 (-0.46 to 0.78)	.61
Number of cigarettes smoked per day reported at baseline, mean	20 (11)	9.3 to 12.7	20 (11.9)	9.5 to 14.3	40 (11.5)	10 to 12.9	0.19 (-0.42 to 0.80)	.55
CAGE ^e Substance Abuse Screening Tool score at baseline, mean	18 (0.9)	0.3 to 1.5	19 (0.9)	0.2 to 1.6	37 (0.9)	0.5 to 1.3	0.004 (-0.61 to 0.62)	.99

^an=3 missing in control group at follow-up.

^beCO: exhaled carbon monoxide.

^cppm: parts per million.

^dCES-D: Center for Epidemiologic Studies–Depression Scale.

^eCAGE: cut, annoyed, guilty, and eye.

Table 3. Change in exhaled carbon monoxide in parts per million from baseline to 12 weeks by study arm.

Arm	Baseline eCO ^a		eCO at 12 weeks		Effect sizes in change (95% CI)	P value
	Participants, n	Mean (SD)	Participants, n	Mean (SD)		
Control	20	13.1 (6.3)	17	11.6 (7.4)	0.36 (-0.14 to 0.85)	.16
Intervention	20	14.5 (6.5)	20	11.2 (9.0)	0.44 (-0.03 to 0.89)	.06
Both	40	13.8 (6.4)	37	11.4 (8.2)	0.41 (0.07 to 0.74)	.02

^aeCO: exhaled carbon monoxide.

NRT Use

At the follow-up study visit, participants self-reported their NRT use. A total of 46% (17/37) of all study participants reported daily NRT use, 45% (9/20) in the intervention arm reported daily NRT use, and 47% (8/17) in the control arm reported daily NRT use. There was no significant difference in NRT use between participants in the study arms.

In-depth Interviews

Findings from the in-depth interviews are organized according to the FITT framework, which provided for a better understanding of the factors contributing to the engagement and perceived usefulness of the intervention. Sample quotes that are exemplars of each of the constructs of the framework are detailed in [Table 4](#).

Table 4. Exemplars of findings from the in-depth interviews organized by the Fit Between Individuals, Task, and Technology framework.

FITT ^a framework construct	Sample quotes from in-depth interview
Task-technology fit	<ul style="list-style-type: none"> “And it does really help you. It tells you when your day is over. It goes, ‘You have such-and-such more days before you quit.’ That was a good reminder...” “I looked at it a couple times a day. In the beginning when I was smoking, I looked at it almost every time I smoked just to see if it recorded. But after I stopped smoking, I would look at it still...” “...this watch is going to monitor my movement of my hand... I’m not going to be smoking all the time and moving my hand... I already knew that... that I would have to check in and be honest. Honesty was one of my biggest, like I expected to be honest. And that’s what I’ve been...”
Individual-technology fit	<ul style="list-style-type: none"> “The tips were very useful because everything it says in the tips is true...pros and cons...which is another way you can sit there and say is smoking good or bad. Having the support system on there was cool... anytime I wanted to I could contact the support system anytime I needed to speak to somebody...” “[I used the watch] everywhere. If I was in the bathroom; if I was making a delivery if I was at work. It didn’t matter where it was... I was able to text through the watch... I find that very cool, too.” “I think this whole experience was something good for me... I’ve always wanted to stop smoking... I’ve slowed down enough to maybe be able to stop. And it gave me the encouragement, the power and the push to do it in a way that’s not hard...” [51]
Individual-task fit	<ul style="list-style-type: none"> “It’s extremely helpful, it definitely helped me cut back. I’m more confident with the app and like I said, it’s like a little coach with you all the time, 24/7...” “...[the app] did make things very clear, as far as really specifying your habits... In that respect, it’s been good, because it made you conscious of how much you’re smoking, even though you do it normally without the app and you just smoke, and you don’t think about it...” “[The app was] 100% helpful for an individual that’s really focused on not smoking, on quitting, being focused on quitting and wanting to... I mean that was amazing... to have a watch on and when you’re going like this or you know... they always give you the option to say, well, no, I wasn’t smoking at that time; I was eating or something like that... the individual has to be honest, with themselves...”

^aFITT: Fit Between Individuals, Task, and Technology.

Discussion

Principal Findings

This study focused on testing a multicomponent intervention, Lumme Quit Smoking app with nicotine replacement therapy (NRT) and smoking cessation counseling to improve smoking cessation in persons living with HIV. This is especially important given that tobacco use causes increased morbidity and mortality in persons with HIV, and tobacco-related harm is substantially higher in persons with HIV than in smokers in the general population. There were several innovative components of this intervention. The algorithm for detecting the smoking arm movement can be used to interpret data from a smartwatch [54]. The Lumme Quit Smoking app uses a validated sensor to detect participants’ smoking behaviors in real time. This intervention combined biometric data with behavioral interventions specific to smoking behavior, an advancement and innovation not previously tested in persons with HIV. Findings from this study suggest that the intervention was both feasible and acceptable in this population. Participants wore the sensor and used the app. Retention in the study was very good. The high completion rate and continued use of the app for weeks beyond the program end indicates that the dose was not burdensome and could be extended for future smoking cessation studies. Notably, the loss to follow-up and withdrawal were all among control group participants. Therefore, consideration of whether this loss to follow-up is associated with treatment group will need to be considered in the next trial, although it is noted that retention was overall very good, and numbers of participants who dropped out of the study are small.

This pilot study was underpowered to detect statistically significant differences between conditions on efficacy outcomes. There were only 2 participants who quit the smoking in the control group and 3 in the intervention group, verified through biochemical testing. Based on the self-reported quit rates, there were 4 (control) versus 6 (intervention) participants who quit smoking. Nonetheless, these findings allowed us to estimate that the intervention was able to improve the prevalence of 7-day abstinence by 27% in the study sample, and there was a decrease in the eCO over time with an almost medium effect size (Cohen $d=0.44$) in the intervention group.

The ability for a mobile app to deliver content that would burden participants and require staff and clinician time and resources is an innovative approach to the delivery of a tobacco cessation intervention. Importantly, mHealth is a feasible platform for delivering this intervention since there is extremely high mobile phone penetration in the United States [55], especially among racial/ethnic minority groups [56]. mHealth technology can be used for achieving health equity in vulnerable groups because it is a widely available and relatively inexpensive tool for health behavior change [57] and can be adapted to meet the needs of its end users [58-61]. Our work has shown that even the lowest income and most health disparate persons own and use smartphones [62]. Therefore, the Lumme Quit Smoking app is timely, relevant, scalable, and likely to improve health outcomes in persons with HIV who smoke. Even when successful, however, there are barriers to widespread adoption and successful scale-up of tobacco interventions [63,64]. While leveraging accessible mHealth technologies is a strength, our study team acknowledges the target population may not have

access to smartwatches outside of the research study. Nonetheless, if efficacious, the cost of the smartwatch is half of the cost of purchasing cigarettes for 1 month in New York City, estimated at \$320 per month [65] and even more minimal in comparison to the annual cost (\$170 billion) for direct medical care for persons who smoke in the United States [66].

Limitations

There were several important limitations of this study. First, we relied on self-report of NRT use among study participants, and while we tracked our distribution of NRT to study participants, we were limited in our ability to validate whether participants used the NRT. We carefully considered our control condition and ultimately the robustness of the control condition (smoking cessation counseling session and NRT administration) may have underestimated the effect of the Lumme Quit Smoking app.

Conclusion

Notably, smoking cessation efforts have largely been aimed at the general population. Consequently, it is not clear whether

they are suitable or effective for cohorts with population-specific concerns and clinical issues such as persons with HIV [11,22,67,68]. While the Lumme Quit Smoking app is undeniably an innovation in combining sensors, real-time feedback, and behavioral interventions, it was developed for the general population of smokers and was not in any way targeted or tailored for the needs of persons with HIV. This may have contributed to the findings that this intervention was not significantly more efficacious at improving smoking cessation than a standard of care control condition. Future research should focus on identifying the behavioral factors specific to persons with HIV who smoke and developing an intervention to meet their needs. Additionally, the counseling component of the intervention may need to be tailored to persons with HIV. A recent study found that persons with HIV did not understand the relationship between HIV and smoking and described wanting more information about the health effects of smoking for persons with HIV [69].

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Authors' Contributions

RS, PC, and MH conceptualized the study. RS and PC were responsible for methodology. RS was responsible for supervision. RS, JL, GA, and SG wrote the original draft. JL and SG curated the data. JL and SG were responsible for the formal analysis. GA, TP, and SB were responsible for investigation. GA, SG, and PT reviewed and edited the manuscript. TP and SB were responsible for project administration. MH was responsible for software and resources.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Fagerstrom Test for Nicotine Dependence.

[PDF File (Adobe PDF File), 108 KB - [formative_v6i8e28626_app1.pdf](#)]

Multimedia Appendix 2

Smoking cessation pilot interview guide: control.

[PDF File (Adobe PDF File), 63 KB - [formative_v6i8e28626_app2.pdf](#)]

Multimedia Appendix 3

Smoking cessation pilot interview guide: intervention.

[PDF File (Adobe PDF File), 131 KB - [formative_v6i8e28626_app3.pdf](#)]

Multimedia Appendix 4

Smoking cessation pilot: baseline survey.

[PDF File (Adobe PDF File), 627 KB - [formative_v6i8e28626_app4.pdf](#)]

Multimedia Appendix 5

Smoking cessation pilot: follow-up survey.

[PDF File (Adobe PDF File), 388 KB - [formative_v6i8e28626_app5.pdf](#)]

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Abbreviations

CAGE: cut, annoyed, guilty, and eye
CES-D: Center for Epidemiologic Studies–Depression Scale
eCO: exhaled carbon monoxide
FITT: Fit Between Individuals, Task, and Technology
mHealth: mobile health technologies
NRT: nicotine replacement therapy
ppm: parts per million

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Original Paper

Feasibility, Usability, and Implementation Context of an Internet-Based Pain Education and Exercise Program for Chronic Musculoskeletal Pain: Pilot Trial of the ReabilitaDOR Program

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Abstract

Background: Internet-based self-management programs and telerehabilitation initiatives have increased and have been extensively used for delivering health care in many areas. These programs overcome common barriers that patients face with traditional face-to-face health care, such as travel expenditures, lack of time, and high demand on the public health system. During the COVID-19 pandemic, this mode of web-based health care delivery had become more popular. However, there is still a lack of studies testing this mode of delivery in low- and middle-income countries. To gain a better understanding of the context, feasibility, and factors involved in the implementation of a web-based program, pilot and implementation studies are necessary. These studies can better inform whether a strategy is feasible, acceptable, and adequate for its purposes and for optimizing resource allocation.

Objective: This study aims to evaluate the feasibility, usability, and implementation context of a self-management internet-based program based on exercises and pain education (ReabilitaDOR) in people with chronic musculoskeletal pain and to compare this program with a program using only a web-based self-management booklet.

Methods: The study design was a parallel pilot study of a prospectively registered, assessor-blinded, 2-arm randomized controlled trial with economic evaluation. This study was performed using waiting lists of physiotherapy and rehabilitation centers and advertisements on social media networks. The participants were 65 patients with chronic musculoskeletal pain aged between 18 and 60 years. The effects of an 8-week telerehabilitation program based on exercises and pain education (intervention group) were compared with those of a program based only on a web-based self-management booklet (control group). The main outcome measures were implementation outcomes of patients' perceptions of acceptability, appropriateness, feasibility, and usability of the program and the societal costs and feasibility of the main trial at 8-week posttreatment follow-up. Adverse events were also analyzed.

Results: In total, 56 participants were analyzed at the 8-week follow-up. The intervention group showed responses with a mean of 4.5 (SD 0.6) points for acceptability, 4.5 (SD 0.5) points for appropriateness, and 4.5 (SD 0.6) points for feasibility measured on a 1 to 5 scale. All patients in the intervention group showed satisfactory responses to the system usability outcome. There is

satisfactory evidence for the feasibility of the main trial. For costs related to the interventions, health care, patients, and loss of productivity at 8 weeks, we found a total expenditure of US \$278.30 per patient in the intervention group and US \$141.52 per patient in the control group. No adverse events were reported during the intervention period.

Conclusions: We found that the ReabilitaDOR program is feasible, appropriate, and acceptable from the users' implementation perspective. This system was considered usable by all the participants, and the main trial seemed feasible. Cost data were viable to be collected, and the program is likely to be safe.

Trial Registration: ClinicalTrials.gov NCT04274439; <https://clinicaltrials.gov/ct2/show/NCT04274439>

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KEYWORDS

telerehabilitation; musculoskeletal pain; implementation science; feasibility study; chronic pain; pain; pilot study; eHealth; exercise; telehealth; self-management

Introduction

Chronic pain is broadly defined as pain that persists for more than 3 months [1,2]. The most common chronic pain conditions are back and neck pain and knee and hip osteoarthritis, which are part of a broader group often called as chronic musculoskeletal pain [3-5]. Recent literature classifies chronic musculoskeletal pain as conditions characterized by persistent inflammation of infectious, autoimmune, or metabolic etiology [1]. This is a group of pain conditions that affects millions of people around the world and is responsible for an enormous economic burden, which impacts health services globally [5,6]. Chronic musculoskeletal pain is also the major cause of years lived with disability globally [5].

The management of chronic musculoskeletal pain is primarily multimodal, with noninvasive and nonpharmacological therapies as first-line options. These therapies include exercise, pain education, psychological, and physical therapies [7-11]. Although these recommendations from clinical practice guidelines are clear and usually do not involve complex programs [12,13], many people do not have access to adequate and affordable treatments. This can be due to geographical barriers (eg, people living in rural areas or Indigenous communities) or health care systems that may be overstretched with no capacity to provide timely and equitable access to health services [14]. Thus, there is a need for the development of remote strategies such as telerehabilitation [14,15] to improve access to health care.

Telerehabilitation is defined as the use of remote mechanisms and technologies for screening, diagnosis, education, treatment, and monitoring of a given condition [15,16]. Telerehabilitation can be delivered through telephone calls, smartphone apps, websites, or digital platforms that guarantee the population's access to multimodal treatment strategies for chronic pain [14,15]. The use of telerehabilitation strategies has grown exponentially in the past years; however, the great majority of clinical trials and implementation studies of telerehabilitation are still being conducted in high-income countries [17]. Hence, there is a clear need for more clinical studies assessing telerehabilitation in low- and middle-income countries [14,17].

One important step before conducting a large clinical trial is to test the feasibility of the process involved in the main study, such as recruitment rates and the resources needed [18-20].

Trials using web-based interventions may also need to test the user's usability of the system (ie, the degree to which a system is fit to be used) to ensure that the system is accessible, clear, and easy to use [21,22]. A final aspect of testing an intervention is to understand implementation processes and context, such as the acceptability and appropriateness. Feasibility, usability, and other implementation-related outcomes are all important to the translation of research into practice, providing better insights into service delivery [23]. The aim of this study was to test and evaluate the feasibility and usability through an implementation perspective of an internet-based pain education and exercise program for chronic musculoskeletal pain and to compare this program with a program consisting of an intervention with only a web-based self-management booklet.

Methods

Ethical Considerations and Study Design

This is a pilot study of a prospectively registered (NCT04274439), parallel, assessor-blinded, 2-arm randomized controlled trial with economic evaluation. This study was submitted and accepted by the ethics committee Comitê de Ética em Pesquisa da Universidade Cruzeiro do Sul (CAAE 02892918.0.0000.8084), and the study protocol of the main trial has been published elsewhere [24].

Settings and Eligibility

We recruited patients from the waiting lists of physical therapy and rehabilitation centers and through advertisements on social media networks. We included patients aged between 18 and 60 years, who were seeking treatment or who would like to undertake a physical therapy program for any chronic musculoskeletal pain, were able to read and understand Portuguese, and had internet access. We included patients with chronic musculoskeletal pain (pain lasting more than at least 12 weeks) [1] and pain intensity of at least 3 points on a 0-10 Numeric Pain Rating Scale [25]. We did not include patients who had nerve root compromise, serious pathologies (eg, fracture, tumor, inflammatory, autoimmune/infectious diseases), cardiovascular and metabolic diseases (eg, coronary heart disease, heart failure, decompensated diabetes), recent orthopedic surgery (in the last 12 months), surgery scheduled for the next 6 months, or were pregnant. Patients were also excluded if there was any contraindication to exercise measured

with the Physical Activity Readiness Questionnaire Portuguese version [26,27].

Procedures

The conduct of the study as well as the evaluations and 8-week follow-ups were carried out completely remotely through web-based platforms and telephone calls. We invited patients from waiting lists of rehabilitation centers via phone call, or participants seeking physiotherapy care could also contact the researchers of the study. After confirming eligibility of the participant, we scheduled the assessment session (baseline) through a videoconference. This session was performed using the platform Whereby to access an encrypted and personalized room with the patient and the researcher conducting the assessment. In this session, the researcher explained the study and all procedures as well as double checked the eligibility of the participant. Then, the participant received a consent form (signed electronically), completed the baseline assessment of the study, and finally received a login and password to access the study website [28] to be randomized automatically to one of the 2 groups at the first login.

Outcome Measures

Primary Outcomes

All outcomes were measured after the intervention period (8 weeks) through an electronic form, with a study evaluator blinded to the treatment allocation. The primary outcomes were program fit (acceptability, appropriateness, and feasibility), system usability, societal costs, and feasibility of the main trial.

Program Fit

Program fit was measured using 3 measures composed of 4 items each that can be used independently or representing 1 single score [29]:

1. Acceptability of Intervention Measure (AIM): Acceptability is the perception among implementation stakeholders that a given treatment, service, practice, or innovation is agreeable, palatable, or satisfactory [29].
2. Intervention Appropriateness Measure (IAM): Appropriateness is the perceived fit, relevance, or compatibility of the innovation or evidence-based practice for a given practice setting, provider, or consumer, and perceived fit of the innovation to address a particular issue or problem [29].
3. Feasibility of Intervention Measure (FIM): Feasibility is defined as the extent to which a new treatment or an innovation can be successfully used or carried out within a given setting [29].

These measures are composed of 4 items, and the participant can answer as “totally agree,” “agree,” “neither agree nor disagree,” “disagree,” or “strongly disagree.” A value from 1 to 5 is assigned to each answer with a total value of 20 points possible for each measure. There are no cutoff points for these measures, but values closer to 5 in each answer and 20 in the total measure indicate better results for the proposed outcomes.

System Usability

To assess system usability, we used the System Usability Scale [30,31]. The System Usability Scale is composed of 10 items where the patients respond with “strongly disagree,” “disagree,” “neither agree nor disagree,” “agree,” or “strongly agree.” A value from 1 to 5 is assigned to each answer. The responses are summed and multiplied by 2 so that the total score ranges from 0 to 100 points, where scores closer to 100 indicate better usability results.

Societal Costs

We measured societal costs by the estimate of trial intervention costs, health care costs (visits to general practitioners, physiotherapists, alternative therapists, medical specialists, as well as the use of emergency, hospitalization, and medication), patients costs (transportation: the number of public transport tickets needed to get to the health care service), and lost productivity costs (absenteeism). Costs were measured based on the participants’ reported use of the resources by using a cost diary given to the participants at baseline. Participants were asked to send the completed cost diary to the evaluators or respond with the diary data in a web-based questionnaire. The health care costs were also divided into health insurance costs, public health system costs (*Sistema Único de Saúde*), and private costs (out-of-pocket costs). All costs were collected in BRL, inflated to the reference year of the study (2020) using the consumer price index and converted into USD using purchase power parities [32].

The intervention costs were estimated based on the total costs of website development, creation of the content included in the physical therapy program, internet hosting, and costs of text messages and phone calls present in each work group. The development and creation costs were considered from the perspective of using the program for over 5 years, based on the time of updating the information for the treatment in clinical practice guidelines. The value for 5 years of use was divided by the number of patients who would benefit from the treatment in each of the main clinical trial groups.

The unit prices of the health care services were calculated based on the Brazilian database (*Banco de Preços em Saúde*) [33] or from the Brazilian professional regulatory councils [34]. The unit prices of the medications that were not present in the Brazilian database were valued through a web-based commercial consultation in pharmacy chains (the unit average of these medications was calculated using the prices found in 5 pharmacy chains).

The transportation costs were estimated using the public transport price in the city of São Paulo, Brazil [35]. The lost productivity costs included absenteeism from paid work. Absenteeism was estimated by asking patients the number of hours not worked owing to chronic musculoskeletal pain and valued according to the Human Capital Approach using sex-specific price weights [36].

Feasibility of the Main Trial

The criteria to judge the feasibility of progressing to a full trial were as follows:

1. Fifty percent or more of the invited participants were willing to be recruited into the feasibility study.
2. Seventy percent or more of the participants in the intervention group have completed the 8-week program (compliance).
3. Data on key outcomes were collected at postintervention for $\geq 70\%$ of participants.
4. Less than 10% of adverse events are caused by the intervention.

We also collected the response rate at follow-up and adherence to the program.

Secondary Outcomes

A key aim of the pilot study was to determine whether the primary and secondary outcomes for a proposed full trial could be measured for all the participants. This pilot study was not powered to detect significant differences in these measures but was able to describe observed changes between time points and their direction. Thus, the secondary outcomes of this study were pain intensity and function measured at baseline and postintervention (8 weeks) and adverse events measured during the intervention period.

1. Pain intensity was measured using the Numeric Pain Rating Scale [25], a numerical scale where 0 indicates no pain and 10 indicates the worst possible pain.
2. Function was measured with the Patient-Specific Functional Scale [25], a self-reported scale specific for the measurement of functionality, where the patients nominate up to 3 activities relevant to them and rate their ability to perform each activity on a 0 to 10 scale, with 0 representing the inability to perform that activity and 10 the total capacity to perform the activity. The sum total of the values for the 3 activities will be considered the final score on a 0 to 30 scale.
3. Adverse events: number and percentage of participants experiencing any adverse events during the intervention period (eg, exacerbation of symptoms).

Random Allocation

The random allocation sequence was generated using computer software with a 50% chance of allocation for each of the groups. After the initial screening and baseline outcome assessment, patients were given a login and password to access the study site. As soon as the participant entered the site for the first time, they were randomly allocated to one of the 2 study groups.

Blinding

The outcome assessor was blinded to the treatment groups. Owing to the nature of the interventions, it was not possible to blind the patients or the therapists.

Interventions

Intervention Group: Internet-Based Pain Education and Exercise Program

The patients allocated to the intervention group received a login and password for individual access to the website developed for the study [28]. The content of this intervention included videos and animations based on pain education, promotion of

physical activity, and general exercises. The pain education component was based on the e-pain intervention developed by Reis et al [12], which had 9 main features: (1) acceptance, (2 and 3) pain education, (4) sleep hygiene, (5) recognition of stress and negative emotions, (6) increased positive coping in lifestyle, (7) exercise, (8) communication, and (9) prevention. The exercise program was created by professional physiotherapists with at least 5 years of clinical experience, who are specialists in the treatment of chronic pain and who used exercise-based treatment. After its elaboration, it was submitted to a round of suggestions and adjustments to the program by a panel of experts. After this round of suggestions, the exercise component was sent by email to a group of experts who are references in the treatment of chronic pain in São Paulo, Brazil. After the last round of suggestions and corrections, the exercise program was modified to be simple and assertive for the population studied. The exercise component included general exercises with the aim of improving strength, flexibility, control, and coordination.

The total duration of the intervention was 8 weeks. There was new content every week of the intervention, and the patients were instructed to perform the video exercises at least 3 times a week and watch the videos as necessary. Patients in this group also received weekly text messages and a health coach over the phone. The text messages included information on the benefits of exercise and motivational and positive messages on how to deal with pain. The health coaching sessions were conducted once a week until the end of the intervention (8 weeks) by a physiotherapist with 5 years of experience and prior training for the coach's performance. The goal of the health coach component is to keep patients motivated to continue with the program. This included encouragement, motivation, coping, revision of instructions and, if necessary, adaptation of the content of the intervention. For example, if a patient felt some discomfort when doing an exercise, the coach slightly modified the exercise (eg, dose, range of motion).

Control Group: Web-Based Self-management Booklet

Patients allocated to the control group had access to a web-based booklet containing general information on self-management of chronic pain, including pain education, advice on healthy lifestyle and sleeping habits, and promotion of physical activity. They also received a call in week 4 and motivational text messages once a week during the study period.

Statistical Methods

Calculation of the Sample Size

For the pilot study, we determined a value of at least 40% of the total sample size of the main study. Our sample size calculation determines that a minimum of 160 individuals would be required for the main study analysis; therefore, at least 64 patients were necessary for the pilot phase.

Data Analysis

The normality of the data was tested by visual inspection of the histograms. The baseline characteristics of the participants were analyzed using descriptive statistics and summarized in a descriptive table. We consider the system's usability greater

than 53 points on a scale from 0 to 100 to be satisfactory in at least 70% of the responses observed. Primary and secondary outcomes were presented descriptively with means and standard deviations or number of participants and percentages for each group. Results were all presented in descriptive tables.

Results

Participant Characteristics

A total of 65 participants were recruited between February 2020 and June 2020. Of these, 64 was randomized in the study. One

participant was not randomized due to contraindication to exercise. A total of 31 participants were randomized to the intervention group and 33 participants to the control group (Figure 1). The participants were mostly women (43/64, 67%), with a mean age of 39.5 (SD 11.3) years, mean pain intensity of 6.3 (SD 1.6) points, and a median duration of symptoms of 36 (IQR 11-90) months. For the location of pain characteristics, patients were able to name more than one pain site. There was no difference between the groups at the baseline. A summary of the characteristics of the participants is shown in Table 1.

Figure 1. Flow diagram of recruitment. PAR-Q: Physical Activity Readiness Questionnaire.

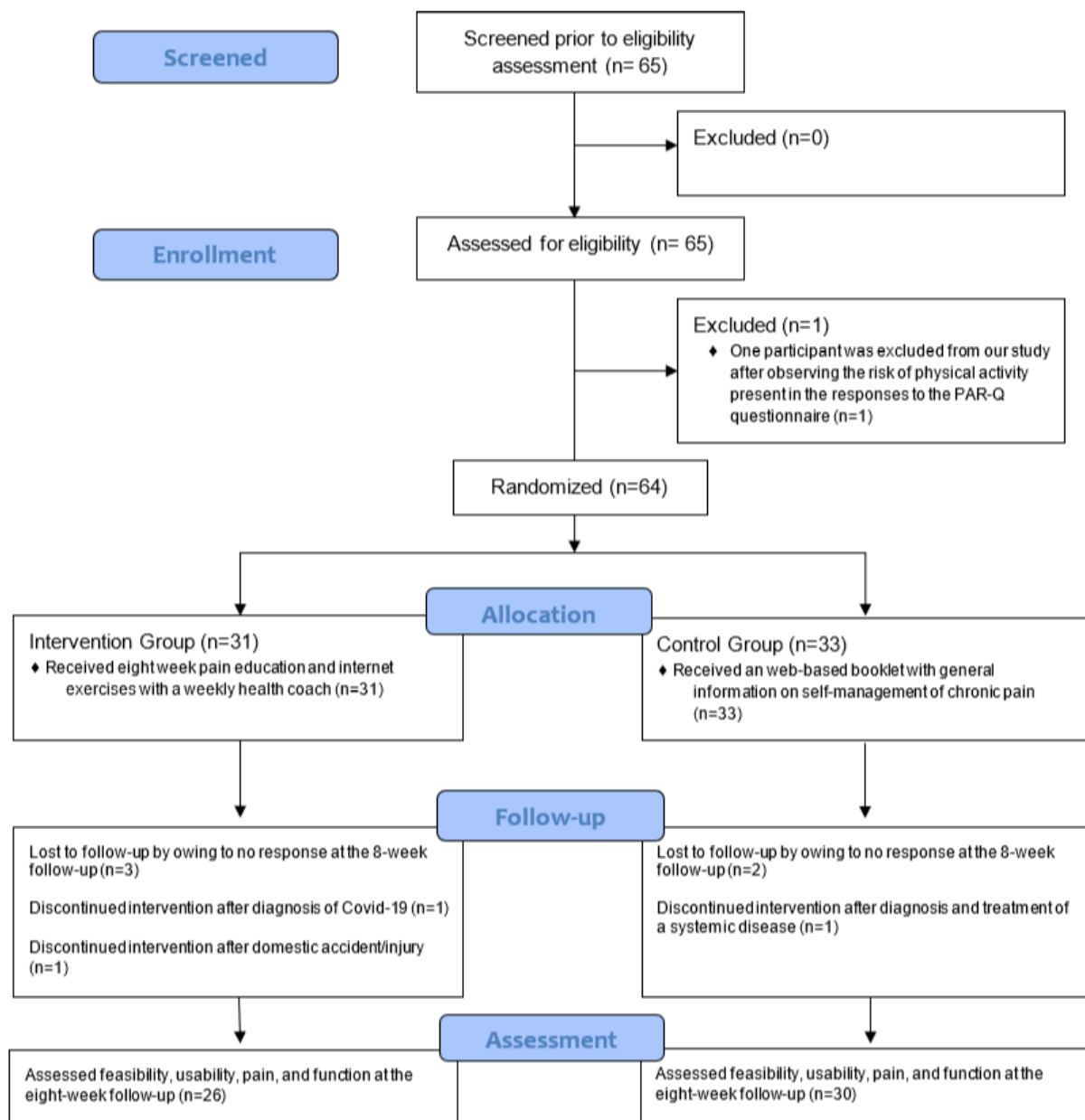


Table 1. Baseline characteristics of the participants (N=64).

Characteristics	Intervention group (n=31)	Control group (n=33)
Age (years), mean (SD)	40.2 (11.6)	38.8 (10.9)
Weight (kg), mean (SD)	77.1 (15.1)	76.6 (17.8)
Height (cm), mean (SD)	169.4 (8.6)	166.4 (7.1)
Sex, n (%)		
Male	12 (39)	9 (27)
Female	19 (61)	24 (73)
Location of pain, n (%)		
Low back	16 (52)	19 (58)
Cervical	5 (16)	8 (24)
Dorsal	4 (13)	3 (9)
Knee	9 (29)	8 (24)
Shoulder	7 (23)	7 (21)
Hip	5 (16)	7 (21)
Ankle	2 (6)	4 (12)
Elbow	2 (6)	3 (9)
Hand/wrist	1 (3)	3 (9)
Nonrespondent	4 (13)	7 (21)
Education status, n (%)		
Primary education	4 (13)	0 (0)
Secondary education	8 (26)	11 (33)
Undergraduate	19 (61)	22 (67)
Physically active, n (%)	15 (48)	18 (55)
Type of physical activity, n (%)		
Walking	3 (10)	4 (12)
Strength exercises (gym)	9 (29)	9 (27)
Stretching exercises	0 (0)	2 (6)
Aerobics	1 (3)	1 (3)
Running	1 (3)	1 (3)
Functional training	1 (3)	0 (0)
Pilates	1 (3)	2 (6)
Dancing/ballet	3 (10)	4 (12)
Cycling	0 (0)	1 (3)
Football	2 (6)	2 (6)
Swimming/hydro	1 (3)	1 (3)
Volleyball	1 (3)	0 (0)
Yoga	0 (0)	1 (3)
Medication use, n (%)	13 (42)	14 (42)
Type of medication, n (%)		
Anti-inflammatory	4 (13)	6 (18)
Analgesic	8 (26)	9 (27)
Opioids	4 (13)	3 (9)
Anticonvulsant	1 (3)	1 (3)

Characteristics	Intervention group (n=31)	Control group (n=33)
Antidepressant	1 (3)	2 (6)
Pain duration (months), median (IQR)	36 (10-60)	36 (12-120)
Pain intensity (0-10), mean (SD)	6.0 (1.7)	6.5 (1.4)
Function (0-30), mean (SD)	18 (6.5)	17 (6.3)

Adherence to the Trial Protocol

A total of 56 responses were obtained after the 8-week period of initiation of treatment in our study: 26 in the telerehabilitation group and 30 in the control group. Eight patients dropped out from the study because they did not answer our questionnaires on the correct date of follow-ups. For this pilot study, answers to questionnaires sent after the follow-up deadline were disregarded in order to calculate the possible sample loss. Adherence to the 8-week program (telerehabilitation group) was high, with a mean of 7.2 (SD 1.4) intervention weeks accessed by the patients on the program website. The weekly health coaching was successful in 92% (24/26) of the patients.

Program Fit

All patients in the telerehabilitation group showed acceptable responses with satisfactory scores in all the responses for AIM, IAM, and FIM. Patients in the intervention group showed responses with a mean of 4.5 (SD 0.6) points for AIM, 4.5 (SD 0.5) points for IAM, and 4.5 (SD 0.6) points for FIM. For patients in the control group, satisfactory scores were found in 95% (114/120) of the responses for AIM, 95.8% (115/120) of the responses for IAM, and 99.2% (119/120) of the responses for FIM. Patients in the control group showed responses with a mean of 4.1 (SD 0.9) points for AIM, 4.1 (SD 0.8) points for IAM, and 4.3 (SD 0.6) points for FIM (Table 2).

Table 2. Description of the implementation outcomes of acceptability, appropriateness, feasibility, and usability.

Measures	Intervention group (n=26)	Control group (n=30)
Acceptability of Intervention Measure, mean (SD)		
I approve the ReabilitaDOR program	4.68 (0.6)	4.3 (0.7)
ReabilitaDOR program is appealing to me	4.36 (0.7)	3.86 (1.0)
I like the ReabilitaDOR program	4.48 (0.6)	4.2 (0.8)
I welcome the ReabilitaDOR program	4.48 (0.7)	4.23 (0.8)
Total score	4.5 (0.6)	4.1 (0.9)
Intervention Appropriateness Measure, mean (SD)		
ReabilitaDOR program seems fitting	4.56 (0.5)	4.23 (0.8)
ReabilitaDOR program seems suitable	4.52 (0.5)	4.2 (0.8)
ReabilitaDOR program seems applicable	4.48 (0.5)	4.2 (0.7)
ReabilitaDOR program seems like a good match	4.6 (0.5)	4.13 (0.8)
Total score	4.5 (0.5)	4.1 (0.8)
Feasibility of Intervention Measure, mean (SD)		
ReabilitaDOR program seems implementable	4.62 (0.6)	4.26 (0.6)
ReabilitaDOR program seems possible	4.72 (0.5)	4.26 (0.7)
ReabilitaDOR program seems doable	4.56 (0.6)	4.33 (0.5)
ReabilitaDOR program seems easy to use	4.48 (0.7)	4.33 (0.6)
Total score	4.5 (0.7)	4.3 (0.6)
System Usability Scale		
Worst imaginable (0-20.5), n (%)	0 (0)	1 (3)
Poor (21-38.5), n (%)	0 (0)	0 (0)
Average (39-52.5), n (%)	0 (0)	2 (7)
Good (53-73.5), n (%)	3 (12)	12 (40)
Excellent (74-85.5), n (%)	7 (27)	11 (37)
Best imaginable (86-100), n (%)	16 (62)	4 (13)
Total score, mean (SD)	87 (10.7)	70 (17.9)

System Usability

All patients in the intervention group showed satisfactory responses to the usability outcome, with 16 patients responding as “best imaginable,” 7 responding as “excellent,” and 3 responding as “good” for all system features. The total mean score for usability in the intervention group was 87 (SD 10.7) points, classifying the usability by this group as “best imaginable.” In the control group, we observed 4 patients responding as “best imaginable,” 11 responding as “excellent,” 12 as “good,” 2 as “average,” and 1 responding as “worst imaginable.” The total mean score for usability in the control group was 70 (SD 17.9) points, classifying the usability by this group as “good” (Table 2).

Societal Costs

A total of 55 responses were obtained from the cost diaries in the 8-week assessment. One patient in the control group did not respond to the cost diary; thus, the costs of this patient were not analyzed. The cost diaries of 29 patients in the control group and 26 patients in the intervention group during the 8-week

period were analyzed. The intervention costs were US \$210.60 per patient in the intervention group and US \$20.62 per patient in the control group. The health care costs related to the private costs were US \$54.17 per patient in the intervention group and US \$107.23 per patient in the control group. For the public health system costs, we did not observe any cost in the intervention group, but we observed an expenditure of US \$2.75 per patient in the control group. For the health insurance costs, we observed an expenditure of US \$8.53 per patient in the intervention group and US \$6.63 per patient in the control group. The total sum of individual private costs of the 2 groups presented an expenditure of US \$62.73 per patient in the intervention group and US \$116.63 in the control group. Regarding the transportation used by patients, the intervention group used 72 fares, totaling an expenditure of US \$5.07 per patient. The control group used 68 fares, totaling an expenditure of US \$4.29 per patient. The lost productivity costs for the intervention group were 3.3 hours per patient, totaling an expenditure of US \$64.63 per patient and those for the control group were 15.5 hours per patient, totaling an expenditure of US \$217.30 per patient. All cost values are shown in Table 3.

Table 3. Description of costs at 8-week follow-up.^a

Costs	Intervention group (n=26)	Control group (n=29)
Intervention costs	\$210.60	\$20.62
Health care costs		
Private costs	\$54.10	\$107.23
Public costs	\$0	\$2.75
Health insurance costs	\$8.53	\$6.63
Total health care costs	\$62.63	\$116.61
Patient costs		
Transport	\$5.07	\$4.29
Absence from work		
Hours not worked	\$64.63	\$217.30
Total societal costs	\$342.93	\$358.82

^aAll costs are estimated in USD per patient.

Feasibility of the Main Trial

The feasibility of the main trial was confirmed with regard to our prespecified criteria. A total of 98% (64/65) of the patients who were initially evaluated to enter the study were able to randomize and participate in the trials. A total of 20 patients (77%) of the 26 patients in the intervention group finished the 8-week program, 2 patients (8%) reached at least 6 weeks of the program, 2 patients (8%) reached 5 weeks of treatment, and 2 patients (8%) did not reach half of the treatment.

Pain Intensity and Function

Both groups reported a decrease in pain intensity and improvement in function after 8 weeks. For the intervention

group, we observed a mean of 6 (SD 1.8) points for pain intensity at the baseline and a mean of 3.4 (SD 2.4) points at the 8-week follow-up. In the control group, we observed a mean of 6.5 (SD 1.5) points for pain intensity at the baseline and a mean of 5.6 (SD 1.9) points at the 8-week follow-up. For function, in the intervention group, we observed a mean of 18 (SD 6.7) points at the baseline and a mean of 23 (SD 6.3) points at the 8-week follow-up. In the control group, we observed a mean of 17 (SD 6.4) points at the baseline and a mean of 20 (SD 5.5) points at the 8-week follow-up. No statistical inferential tests were conducted, as this was not the purpose of this pilot study. The means of pain intensity and function are shown in Table 4.

Table 4. Description of the secondary outcomes (pain intensity and function).

Outcome	Baseline		8-week follow-up	
	Intervention group (n=26)	Control group (n=30)	Intervention group (n=26)	Control group (n=30)
Pain intensity, mean (SD) ^a	6.0 (1.8)	6.5 (1.5)	3.4 (2.4)	5.6 (1.9)
Function, mean (SD) ^b	18 (6.7)	17 (6.4)	23 (6.3)	20 (5.5)

^aPain intensity is measured on a 0-10 scale; lower values mean less pain.

^bFunction is measured on a 0-30 scale; higher values mean greater function.

Adverse Effects

No serious adverse effects were observed in carrying out the proposed interventions related to our study. One patient in the intervention group reported having been diagnosed with COVID-19 during the study. The same patient did not answer the posttreatment questionnaire. A patient in the intervention group reported a foot injury, resulting from the fall of a heavy object during a domestic task.

Discussion

We found that the ReabilitaDOR program is feasible, appropriate, and acceptable from the users' implementation perspective. This system has been considered usable by all the participants, and the main trial seems feasible. Costs and clinical outcomes were viable to be collected, the program was unlikely to cause harm, and no adverse events were reported during the intervention period. We had a low loss with follow-up and good levels of adherence and engagement with the health coach. The results of this study can demonstrate the feasibility of the main cost-effectiveness trial without major changes to the program.

Over the last few decades and in the past years of the COVID-19 pandemic, we have observed an increase in studies involving telerehabilitation platforms for patients with chronic pain [17]. However, it is important to emphasize that the intervention implementation processes are dependent on the context, cultural diversity, and characteristics of the population [37,38]. Thus, this study is innovative and novel because it included a population that was never been exposed to telerehabilitation before. Brazil incorporated the first regulation on telehealth in March 2020 after the social isolation policies imposed by the COVID-19 pandemic. These results may pave the way for new initiatives involving telehealth in low- and middle-income countries, since previous studies with this proposal were predominantly carried out in high-income countries [39].

The observation of results in low- and middle-income countries is necessary and meets the needs of care and equity provided by the World Health Organization [14,39]. To reach that, it is extremely important to design studies that prioritize the analysis of outcomes that are related to the implementation process [23,40]. Implementation science can help reduce the actual implementation time of interventions and provide many benefits to science and clinical practice. Thus, the writing of this study followed the recommendations of the CONSORT statement for feasibility and pilot studies [41] and is based on a concrete proposal on how to use implementation science and design studies with this objective, thereby being a differential among

several pilot studies [20,42]. Although we were unable to carry out an intervention mapping process, we followed the observation of the outcomes such as acceptability, adoption, appropriateness, feasibility, program fidelity, and costs [23,40,43].

The future implications of the results observed in this study are toward a better understanding of the processes of use of telerehabilitation in countries that do not have a regulation for its use or have a recent regulation. Our study explores the results of a sample that has never been exposed with the type of intervention that was performed, being extremely important for the real visualization of the implementation outcomes in populations that would benefit from telerehabilitation but for whatever reason did not have this experience. In addition to the clinical implications, this study aims to test the feasibility of the main study, which will provide specific data on the effectiveness and cost-effectiveness of the tested program. Conducting a pilot study with a representative sample can provide insights into the future implementation and feasibility results [44] and should be encouraged, as many pilot studies do not demonstrate outcomes inherent to their role [42].

Our study has some limitations that may be important for the general interpretation of the results. The 3 implementation outcomes tested were initially proposed to measure the acceptability, adoption, and feasibility of clinicians and stakeholders in implementing evidence-based practices [29]. In our study, implementation outcomes were not collected from the stakeholders' perspective; instead, we approached the patients directly. We believe this is also important because asynchronous telerehabilitation strategies are dependent on patients' adherence, acceptance, appropriateness, usability of the system, and willingness to navigate the platform [23,40]. Our research group is also investigating users' barriers and facilitators through qualitative methodologies within the main clinical trial. The arrival of SARS-CoV-19 in Brazil and the declaration of a pandemic by the World Health Organization brought the emergency need for measures to contain the disease, which included social distancing and quarantine [45]. In the period in which we began to recruit patients on the waiting lists of physiotherapy clinics, we faced a drastic decrease in the search for physiotherapy and health care services [46]. Thus, recruitment was carried out primarily through social media, giving the profile of our sample a specific characteristic of patients who already used the internet.

In conclusion, we found that the ReabilitaDOR program is feasible, appropriate, and acceptable from the users' implementation perspective. This system has been considered

usable by all the participants, and the main trial seems feasible. Cost data were viable to be collected and the program is unlikely to cause harm, as no adverse events were reported during the intervention period. Both groups reported being overall satisfied with the platform and the proposed program content.

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Conflicts of Interest

None declared.

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Abbreviations

AIM: Acceptability of Intervention Measure

FIM: Feasibility of Intervention Measure

IAM: Intervention Appropriateness Measure

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Original Paper

Communications Through Contemporary Tools of Information and Communication Technology: Cross-sectional Study Evaluating Health Among Separated Family Members

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Abstract

Background: The number of single-living workers separated from their spouses and families has been increasing due to the need to create a balance between life and work. Workers are assigned everywhere in globalized workplaces while also caring for their family members in the context of Japan's aging society. At the same time, the mental and health status of persons living separately from their families is a matter of concern. The development of interpersonal communication means using information and communications technology (ICT) tools and the internet is remarkable, enabling simultaneous 2-way communication across distances and national borders. The easy accessibility to simultaneous communication is expected to improve the psychosocial status of isolated family members.

Objective: This study aims to clarify the health benefits of ICT by using a psychosocial health assessment, the characteristics of ICT tools, and the frequency of communication among the workers and their families who live separately.

Methods: This was a cross-sectional study planned and conducted in Japan. Study participants, including adults who live separately from other family members or have separately living family members due to work, were recruited to answer a web response survey about ICT usage status, health status, and life and society evaluation. This study recruited 73 participants divided into 2 groups by their communication tools and frequencies, and their separated life, health, and psychosocial status were statistically compared.

Results: Among the 73 study participants, 15 were categorized in the high communication-skilled (HCS) group that used both types of ICT tools to communicate frequently: "live," such as video chat and voice call, and "nonlive," such as SMS text message service and email. A simple comparison between the HCS and reference groups showed significant differences in the cohesion with the neighborhood ($P=.03$), perceived social position ($P=.01$), and happiness ($P<.001$); however, there were no significant differences in the health (psychological distress, $P=.08$; self-rated health, $P=.07$), lifestyle (drinking, $P>.99$; current smoking, $P=.37$), and dyadic trust in family members living separately ($P=.80$). Further, in a multivariate regression analysis adjusted for confounding factors, such as educational history, age, gender, and job status, poor subjective health showed a prevalence odds ratio of less than 1 (OR 0.17, 95% CI 0.03-1.02). The HCS group showed significant positive relationships in the cohesion score with the neighborhood ($P=.01$; $\beta=2.40$, 95% CI 0.56-4.24), perceived social position ($P=.03$; $\beta=1.17$, 95% CI 0.11-2.23), and happiness score ($P=.002$; $\beta=1.46$, 95% CI 0.58-2.34) in the same multivariate regression models.

Conclusions: This study suggested that people who frequently communicate with separated family members by taking advantage of various ICT tools can maintain a better mental state and better social relations among those who live alone and are separated from their families.

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KEYWORDS

family relations; interpersonal communication; internet use; smartphone; home environment; psychosocial functioning

Introduction

In Japanese working households, couples may have a period of living separately due to raising children or caring for parents at the opportunity of a job transfer of a family member. Most Japanese workers are employees, accounting for almost 89% of the workforce [1]. Given that the Japanese company organization adopts the membership system [2], there are many cases where they follow transfer orders by their company until they reach retirement age under lifetime employment [3]. Because Japanese companies have domestic and overseas branches and departments, employees usually experience several different workplaces every few years unless they change companies. Employees belong to the company's membership system; even if their company orders them to change their workplace, it is rare for them to leave their company because of that system. Therefore, if there are family circumstances, such as a child attending a competitive elite school or parents needing care, when workers are ordered to transfer, only the worker will leave and move to a different workplace alone. In Japan, where the birthrate is declining and the population is aging, children's education is an important concern for families [4]. At the same time, caring for aged parents is often managed by some family members with less manpower [5]. In addition, as the working-age population is relatively small, companies have to allocate a small number of employees to various places and suitable positions. The human resource department of Japanese companies usually transfers their employees from one job to another or from one branch to other branches rather than hiring new workers to allocate necessary jobs or branch. Because they are taking the membership employment system, hiring workers means to approve the person as a member. Therefore, such an approval process is fateful and serious, and the human resource department hesitate to make decisions easily. From the high economic growth era until today, many Japanese company organizations seem not to change the membership employment system [2].

The number of single-living workers separated from their spouses and families is increasing. Although it is difficult to determine the accurate number, it has been partially figured out by the government, for example, through the Comprehensive Survey of Living Conditions and the National Census. For instance, available information aggregates male spouses who are single households as single job-transferred workers based on these national statistics [6]. According to this information, there were 750,000 single-living married men in 2015 [6], equivalent to 2.4% of the households with couples. In addition, since 1997, the Ministry of Internal Affairs and Communications has begun reporting the number of female workers living alone,

although they have spouses in the Employment Status Survey. The number has also increased for women from 0.5% of female workers in 1997 to 1.2% in 2017 [7]. Thus, the percentage of single job-transferred workers for both men and women is not high in all households or workers, but it has steadily increased in the past 30 years.

The mental and health status of solitary members living apart from other family members has been a concern according to the increasing number of single job-transferred workers. Several studies on the health (in particular, mental health centered on psychological stress) of single job-transferred workers and their families were published between the 1980s and 2000s. In some studies, the health status of single job-transferred workers did not necessarily deteriorate because the age at the time of transfer, personal qualities (whether or not the transfer is positively considered), and significance of the transfer (whether or not it involves promotion) affected the situation. Therefore, the worsening effect of single job transfer on mental health did not necessarily occur in all cases [8,9]. In addition, a survey was conducted on couples in which one of them was assigned to work alone. An unpredictable life, such as not making a life plan due to an unknown assignment period, was a stress factor, although it depended on the spouses' age and the length of the assignment [8].

Recently, physical health has been also evaluated for single job-transferred workers compared with workers living with their families. With respect to their lifestyle habits, increased smoking and frequency of drinking were higher among those assigned to work alone, and many of them did not eat breakfast [10,11]. Studies have concluded that these were due to stress. The study also reported several symptoms, such as headaches, gastrointestinal disorders, and colds, among single job-transferred workers [10]. In addition, they had a higher prevalence of mental stress, such as irritation, anxiety, and depressive mood, than workers living with family [11]. Comparing the results of health checkups of single job-transferred workers with those of workers living with their families, cholesterol levels and other values were worse for the former [11].

Workers living alone and separated from their families tend to consult with their families about health problems rather than with their close colleagues and medical staff at the working place [10]. It is suggested that communication with their families is important for maintaining their health even when they are isolated physically from them. However, few studies have focused on the communication of single job-transferred workers. Therefore, it is meaningful to evaluate the state of communication as a factor that leads to a better state of life and health of an isolated person living away from the family.

The means of communication available to families living separately have increased dramatically since the 1990s when the official number was first estimated. The development of interpersonal communication means using information and communications technology (ICT) tools is remarkable. In particular, the free call service using the internet network enables simultaneous 2-way communication across distances and national borders. When video functions are added, it enables visual communication and sharing of information by nonverbal transactions. Messenger apps in smartphones, such as WhatsApp, Facebook Messenger, and WeChat, are popular and each has more than 1 billion active users [12]; additionally, these apps have regional characters. In East Asia, LINE is popular in Japan, Kakao Talk is famous in South Korea, and WeChat is used the most in China [13]. These free calling apps over the internet have hundreds of millions of users worldwide and contribute as a communication tool.

Under the background of developing ICT tools, communication means in Japan has also changed. The number of general users of free calling apps, a recent method, is increasing rapidly [14]. According to the Ministry of Internal Affairs and Communications' Communication Usage Trend Survey, the number of communications and communication hours via conventional telephones have decreased in recent years. By contrast, the number of email and social networking service (SNS) users has become more than half. It is reported that 3.8 billion people not only in Japan but also worldwide are using some kind of SNS tool today [15].

Considering communication to build interpersonal relationships, it can be said that the association between social support and health status has been known for a long time [16]. The number of people to talk to daily has been used to determine the effects of social support. The greater the number of individuals with whom one communicates, including those met face-to-face and those who communicate by email, telephone, and SNS, the higher one's self-reported health [17]. In addition, sharing life-related information among family members through various means increases the family's well-being [18]. In the case of spouses, increased sharing of information reduces the incidence of mental disorders in families living apart and improves their mental health [19]. It also positively affects family relationships based on affection and growth [20]. Regarding the level of sharing information, these studies evaluated the frequency of communication between families using internet-based applications (eg, Viber, Imo, and Facebook) and the number of messages sent by instant messaging as an index.

The types of ICT tools used for individual communication have been influenced by socioeconomic factors [18,21]. Nowadays, these tools are regarded as a means for maintaining and promoting health. Effective use of the internet is observed in older adults of higher socioeconomic status and in those who reported less depressive and anxiety symptoms [22]. In addition, increased access behavior to health information has been observed, as internet users are not in the lowest socioeconomic level [23]. In Japan, trials have been conducted by simultaneously sharing photographs [24] and using telemonitoring systems of television's operating state [25] to ensure a secure and safe feeling among family members living

separately. However, these are case reports of experiments among a few families, and psychological health has not been examined. In Japan, where the number of single job-transferred workers is increasing, the relationship between the physical and mental health of separated couples and their families and the usage and frequency of communication tools widely employed today is expected to be examined fully.

Currently, while numerous people are benefiting from ICT to obtain psychological support from remote family and friends, the health of those who live away from their families has not been fully evaluated in this context. Therefore, this study investigated the association between the communication via ICT and the emotional advantages among couples and families who temporarily choose to live separately because of work. This study aimed to clarify the health benefits of ICT by conducting a psychosocial health assessment as well as evaluating the characteristics of ICT tools and the frequency of communication.

Methods

Study Design

This was a cross-sectional study planned and conducted in Japan. Study participants were adults who live separately from families or have separately living family members due to work. Recruitment was conducted for 5 months from November 2019 to March 2020. The survey asked about ICT usage status, health status, and life and society. All answers were collected by the web response system and analyzed statistically.

Participants

The researchers approached their acquaintances to introduce the survey to their family, friends, and colleagues. Most acquaintances were also researchers, specialists, and businessmen working in universities, research institutes, and companies with many branches located both domestically and abroad. They had experienced living alone remotely from their family and were expected to know those temporarily separated for work reasons or who had such families. As the reason for living separately, work and family care were included but not for divorce, family troubles, or other reasons. University students were excluded because many of them were usually not expected to be responsible for the life of the rest of their family members, although many of them lived alone apart from their families.

Participants were recruited by the snowball sampling method. First, by meeting directly, sending email, or calling over the telephone, the researchers asked them to be the first introducer. The researchers then asked them to send a recruitment message to the mailing list of the Young Scientist Group of the Japan Epidemiological Association. If the potential participant accepted to be an introducer, the researchers asked him/her to introduce them to 1-3 acquaintances who met the inclusion criteria and send an email of the survey site link, a token key, and the research explanatory material. If a reader of the mailing list wanted to participate in the survey and was confirmed that he/she met the criteria of living separately, the researchers directly sent a similar email with the information of a link, a token, and a research explanatory material. If the first applicants

accepted the research conditions and participation in the survey, they anonymously started answering the questionnaire using the token key received. Once they finished answering the questions, a new token key and a message appeared, which asked them to send the token key to the family living separately from the first participants to allow them to participate in the survey. Finally, 73 participants were chosen to have given valid responses, and it included 12 family pairs living separately.

Survey Variables

The survey was conducted using a free and open-source online statistical survey web app, LimeSurvey [26], and responses were collected using an anonymous self-completed survey form. Separated family pairs were identified by the tokens distributed with the survey guide. Regarding the ICT usage status, the following items were suggested to understand the types of communication tools often used: “phone calls by cellphone and telephone,” “online free calls,” “video chat using the Internet,” “short text message on cellphones,” “group text chats like LINE, FB messenger, etc.,” and “e-mail” as well as the frequency of communication with each tool from the following options: “never use,” “once a month,” “few times a month,” “once a week,” “two or three times a week,” “four or five times a week,” and “almost every day.” The detailed questionnaire is presented in [Multimedia Appendix 1](#). In addition to the basic attributes, the researchers asked about their separated living status, such as the relationship status for participants, period of separation, time and cost required to meet, and frequency of meeting.

The outcome indicators for the evaluation of the communications were mental health; K6, a 6-item screening scale for psychological distress [27]; subjective self-rated health [28]; and lifestyle habits, such as drinking and smoking. Moreover, this study investigated trust with the family [29]; subjective happiness level [30]; perceived social position, as assessed by a social stratification ladder called the Cantril Ladder [31]; and cohesion with neighborhoods [32]. These validated indicators were selected to assess the psychosocial health status.

Statistical Analysis

First, a simple tabulation was presented about the basic attributes and separation status of the research participants. Furthermore, the communication tools were divided into 2 groups: “live,” which included voice and video options, such as phone call, internet free call, and video call; and “nonlive,” which included sending texts via email, group text chats such as LINE, and SMS text message. Communication frequency was calculated as the average score for each combination of the most frequently used tool and the next most frequently used tool. Participants with high-frequency scores, including both live and nonlive tools used as the first and second choices, were classified into the high communication-skilled (HCS) group and compared with the remaining participants, now treated as the reference group. For statistical comparison, the Student *t* test or the Wilcoxon rank-sum test was used for continuous variables depending on the observed data distributions. Similarly, the chi-square test or Fisher exact test was used for categorical variables. After making a simple comparison, the effects of HCS were estimated by adjusting the educational history, age,

gender, and having a job or not, which were thought to be confounded by a multivariate regression model. For the statistical estimation of the effects of HCS on psychological health-related outcomes, logistic regression was used for dependent variables with a binary value of 0 or 1, and ordinary least-squares linear regression was used for continuous dependent variables. The significance level (*P* value) of all statistics was 5%, and analysis was performed using Stata version 16 (StataCorp, Inc.).

Ethics Approval

The Kyushu University Medical District Institutional Review Board for Clinical Research approved the protocol of this verification study in 2018 (approval no. 30-335). The main study has also been approved for implementation.

Results

Among the study participants who agreed to join the survey, 73 completed the questionnaire, including 61 family pairs consisting of couples or parent-child relationships. Their basic demographic characteristics and the status of separate living are summarized in [Table 1](#). Mobility data on returning home to meet the family differed according to distance, and these were summarized based on the difference between domestic and international travels. A total of 53 pairs lived separately in the same country, 7 pairs were separated internationally, and 1 pair did not provide their residence status.

[Figure 1](#) shows the types of ICT tools used in family communication and the communication frequency among family members. ICT tools were divided into 2 types of systems: live and nonlive. Phone calls were the most frequently used option by study participants for family communication among the live-type systems. Among nonlive-type systems, most used email every day.

The study participants were summarized for each combination of the most frequently used and the second most frequently used tool for family communication. The average value of the scores of communication frequencies for each combination and the number of participants are shown in [Table 2](#). The combination tools that had the highest average score for frequency of use of the combined tools (ie, both live and nonlive systems) were (1) phone calls and SMS text messages (score 16.3 + 6.4; n=9), video calls and group messages (15.5 + 4.6; n=6), or video calls and SMS text messages (score 14; n=1). The 15 people included in these combinations were chosen as the HCS group. We then compared the health and psychosocial states of the HCS group with the rest of the participants, who were considered the reference group.

[Tables 3](#) and [4](#) list and compare the attributes of the HCS and reference groups. The HCS group included more graduates (15/16, 94%) than the reference group (29/57, 51%). However, there were no statistically significant differences in other attributes, such as age (*P*=.37), gender ratio (*P*=.94), engaged in a job (*P*=.58), or living status (*P*=.70). In addition, there was no difference in the status of separation between the HCS and reference groups on the frequency of actual meeting with the separated family, the travel time, and the cost.

A simple comparison was conducted with the reference group regarding health status, lifestyle, and evaluation of life and surroundings in the HCS group (Table 5). No significant differences were observed in health (psychological distress, $P=.08$; self-rated health, $P=.07$) or lifestyle (drinking, $P>.99$; current smoking, $P=.37$). The HCS group also showed no

statistical difference in dyadic trust in family members living separately with that of the control group regarding interpersonal relationships ($P=.80$). However, the HCS group had higher scores of neighborhood social cohesion ($P=.03$), perceived higher social positions ($P=.01$), and higher level of happiness ($P<.001$) than the reference group.

Table 1. Basic characteristics of the study participants (n=73).

Characteristics	Value
Age (years), mean (SD)	45.5 (10.1)
Gender (female), n (%)	45 (62)
Education (graduate school), n (%)	44 (60)
Job (yes), n (%)	68 (93)
Living status (living alone), n (%)	53 (73)
Resident area (domestic), n (%)	69 (95)
Familial relationship (n=61)^a, n (%)	
Spouse	54 (89)
Parent-child	7 (11)
Separation period, median (range)	1.7 years (1 month-12.7 years)
Return home to meet the family	
Once and more per month (yes), n (%)	
Domestic (n=54)	32 (59)
Foreign (n=7)	1 (14)
Travel time (hours), median (25%-75%)	
Domestic (n=54)	4 (3-6)
Foreign (n=7)	15 (10-20)
Travel fee (US \$)^b, median (25%-75%)	
Domestic (n=54)	136 (91-273)
Foreign (n=7)	909 (545-1182)

^aNot both of the paired family members are responding.

^bMost of the respondents answered in yen, which was converted to US \$ (US \$1=¥110).

Figure 1. Types and frequencies of communication tools used between separated families (n=73; multiple choices for tool types).

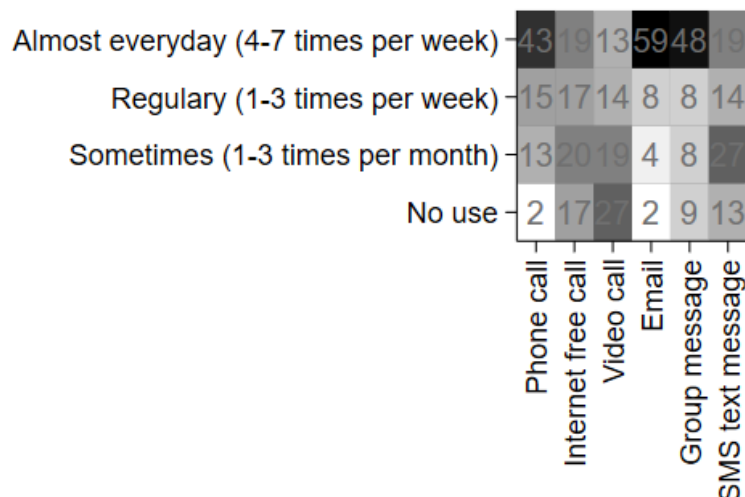


Table 2. Communication frequency score by the combination^a of the first and second most used tools in family^b.

Communication tool	Phone call, n; mean (SD)	Free internet call, n; mean (SD)	Video call, n; mean (SD)	Email, n; mean (SD)	SMS text message, n; mean (SD)
Group message ^c	17; 10.2 (3.7)	11; 10.9 (3.0)	<i>6; 15.5 (4.6)</i>	4; 11.5 (3.7)	3; 16.0 (5.6)
SMS	<i>9; 16.3 (6.4)</i>	1; 6 (0)	<i>1; 14 (0)</i>	1; 10 (0)	N/A ^d
Email	6; 9.7 (3.0)	N/A	N/A	N/A	N/A
Video call	5; 18.4 (4.7)	4; 11.50 (6.14)	N/A	N/A	N/A
Free internet call	5; 12.4 (3.7)	N/A	N/A	N/A	N/A

^aThe combination tool including both “live” types (voice and video) and “nonlive” types (text).

^bItalicized numbers in each cell indicate that the mean scores for communication frequency are relatively higher than others concerning the combination of both types of ICT tools.

^cGroup message means group-based text chat using Facebook messenger, Skype, and LINE, among others.

^dN/A: not applicable.

Table 3. Comparison of the basic characteristics between the high communication skilled group and the reference group.

Characteristics	High communication skilled (n=16)	Reference (n=57)	<i>P</i> value
Age (years), mean (SD)	47.7 (10.1)	44.9 (11.2)	.37 ^a
Gender (female), n (%)	10 (63)	35 (61)	.94 ^b
Education (graduate school), n (%)	15 (94)	29 (51)	.002 ^c
Job (yes), n (%)	16 (100)	52 (91)	.58 ^c
Living status (living alone), n (%)	5 (31)	15 (26)	.70 ^b
Resident area (domestic), n (%)	15 (94)	54 (95)	>.99 ^c

^a*P* value was calculated using the Student *t* test for continuous variables assumed to be a normal distribution.

^b*P* value was calculated using the chi-square test for categorical variables; the sample is large enough (>5 [observed number in the sample] in matrix cell).

^c*P* value was calculated using the Fisher exact test for categorical variables; the sample was not large enough (<5 [observed number in the sample] in any matrix cell).

Table 4. Comparison of the characteristics between the pairs in the high communication skilled group and the pairs in the reference group.

Characteristics	High communication skilled pairs (n=13)	Reference pairs (n=48)	P value
Familial relationship			.95 ^a
Spouse, n (%)	13 (100)	41 (85)	
Parent-child, n (%)	0 (0)	7 (15)	
Separation period (years), median (range)	1.7 (0.7-3.7)	1.7 (1.3-2.7)	.33 ^b
Return home to meet family			
Once and more per month (“Yes”), n/N (%)			
Domestic (n=54)	7/12 (55)	25/42 (60)	.94 ^c
Foreign (n=7)	1/1 (100)	0/6 (0)	.14 ^b
Travel time (hours), median (25%-75%)			
Domestic (n=54)	4 (3.3-5.5)	4.5 (3-6)	.93 ^a
Foreign (n=7)	9 (—)	15.5 (12-20)	.29 ^a
Travel fee^d, median (25%-75%)			
Domestic (n=54)	159 (136-250)	136 (73-273)	.24
Foreign (n=7)	1091 (—)	773 (545-1182)	.86

^aP value calculated using the Wilcoxon rank-sum test for continuous variables assumed not to be a normal distribution.

^bP value was calculated using the Fisher exact test for categorical variables; the sample was not large enough (<5 [observed number in the sample] in matrix cell).

^cP value was calculated using the chi-square test for categorical variables; the sample is large enough (>5 [observed number in the sample] in matrix cell).

^dMost respondents answered in yen, which was converted to US \$ (US \$1=¥110).

Table 5. Simple comparison of health, lifestyle, and psychological evaluation with human relationships and life between the high communication skilled and reference groups.

Comparison items of health, lifestyle, and psychological evaluation to human relationships	High communication skilled (n=16)	Reference (n=57)	P value ^a
Psychological distress (“Bad” by K6 ^b), n (%)	2 (13)	21 (37)	.08
Self-rated health (“Bad” or “Not good”), n (%)	2 (13)	22 (39)	.07
Drinking (“≥20 g alcohol/day”), n (%)	3 (19)	10 (18)	>.99
Current smoking (“Yes”), n (%)	1 (6)	8 (14)	.37
Dyadic trust (scores), median (25%-75%)	48 (40-55)	48 (40-51)	.80
Neighborhood social cohesion (scores), median (25%-75%)	16 (16-20)	16 (14-17)	.03 ^c
Perceived social position (points), median (25%-75%)	7 (7-8)	7 (5-7)	.01 ^c
Life satisfaction (points) median (25%-75%)	8 (8-9)	7 (6-7)	<.001 ^c

^aP values by Wilcoxon rank-sum test for continuous variables and Fisher exact test for categorical variables.

^b“Bad” is defined by a cutoff point of 5 and more scores by the K6 to screen for psychological distress.

^cStatistically significant values are in italics.

One’s level of education, communication methods, and evaluation of life may be influenced by educational history. Therefore, a multivariate regression analysis adjusted for confounding factors, such as educational history, age, gender, and job status, was performed (Tables 6 and 7). As a result, poor subjective health showed a prevalence odds ratio of less than 1 (0.17, 95% CI 0.03-1.02), but psychological distress ($P=.09$), lifestyle (drinking, $P=.60$; current smoking, $P=.36$),

and dyadic trust with a family partner ($P=.93$) showed no significant association with those of the reference group, as was the case with the simple comparison. In the HCS group, the cohesion score with the neighborhood ($\beta=2.40$, 95% CI 0.56-4.24), perceived social position ($\beta=1.17$, 95% CI 0.11-2.23), and happiness level ($\beta=1.46$, 95% CI 0.58-2.34) were all higher.

Table 6. Results of multivariate regression of the association of health and lifestyles with the high communication–skilled group who used various types of information and communications technology tools for higher frequent communication with family.

Items of health and lifestyle	Prevalence odds ratio (95% CI)	<i>P</i> value	Adjusted ^a prevalence odds ratio (95% CI)	<i>P</i> value
Psychological distress (“Bad” by K6^b)				
Reference	1		1	
High communication skilled	0.24 (0.05-1.18)	.08	0.23 (0.04-1.23)	.09
Self-rated health (“Bad” or “Not good”)				
Reference	1		1	
High communication skilled	0.23 (0.05-1.10)	.07	0.17 (0.03-1.02)	.05
Drinking (“≥20 g alcohol/day”)				
Reference	1		1	
High communication skilled	1.08 (0.26-4.53)	.91	1.59 (0.29-8.69)	.60
Current smoking (“Yes”)				
Reference	1		1	
High communication skilled	0.41 (0.05-3.53)	.42	0.34 (0.03-3.49)	.36

^aAdjusted for level of education, age, gender, and employment.

^b“Bad” is defined by a cutoff point of 5 and more scores by the K6 to screen for psychological distress.

Table 7. Results of multivariate regression of the association of psychological status with the HCS group that used various types of ICT tools for higher frequent communication with family.

Items of psychological status	Correlation coefficient (β) (95% CI)	<i>P</i> value	Adjusted ^b β (95% CI)	<i>P</i> value
Dyadic trust (scores)				
Reference	0		0	
High communication skilled	-0.02 (-4.95 to -4.90)	.99	0.24 (-4.28 to 5.6)	.93
Neighborhood social cohesion (scores)				
Reference	0		0	
High communication skilled	2.04 (0.37 to 3.71)	.02	2.40 (0.56 to 4.24)	.01
Perceived social position (points)				
Reference	0		0	
High communication skilled	1.14 (0.17 to 2.09)	.02	1.17 (0.11 to 2.23)	.03
Life satisfaction (points)				
Reference	0		0	
High communication skilled	1.40 (0.60 to 2.19)	.001	1.46 (0.58 to 2.34)	.002

^aItalics indicates statistical significance for estimated values by regression analyses.

^bAdjusted for level of education, age, gender, and employment.

Discussion

Principal Findings

In this study, people who frequently communicated using ICT took more advantage of its characteristics even if they were separated from their families, experienced more social cohesion with their neighborhood, and exhibited a higher degree of social position and a higher level of happiness in their life than people who did not communicate frequently using various ICTs. There was no relationship between the variety and frequency of communication methods and the sense of trust in the other

family member living separately. In addition, as long as they communicate with each other with sufficient frequency by taking advantage of ICTs, separated persons from family maintained good health, although it was not statistically significant.

Separation, such as a single job transfer process without family, causes a great inconvenience in life, making the health condition worse. Therefore, single job-transferred workers have reported worse health than workers who move with family at job transfer [10,11]. However, this study could modify these findings. Our results show that a separated person who communicates more using various ICT tools may have a useful skill in maintaining

good mental health. The study design was different from previous studies, and people who were not separated were not evaluated as a reference group in this study. However, good psychosocial effects were achieved by taking advantage of ICT tools and having enough frequency of communication, which can be useful for mitigating the inconvenience and stress in the life of single job-transferred workers in the future. Preferably, to identify the effective intervention methods necessary to improve the quality of life of separated families, additional studies are needed to evaluate the relationship between the state of detailed communication and the sociopsychological health status of both individuals separated and not separated.

It would be meaningful to evaluate the psychological health status of separated families considering their current infrastructure background, as ICT tools are now highly developed and the mobility of traffic movement has become increasingly flexible. In Japan, family members often separate temporarily for job reasons, and single job transfers were introduced by many Japanese companies during the period of high economic growth starting in the 1960s and 1970s and have been widely accepted among families. According to Japan's public employment statistics, a survey on the number of households having a worker of single job transfer began in 1981. Since then, several evaluations have been conducted, focusing on the stress status of family members, the roles of parents, and the development of children [8]. Recent studies have also revealed that single-living workers separated from their families have poor lifestyles, poor psychological conditions, and poor medical examination results [10,11]. However, new communication devices, such as smartphones and tablets, are expected to significantly enhance the effects of communications using the internet, which were introduced after 2009 and have developed continuously. When using a smartphone, there were a few technical difficulties, such as the need for other devices and systems, at the time of its introduction. The communication cost is relatively low because the existing internet network can be used. In addition to texts, it is possible to communicate with a large amount of information, such as images and videos, so it has become possible to evaluate psychological health conditions considering the relationship of health conditions with both quality and quantity of communication methods. In Japan, the ownership rate of different information and telecommunications devices indicated that smartphones were the most common, accounting for up to 83.4% in 2019 [14].

Previous studies have already pointed out that the psychological state of single job-transferred workers may be improved by improving communication. It has been observed that when single-living employees have a health problem, more than half of them consult with a family member living far away rather than with colleagues or medical staff closer to them [10]. Thus, there is a possibility that sociopsychological indicators can be kept high by mastering and using diversified means of communication. As ICT is expected to continue to develop in the future, our results suggest evaluating the current transitional situation. In any case, as long as people learn and use ICT tools appropriately, the range of communication means will expand, eventually giving more merit.

Limitations

As this study used a cross-sectional design, causal relationship cannot be proven. The relationship between cause and effect was not evaluated, such as whether the sociopsychological utility, such as happiness level, has increased due to sufficient communication, or whether the communication has become active because separated individuals had an insufficient connection with the surroundings and a suitable level of perceived social position. A longitudinal research design in the near future can be adopted to monitor life evaluation changes and the physical and mental health status before and after the start of separation or during separation and after the end of the separation period together with the quality and quantity of communication.

In addition, because only few participants ($n=73$) were evaluated in this study, there is a possibility that participants' characteristics are biased. Looking at the attributes, it is possible that a large number of highly educated individuals with high socioeconomic status have gathered, so caution should be exercised when generalizing the results. Comparing single job-transferred employees with those living with family members, many single job-transferred employees held executive and managerial posts [11]. The annual incomes of these single job-transferred employees were usually higher than the average annual income of Japanese employees [8]. Therefore, participants in this study possibly had higher education and socioeconomic status than general people in households, including no single job-transferred members. In other words, highly educated people were likely to have family members living separately, so the results may apply to many households whose members live separately.

Moreover, this study used subjective health evaluation and did not use objective indicators, such as health checkup measurements, as in past studies. No statistically significant difference in the health indicators considered in this study might be attributed to the small number of participants, and the power was low. As we did not extract households, including single job-transferred workers, from a specific company or group, the diversity of evaluation targets was one of the strengths of the study when generalizing the findings. However, the small number of study participants threatened the reliability of research evaluation.

Conclusions

Despite the aforesaid research limitations, those who frequently communicate with separated family members by taking advantage of various ICT tools can maintain a better mental state and better social relations among those who live alone and are separated from their families. This study suggested that cohesion with the surroundings, subjective social position, and happiness level are higher among those who communicate better using various tools and more frequently than those who have less communication. It is expected that there will be increasing opportunities to go to a new location, workplace, or school alone away from the family in this contemporary society according to ICT development and the increasing frequency of mobility. Therefore, it would be useful to evaluate how to communicate

better to maintain a good mental state using technical aspects and frequency indicators in future studies.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Questionnaire for the ICT usage status.

[DOCX File, 15 KB - [formative_v6i8e34949_app1.docx](#)]

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Abbreviations

- HCS:** high communication skilled
ICT: information and communications technology
SNS: social networking service

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Original Paper

Utility and Acceptability of a Brief Type 2 Diabetes Visual Animation: Mixed Methods Feasibility Study

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Abstract

Background: Visualizations of illness and treatment processes are promising interventions for changing unhelpful perceptions and improving health outcomes. However, these are yet to be tested in patients with type 2 diabetes mellitus (T2DM).

Objective: This study assesses the cross-cultural acceptability and potential effectiveness of a brief visual animation of T2DM at changing unhelpful illness and treatment perceptions and self-efficacy among patients and family members in 2 countries, New Zealand and Saudi Arabia. Health care professionals' views on visualization are also explored.

Methods: A total of 52 participants (n=39, 75% patients and family members and n=13, 25% health care professionals) were shown a 7-minute T2DM visual animation. Patients and family members completed a questionnaire on illness and treatment perceptions and self-efficacy before and immediately after the intervention and completed semistructured interviews. Health care professionals completed written open-ended questions. Means and 95% CIs are reported to estimate potential effectiveness. Inductive thematic analysis was conducted on qualitative data.

Results: All participants rated the visual animation as acceptable and engaging. Four main themes were identified: animation-related factors, impact of the animation, animation as an effective format for delivering information, and management-related factors. Effect sizes (ranged from 0.10 to 0.56) suggested potential effectiveness for changing illness and treatment perceptions and self-efficacy among patients and family members.

Conclusions: Visualizations are acceptable and may improve the perceptions of patients' with diabetes in a short time frame. This brief visual animation has the potential to improve current T2DM education. A subsequent randomized controlled trial to investigate the effects on illness and treatment perceptions, adherence, glycemic control, and unplanned hospital admission is being prepared.

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KEYWORDS

illness perception; visualization; animation; intervention; mobile phone; type 2 diabetes mellitus

Introduction

Background

Type 2 diabetes mellitus (T2DM) is a metabolic condition characterized by high blood sugar levels owing to a loss of pancreatic beta cell function [1]. An estimated 463 million people had diabetes worldwide in 2019, and T2DM accounts for 90%-95% of all diabetes cases [2]. In New Zealand, 5.5% of people aged ≥ 15 years have diabetes [3]. Māori (indigenous New Zealanders) and Pacific groups are disproportionately affected by diabetes, with the latest report showing the prevalence rate of diabetes is 1.8 and 2.6 times higher in Māori and Pacific groups than non-Māori and non-Pacific groups [3]. In Saudi Arabia, the incidence rate of diabetes has substantially increased over the past 30 years, and the prevalence of diabetes was 18.3% in adults aged 20-79 years in 2019 [4].

T2DM requires ongoing self-management and lifestyle changes to achieve glycemic control and minimize the risk of complications [4]. Patients with T2DM are recommended to engage in a range of self-care behaviors, including taking medications as prescribed, following a healthy diet, and being physically active. Other self-care behaviors include blood glucose testing, foot care, smoking cessation, and attending clinic appointments [5].

However, research has shown that low adherence to diabetes self-care behaviors is common [6], and approximately 50% of patients with T2DM in New Zealand and Saudi Arabia do not reach glycemic control (HbA_{1c}) targets [7,8]. Ethnic disparities in T2DM management exist, where the Māori and Pacific groups are at greater risk of exhibiting lower adherence to metformin (first-line glucose-lowering oral medications; [6]), higher HbA_{1c} levels [9], and experiencing more diabetes-related complications compared with New Zealand European groups [8]. This is concerning because low adherence is associated with suboptimal glycemic control, increased medical cost, hospitalization, and mortality [10,11].

There is a growing awareness of the importance of psychosocial factors in the management of diabetes, as highlighted by recommendations to integrate psychosocial support into routine diabetes care [12]. Evidence-based psychological interventions for patients with diabetes include illness-perception interventions [13,14]. These interventions are based on the common sense model (CSM) [15,16], in which patients are active problem-solvers who use coping strategies based on their cognitive and emotional representations of illness. Research has demonstrated that these mental representations (known as illness perceptions) are associated with health outcomes [17-22]. The central dimensions include perceptions of the identity, timeline, causes, consequences, and control of illness.

Related to CSM is the necessity-concerns framework, which proposes that patients also have beliefs about medicine and that these beliefs influence adherence to treatment [23,24]. Patients who perceive medicine as necessary and have fewer concerns about its side effects are more likely to adhere to medication [24].

In diabetes, systematic reviews have established that patients' perceptions of personal control over their illness are associated with better glycemic control, whereas greater illness identity perceptions (attributing more symptoms to diabetes), greater consequences perceptions (perceiving diabetes to have severe consequences), higher emotional distress, and concern perceptions about diabetes were associated with suboptimal glycemic control [17,22]. Illness perceptions have also been linked to other outcomes in diabetes, including adherence to self-care behaviors [25], quality of life, and depressive and anxiety symptoms [26]. Similarly, evidence from reviews shows that higher necessity beliefs and fewer concerns about side effects were associated with higher adherence to medicines across studies [27,28].

Illness perceptions of family members can also influence patients' health behaviors, as many self-care behaviors in diabetes occur within patients' social contexts. Patients with chronic conditions tend to have better health outcomes when their perceptions align with those of their family members [29]. In diabetes research, mediation studies have shown that partners' perceptions can mediate the effects of patients' perceptions on adherence to self-care behaviors [30,31]. For example, a study with recently diagnosed patients with T2DM and their partners found that partners' personal control and treatment control perceptions fully mediated the effects of patients' perceptions on their adherence to blood glucose testing (mediation effects of 0.050 and 0.095, respectively). Partners' consequence perceptions also mediated the effects of patients' consequence perceptions on their adherence to exercise, foot care, and blood glucose testing, with mediation effects ranging from -0.052 to 0.062 [30]. This research highlights the importance of family members' perceptions of diabetes and the need to involve family members or significant others when designing interventions to improve patient health outcomes [32].

Research suggests that addressing unhelpful illnesses and treatment perceptions can result in better coping behaviors and improved health outcomes [29]. Interventions to change illness perceptions have shown promising results in patients with T2DM. For example, a family-based intervention resulted in improved understanding of T2DM, increased perceptions of personal and treatment control, fewer symptoms attributed to T2DM, and decreased concerns and emotional distress [14]. This intervention also improved adherence to diet, exercise, self-efficacy, well-being, and family support at 6-month follow-up [14]. Other similar interventions have resulted in improved adherence to self-care behaviors [13]. Although these interventions improve diabetes management and other psychological outcomes, they are time-consuming and are often conducted over multiple sessions. Owing to short medical consultations and constrained health budgets, illness perception interventions need to be more scalable to increase clinical utility [33]. The inclusion of visualization (eg, an animated pictorial explanation) of illness and its treatment could reduce delivery time.

Robust theoretical models (eg, cognitive theory of multimedia learning) and published empirical studies support the use of visuals to improve learning [34,35]. In health psychology research, visualizations have been shown to be an effective

medium to deliver information about illnesses and treatment processes, help explain abstract concepts, and show how treatment processes work inside the body [36]. Other benefits are that visualizations can be brief (eg, 10-15 minutes), improve visual appeal, do not require advanced training to deliver, and can be delivered in all settings (eg, in person or on the web; [33,37-39]). Research has shown that visualizations improve not only perceptions but also health behaviors [37,40]. For example, visual interventions with acute coronary syndrome, osteoporosis, HIV, and oncology patients have been shown to improve understanding and control perceptions in a short timeframe [33,38], increase adherence to antiretroviral therapy [41,42], increase exercise and improve return to normal activities [33], and improve postoperative mobility [43]. This research suggests that visualization can improve patients' perceptions and health-related behaviors in a number of conditions.

Objectives

Research on the effects of visualization on illness and treatment perceptions of T2DM is lacking. Therefore, this pilot study aimed to explore the cross-cultural acceptability of a brief visual animation of T2DM among patients and family members across 2 countries and collect feedback from health care professionals (HCPs) to highlight ways in which the visual animation could be improved. The study also assessed potential effects of the visual animation on illness and treatment perceptions and self-efficacy to inform a future trial on adherence to medication, diet and exercise behaviors, and health outcomes (eg, glycemic control and unplanned hospital admissions).

Methods

The authors followed the Standards for Reporting Qualitative Research [44] and CONSORT (Consolidated Standards of Reporting Trials) guidelines for pilot studies [45].

Design and Sample Size

This pilot study used a mixed methods design, involving pre-post assessment and semistructured interviews with patients with T2DM and family members across 2 countries (New Zealand and Saudi Arabia). This study also explored views about the visual animation among HCPs in New Zealand using open-ended questions. Given its exploratory nature, this study was not powered to detect statistical significance; however, it assessed potential effects on illness and treatment perceptions and self-efficacy by looking at changes in mean scores from before to after the intervention. The effect sizes were calculated from the means and SDs, which may be useful for a power calculation for a future trial. A previous study using visual animation found small effect sizes for illness identity perceptions and return to normal activities in patients with acute coronary syndrome [33], but effect sizes may differ in this population. To meet the study aims, we planned to recruit 32 patients (16 patients from each county) and as many family members as possible.

Participants

Primary participants were patients with T2DM. Patients were eligible to participate if they were aged ≥ 18 years, had a formal diagnosis of T2DM for ≥ 1 year, were prescribed diabetes

medications, lived in New Zealand (for the New Zealand participant group) or Saudi Arabia (for the Saudi Arabia participant group), and had access to the internet and a smartphone or computer. Eligible participants were encouraged to invite their family members to participate in the study. A family member was defined as a relative in regular contact with a person with T2DM. Participating family members had to be aged ≥ 18 years, living in New Zealand or Saudi Arabia, and with access to the internet and a smartphone or computer. Patients were allowed to participate by themselves if they did not want to invite a family member. Family members were also allowed to participate by themselves if they found it more convenient for them.

HCPs were consulted for feedback on the visual animation. In addition to working at an outpatient diabetes clinic, there were no other inclusion or exclusion criteria for this group. All participants were recruited between March and July 2021.

Brief Visual Animation of T2DM

The brief visual animation was developed by a multidisciplinary team including health psychologists, endocrinologists, and developers. The developmental process involved iterative feedback from the multidisciplinary team to refine the visual content. Māori and Pacific HCPs were consulted to ensure cultural appropriateness.

The visual animation is a 7-minute video that begins with introductory statements explaining the focus and purpose of the visual animation. The visual animation shows the production of glucose in the body after food consumption, glucose levels in the blood, and how glucose and insulin interact to allow glucose to enter body cells using the lock-and-key analogy. The visual animation then depicts what happens when patients have T2DM (eg, glucose cannot enter body cells because of inadequate insulin or insulin resistance, which leads to increased glucose levels in the blood). Symptoms and long-term complications associated with T2DM are visually depicted. The visual animation shows how treatment (with a particular focus on metformin, healthy eating, and regular exercise) can help control blood glucose levels. The visual animation concludes with an emphasis on the importance of family and significant others as a source of support and motivation. We developed 2 versions of the visual animation, one in English suited for the New Zealand context and one in Arabic suited for the Saudi context. Differences included the appearance and dress of the characters, food depicted, and pictures of the environment when the character was exercising outside (Figures S1-S11, [Multimedia Appendix 1](#)).

Procedure

Participants were recruited from an outpatient diabetes clinic at the Greenlane Clinical Centre in Auckland, New Zealand, a specialized diabetes clinic at a tertiary hospital in Riyadh, and Facebook diabetes support groups and community groups. Patients and their family members were approached in the waiting rooms by a student researcher (New Zealand sample) or a medical intern (Saudi sample) who introduced the study and invited them to participate. A study flyer was posted on community and diabetes support pages on Facebook outlining

brief information about the study and the research team contact details. Interested participants were provided with a link to the study on Qualtrics (web-based software for data collection; [46]).

On Qualtrics, participants confirmed their eligibility, viewed and downloaded participant information sheets, provided web-based consent, completed baseline questionnaires, and chose a time for the interview. At the beginning of each semistructured interview, participants were shown the brief visual animation either on web using Zoom software (New Zealand sample) or face-to-face at a clinic in an office room (Saudi sample). The participants then completed a web-based questionnaire immediately after the intervention. Participants were then interviewed, and only the participants and interviewers were present. All interviews were audio recorded and lasted for up to 60 minutes (Multimedia Appendix 2 provides the interview schedule). As a token of appreciation for their time, each participant in the New Zealand sample received a NZ \$50 (US \$31) voucher. The participants in the Saudi patient sample did not receive compensation.

The interviews were conducted by the first author (MA), a male PhD health psychology student originally from Saudi Arabia but studying or residing in New Zealand, and a female medical intern living in Riyadh, Saudi Arabia. The interviewers had no relationships with the participants before the commencement of the study.

HCPs working at an outpatient diabetes clinic at the Greenlane Clinical Centre in Auckland, New Zealand, were asked to provide feedback about the visual animation. The first author (MA) gave a presentation during the clinic staff meeting and showed the brief visual animation of T2DM. HCPs responded to 7 written open-ended questions related to the visual animation (Multimedia Appendix 2 provides the open-ended questions).

Measures

Patients with T2DM provided their age, sex, ethnicity, marital status, educational level, partnership status, employment status, type of prescribed diabetes medications, and duration of T2DM. Family members also provided information on age, sex, ethnicity, educational level, and relationship with the patient.

At baseline, patients' perceptions of T2DM were assessed using 4 items of the Brief Illness Perception Questionnaire (B-IPQ; [47]). The items included consequence, personal control, coherence, and concern perceptions. These 4 items were chosen as they have been consistently identified to be related to outcomes in diabetes (eg, glycemic control; [17,22], and perceptions of personal control and coherence are among the most frequently changed perceptions in trials using CSM in diabetes [32]. These perceptions were targeted in the intervention. These items were scored on a scale from 0 to 10, with higher scores indicating stronger perceptions. The B-IPQ has been previously used with Māori, Pacific, and Saudi patients with T2DM [48,49] and with family members [50]. The B-IPQ has demonstrated robust psychometric properties [17,47].

Patients' perceptions regarding the effectiveness of treatment (medication, healthy eating, and regular exercise) in controlling T2DM were assessed using 3 items adapted from previous

research ([25]; eg, *How much do you think your medication can help control your diabetes?*). Patients' confidence in managing their T2DM (self-efficacy) was evaluated using a single item (*How confident do you feel in managing your diabetes?*). These items were scored on a scale from 0 (not helpful or not confident at all) to 10 (extremely helpful or extremely confident). Patients' beliefs about the necessity of taking diabetes medications daily were assessed using a single yes or no question. Participants were asked to explain their answer as to whether they perceived it necessary to take diabetes medication every day.

Immediately after watching the visual animation, patients completed the same questionnaire administered at baseline. Participants further completed 3 yes or no questions related to their perceptions of T2DM (eg, *Did the animation make you think about [the potential consequences of your diabetes, [things you could do to help control your diabetes, and [your diabetes medication]?*). These questions were designed to assess whether the visual animation prompted the patients to actively think about their T2DM.

Family members completed similar questionnaires at baseline and immediately after viewing the visual animation; however, the questions were slightly modified to ask about their perceptions of their family members' T2DM (eg, *How much control do you feel your family member has over their diabetes?*).

Data Analysis

Qualitative Data

Interviews with Saudi patients were translated and transcribed into English by an independent researcher from Saudi Arabia who held a bachelor's degree in English literature. The transcriptions were then checked against the original recordings for accuracy by the first author (MA), who was fluent in Arabic and English. Interviews with patients from New Zealand and family members were transcribed by the first author (MA). Transcriptions were emailed to participants who wished to review their interview transcriptions and were instructed to return any comments within 2 weeks. All qualitative data from interviews and responses to open-ended questions provided by HCPs were coded and analyzed using an inductive thematic analysis approach [51]. Thematic analysis and coding were conducted independently by 2 researchers: the first author (MA) and a female health psychology researcher (ML) experienced in thematic analysis. Both researchers followed the 6 phases of thematic analysis [51].

First, data familiarization was achieved through manually transcribing, reading, and rereading the data. During this phase, a list of initial ideas regarding the data set was generated. Second, the entire data set was coded and each code was matched to the data extracts. Third, the generated codes were sorted and combined to form the initial themes and subthemes, and all relevant coded data extracts were collated within each initial theme and subtheme. All coded data extracts were reviewed to ensure coherence and meaningfulness. Themes were then further refined in relation to the entire data set to ensure that each theme was distinct. Themes and subthemes were assigned labels that captured their essence. Discussions

between the researchers ensued until a consensus was reached on the themes and the strongest quotes to support each theme and subtheme.

Quantitative Data

Descriptive statistics were used to analyze the data. Frequencies and percentages were calculated for dichotomous data. Continuous data were summarized using the mean and 95% CI at baseline and immediately after the intervention. Effect size (*r*) was calculated and interpreted using Cohen’s guidelines (*r*=0.1, small; *r*=0.3, medium; and *r*=0.5, large) [52] to determine the sample size calculation for a subsequent trial. All the analyses were performed using SPSS (version 27; IBM Corp).

Ethics Approval

This study was reviewed and approved by the Auckland Health Research Ethics Committee (reference number AH3217) and

the General Directorate of Health Affairs, Najran Institutional Review Board, Saudi Arabia (IRB 20 - 040E).

Results

Overview

There were 52 participants (n=15, 29% New Zealand patients; n=17 (33%) Saudi patients; n=7, 13% New Zealand family members; and n=13, 25% HCPs). Figure 1 provides the participant flowchart. Mean age of the participants was 54 (SD 11.16) years for patients and 44.1 (SD 11) years for family members. Patients had been living with T2DM for an average of 9 (SD 7.09) years. Table 1 shows the participant characteristics. The participating family members included 1 parent, 3 spouses, 2 children, and 1 other family member of the patient with T2DM. Most HCPs were diabetes nurses (6/13, 46%), followed by medical and nursing students (4/13, 31%), doctors (2/13, 15%), and a diabetes care coordinator (1/13, 8%).

Figure 1. Participant flowchart. NZ: New Zealand; SA: Saudi Arabia.

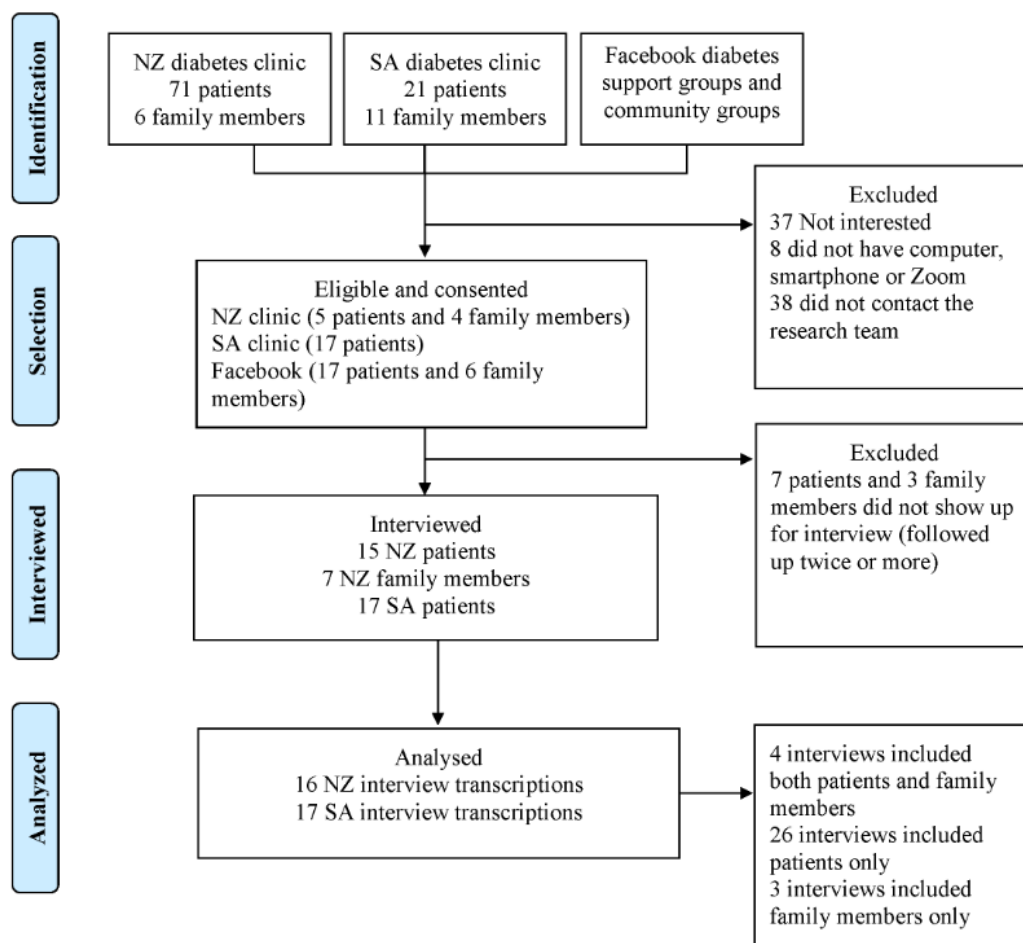


Table 1. Demographic and clinical characteristics of the sample.

Characteristics	NZ ^a patients (n=15)	SA ^b patients (n=17)	NZ family members (n=7)
Age (years), mean (SD)	55.5 (11.1)	52.7 (11.4)	44.1 (11.0)
Female, n (%)	10 (67)	9 (53)	6 (86)
Ethnicity, n (%)			
NZ European	7 (47)	0 (0)	3 (43)
Māori	3 (20)	0 (0)	0 (0)
Cook Island	1 (7)	0 (0)	0 (0)
Niuean	0 (0)	0 (0)	1 (14)
Indian	1 (7)	0 (0)	2 (29)
Saudi	0 (0)	15 (88)	0 (0)
Other	2 (13; Palestinians) and 1 (7; Filipino)	1 (6; Egyptian) and 1 (6; Yemeni)	1 (14; South Asian)
Education level, n (%)			
No formal education	2 (13)	2 (12)	0 (0)
Secondary education	3 (20)	2 (12)	0 (0)
High school	4 (27)	4 (23)	1 (14)
University education	6 (40)	9 (53)	6 (86)
Partnership status, n (%)			
Single	4 (27)	0 (0)	— ^c
Married or civil union	9 (60)	15 (88)	—
Couple or de facto	1 (7)	0 (0)	—
Widowed	1 (7)	2 (12)	—
Working (yes), n (%)	8 (53)	6 (35)	—
Taking metformin (yes), n (%)	13 (87)	14 (82)	—
Diabetes medications, n (%)			
Oral medications only	9 (60)	11 (65)	—
Insulin therapy only	1 (7)	2 (12)	—
Oral and insulin	5 (33)	4 (23)	—

^aNZ: New Zealand.

^bSA: Saudi Arabia.

^cNot available.

Qualitative Findings (Patients and Family Members)

Overview

Four main themes were identified from the patients' and family members' combined data set: (1) animation-related factors, (2) impact of the animation, (3) animation as an effective format, and (4) diabetes management-related factors. Subthemes have been presented in the text using *italics*. A small number of quotes have been included in the main text to illustrate the major points, and further quotes are provided in [Multimedia Appendix 3](#).

Theme 1: Animation-Related Factors

This theme covered participants' perceptions and views of the visual animation. Participants viewed the visual animation as *succinct and simple*, which provided basic "need to know"

information on T2DM. The simplicity and short length of the visual animation helped to keep the participants engaged. Participants highly appreciated this and reported that this animation might be more suitable for people who do not want too much detail or people who are newly diagnosed with T2DM.

Participants reported that a longer visual animation would have probably made them lose interest. A few participants from New Zealand noted that the visual animation was slow with some unnecessary pauses, whereas some family members and participants from Saudi Arabia reported that it was too fast for them.

The use of simple nonmedical language and creative visuals were identified as important elements that made the visual animation *easy to understand*, especially for older adults and those with low health literacy. Participants reported that the visual animation was *informative*, and increased their

understanding of T2DM and its management. The participants appreciated that the visual animation not only focused on explaining what T2DM is, its symptoms, and related complications but also on what can be done to help control T2DM. This made them feel that their T2DM was manageable by taking medication as prescribed, eating healthy food, and exercising regularly in addition to other self-care behaviors such as self-monitoring of blood glucose levels and foot care:

I felt I can be more in control now by doing the simple three stuff, take my medication every day, eat healthy and watch my portions and exercise daily. [Saudi female patient 2, 49 years]

I suppose we know it's manageable, what it made me think was I've got to make it more manageable. [New Zealand male patient 15, 56 years]

Participants identified with the *characters* in the visual animation and said that they were “relatable.” The main character showed emotions (eg, happy and sad), which made them look more realistic than the static pictures found in brochures and pamphlets. More participants from Saudi Arabia identified with the characters compared with participants from New Zealand, and this might be because New Zealand is more multicultural than Saudi Arabia; therefore, it is harder to make the animated characters relatable for all cultures in New Zealand.

Participants highlighted the importance of making the characters context-specific, where characters reflect culture. This made the visual animation feel inclusive of minority groups such as the Māori and Pacific groups in New Zealand who are at higher risk of developing T2DM. Participants from Saudi Arabia also appreciated that the visual animation was custom-made to suit their cultural context.

Some participants felt that they would relate more to the animated characters if they were personalized to match participants' demographics. However, others acknowledged that diabetes can affect anyone regardless of ethnicity or gender and said that personalizing the animated characters was unnecessary.

Theme 2: Impact of the Animation

This theme was related to the perceived impact of the visual animation, in which *participants reflected on their' and their family members' T2DM*. The visual animation made patients think about the status of their T2DM (eg, whether controlled or uncontrolled) and the importance of adhering to the treatment regimen. For some participants, the visual animation was “a wake-up call” that reinforced the fact that diabetes is a chronic illness and the potential consequences of uncontrolled diabetes and motivated them to make positive lifestyle changes:

It is sort of a bit of a wakeup call now that I can understand it better. Sort of how important it is to follow that [lifestyle changes]. [New Zealand female patient 5, 62 years]

For others, the visual animation reinforced what they had been told in the past about the importance of self-care behaviors and reassured them that diabetes medications work to control their blood glucose levels. Other participants who managed their

T2DM well felt reassured that they were on the right track. A few participants reflected on their low adherence to diabetes self-care behaviors and reported feelings of guilt.

Of note, participants from Saudi Arabia reported that the visual animation specifically made them think about the potential complications of T2DM and the need to improve their adherence to delay or avoid these events, whereas participants from New Zealand did not. Participants from New Zealand reported general concerns about T2DM-related complications, but this was not related to the visual animation itself:

I thought about the consequences of diabetes, especially on the body organs. I felt that if I really do not control my diabetes, I will suffer more, and I will have more serious complications than I have so far. [Saudi female patient 6, 59 years]

For family members, the visual animation made them reflect on what they were already doing and what they could do to better support the patient, including preparing healthier meals and reminding them to take their medications. For those who lived apart from the patient, there was some uncertainty about whether the patients were, in fact, adherent to self-care behaviors:

That worked well for him, cutting down his portions yeah. It gives you a sense of control. That's what you should be eating and aiming for. [New Zealand female family member 19, 58 years]

Family members reported a sense of pride about their relatives with T2DM who were making significant lifestyle changes to control their T2DM. They were seen as role models who could influence other family members to have a better lifestyle, including improving physical activity and watching the type and portions of their food:

I was thinking about how he's doing all that like every day, whether it rains or shines, he gets up and goes for his exercise. And even the food, even if he likes certain food, he restricts the amount that he eats, which also makes other people in the family realize OK you have to control your portion of food that you're eating even if you really love it. [New Zealand female family member 16, 57 years]

Theme 3: Animation as an Effective Format

This theme covered the participants' perceived reasons for why the visual animation was an effective format. Information that participants had come by or received in the past (either written or verbal) was often described as confusing and medical. Many participants reported not reading diabetes pamphlets available at clinics and pharmacies, and those who read them thought they were often limited and primarily diet based. The visual animation was regarded as superior to written information as *visuals helped participants conceptualize T2DM and its treatment processes*. Some abstract thinking is needed to understand T2DM, and the participants acknowledged the value of being able to “see inside the body,” what it meant to have T2DM, the role of insulin, and how metformin works inside the body. Visual information is easier to understand and retrieve from the memory. Participants perceived the visual animation

as more engaging compared with other forms, such as written information. The visual animation was also regarded as culturally responsive to people with limited education, low health literacy, and diabetes-related vision problems:

We have seen pamphlets, but we often throw them out. They are hard to understand and too many words...I think the video is much better because you can see inside the body. I knew things before, but in my mind, I never pictured it. Now, I know how insulin works. [New Zealand male patient 8, 71 years]

It is powerful, you know, seeing how food is broken down into sugar, going through the bloodstream, and used for energy. How insulin is essential for this process and without it, like in type 1 diabetes, you can die. [Saudi male patient 11, 43 years]

It is culturally responsive to a whole section of society that might find it valuable, because it's not just written literature, that it is very medical with medical speak. I think that the visual aspect is very good. [New Zealand female family member 3, 48 years]

Despite having been living with T2DM for years, the animation presented *new information* for some participants. For example, using the lock-and-key analogy to explain the role of insulin was new to most participants. Participants reported having not previously been told about some of the explanations covered in the brief visual animation, including how metformin and insulin work inside the body. In some instances, there was a complete lack of knowledge about self-testing of blood glucose and foot care despite the importance of these behaviors. Participants reported that the visual animation helped bridge this knowledge gap and motivated them to discuss these issues further with their care team:

It is more than what I have been told by anybody else basically...I had no clue about that, testing your sugar levels daily! [New Zealand female patient 2, 61 years]

I got to know more about diabetes, most of which I hadn't known previous to watching the video. [Saudi female patient 13, 60 years]

Theme 4: Diabetes Management–Related Factors

This theme covered general issues around diabetes management (knowing and doing are 2 different things), which were not related to the visual animation itself. Participants identified main *barriers to adherence* to medication, healthy eating, and exercise, including poor understanding of the chronicity and progression nature of diabetes, forgetfulness, older age, intentionally skipping doses as they felt okay, busy work or personal schedules, physical disability, poor weather, lack of willpower and motivation, and stress.

Participants expressed *concerns* and *frustrations* related to diabetes management. These included concerns about medication side effects, especially insulin, such as weight gain. A few participants reported hesitancy about going on insulin despite being asked a few times by their doctors. This was in part because of poor understanding of the progressive nature of diabetes, and going onto insulin was seen as a sign of personal failure to control diabetes:

I've actually had an aversion to the idea of insulin, but before this meeting, I was saying to myself if I go on insulin, then it's over for me basically. [New Zealand male patient 10, 36 years]

Participants expressed frustration about the cost and funding for new diabetes medications such as empagliflozin (Jardiance). This medication is funded in New Zealand only for people with T2DM if they fulfill various eligibility criteria such as being at high risk of heart and kidney complications. Patients who wanted to go onto this new medication but did not meet the eligibility criteria chose to pay the cost themselves, creating financial strain and additional concerns. Another frustration patients and family members experienced was the dismissal by HCPs in instances where patients came to their appointments having done some research on the internet and prepared their questions.

Other participants were concerned about long-term complications if they did not control their T2DM. For some participants, understanding the chronicity and progressive nature of T2DM, in addition to being fearful of potential complications, pushed them to improve their adherence and make serious lifestyle changes.

The impact of culture, especially around eating habits, was highlighted as a factor that could hinder people's ability to manage their T2DM. In some instances, it is considered rude and unacceptable to refuse food, especially when invited to someone else's house.

Support from family members and significant others was seen as important for optimal management. Family members can remind patients to take medications and motivate them to eat healthily and exercise regularly. Participants acknowledged the social impact of T2DM and that caring for someone with T2DM could be highly stressful. One way to mitigate this is through a better understanding of T2DM.

Problems can arise when patients do not want help or live alone, or when family members are not supportive for any reason, including low health literacy. Participants expressed frustration when, for example, family members cooked unhealthy meals or perceived T2DM as something that is easily fixed and not chronic.

Qualitative Findings (HCPs)

Inductive thematic analysis of the HCPs' data set resulted in a single theme consistent with the first theme identified from the patients' and family members' data set, "animation-related factors." HCPs perceived the visual animation as *brief and succinct, easy to understand, informative, and culturally appropriate* (Multimedia Appendix 4 provides themes, subthemes, and supporting quotes).

Suggested Changes to the Visual Animation

Participants from all groups provided suggestions for improvement, including using a less formal and female voiceover, changing medical terms to lay terms (eg, chronic to long-term, glucose to sugar), personalizing the animated characters based on the patient's demographics, and adding subtitles to accommodate those with hearing difficulties. The

participants also suggested adding greetings in Te Reo Māori and other Pacific languages.

Furthermore, the participants expressed a need for more visual content that covered other important issues in diabetes such as how insulin therapy works, daily self-monitoring of blood glucose, HbA_{1c} testing, and foot care. Brief, simple, and accessible educational digital content in the form of animated videos could be developed for each topic.

Potential Effects on Illness and Treatment Perceptions and Self-efficacy

Data support the potential effectiveness of the brief visual animation on patients' perceptions and self-efficacy (Table 2). Increases in means from baseline to immediately after intervention for perceptions of consequences, personal control, coherence, medication effectiveness, and self-efficacy among patients from New Zealand suggest medium to large effects ($r=0.43-0.56$). Changes in mean concern, healthy eating, and perceptions of regular exercise effectiveness were smaller. A

similar pattern of positive changes was observed among patients from Saudi Arabia, with medium effects ($r=0.34-0.47$) for increases in personal control perceptions, coherence perceptions, medication effectiveness perceptions, healthy eating effectiveness perceptions, and self-efficacy. Changes in consequences, concerns, and perceptions of regular exercise effectiveness were smaller. Finally, perceptions of family members from New Zealand changed in the expected direction, with effect sizes ranging from small to large ($r=0.10-0.55$).

All patients and family members (100%) believed that it was necessary to take diabetes medication every day at baseline and after the intervention. The cited reasons included controlling blood glucose levels, avoiding and delaying complications, and having a better quality of life. After the intervention, most patients and family members reported that the brief visual animation made them actively think about the potential consequences of T2DM, things they could do to control their T2DM, and diabetes medications.

Table 2. Illness and treatment perceptions and self-efficacy scores at baseline and immediately after the intervention.

Variable	Baseline, mean (95% CI)	Immediately after intervention, mean (95% CI)	Effect size (<i>r</i>)
NZ^a patients (n=15)			
Illness perceptions			
Personal control	5.40 (4.11-6.69)	8.07 (7.03-9.10)	0.52
Coherence	6.67 (5.35-7.98)	9.07 (8.42-9.71)	0.56
Consequences	7.53 (6.47-8.60)	9.27 (8.69-9.84)	0.43
Concerns	7.87 (6.61-9.12)	8.67 (7.98-9.35)	0.27
Treatment perceptions			
Medication	7.67 (6.55-8.79)	9.33 (8.88-9.79)	0.48
Eating healthy food	8.53 (7.58-9.49)	9.07 (8.42-9.71)	0.19
Regular exercise	7.87 (6.46-9.27)	8.93 (8.17-9.70)	0.27
Self-efficacy	6.13 (4.73-7.54)	8.40 (7.78-9.02)	0.52
SA^b patients (n=17)			
Illness perceptions			
Personal control	7.18 (5.53-8.82)	8.59 (7.77-9.40)	0.36
Coherence	7.65 (6.05-9.24)	9.00 (8.19-9.81)	0.41
Consequences	8.00 (6.33-9.67)	9.18 (8.57-9.79)	0.23
Concerns	6.88 (5.15-8.62)	5.59 (4.06-7.12)	0.24
Treatment perceptions			
Medication	8.12 (6.89-9.35)	9.29 (8.67-9.92)	0.47
Eating healthy food	8.18 (6.89-9.46)	9.18 (8.69-9.67)	0.38
Regular exercise	8.71 (7.52-9.89)	9.41 (9.09-9.73)	0.24
Self-efficacy	7.71 (6.22-9.19)	9.06 (8.47-9.65)	0.34
NZ family members (n=7)			
Illness perceptions			
Personal control	6.71 (3.57-9.86)	8.43 (6.93-9.93)	0.44
Coherence	7.14 (5.90-8.39)	8.57 (6.98-10.16)	0.37
Consequences	8.86 (7.40-10.31)	9.00 (7.81-10.19)	0.10
Concerns	8.00 (5.38-10.62)	6.71 (4.23-9.20)	0.39
Treatment perceptions			
Medication	6.71 (4.11-9.31)	9.43 (8.03-10.83)	0.51
Eating healthy food	7.86 (5.44-10.27)	9.29 (8.59-9.98)	0.40
Regular exercise	8.57 (7.39-9.75)	9.57 (8.84-10.30)	0.55
Self-efficacy	6.14 (3.56-8.73)	7.57 (5.66-9.49)	0.23

^aNZ: New Zealand.

^bSA: Saudi Arabia.

Discussion

Principal Findings

This pilot study showed that a brief animation was acceptable and engaging for patients with T2DM and their families. Inductive thematic analysis revealed 4 main themes related to the brief animation, the impact of animation, animation as an effective format for delivering information, and diabetes

management-related factors. Preliminary analysis showed potential cross-cultural effectiveness for improving illness and treatment perceptions and self-efficacy in all patients and family members, with larger effect sizes observed in the New Zealand patient group than in the Saudi patient group. Room for change in the New Zealand patient group may have been larger given the lower baseline means for many of the perception dimensions. Given the explanatory nature of this study, baseline

characteristics were not used in the analysis but could be used in a subsequent trial.

The visual animation was well received. Nearly all patients and their family members reported that the visual animation was informative and understandable. This is consistent with previous studies that have shown that visual interventions (eg, animations covering general information about diabetes, symptoms, risk factors, and management) improved diabetes health literacy [53] and knowledge about foot care [54].

Visualizing both the illness and its treatment are important [36]; this is because visualizing T2DM, related symptoms, and serious complications can potentially increase anxiety and fear. Heightened negative emotions alone are not sufficient to elicit changes in perceptions and behaviors; therefore, information on how T2DM can be managed is essential. This visual animation explained T2DM and how treatment (eg, metformin) works inside the body to help control T2DM, which was highly appreciated by the participants. Participants felt that their T2DM was more manageable and increased their control perceptions, self-efficacy, and motivation to make lifestyle changes. This finding is in line with previous research that showed visualizations can increase the motivation to for taking medicine in patients with osteoporosis [38].

Many of the reported barriers to adherence to self-care behaviors (eg, poor understanding, forgetfulness, and concerns about medication side effects and costs) are similar to previous findings [55]. One additional barrier is known as “psychological insulin resistance,” where patients are hesitant to initiate and or adhere to insulin therapy [56-59]. This barrier represents a complex set of beliefs (eg, sense of failure and incompetency) and attitudes (eg, fear of injections and hypoglycemia) toward insulin therapy [56].

Some participants reported avoiding going onto insulin therapy despite the necessity as going onto insulin was seen as a sign of personal failure for not being able to control their T2DM through oral medications and other self-care behaviors. This phenomenon is not uncommon in the literature [60]. This was reported by patients from New Zealand but not by patients from Saudi Arabia, which could have been because the interviewer for the Saudi participants did not encourage the patients to comment further on their perceptions and attitudes toward diabetes insulin therapy. Nonetheless, studies with insulin-naïve patients including patients from Saudi Arabia with T2DM have reported that approximately 30% of the patients were unwilling to initiate insulin therapy if recommended because of various factors including perceptions of failure and self-blame [61-63]. Therefore, it is important that HCPs listen to and address patients' concerns about insulin and provide accurate and adequate education on the progressive nature of T2DM and the ultimate need for insulin therapy at some point early on.

Although it has been established that illness perception interventions, often delivered over multiple sessions, can change perceptions and improve outcomes in T2DM [13,14], it is encouraging to find that a brief visual intervention (as short as 7 minutes) has the potential to change patients' perceptions. This brief visual animation may improve current T2DM education and, if incorporated within larger illness perception

interventions, could reduce intervention delivery time and therefore increase clinical utility.

This evidence is consistent with the findings from previous randomized controlled trials using different patient samples [37]. For example, both 3D models and an animation on osteoporosis increased perceived consequences, personal and treatment control, coherence perceptions and treatment motivation, and medication necessity beliefs, and decreased timeline perceptions and medication concerns [38]. A similar study found not only positive changes in perceptions (eg, increased treatment control and timeline perceptions and decreased identity perceptions) but also improved exercise and faster return to normal activities in patients with acute coronary syndrome compared with the control group [33]. Other visualization trials have reported improved adherence to antiretroviral therapy using viral load in patients with HIV [41,42] and increased postoperative mobility in oncology patients [43].

Family members' perceptions have been shown to mediate relationships between patients' perceptions and outcomes [30,31]. A recent review of CSM interventions in T2DM found that the inclusion of family members was important for improving patients' glycemic control [32]. This study suggests that diabetes visualizations are also suitable for family members.

Strengths and Limitations

A key strength of this study was the inclusion of 2 culturally specific versions of the visual animation and the cross-cultural patient samples. A second strength is the mixed methods design, which allowed us to gather both quantitative and qualitative data regarding the utility and acceptability of the visual animation. However, this study has a few limitations. First, patients and family members were not involved in co-designing the initial storyboards, scripts, or the visual animation assessed in this study; therefore, valuable input may have been missed. Second, because of convenience sampling, pre-post pilot design, and lack of a control group, our findings on changes in perceptions and self-efficacy must be interpreted with caution, and the study was not sufficiently powered to analyze scores by ethnicity (Māori, Pacific groups). Third, all patients perceived diabetes medications as necessary, and therefore it would be interesting to find out what a less receptive audience thinks about the visual animation and how it may influence their illness and treatment perceptions. Finally, data collection for this study was handled differently for the New Zealand and Saudi samples. Although extensive efforts were made to conduct the study completely on web, face-to-face recruitment from diabetes clinics was more successful in both countries. The New Zealand sample was comfortable using technology and therefore interviews were conducted over Zoom. Patients in the Saudi sample opted to perform the study in person at the clinic, either while waiting to be seen by the clinician or immediately afterward. In doing so, the opportunity for family members to participate was severely limited. Nonetheless, this study did help demonstrate the cross-cultural applicability of the visual animation. This also informs the practical aspects of recruitment for planning a future trial.

Implications for Our Brief Visual Animation and Future Research

The brief visual animation will be adapted in light of the participants' suggestions and feedback. This will include adding greetings in Te Reo Māori (for the New Zealand version), using a female Māori narrator voice, simplifying the language to overcome health literacy barriers, personalizing the animated characters to match the viewer's gender and ethnicity, and adding subtitles to accommodate patients with hearing difficulties. The next step is to conduct a cross-cultural randomized controlled trial to investigate the effects on illness perceptions, adherence to medication, diet and exercise behaviors, glycemic control, and unplanned hospital admissions.

The effect sizes found from this preliminary analysis will inform the sample size; therefore, the study will be sufficiently powered to conduct subgroup analyses by ethnicity. This future trial will ensure the recruitment of Saudi family members by offering incentives and allowing web-based participation for convenience. The inclusion of family members in the intervention is likely to have a larger impact on families and community health and improve the quality of life. This future trial could use the visual animation intervention as a stand-alone or as a component of a larger illness perception intervention. This future research would also look at how such an intervention could reduce or eliminate ethnic disparities and contribute to health equity.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Visual animation of type 2 diabetes mellitus.

[[DOCX File , 6907 KB - formative_v6i8e35079_app1.docx](#)]

Multimedia Appendix 2

Interview schedule and open-ended questions.

[[DOCX File , 29 KB - formative_v6i8e35079_app2.docx](#)]

Multimedia Appendix 3

Patients' and family members' themes.

[[DOCX File , 36 KB - formative_v6i8e35079_app3.docx](#)]

Multimedia Appendix 4

Health care professional's themes.

[[DOCX File , 29 KB - formative_v6i8e35079_app4.docx](#)]

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Abbreviations

- B-IPQ:** Brief Illness Perception Questionnaire
CONSORT: Consolidated Standards of Reporting Trials
CSM: common sense model
HCP: health care professional
T2DM: type 2 diabetes mellitus

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Original Paper

Contributions of Trustworthiness, Health Literacy, and Self-Efficacy in Communicating With COVID-19 Vaccine–Hesitant Audiences: Web-Based Survey Study

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Abstract

Background: Large-scale health communication challenges during the COVID-19 pandemic, such as widespread misinformation and distrust in health care professionals, have influenced reluctance to take the COVID-19 vaccine, also known as vaccine hesitancy. Trust in health professionals, adequate health literacy, and high self-efficacy are key components of actively pursuing preventative and protective health care measures. These factors may be associated with intentions to seek and complete a COVID-19 vaccine dosing.

Objective: The objective of this analysis was to identify factors associated with COVID-19 vaccine hesitancy.

Methods: In February 2021, US adults (N=5872) responded to a web-based survey on COVID-19 vaccine hesitancy and components of health communication (trust in sources of health information, health literacy, and self-efficacy). Multivariable logistic regression models were used to explore associations between these factors and vaccine hesitancy while adjusting for key demographics. We hypothesized that low levels of trust, health literacy, and self-efficacy would be associated with increased vaccine hesitancy.

Results: The adjusted odds of vaccine hesitancy was greater among those who placed little to no trust in health professionals compared to those who held a lot of trust (adjusted odds ratio [AOR] 8.54, 95% CI 6.52-11.19). The odds of vaccine hesitancy was also greater among those who felt frustrated about finding health information compared to those who did not (AOR 2.10, 95% CI 1.62-2.70). Participants who had little to no confidence in receiving health advice or information had greater odds of vaccine hesitancy compared to those who had a lot of confidence (AOR 3.05, 95% CI 2.34-3.97).

Conclusions: This study underscores the importance of trust between health professionals and their patients, and a need for improving health literacy regarding vaccines. Perceptions of mistrust and low levels of health literacy were associated with high levels of vaccine hesitancy, providing empirical support of framing these factors as perceived barriers to vaccine uptake.

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KEYWORDS

vaccine hesitancy; health literacy; COVID-19; COVID-19 vaccine hesitancy; health communication; vaccination; health professional; health information

Introduction

Background

Between March 2020 and February 2022, the spread of the SARS-CoV-2 virus led to over 500 million cases of COVID-19 disease and over 6 million deaths globally [1]. Since the start of the pandemic, efforts to slow or prevent the spread of COVID-19 have included business lockdowns and stay-at-home policies; international border closings and movement restrictions and mandating or encouraging mask wearing, frequent handwashing, and physical distancing imposed by federal, state, and local governments [2]. More recently, COVID-19 vaccine acceptance and uptake as well as booster completion have become critical components to decreasing the incidence of COVID-19 and ultimately ending the pandemic. However, within the United States, there have been large-scale health communication challenges regarding the COVID-19 vaccines that have impeded efforts toward achieving herd immunity. These challenges include concerns regarding vaccine safety, the spread of misinformation, belief in personal freedom and choice, and lack of access to reliable public health information [3,4]. A reluctance to taking a vaccine, also known as vaccine hesitancy, poses significant dangers to public safety during a pandemic given that unvaccinated individuals can more easily contract and spread disease to others and may contribute to development of strains not contained by the vaccine [5].

Vaccination Rates and Related Factors

In the United States, vaccine rollout began in late December 2019 prioritizing health care professionals and residents of long-term care facilities before expanding to other essential workers and businesses, and eventually to all adults. COVID-19 vaccination rates have consistently climbed since the vaccine was made available to all persons over the age of 18 years on April 19, 2021 [6]; as of February 2022, over 550 million doses of the vaccine have been administered, amounting to approximately 78% of the population with at least one dose. From April 2021 to the present, there have been challenges in reaching those who might be vaccine-hesitant. Most commonly reported reasons for vaccine hesitancy include skepticism of the vaccine, more specifically a lack of knowledge surrounding the components and safety of the vaccine [5,7,8]. Further, some are now using the term “pandemic of misinformation” to describe the circulation of mixed messaging and potentially inaccurate news being shared via social media [9-11]. The Edelman Trust Barometer Report, one of the longest-running surveys on trust, found that globally in 2021, over 70% of respondents were worried about the spread of false news, and reported high levels of distrust in government entities and media [12]. This skepticism coupled with the spread of misinformation have led to widespread reluctance in uptake of the COVID-19 vaccine across the United States.

Definitions

Source Credibility and Health Literacy

Health communication refers to the study and practice of delivering information intended to promote health and well-being among a particular audience. Activities in the health communication space range from large-scale, multifaceted public health campaigns to private patient-provider interactions [13]. Broadly speaking, health communication seeks to improve public health through increasing awareness of a health issue or influencing individual behaviors and practices through a variety of messaging approaches (eg, demonstrating the benefits of a health intervention). Appraisal of health messages by a particular audience depends on many different intersecting factors, including source credibility and health literacy [4,13-15].

Source credibility—or the extent to which an information source is perceived as believable [16]—is one factor that is thought to influence message acceptance by an audience [17]. Theoretically, the vast majority of conceptualizations surrounding source credibility distinguish between two overlapping yet distinct perceptions involved in gauging credibility: (1) trustworthiness of the source and (2) expertise of the source. Within the credibility literature, trustworthiness has been defined as “the degree of confidence in the communicator’s intent to communicate the assertions he considers most valid,” whereas expertise is understood to mean “the extent to which a communicator is perceived to be a source of valid assertions” [18]. Moreover, while information accuracy is thought to be involved in the message appraisal process, the degree to which information is accurate is conceptually different from perceptions around the credibility of a source [16], which has important implications for understanding and responding to disinformation and misinformation campaigns related to COVID-19 vaccinations.

In the context of COVID-19 vaccine hesitancy, some preliminary qualitative findings from Bateman and colleagues [19] suggested that mistrust is an important factor that may be influencing the widespread COVID-19 vaccine hesitancy among Latinx and African American communities in the Deep South. More specifically, the authors identified interesting subthemes within the data differentiating between (1) historical *mistrust*, or *mistrust* that is related to systemic racism and historical oppression; (2) vaccine development *mistrust*; and (3) *mistrust* in politicians [19]. However, another survey among a US sample living in Phoenix, Arizona, and New York City, New York, found that those who held higher trust in government were less likely to intend to get vaccinated against COVID-19 [20]. Several studies have shown that, in multiple contexts, trust in self-seeking information is critical to behavior change [21-23]. Therefore, given these preliminary findings, there exists a critical need to clarify the way source trustworthiness is associated with COVID-19 vaccine hesitancy within the United States.

Health literacy is also a critical factor that can either facilitate or thwart the process of appraising health information. Aligning with the findings from a systematic review [24] examining common definitions and conceptualizations related to the construct, we view health literacy as being

linked to literacy and entails people's knowledge, motivation and competences to access, understand, appraise, and apply health information in order to make judgments and take decisions in everyday life concerning healthcare, disease prevention and health promotion to maintain or improve quality of life during the life course.

Some recent evidence demonstrates robust and intricate relationships between health literacy and COVID-19 vaccine hesitancy. For instance, Kricorian and colleagues [25] determined that vaccine-hesitant individuals were more likely to find information related to the COVID-19 vaccine difficult to comprehend compared to individuals who did not express hesitancy. Furthermore, in a study of adults residing in China, researchers determined that higher levels of health literacy were protective against COVID-19 vaccine-hesitant attitudes, although this protective effect was only observed among individuals with low to moderate levels of stress [26]. Additionally, Turhan and colleagues [27] determined that a sample of Turkish social media users were more likely to report hesitant attitudes if they held low levels of health literacy and high levels of distrust in government. Their study further showed that “health literacy mediated the relationship between health care system distrust and vaccine hesitancy,” which implicates health literacy as an important factor to be considered in the design of health communication campaigns and health promotion interventions that attempt to modify COVID-19 vaccine hesitancy among communities [27].

Self-efficacy Theory

Self-efficacy is a cornerstone construct in the study of motivation and behavior. Originally stemming from Albert Bandura's Social Cognitive Theory developed in the 1960s, self-efficacy refers to an individual's perceptions of their capacity and capability to learn or behave in a particular way [28]. Since its inception, the construct has been applied and adapted to various theories of health behavior, including the Health Belief Model [29], Theory of Planned Behavior [30], and Transtheoretical Model of Behavior Change [31].

High levels of self-efficacy have been previously associated with intentions to be vaccinated against COVID-19. For example, Guidry et al [32] determined that those who scored high in self-efficacy to overcome vaccination barriers were more likely to form intentions about receiving the COVID-19 vaccine. Another online study of Korean internet users examined the relationships between self-efficacy and health literacy in the context of COVID-19 vaccine hesitancy, and reported that self-efficacy was negatively associated with hesitancy. These authors also reported that individuals who maintained high levels of eHealth literacy—a specific subtype of health literacy—were more likely to exhibit high levels of self-efficacy. Aligning with evidence from other health contexts, these scholars ultimately advance that given their findings, it is

important for interventionists to target health literacy in prevention activities as a potential mechanism to enhance an individual's self-efficacy and thus prevent COVID-19 vaccine hesitancy [33]. However, other studies—such as that conducted by McElfish et al [34] with a sample of individuals residing in Arkansas, United States—have found no significant difference in COVID-19 vaccine hesitancy according to levels of protection self-efficacy, operationalized as an individual's belief in their ability to protect themselves against COVID-19. Given this mixed evidence, it is imperative to further elucidate the role self-efficacy has in the larger issue of COVID-19 vaccine hesitancy.

Purpose and Hypothesis

Trust in sources of health information, adequate health literacy, and high self-efficacy are key components of actively pursuing preventative and protective health care measures. These factors may be associated with intentions to seek and complete a COVID-19 vaccine dosing. In this study, we (1) evaluated the relative levels of these constructs among a population of US adults who use social media and (2) quantified the relationships between these constructs on COVID-19 vaccine hesitancy. We hypothesized that distrust in sources of health information, inadequate health literacy, and low self-efficacy are associated with being unsure about or choosing not to get the COVID-19 vaccine.

Methods

Sample Description

From February 3 to March 2, 2021, a web-based self-report survey was disseminated through social media platforms (eg, Facebook, Instagram, LinkedIn, Twitter) and through email lists accessible to the authors. Specifically, the survey was disseminated on the lead author and principal investigator's personal and professional social media accounts. Social media users could follow the shared link and were first asked eligibility questions regarding their age and US residence status. If users were younger than 18 years or resided outside of the United States, they could not proceed with the survey. No incentives were provided for taking the survey.

Ethical Considerations

Institutional review board approval was obtained prior to survey dissemination (HSC-SPH-20-0346). Participants met eligibility criteria if they were 18 years or older and resided within the United States. Before the start of the survey, participants were informed about the purpose and estimated time required to complete survey, that their participation was voluntary, and that they could skip any questions they did not wish to answer. All respondents provided written consent to participate before proceeding to the questions.

Measures

Primary Outcome

The survey asked participants “Have you taken the COVID-19 vaccine?” Participants could select “Yes” or “No”; if a participant selected “No,” they were then prompted with the question “Will you receive the COVID-19 vaccine when it is

available to you?"; participants could then select "Yes," "No," "Unsure," or "I prefer not to say." Vaccine hesitancy is understood to mean reluctance to take a vaccine; therefore, those who selected "No" or "Unsure" about their plans to receive the vaccine when available were considered to be vaccine-hesitant. Those who either already received or planned to receive the vaccine were the referent group. The "I prefer not to say" responses were treated as missing since the attitude toward the vaccine could not be determined (n=7; 0.3%).

Exposures

There were several measurements of the two major components of health communication that were explored in this analysis. All health communication questions were adapted from the Health Information National Trends Survey questionnaire [35]. The survey asked participants to report on a Likert scale (ie, *A lot*, *Some*, *A little*, and *Not at all*) their level of trust in the following sources of health or medical information: (1) government agencies, (2) a doctor or health professional, (3) family or friends, and (4) religious organizations and leaders. Responses *Some*, *A little*, and *Not at all* were collapsed to represent "Not a lot of trust or not at all"; the variable was a binary variable to reflect "A lot of trust" and "Not a lot or not at all." Participants were also asked about health communication accessibility and comprehension as a measurement of health literacy. Specifically, the survey asked participants to report on a Likert scale (ie, *Strongly agree*, *Somewhat agree*, *Somewhat disagree*, and *Strongly disagree*) how much they agreed or disagreed with the following statements based on the results of their most recent search for information about health or medical topics: (1) *It takes a lot of effort to get health or medical information you need* and (2) *Felt frustrated during your search for health or medical information*. Responses *Strongly agree* and *Somewhat agree* were collapsed to represent "Agree," while the responses *Somewhat disagree* and *Strongly disagree* were collapsed to represent "Disagree"; the variable was a binary variable to reflect "Agree" and "Disagree." Finally, the survey asked participants a question regarding confidence in one's ability to find, understand, and make health-related choices (ie, self-efficacy). The survey asked participants to report on a Likert scale (ie, *Strongly agree*, *Somewhat agree*, *Somewhat disagree*, and *Strongly disagree*) how much they agreed or disagreed with the following statement: *Confidence in getting advice or information about health or medical topics*. Responses *Strongly agree* and *Somewhat agree* were collapsed to represent "Agree," while the responses *Somewhat disagree* and *Strongly disagree* were collapsed to represent "Disagree"; the variable was a binary variable to reflect "Agree" and "Disagree."

Although these Likert-scale questions have previously been analyzed both on a continuous scale and categorically [36,37], the response categories for the exposure variables were collapsed due to one or more of the following reasons: the sample sizes were small (<1%) within categories, the distinction between "strongly agree" and "agree" (and other responses) was minor or indistinguishable, or analyses were run that included the original exposure variable categories and odds of vaccine hesitancy did not vary significantly across the categories that were ultimately collapsed (results not shown).

Covariates

Sociodemographic variables (ie, covariates) included age in years (on a continuous scale), self-identified sex (male/female), race/ethnicity (white non-Hispanic/other), education level (less than college/college or more), and annual household income based on 2019 Medicaid expansion guidelines (138% below poverty; <US \$30,000/year; US \$30,000-\$80,000/year; and >US \$80,000) [38].

Statistical Analyses

Summary statistics are used to describe the study sample. Frequencies were tabulated and χ^2 tests were performed for each health communication and literacy factor and the sociodemographics and outcome (vaccine hesitancy). Multivariable logistic regression was used to further explore the associations between the outcome and each exposure. Separate models were run for each exposure while adjusting for key demographics (age, sex, race, income, and education level). A posthoc exploratory analysis was performed to find political ideology and gender differences in vaccine-hesitant status (results not shown). Analyses were performed using Stata statistical software version 15.1.

Results

The survey instrument captured a total of 6471 respondents; of those, 6452 (99.71%) met the eligibility criteria and 5872 (90.74%) consented to participate. Ultimately, 5356 participants responded to the series of vaccine plans-related questions, which was the final analytical sample size. The mean age of the sample was 45 years (SD 11.5); the majority were female and non-Hispanic white. As of February 2021, just over 50% of the sample had already received at least one dose of the COVID-19 vaccine. Of those who did not, approximately 5% reported that they were not going to receive it or were unsure (vaccine-hesitant). Over 50% of the total sample placed little to no trust in government agencies for health or medical information and 79% placed a lot of trust in doctors or health professionals (Table 1).

Table 1. Descriptive characteristics of the study sample (N=5872).

Characteristics	Value
Sociodemographics	
Age (years), mean (SD)	44.8 (11.5)
Sex, n (%)	
Male	665 (12.2)
Female	4782 (87.8)
Race/ethnicity, n (%)	
Non-Hispanic white	5107 (93.9)
Other	332 (6.1)
Educational attainment, n (%)	
Less than college	675 (12.5)
College or more	4733 (87.5)
Annual household income prior to the pandemic (US \$), n (%)	
<30,000	131 (2.5)
30,000-\$80,000	987 (18.6)
>\$80,000	4190 (78.9)
Already received the COVID-19 vaccine, n (%)	
Yes	2744 (50.7)
No	2665 (49.3)
Plan to get a COVID-19 vaccine when available as of February 2021, n (%)	
Yes, or already received	5077 (94.8)
No or unsure (vaccine-hesitant)	279 (5.2)
Trust in resources regarding health or medical information, n (%)	
Government agencies	
A lot	2136 (36.4)
Not a lot or not at all	3075 (52.4)
A doctor or other health professional	
A lot	4612 (78.5)
Not a lot or not at all	604 (10.3)
Family or friends	
A lot	176 (3.0)
Not a lot or not at all	5035 (85.8)
Religious organizations and leaders	
A lot	94 (1.6)
Not a lot or not at all	5102 (86.9)
Health literacy, n (%)	
It takes a lot of effort to get health or medical information you need	
Disagree	3354 (57.1)
Agree	1834 (31.2)
Felt frustrated during your search for health or medical information	
Disagree	3490 (59.4)
Agree	1664 (28.3)
Confidence in getting advice or information about health or medical topics	

Characteristics	Value
Extremely or very confident	4193 (71.4)
Little to no confidence	992 (16.9)

Overall, the vaccine-hesitant sample appeared to be younger, disproportionality more male, disproportionately having less than a college degree, and disproportionately having an annual household income of US \$30,000-\$80,000 than the nonvaccine-hesitant sample. Lack of trust in doctors and health professionals was more prevalent in the vaccine-hesitant compared to those who already received a COVID-19 vaccine or had plans to. More vaccine-hesitant participants reported that it takes a lot of effort to access necessary health information and felt frustrated during their search for health information compared to those who already received or planned to receive the vaccine. Over three-quarters of those who already received or planned to receive the vaccine were extremely or very confident in getting advice or information about health or medical topics compared to only slightly more than half of those who were vaccine-hesitant (Table 2).

After adjusting for covariates, the odds of being vaccine-hesitant were greater among those who lacked trust in doctors or health professionals and those who felt frustrated about finding health

information, as compared to those who placed a lot of trust in either resource. Similarly, the adjusted odds of being vaccine-hesitant were almost eight times greater among those who placed little to no trust in government agencies regarding health or medical information compared to those who placed a lot of trust in government agencies. The adjusted odds of being vaccine-hesitant were 75% lower among those who placed little to no trust in religious leaders and organizations, compared to those who placed a lot of trust in religious leaders and organizations. Participants who had little to no confidence in getting advice or information on health topics had 3.05 greater adjusted odds of vaccine hesitancy compared to those who already received or planned to receive the vaccine. Participants who felt frustrated during their search for health or medical information had 2.10 greater odds of being vaccine-hesitant, and participants who agreed that it takes a lot of effort to obtain the health or medical information they need had 1.59 times greater odds of being-vaccine hesitant compared to the referent group after adjusting for covariates (Table 3).

Table 2. Bivariate relationships between planning to get the COVID-19 vaccine when available as of February 2021 and health communication factors (N=5356).

Characteristics	Planning to get COVID-19 vaccine		P value
	Yes, or already received (n=5077)	Vaccine-hesitant (no or unsure) (n=279)	
Sociodemographics			
Age (years), mean (SD)	44.8 (11.6)	42.6 (9.8)	.002
Sex, n (%)			<.001
Male	597 (11.8)	55 (19.7)	
Female	4477 (88.2)	224 (80.3)	
Race/ethnicity, n (%)			.81
Non-Hispanic white	4757 (93.9)	260 (93.5)	
Other	310 (6.1)	18 (6.5)	
Educational attainment, n(%)			<.001
Less than college	601 (11.9)	62 (22.3)	
College or more	4467 (88.1)	216 (77.7)	
Annual household income prior to the pandemic (US \$), n (%)			.01
<30,000	122 (2.5)	7 (2.6)	
30,000-80,000	908 (18.2)	69 (25.3)	
>80,000	3947 (79.3)	197 (72.2)	
Trust in these resources regarding health or medical information, n (%)			
Government agencies			
A lot	2084 (41.1)	23 (8.2)	<.001
Not a lot or not at all	2787 (54.9)	242 (86.7)	
A doctor or other health professional, n (%)			
A lot	4408 (86.8)	139 (49.8)	<.001
Not a lot or not at all	467 (9.2)	126 (45.2)	
Family or friends			
A lot	166 (3.3)	7 (2.5)	.49
Not a lot or not at all	4703 (92.6)	259 (92.8)	
Religious organizations and leaders			
A lot	75 (1.5)	17 (6.1)	<.001
Not a lot or not at all	4781 (94.2)	249 (89.3)	
Health literacy, n (%)			
It takes a lot of effort to get health or medical information you need			
Disagree	3174 (62.5)	142 (50.1)	<.001
Agree	1676 (33.0)	123 (44.1)	
Felt frustrated during your search for health or medical information			
Disagree	3310 (65.2)	133 (47.7)	<.001
Agree	1508 (29.7)	131 (47.0)	
Confidence in getting advice or information about health or medical topics			
Extremely or very confident	3988 (78.6)	152 (54.5)	<.001
Little to no confidence	860 (17.0)	110 (39.4)	

Table 3. Multivariable odds of COVID-19 vaccination hesitancy when available as of February 2021 (N=5356).

Variable ^a	Vaccine-hesitant ^b , OR ^c (95% CI)
Trust in these resources regarding health or medical information	
Government agencies	
A lot	Reference
Not a lot or not at all	7.79 (5.05-12.02)
A doctor or other health professional	
A lot	Reference
Not a lot or not at all	8.54 (6.52-11.19)
Family or friends	
A lot	Reference
Not a lot or not at all	1.30 (0.60-2.83)
Religious organizations and leaders	
A lot	Reference
Not a lot or not at all	0.25 (0.14-0.44)
Health literacy	
It takes a lot of effort to get health or medical information you need	
Disagree	Reference
Agree	1.59 (1.23-2.04)
Felt frustrated during your search for health or medical information	
Disagree	Reference
Agree	2.10 (1.62-2.70)
Confidence in getting advice or information about health or medical topics	
Extremely or very confident	Reference
Little to no confidence	3.05 (2.34-3.97)

^aSeparate models were run for each variable and adjusted for age, sex, race, income, and education level.

^bVaccine-hesitant: those who reported “no” or “unsure” regarding plans to get the COVID-19 vaccination.

^cOR: odds ratio; odds are in relation to those who already received or planned to receive the vaccine.

Discussion

Principal Findings

This analysis explored components of health communication that are related to vaccine hesitancy among a large convenience sample of US adults. Distrust in health professionals, lack of access to health information, and inadequate health literacy were significantly associated with vaccine hesitancy. Specifically, trust in health care professionals is a fundamental piece of the patient-doctor relationship that can significantly impact personal and public health [39]. According to a 2018 New York Times article, trust in health professionals is on the decline in the United States [40]. According to a 1966 poll, 73% of respondents reported confidence in medical professionals, and by 2012 that number had dropped to 34% [41]. Studies and surveys have shown that trust in the health care system is directly related to following treatment plans, consistently taking medications, and health competence [42,43]. Specifically in the context of COVID-19, Antinyan et al [44] found that, on a global scale, having a health care system that citizens trust is more

likely to encourage treatment-seeking behavior upon development of first COVID-19 symptoms. This evidence underscores the importance of trust in health professionals as an element that influences vaccine uptake, and also speaks to the ability to follow COVID-19 preventative measures such as mask-wearing, handwashing, and physical distancing.

Comparison With Prior Work

Lack of trust in religious organizations and leaders was associated with a decreased odds of vaccine hesitancy, while the opposite can also be concluded (ie, trust in religious organizations may be associated with increased vaccine hesitancy). Multiple surveys and polls have shown that certain faith communities within the United States are among the least vaccinated demographic groups, and contain the highest proportion of vaccine-hesitant individuals due to personal religious beliefs, wariness of science, and distrust in institutions [45-47]. This supports our finding that trust in religious organizations may be associated with increased vaccine hesitancy. Our finding also highlights the role religious leaders play in individuals' decision-making regarding their health. If

those who are vaccine-hesitant are more likely to trust their religious organizations for health and medical information, and alternatively, if in some cultures religious leaders are considered authorities on health and medical issues [48,49], religious organizations should be equipped with the tools and knowledge to provide constituents with evidence-based advice. Religious groups and leaders should not be excluded from conversations about COVID-19.

Access to health information and confidence in one's ability to use health information may be one of the most critical aspects in decision-making regarding COVID-19 vaccine uptake. This study found that those who felt frustrated during their search for health information and those who lacked confidence in finding health information had greater odds of being vaccine-hesitant. Both of these factors are also related to inadequate health literacy, specifically eHealth literacy. Regular and reliable access to health information and services is associated with increased quality of life, and is known to prevent disease and disability due to early detection of illnesses and health conditions [50]. However, the literature also outlines the negative impact that health information found on the internet has on patient health. In one survey, 85% of physicians reported a patient bringing internet information regarding their health to a visit and expressed that it made the visits less efficient [51]. Additionally, information found on the internet regarding health and medicine can be harmful toward patient health since it can be misleading or entirely fabricated, whether intentionally or unintentionally [52,53]. For example, in the early stages of the pandemic, a video was widely shared on social media platforms that expressed cynicism and distrust in governmental figures and agencies, and made false claims about an eventual COVID-19 vaccine that had yet to be fully developed at the time [54]. This video changed the global and national conversation regarding the vaccines and the pandemic itself, causing significant damage to COVID-19 prevention efforts [55]. Misleading, false, and confusing health-related information can lead to frustration and deteriorate confidence when it comes to finding reliable information. This finding is echoed by the results in the Edelman Trust Barometer Report [12]. Studies have explored why conspiracy theories tend to take a stronghold on popular thought during traumatic large-scale events [56]; although there are several influential factors, one is a lack of access to accurate information due to the inherent novelty of the event [57,58]. The findings of this study underscore the importance of regaining trust in doctors and health professionals, and the importance of including nonhealth-related groups and organizations (ie, religious organizations) in the larger conversation about health education. The COVID-19 pandemic points to needs in partnerships for doctors and health professionals to work with trusted community lay health workers or community workers that may have greater trust in their community and reach to populations most at risk.

Limitations

The results of this analysis should be considered in light of a few limitations. Primarily, all data collected were self-reported, which may be impacted by social desirability bias. However, the experiences reported were collected across a large sample. Further, the cross-sectional nature of this study limits our ability

to assess temporality between our exposures (health communication components) and our outcome (vaccine hesitancy). Given the ongoing pandemic, the cross-sectional data do represent pandemic periods across variants. In the future, longitudinal data would be helpful to assess the impact of these critical components on increasing vaccine uptake. Finally, due to the convenience sampling method, the sample is not representative of the entire United States; therefore, the findings may not be generalizable to the national population. Specifically, 5.2% of our sample was vaccine-hesitant, which, in some states, is less than the proportion of the population who is vaccine-hesitant. According to the Centers for Disease Control and Prevention, the rate of vaccine hesitancy across states ranges from 2.9% to 27% [59]. In the United States, the vaccine-hesitant tend to be younger in age, less educated, and female, with some studies showing that non-Hispanic Black Americans have higher odds of vaccine hesitancy than non-Hispanic white Americans [60-62]. While our total sample consisted of primarily educated, non-Hispanic white, middle-aged women, our vaccine-hesitant sample tended to be less educated, younger, non-Hispanic white, and mostly women. While there are some similarities between our vaccine-hesitant sample and samples in the recent literature, there are also several differences, notably regarding race/ethnicity. Aside from demographic factors and related lived experiences contributing to vaccine hesitancy, others have found that political ideology is strongly associated with COVID-19 vaccination plans. Specifically, those who hold conservative ideologies tend to be more vaccine-hesitant [59-62]. Therefore, we conducted a posthoc exploratory analysis of political ideology and gender with vaccine-hesitant status, and found that significantly more vaccine-hesitant respondents identified as Republican (45% vs 12%, $P < .001$) and significantly more men identified as Republican (22% vs 13%, $P < .001$) in this sample. The political ideology divide could explain the slightly higher prevalence of men in the vaccine-hesitant sample within this study. The disparities between the vaccine-hesitant demographics in our sample compared with those of other studies is likely due to the primary recruitment strategy being through social media platforms among the study investigators (who are public health professionals). Despite this, these findings demonstrate the importance of trustworthiness of health professionals, adequate health literacy, and self-efficacy in decision-making to receive a COVID-19 vaccine. The small differences in the percentages found in our bivariate analysis could be due to the large and overpowered sample size.

Conclusions

In 2019, the World Health Organization listed vaccine hesitancy as one of the top 10 threats to global public health [63]. While the factors explored in this analysis are critical elements in the discussion of vaccine hesitancy, there are a myriad of factors and external influences (eg, philosophical ideals, political affiliation, situational factors) that intersect with an individual's decision-making regarding the COVID-19 vaccine, and vaccines in general [4]. The findings of this study underscore the importance of building trust between health professionals and their patients, involving nonhealth-related institutions in the

conversation regarding health, and easing access to and raising self-efficacy in finding accurate and reliable health information.

Conflicts of Interest

None declared.

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Abbreviations

AOR: adjusted odds ratio

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Original Paper

Equity and Accessibility of Washington State's COVID-19 Digital Exposure Notification Tool (WA Notify): Survey and Listening Sessions Among Community Leaders

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Abstract

Background: In November 2020, WA Notify, Washington State's COVID-19 digital exposure notification tool, was launched statewide to mitigate ongoing COVID-19 transmission. WA Notify uses the Bluetooth proximity-triggered, Google/Apple Exposure Notification Express framework to distribute notifications to users who have added or activated this tool on their smartphones. This smartphone-based tool relies on sufficient population-level activation to be effective; however, little is known about its adoption among communities disproportionately impacted by the COVID-19 pandemic or what barriers might limit its adoption and use among diverse populations.

Objective: We sought to (1) conduct a formative exploration of equity-related issues that may influence the access, adoption, and use of WA Notify, as perceived by community leaders of populations disproportionately impacted by the COVID-19 pandemic; and (2) generate recommendations for promoting the equitable access to and impact of this novel intervention for these communities.

Methods: We used a 2-step data collection process to gather the perspectives of community leaders across Washington regarding the launch and implementation of WA Notify in their communities. A web-based, brief, and informational survey measured the perceptions of the community-level familiarity and effectiveness of WA Notify at slowing the spread of COVID-19 and identified potential barriers and concerns to accessing and adopting WA Notify (n=17). Semistructured listening sessions were conducted to expand upon survey findings and explore the community-level awareness, barriers, facilitators, and concerns related to activating WA Notify in greater depth (n=13).

Results: Our findings overlap considerably with those from previous mobile health equity studies. Digital literacy, trust, information accessibility, and misinformation were highlighted as key determinants of the adoption and use of WA Notify. Although WA Notify does not track users or share data, community leaders expressed concerns about security, data sharing, and personal privacy, which were cited as outweighing the potential benefits to adoption. Both the survey and informational sessions indicated low community-level awareness of WA Notify. Community leaders recommended the following approaches to improve engagement: tailoring informational materials for low-literacy levels, providing technology navigation, describing more clearly that WA Notify can help the community, and using trusted messengers who are already engaged with the communities to communicate about WA Notify.

Conclusions: As digital public health tools, such as WA Notify, emerge to address public health problems, understanding the key determinants of adoption and incorporating equity-focused recommendations into the development, implementation, and communication efforts around these tools will be instrumental to their adoption, use, and retention.

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KEYWORDS

COVID-19 exposure notifications; digital public health; health equity; mHealth; mobile health; mHealth equity; digital health tool; public health; surveillance; COVID-19; smartphone; health inequity; sociodemographic factor; epidemiology

Introduction

WA Notify

In the spring of 2020, public health authorities partnered with Google and Apple in the development of smartphone-based COVID-19 exposure notification (EN) tools that could be activated on Android and iPhone devices. Public health officials hoped that these tools would supplement public health measures—such as manual case investigation and contact tracing, masking mandates, guidance regarding physical distancing and limited social gatherings, and COVID-19 testing—to mitigate the spread of COVID-19 [1]. WA Notify uses the privacy-preserving Google/Apple EN Express framework to distribute Bluetooth proximity-triggered notifications to users who have added or activated this tool on their smartphones [2]. Digital EN tools send alerts to smartphone users to let them know that they have potentially been exposed to someone who has tested positive for COVID-19. To do this, digital EN users who test positive for COVID-19 (ie, index cases) verify their test results through the tool which anonymously alerts other users of their potential exposure.

Recent evidence suggests that these tools can help mitigate the spread of COVID-19 [3-5]. However, their performance relies, in part, on sufficient adoption by smartphone owners [6]. Identifying the challenges to adoption could inform strategies to increase activations and communicate the value of digital EN tools to improve retention. In particular, understanding the barriers and facilitators to adoption and use by communities disproportionately impacted by the COVID-19 pandemic [7-11] could help tailor marketing campaigns to promote adoption and increase the likelihood that all populations benefit from this new public health technology.

On November 30, 2020, WA Notify, the Washington (WA) State digital EN tool, was launched statewide [2]. Early in the development and testing phases for WA Notify, the WA State Department of Health (DOH) and the University of Washington School of Public Health entered into an interagency agreement to conduct an evaluation of WA Notify as a public health strategy to mitigate COVID-19 transmission. One aim of this evaluation sought to identify the barriers and facilitators to the statewide adoption and use of WA Notify and ascertain potential unintended impacts of this novel technology. Between its launch and the time period in which this study was conducted (from November 30, 2020, to September 05, 2021), WA Notify had been activated on over 2.4 million smartphones across the state, representing an adoption rate of 54.8% of the state adult population. Privacy constraints do not allow for users, user characteristics or demographics, or their location to be identified,

so it is not possible to know whether the residents of communities most disproportionately impacted by COVID-19 were adopting or benefiting from WA Notify.

Equity and Mobile Health Interventions

Health equity research focused on mobile health (mHealth) tools investigates how to address, simplify, and remove structural barriers to act upon and benefit from health information presented in public health interventions [12,13] and ensure that the technology does not create additional barriers for different subpopulations [14,15]. The wide adoption and penetration of smartphone ownership across diverse subpopulations [16,17] has supported a proliferation of smartphone-based tools, programs, and interventions. Along with this growth, there have been concerns that interventions delivered solely through these devices may result in inequalities that exacerbate, rather than mitigate, existing health inequities [13,15,18-21]. Approaches suggested to address these issues and encourage a wider adoption of mHealth tools include providing training and technical assistance, leveraging familial and community connections, partnering with trusted institutions, and offering users control over the levels of privacy and anonymity [18-24], as well as developing these tools using user-centered and participatory design processes that engage community members and other potential end users [21,25].

However, identifying the optimal design elements and implementation strategies that enable a novel mHealth tool to promote health equity requires time. The COVID-19 pandemic was unprecedented in scope and urgency. There was little time to engage in formal research, iterative design cycles, or systematic evaluations before the launch of WA Notify. Additionally, public health's ability to conduct equity, accessibility, and usability studies were constrained by a rapidly shifting landscape and competing priorities such as COVID-19 vaccine distribution efforts [26]. Our work aimed to address this gap in understanding by speaking directly with community leaders about their experiences, concerns, and opinions about WA Notify.

Methods

Ethical Considerations

The project plan was reviewed by the University of Washington Institutional Review Board and determined to be a public health surveillance quality improvement activity that did not require human subjects research review.

Sample

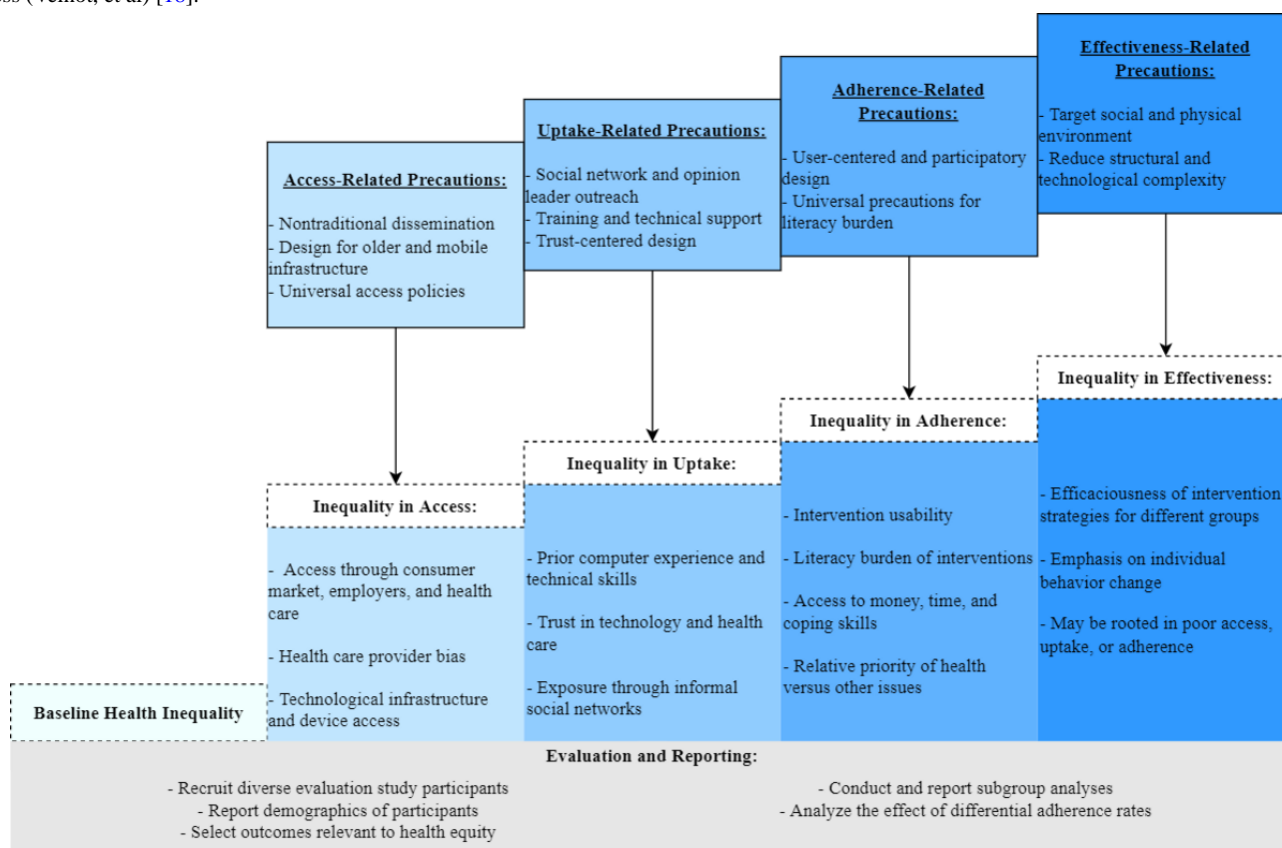
We sought to enroll community leaders that were engaged with community-based COVID-19 mitigation efforts and representative of the diversity of populations and regions across WA state. Information and outreach about the project were circulated to key stakeholders, organizations, and equity advocates with the assistance of the WA State DOH COVID-19 Vaccine Implementation Collaborative (VIC), a group working to ensure equitable COVID-19 vaccine access across the state [27]. VIC membership includes community-based organization (CBO) leaders; community and social service group advocacy representatives; tribal health, public health, and health care organization representatives; and interested community members. These individuals were recruited because of their deep knowledge of their communities and their experience

directly engaging community members around COVID-19 interventions including masking, vaccination, and WA Notify.

Framework

We used Veinot et al [18]’s model for intervention-generated inequality as a framework to inform our data collection efforts and contextualize our findings (Figure 1). This model proposes that inequalities in mHealth access, uptake, adherence, and effectiveness determine how these interventions influence pre-existing inequities [18]. Our data collection efforts primarily focused on investigating the potential access and uptake inequalities of WA Notify as the community-level adoption of this tool will influence its downstream effectiveness for diverse subpopulations. Additionally, we used this model to conceptualize how the issues and recommendations reported by participants influence the ability of this novel intervention to promote equitable health outcomes.

Figure 1. Intervention-Generated Inequality (IGI) Prevention Model adapted for clarity of presentation, used with permission of Oxford University Press (Veinot, et al) [18].



Procedures

Exploratory Sequential Approach

For this evaluation, we used 2 data collection instruments: an informational survey followed by semistructured listening sessions. This exploratory sequential approach was chosen to quantify the levels of awareness, facilitators, barriers, and concerns with activating WA Notify across diverse settings and subsequently investigate the underlying community contexts that may influence the adoption of WA Notify. The 2 instruments were designed and used as follows.

Informational Survey

The survey was designed to take no more than 15 minutes to complete. In addition to gathering information regarding the respondent’s role or position in their community or organization, survey items focused on respondents’ description of conditions or contributors to the disproportionate impacts of COVID-19 on their communities (such as access barriers, underlying health conditions, and systemic inequities); the level of familiarity with WA Notify; perceptions regarding the effectiveness of WA Notify in limiting the spread of COVID-19; and the barriers and facilitators to the adoption and use of WA Notify by their community members.

The survey was programmed and distributed through the REDCap web-based platform (REDCap Consortium) [28] and available in hard-copy format upon request. The recruitment of CBO leaders and community advocates serving on the VIC was conducted by email in April 2021. Surveys closed in August 2021.

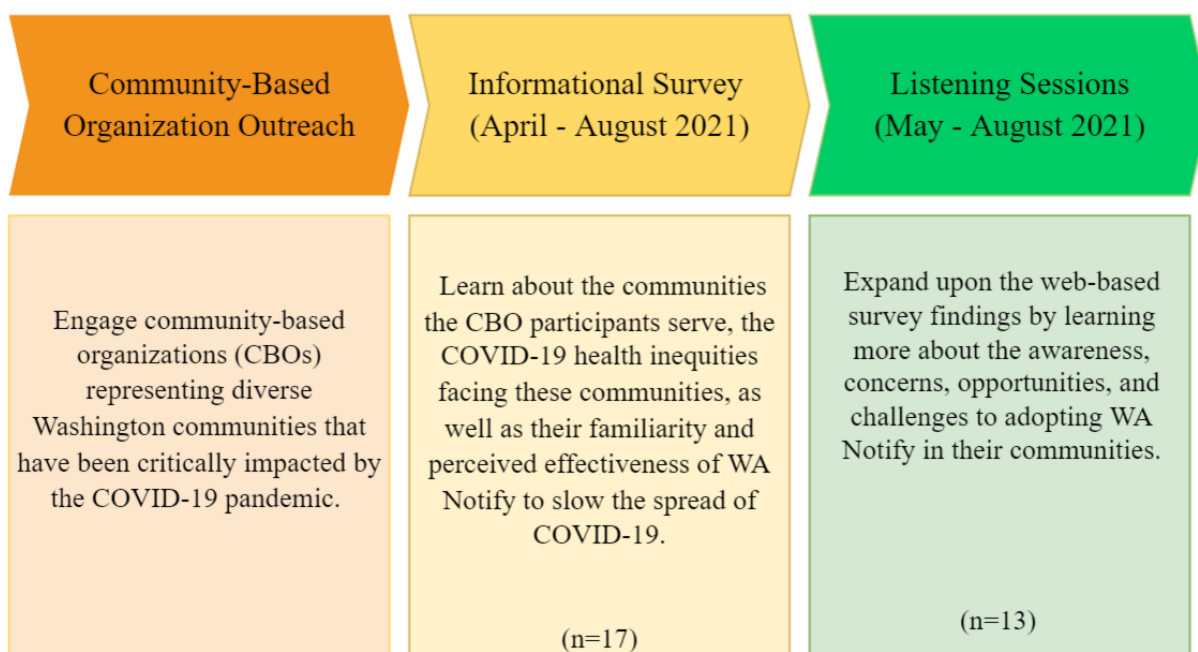
Semistructured Listening Sessions

The listening sessions were designed to capture details regarding the impact of COVID-19 in the participants’ community; awareness of WA Notify, how it works, and what communications have been received around its adoption and use; community concerns about using a digital EN tool;

challenges and opportunities that might be leveraged to improve communications about WA Notify; and feedback regarding the best avenues for informing their communities about the value of using digital EN tools to protect oneself and loved ones.

Listening sessions were designed to last approximately 1 hour and were conducted remotely over Zoom software (Zoom Video Communications) at the participant’s convenience. Sessions were recorded to aid in notetaking with the participant’s permission. CBO leaders and community advocates who completed the informational survey were invited to participate in the listening sessions by email. The listening sessions were conducted between May and August 2021 (Figure 2).

Figure 2. Equity and accessibility evaluation procedures.



Analysis

Descriptive statistics were used to summarize the survey data. Listening session notes were qualitatively analyzed by 2 team members to identify emergent themes related to the intervention-generated inequality concepts of mHealth tool access, uptake, adherence, and effectiveness. Survey and listening session findings were synthesized to generate the results and recommendations for further outreach and communications that may improve the adoption and use of WA Notify in communities disproportionately impacted by COVID-19.

Stakeholder Reflection

The synthesis of results and themes were circulated to DOH stakeholders and all participants in November 2021 to gather feedback on the results as well as capture any changes in perceptions on the adoption and use of WA Notify in participants’ communities. This input was incorporated into the thematic synthesis of results described in the next section.

Results

Participants

In our participant sample, 17 individuals completed the informational survey and 13 subsequently participated in listening sessions (Table 1). Community and CBO representation was broad, with participants from across the state and including CBO leaders and those advocating for or representing the following groups: older adults; low-income families; people with disabilities; essential and frontline workers; justice-impacted communities; individuals whose health care access is limited or impacted by stigma and bias such as individuals who identify as Lesbian, Gay, Bisexual, Transgender, Queer/Questioning, Asexual, and other identities (LGBTQIA+); American Indian or Alaska Native, Asian, Black or African American, Latinx, Muslim, and multiracial communities; immigrant, refugee, and undocumented communities; and rural and frontier communities (Table 1).

Table 1. Informational survey and listening session participants.

Represented communities ^a	Informational survey (n=17)	Listening session (n=13)
Essential workers and seniors with disabilities	✓	✓
Black, Indigenous, and People of Color; disabled; and justice-impacted communities	✓	✓
African American communities	✓	
Latinx communities, immigrants and refugees, and rural and frontier communities	✓	✓
Youth and seniors that cannot gain access to COVID-19 vaccines	✓	
Low-income families with young children, immigrants, and refugees	✓	✓
Amharic-speaking communities	✓	✓
Undocumented individuals and Latinx communities	✓	✓
Arabic-speaking immigrants and refugee	✓	✓
Muslims communities, individuals whose health care is impacted by stigma and bias, and LGBTQIA+ ^b communities	✓	✓
Latinx communities	✓	✓
Asian American Pacific Islander, Black, Indigenous, Latinx, and multiracial communities	✓	✓
People with disabilities	✓	
Immigrants and refugees from Arabic countries (Afghanistan, Iran, Iraq, Somalia, India, and Pakistan)	✓	
Essential and frontline workers	✓	✓
Blind, low-vision, and deafblind communities with various intersectional identities	✓	✓
Low-income older adults and people with disabilities	✓	✓

^aOverlap and intersectionality among the communities represented listed above reflects the descriptions provided by participants.

^bLGBTQIA+: Lesbian, Gay, Bisexual, Transgender, Queer/Questioning, Intersex, Asexual, and other identities.

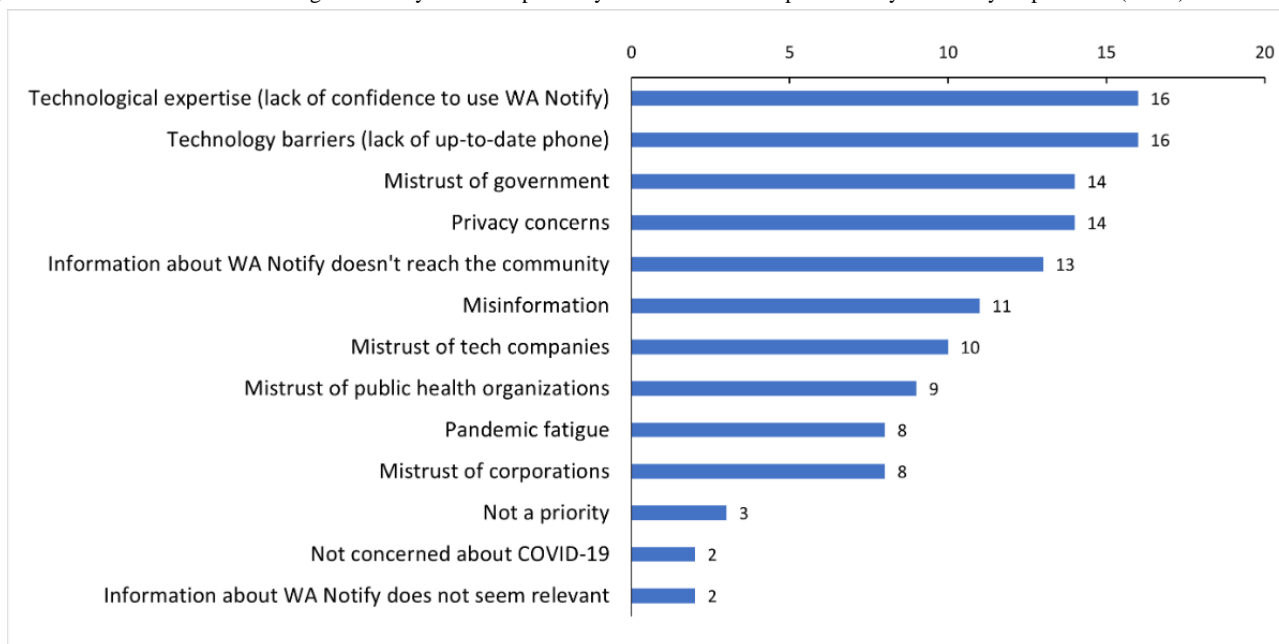
WA Notify Awareness

Participants perceived that the awareness and adoption of WA Notify was low in their communities. In the listening sessions, 1 participant who advocates for justice-impacted communities pointed out how they had not heard about WA Notify outside of their engagements with the DOH's VIC, whereas most other participants mentioned only seeing communications during WA Notify's initial launch in the fall of 2020. Participants also reported that without a basic understanding of what WA Notify is and how it works, adoption and use would be unlikely. For community members who wish to learn more about WA Notify, they currently need to actively seek information about the tool (via the DOH website, fact sheets, or videos), which was

perceived as a barrier. Promotion by community leaders was identified as a key strategy to elevate community awareness; however, participants stated that unless community leaders themselves understand the "ins and outs" of WA Notify, they may be hesitant or ill-equipped to advocate in the community on its behalf.

Possible contributors to the limited awareness and penetration of the tool were identified in the survey question, "Of these known barriers to adding WA Notify to a smartphone, which are relevant for your community?" (Figure 3) and further investigated during the listening sessions. The latter activity additionally captured suggested mechanisms or approaches for improving awareness, acceptance, and adoption.

Figure 3. Perceived barriers to adding WA Notify to a smartphone by the communities represented by the survey respondents (N=17).



Thematic Synthesis

Themes

Digital expertise and confidence, privacy and security concerns, trust, and health and digital literacy levels emerged as key

determinants of WA Notify awareness, acceptance, and adoption among vulnerable communities that might benefit from using WA Notify to help limit the spread of COVID-19 (Textbox 1).

Textbox 1. The 5 emergent themes after the synthesis of survey and listening session results.

Themes

- Limited experience, expertise, and comfort with technologies, as well as access to smartphones, are substantial barriers to the adoption and use of WA Notify.
- Concerns about data security, tracking, and privacy outweigh or diminish the perceived value, benefits, and performance expectations of WA Notify for limiting the spread of COVID-19.
- The mistrust of government, law enforcement, and technology companies and the fear of negative consequences from engaging with exposure notification tools are substantial barriers to adoption.
- Language translations alone are not sufficient to ensure that WA Notify is accessible to communities with diverse health literacy, digital literacy, numeracy, and preferences for accessing information.
- Uptake may be improved by lowering literacy burdens, providing technology navigators, and disseminating tailored outreach and informational materials through trusted community social networks and opinion leaders.

Theme 1: Limited Experience, Expertise, and Comfort With Technologies, as Well as Access to Smartphones, Are Substantial Barriers to the Adoption and Use of WA Notify

The top 2 barriers to WA Notify adoption identified by survey respondents (N=17) concerned technology—the lack of an up-to-date phone (n=16, 94%) and lack of confidence to use a tool such as WA Notify (n=16, 94%; Figure 3). After exploring these issues further during our listening sessions, participants reported that a portion of their community members do not own or have access to a smartphone. In addition, CBO leaders working with immigrant and refugee communities noted a technology access divide based on gender and age, reporting that mobile phones are typically owned by men or household “breadwinners.”

Regarding community members who own or have access to a smartphone, there were concerns about the digital knowledge and skills required to use WA Notify. The process of adding or activating WA Notify requires several steps. Navigating through menus and downloading apps, even if the information is provided in the smartphone user’s native language, may be unfamiliar for those with limited digital skills.

Theme 2: Concerns About Data Security, Tracking, and Privacy Outweigh or Diminish the Perceived Value, Benefits, and Performance Expectations of WA Notify for Limiting the Spread of COVID-19

Survey respondents perceived privacy concerns (14/17, 82%) and misinformation (11/17, 65%) as barriers to adoption (Figure 3). Although WA Notify does not track its users or their locations, security and privacy were universal concerns reported

during the listening sessions. In some communities, CBO leaders reported that misinformation about data privacy persists, perhaps due to a lack of information readily available to rectify this misperception or few opportunities for the community to present their questions or concerns. Additionally, an LGBTQIA+ community advocate highlighted that without a proper understanding of how WA Notify works, community members cannot fully discern the benefits it may provide them.

Related to Theme 1, to understand WA Notify’s benefit, some level of digital fluency is required to accept the premise that contact between 2 users is determined by proximity (via the exchange of randomized codes over Bluetooth), not location. Furthermore, unless communities understand what WA Notify is and how it works, its value in helping to protect community members and limit the spread of COVID-19 is not apparent.

Theme 3: The Mistrust of Government, Law Enforcement, and Technology Companies and the Fear of Negative Consequences Are Substantial Barriers to Adoption

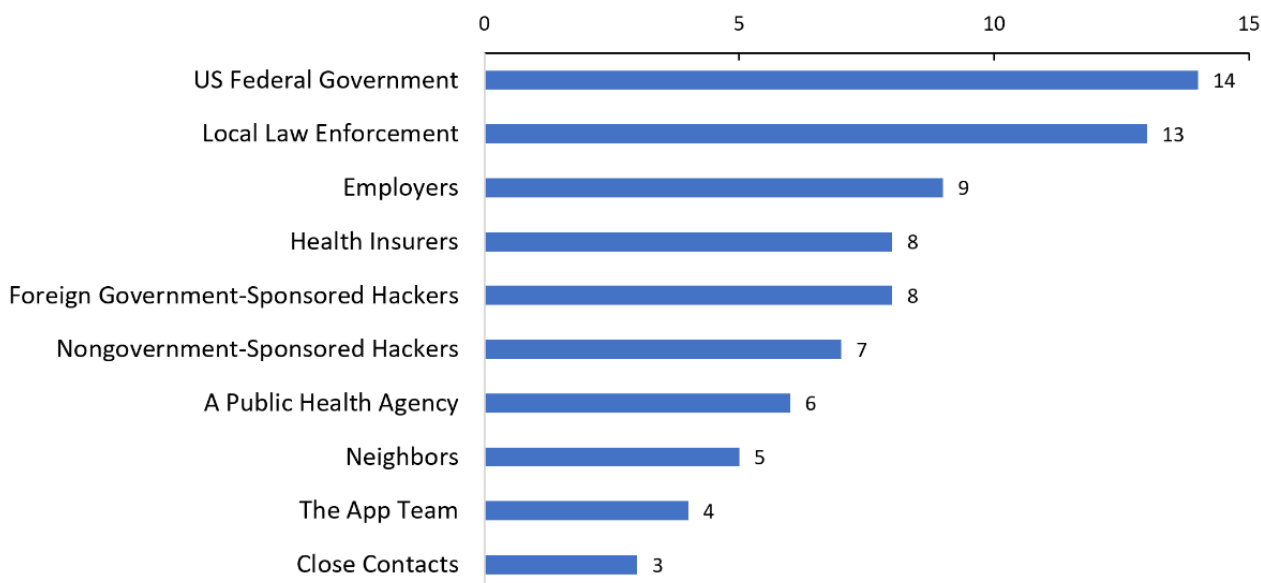
Survey respondents identified the mistrust of government (14/17, 82%), tech companies (10/17, 59%), public health organizations (9/17, 53%), and corporations (8/17, 47%) as barriers to adoption within their communities (Figure 3). During the listening sessions, participants pointed out that the historical context between the government and their communities and the fear of repercussions influence the willingness to adopt an intervention such as WA Notify. Gaining trust in these communities from the “outside” is challenging. Related to Themes 1 and 2, in the absence of a clear understanding of how WA Notify works and how it can help both the individual user and their community without jeopardizing privacy and security, the risks of adoption outweigh the potential benefits.

When asked, “Who do you think members of your communities would be worried about having access to the information from the WA Notify tool?” respondents (N=15) identified the US federal government (n=14, 93%) and local law enforcement (n=13, 87%) as the entities of greatest concern (Figure 4).

Although WA Notify’s anonymous design appears to cater to the preferences of some communities to remain anonymous from the government, CBO leaders working with undocumented communities noted concerns that information could be collected by WA Notify and put individuals at risk of deportation. In communities that have seen cooperation between local government and the US Immigration and Customs Enforcement leading to deportation, this fear is especially prevalent. As noted by 1 participant, community members are always asking themselves, “Am I opening myself up to deportation by doing this?” In Afghani immigrant communities, CBO leaders reported that those with Special Immigrant Visas will avoid any activity, such as activating WA Notify, that could potentially jeopardize their residency status.

The negative consequences associated with employers (9/15, 60%) accessing information through WA Notify were also brought up in the listening sessions. Included in a WA Notify alert of possible exposure is public health guidance to engage in protective behaviors such as getting tested and quarantining (quarantine guidance during the time of this evaluation was 10 days). Participants noted that low-income community members may be particularly vulnerable to the consequences of receiving an EN and cannot risk losing multiple days of income. To activate WA Notify, these community members need a compelling answer to the question, “What am I getting out of this?” as well as assurance that comprehensive resources and support will be available to them upon receiving an EN.

Figure 4. Entities of greatest concern to community members for accessing information through WA Notify (N=15).



Theme 4: Language Translations Alone Are Not Sufficient to Ensure That WA Notify Is Accessible to Communities With Diverse Health Literacy, Digital

Literacy, Numeracy, and Preferences for Accessing Information

Listening session participants representing non-English-speaking, immigrant, and refugee communities

repeatedly stated that the translation of materials into languages other than English is not an end point for ensuring equitable access to WA Notify. First, community members are often unaware that translated resources are available. In addition, even when translated, existing public health outreach materials and graphics may be difficult to understand for community members with lower levels of digital and health literacy. Multiple participants pointed out that current informational materials, while appropriate for individuals who are college educated, would need to be simplified to be appropriate for all members of their communities.

Listening session participants that advocate for diverse disability communities also identified the need to evaluate to what extent

WA Notify is interoperable with critical assistive technologies (such as text-to-speech systems or screen readers) and identify strategies to ensure that the information and resources provided by this tool are accessible in a variety of formats.

Theme 5: Uptake May Be Improved by Lowering Literacy Burdens, Providing Technology Navigators, and Disseminating Tailored Outreach and Informational Materials Through Trusted Community Social Networks and Opinion Leaders

During the listening sessions, CBO leaders shared suggestions for improving the acceptance and adoption of WA Notify in their communities ([Textbox 2](#)).

Textbox 2. Participant recommendations for improving the acceptance and adoption of WA Notify.

Recommendations

- Ensure that communication and informational materials are accessible at all literacy levels and work with assistive technologies
- Provide technology navigators
- Use trusted messengers who are known, credible, and already engaged in the community

Recommendation 1: Ensure That Communication and Informational Materials Are Accessible at All Literacy Levels and Work With Assistive Technologies

CBO leaders advocated for WA Notify and its promotional materials to use simple, easy-to-understand design elements. One CBO leader who had been providing Wi-Fi hot spots to immigrant and refugee families during the initial phase of the COVID-19 pandemic recalled needing to configure the devices to (1) limit the number of taps or clicks needed to access information; (2) use symbols to simplify navigation; and (3) provide a readily available technical support telephone line for troubleshooting. This participant emphasized that it is the responsibility of implementers, not the community members, to ensure that WA Notify is easy to understand and use.

Recommendation 2: Provide Technology Navigators

Activating WA Notify on a smartphone is difficult without technical or hands-on support. CBO leaders suggested that technical assistance be paired with existing community outreach activities, such as tabling sessions, workplace initiatives, and community health worker programs. CBO leaders also noted that for some families in their communities, the adult parent or guardian's initial exposure to technology occurs through their children. For these communities, youths, particularly high school- and college-aged students, might be engaged as technology navigators due to their high digital literacy and familiarity with community networks. In addition, leveraging schools and libraries to provide technology assistance may help resolve some technology barriers. In summary, there is a need for interactive, low-barrier assistance to ensure that community members with limited digital skills are supported in activating and using WA Notify.

Recommendation 3: Use Trusted Messengers Who Are Known, Credible, and Already Engaged in the Community

Engaging trusted messengers was viewed as an effective means of circulating accurate information about WA Notify, especially

for individuals not reached through previous communication efforts. Trusted messengers referenced during listening sessions include faith-based organizations, community health workers, health care providers, and CBO leaders. Providing information through these messengers could not only help elevate the awareness of WA Notify but may also address the dual challenges of mistrust and misinformation that limit adoption. One participant who advocates for immigrant and refugee communities articulated that their community members would likely ignore or scroll by WA Notify advertisements unless they were shared by a familiar organization. Engaging trusted messengers could help facilitate greater bidirectional communication between the DOH and communities regarding WA Notify, where trusted messengers could serve as nonjudgmental resources that directly engage with their community about their concerns and advocate for the requested changes to WA Notify.

Discussion

Principal Findings

This evaluation sought to uncover the equity and accessibility issues that may influence the access, adoption, and use of digital EN tools among diverse populations disproportionately impacted by COVID-19. Our findings suggest that digital literacy, trust, and information accessibility are key determinants of the adoption and use of WA Notify. Consistent with other mHealth equity evaluations of tools and interventions delivered over smartphones to disadvantaged and diverse populations, our results predominantly concerned limited health literacy, the ease of adoption and use, and issues related to the accessibility, relevance, and clarity of delivered content. However, misinformation and the fear of negative consequences related to using a digital EN tool emerged as unique determinants. These concerns may be barriers unique to a digital EN intervention or may be part of broader concerns among disenfranchised groups related to COVID-19 mitigation

measures such as masking, contact tracing, and vaccination [29].

This evaluation also sought to generate recommendations from populations experiencing COVID-19–related health inequities to prevent WA Notify from contributing to the adverse effects of public health interventions and ensure that it is accessible, relevant, useful for diverse communities. To address inequalities in technology access and digital skills, we recommend providing technology navigation through social networks and as extensions of existing community-based programs. To prevent inequalities in adoption, we recommend expanding partnerships with trusted messengers to elevate awareness, address misinformation, and promote trust in this novel technology, especially among community members who may not have been engaged through previous communication efforts. To address inequalities in using or adhering to WA Notify, information should be simple, easy to navigate, and accessible in a variety of formats. Lastly, to prevent inequalities in effectiveness and ensure that digital EN tools actively narrow COVID-19–related health inequities, implementers need to identify critical structural barriers faced by vulnerable populations and develop strategies to help users address, navigate, or simplify these barriers. In essence, WA Notify should serve a dual purpose: (1) to notify individuals of a COVID-19 exposure and (2) provide comprehensive resource navigation to ensure that all users are able to engage in protective behaviors. By developing effective connections with CBOs, local health jurisdictions, and other social support or medical services, WA Notify could ensure greater benefits for disadvantaged individuals and maximize its potential impact against COVID-19–related morbidity and mortality.

Limitations

This evaluation is subject to several limitations. First, although the project focused on identifying factors that could help WA Notify promote health equity, the direct measurement of the impact of WA Notify on COVID-19–related outcomes or health equity was not possible. Estimating the impact of digital EN systems is an ongoing area of evaluation, but the privacy-preserving design of this intervention does not allow for the identification of specific users, let alone their health

status. Second, recruitment efforts were concentrated on a small, purposive sample of community leaders. Although these leaders provided invaluable insight into their communities, these individual perspectives are unlikely to capture the heterogeneity of lived experiences, insights, and recommendations of their communities or state. Additionally, leaders participating in both the survey and informational sessions identified themselves as representing more than one community, so it is not possible to know whether the perceptions they shared were those of one specific community. Subsequent phases of this evaluation will seek to engage community members directly to supplement and expand upon the insights shared by the community leaders. Lastly, our findings reflect the conditions experienced by diverse communities during the first year of WA Notify's implementation. As the pandemic landscape changes, some of our results may no longer be generalizable to this new context. In the months following the completion of this evaluation, WA Notify has undergone iterative design changes, new variants (eg, Omicron) have emerged, and COVID-19 guidance has been modified. Future evaluations will need to take this altered landscape into account.

Conclusion

WA Notify is more than just a digital EN tool. It is an intervention on an individual's phone that represents public health and serves as a novel opportunity for public health agencies to communicate, alert, and engage with the communities they serve. WA Notify is part of a larger shift toward digital public health, which encompasses emerging tools such as vaccine verification initiatives and symptom-monitoring platforms, and seeks to improve the efficiency, scalability, and acceptability of traditional public health workflows. As an innovation that is changing how public health and outbreak response are conducted, WA Notify can empower its users to engage in the protective measures needed to keep themselves, their families, and their communities safe. Incorporating our equity-related findings and recommendations into the development, implementation, and communications efforts around digital pandemic and emergency preparation and response tools such as WA Notify will ensure that all communities can benefit.

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Conflicts of Interest

None declared.

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Abbreviations

CBO: community-based organization

DOH: Department of Health

EN: exposure notification

LGBTQIA+: Lesbian, Gay, Bisexual, Transgender, Queer/Questioning, Intersex, Asexual, and other identities

mHealth: mobile health

VIC: Vaccine Implementation Collaborative

WA: Washington

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Original Paper

Knowledge, Attitude, Practices, and Vaccine Hesitancy Among the Latinx Community in Southern California Early in the COVID-19 Pandemic: Cross-sectional Survey

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Abstract

Background: The Latinx population in the United States has experienced high rates of infection, hospitalization, and death since the beginning of the COVID-19 pandemic. There is little data on the knowledge, attitude, and practices (KAP) specifically in Latinx communities in the United States.

Objective: We aimed to assess COVID-19 KAP and vaccine hesitancy among a Latinx cohort in the early stages of the COVID-19 pandemic (from July 2020 to October 2020), at a unique time when a vaccine was not available.

Methods: Participants aged ≥ 18 years were recruited at a primary care clinic in Southern California and asked to self-report sociodemographic characteristics, KAP, and vaccine hesitancy. A subset of the participants answered the vaccine hesitancy assessment as it was added after the start of data collection. KAP items were summed to create composite scores, with higher scores reflecting increased COVID-19 knowledge, positive attitudes toward the COVID-19 pandemic, and disease prevention practices. Bivariate and multivariable regression models were fitted to test associations between sociodemographic characteristics and KAP scores. For our analysis, we only included patients who self-identified as Latinx.

Results: Our final data set included 265 participants. The participants had a mean age of 49 (IQR 38.5-59) years, and 72.1% (n=191) were female, 77% (n=204) had at most a high school degree, 34.7% (n=92) had an annual income <US \$25,000, and 11.7% (n=31) had previously tested positive for COVID-19. We found high knowledge regarding transmission and spread; moderate knowledge regarding symptoms awareness; overall negative attitudes, which included high pessimism in government public health efforts and high amounts of fear, anxiety, and frustration due to COVID-19 pandemic; and moderate participation in preventive practices. A college education was positively associated with a higher knowledge score than those without a college education ($\beta=0.14$, 95% CI 0.01-1.60; $P=.04$) when adjusted for covariates. Male gender had a positive association with COVID-19 attitude scores compared to female gender ($\beta=1.61$, 95% CI 0.50-2.72; $P=.05$), and male gender was negatively associated with the COVID-19 practices score compared to female gender ($\beta=-0.16$, 95% CI -0.56 to -0.06; $P=.03$), when both were adjusted for covariates. Among a subset of 203 patients, 26.6% (n=54) indicated that if the vaccine was available, they would not take a COVID-19 vaccine, and 18.7% (n=38) were unsure.

Conclusions: Good knowledge and preventative practices in the population may have reflected effective public health messaging and the implementation of public health laws during the first wave of the pandemic; however, the overall fear and anxiety may have reflected the negative impact that the pandemic had on vulnerable populations such as the Latinx community. Although our data are a reflection of a previous time in the pandemic, we believe it captures a critical time that can be used to provide unique insights regarding potential avenues to better protect the Latinx communities against future vaccine-resistant COVID-19 strains.

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KEYWORDS

COVID-19; knowledge; attitude; practices; KAP survey; vaccine hesitancy; Latinx; Latinx cohort; minority population; primary care; sociodemographic characteristic; public health; vulnerable population; epidemiology

Introduction

In early 2020, the global community was overwhelmed by the COVID-19 pandemic caused by the SARS-CoV-2 virus, leading to quickly rising incidence and death rates with no available vaccine. By December 2020, COVID-19 had infected almost 20 million people and caused more than 300,000 deaths in the United States [1]. As cases of COVID-19 climbed across the United States throughout 2020, racial/ethnic minority populations were more likely to be infected, experience complications, and die from COVID-19 than the general population during a time when the vaccine was not available [2]. Although Latinx populations made up only 38.9% of the total population in California, they accounted for almost 60% of COVID-19 cases and approximately 50% of COVID-19-related deaths during the early pandemic in 2020 [3].

In 2021, the Moderna and Pfizer vaccines were made accessible to thousands of Latinx individuals in California [4], especially due to outreach and advocacy by organizations such as the Latin Community Foundation, Hispanic Federation, and the Orange County Public Health Department [5-7]. Despite this important milestone in the pandemic, the Latinx, Black, and American Indian or Alaska Native communities had similarly slow rates of vaccine uptake throughout 2020 and 2021 compared to Asian and White populations. As expected, Black and Latinx communities reported increased vaccine hesitancy compared to White and Asian populations in the United States [8,9].

The Latinx community remained one of the most vulnerable groups in terms of infection and death rates compared to the rest of the state population in the emergence of the new Omicron variant [10].

As we enter the third year of the COVID-19 pandemic, we still have not fully investigated the risk factors that predisposed the Latinx population in California to significantly higher incidence rates in the first year of the pandemic compared to other communities. In addition to the greater lack of access to care in the Latinx community, there are many other structural disparities that contribute to decreased health equity and increased risk behaviors in this population [11-14]. The Knowledge, Attitude, and Practices (KAP) theory is a health behavior theory based on the belief that knowledge is the foundation of behavior change and helps form attitudes and practices that drive behavior change [15,16]. Numerous global

studies from the beginning of the pandemic showed that a lack of COVID-19 knowledge, negative attitudes toward the pandemic, and the lack of disease preventative practice were more common in communities with high disease rates [14,17-21]. Further, vaccine hesitancy has been a persisting issue for the last few decades during the presence of numerous pandemics, especially within minority populations [22,23]. In the beginning of the COVID-19 pandemic, few studies measured the vaccine hesitancy of a potential COVID-19 vaccine before the vaccine was made available [24,25]. It is possible that if this data was measured early on, there would be more information to assist public health programs to combat vaccine misinformation and mistrust at the start of the vaccine release to the public [26]. There have been a small number of other studies that have explored the differences in KAP between different ethnic groups and genders in the United States, but none have specifically focused on the Latinx population.

In this study, we sought to investigate COVID-19 KAP and vaccine hesitancy among a Latinx population in Southern California. Specifically, we aimed to capture information on KAP and vaccine hesitancy from a critical time early in the COVID-19 pandemic when the vaccine was not available. The findings of this work provide unique insights regarding vulnerabilities and potential avenues for better protecting Latinx communities in future pandemics and against new vaccine-resistant COVID-19 strains, such as the currently circulating Omicron strain.

Methods

Study Design

We conducted a cross-sectional study from July to October 2020 in Southern California, during the “stay at home” order period that was implemented by the state government of California. We carried out our surveys at 2 primary health care centers in Santa Ana and Anaheim, California. Using consecutive sampling methods, we predominately recruited and surveyed patients presenting for telehealth appointments but also recruited patients presenting for in-person appointments at the clinics. Patients were eligible for study participation if they were (1) aged ≥ 18 years and (2) an enrolled patient of Amistad Medical Clinic Santa Ana or Amistad Medical Clinic Anaheim. For this analysis, we only included participants who self-identified as Latinx. Our study design, which included

in-person and telemedical recruitment, and data collection methods have been previously described [27].

Survey Validation

Our KAP survey was adapted from the World Health Organization's (WHO) Guide to Developing Knowledge, Attitude, and Practice Surveys [15], in addition to the few existing global COVID-19 KAP studies from the time period [28-30]. The most current COVID-19 symptoms included in the knowledge survey were identified using Centers for Disease Control and Prevention symptom reports that were the most current at the time of data collection. No standardized questionnaire for COVID-19 KAP had been created at the time of the study due to the early nature of the pandemic. Therefore, we pretested our KAP survey among 10 participants before implementing it.

Questions about vaccine hesitancy were added to the survey after the start of data collection. The vaccine hesitancy questions were adapted from the Vaccine Hesitancy Scale by WHO's Strategic Advisory Group of Experts on Immunization [31]. The survey was pretested among 10 participants before including it in our data collection.

Measures

Sociodemographic Characteristics

We asked participants to self-report sociodemographic characteristics including age (in years); gender (male vs female); education level completed (elementary school, middle school, high school, college degree, or graduate degree); annual income (less than US \$25,000, US \$25,000 to US \$49,999, US \$50,000 to US \$99,999, and US \$100,000 or more); marital status (single/never married, married, divorced, separated, or widowed); ethnicity (Latinx vs non-Latinx); and employment status (currently employed, recently unemployed or on temporary leave due to COVID-19, unemployed before COVID-19, retired, or a student). We also asked participants to self-report whether they had ever tested positive for COVID-19 (yes vs no).

COVID-19 KAP Survey

The COVID-19 KAP survey was comprised of 3 parts: (1) COVID-19 knowledge, (2) COVID-19 attitudes, and (3) COVID-19 practices. Knowledge included questions about disease transmission and spread through 12 dichotomous (yes vs no) questions and 1 open-ended question. It also measured knowledge of the most common COVID-19 symptoms through a multiple mark-style question in which participants were able to endorse 1 or more symptoms. All items were then summed to create a composite knowledge score ranging from 0 to 12, with higher scores indicating greater COVID-19 knowledge. Correct answers were based on current COVID-19 data at the time that was disseminated by the WHO to the general public [32].

COVID-19 attitudes were assessed through 5 items regarding confidence in the government control of the pandemic and emotions about the pandemic. All items were measured on a 5-point Likert-type scale ranging from 1 (strongly disagree) to 5 (strongly agree) and were summed to create a composite

attitude score, ranging from 5 to 25, with lower scores indicating more negative attitudes. COVID-19 practices consisted of 2 items that assessed participants' engagement in behaviors that reduce COVID-19 transmission. Both items were measured using a 5-point Likert-type scale ranging from 1 (never) to 5 (always) and were summed to create a composite practices score, ranging from 2 to 10, with higher scores indicating greater engagement in COVID-19 preventative behaviors.

COVID-19 Vaccine Hesitancy

Additionally, a question regarding vaccine hesitancy was added to the study after the start of data collection, and a subset of participants provided information on their willingness to take a potential COVID-19 vaccine through their responses (yes, maybe, or no) to the following question, "If a COVID-19 vaccine was available, would you get one?" Those who indicated "no" or "maybe" to this question were then asked to report their reason for their vaccine hesitancy. Response options included "I don't think it would work," "I'm concerned about the possible side effects," "I'm worried about the cost," "I don't think it's necessary," and "Other people will get it so I won't need to."

Statistical Analyses

We performed descriptive analysis for participant sociodemographic characteristics and COVID-19 vaccine hesitancy. Bivariate linear regression models were fitted to test associations between sociodemographic characteristics and COVID-19 KAP scores. Multivariable linear regression analyses were then conducted to further test the associations between sociodemographic characteristics and COVID-19 KAP scores while controlling for covariates found to be associated with the variables of interest in the bivariate analyses ($P < .05$). As determined a priori, variables associated with COVID-19 KAP in the bivariate analysis were retained for inclusion in the multivariable analysis. In addition, other sociodemographic variables previously found to be associated with COVID-19 KAP in the literature (ie, age, education, gender, income, gender, and marital status) were also included as covariates in the multivariable models [33-35]. All analyses were conducted in SPSS statistical software (version 9.8.0; IBM Corp).

Ethical Approval

The study was exempted from review by the University of California, San Diego Institutional Review Board on June 22, 2020. Patients' names or other identifying information were not collected. Participants were informed of the confidential nature of the study and were allowed to terminate the survey at any time.

Results

Demographics

A total of 323 participants completed the COVID-19 KAP survey. Our final data set included 265 participants after 58 individuals who did not self-identify as Latinx were excluded from analysis. Among the 265 participants, the mean age was 49.3 (IQR 38.5-59) years, and 191 (72.1%) identified as female, 139 (52.5%) were married, 109 (41.1%) indicated they had a middle school education or below, 89 (33.6%) had lost their

job or were on temporary leave due to COVID-19, 92 (34.7%) reported a current or previous positive test for COVID-19 (Table 1). had an annual income less than US \$25,000, and 31 (11.7%)

Table 1. Sociodemographic and clinical characteristics among Latinx clinic attendees in Southern California (N=265).

Variable, category	Participant
Gender, n (%)	
Female	191 (72.1)
Male	74 (27.9)
Age (year), mean (IQR)	49.3 (38.5-59)
Marital status, n (%)	
Single/never married	84 (31.7)
Married	139 (52.5)
Divorced	10 (3.8)
Separated	19 (7.2)
Widowed	11 (4.2)
Refused to answer	2 (0.8)
Highest educational level, n (%)	
Middle school or below	109 (41.1)
High school	95 (35.8)
College degree	36 (13.6)
Graduate school	4 (1.5)
Refused to answer	21 (7.9)
Employment status, n (%)	
Currently employed	59 (22.2)
Lost job or on temporary leave due to COVID-19	89 (33.6)
Unemployed currently and before COVID-19	74 (27.9)
Retired	40 (15.1)
Student	2 (0.8)
Refused to answer	1 (0.4)
Annual household income (US \$), n (%)	
<25,000	92 (34.7)
25,000-49,999	30 (11.3)
50,000-99,999	18 (6.8)
≥100,000	7 (2.6)
Refused to answer	118 (44.5)
Previously tested positive for COVID-19, n (%)	
Yes	31 (11.7)
No	234 (88.7)

COVID-19 Knowledge

Of the total 265 participants, 254 (95.8%) correctly knew that COVID-19 is spread when an infected person coughs, sneezes, or speaks; 251 (94.7%) correctly knew that COVID-19 is spread through touching contaminated surfaces and then touching the eyes or mouth; and 243 (91.7%) correctly knew to stand 6 feet or more away from another person to be safe from COVID-19

(Table S1 in [Multimedia Appendix 1](#)). However, 212 (80%) participants incorrectly believed that only older individuals (aged >65 years) are susceptible to COVID-19. Additionally, 196 (74%) participants correctly knew that individuals with pre-existing medical conditions are more susceptible to COVID-19, and 224 (84.5%) correctly identified that asymptomatic individuals with COVID-19 can still infect someone else. When asking participants for common symptoms

of COVID-19, 171 (64.5%) correctly identified fever, 111 (41.9%) correctly identified cough, 109 (41.1%) correctly identified headache, 100 (37.7%) correctly identified shortness of breath, 91 (34.3%) correctly identified body aches, 46 (17.4%) correctly identified loss of taste, and 34 (13.6%) correctly identified loss of smell.

In the multivariate analysis, when adjusting for age, gender, annual household income, and education, having a college degree was significantly associated with a higher knowledge score than those who completed middle school or below ($\beta=0.14$, 95% CI 0.01-1.60; $P=.04$; [Table 2](#)).

Table 2. Bivariate and multivariable analysis of factors associated with COVID-19 knowledge among Latinx individuals in Southern California (N=265).

Factor	Bivariate analysis, β (95% CI)	<i>P</i> value	Multivariate analysis, $a\beta$ (95% CI)	<i>P</i> value
Age	-0.19 (-0.04 to -0.01)	.002	-0.01 (-0.03 to 0.01)	.26
Gender				
Female (ref ^a)	— ^b	—	—	—
Male	-0.04 (-0.34 to 0.72)	.30	0.06 (-0.53 to 0.56)	.95
Marital status				
Married (ref)	—	—	—	—
Single	0.01 (-0.51 to 0.55)	.93	—	—
Divorced	0.09 (-0.24 to 1.63)	.14	—	—
Widowed	-0.10 (-2.21 to 0.18)	.09	—	—
Separated	0.01 (-1.18 to 1.32)	.91	—	—
Annual household income (US \$)				
<25,000 (ref)	—	—	—	—
25,000-49,999	0.07 (-0.28 to 1.19)	.23	0.01 (-0.69 to 0.83)	.87
50,000-99,999	0.14 (0.17-2.03)	.02	0.09 (-0.28 to 1.69)	.19
≥100,000	0.13 (0.15-3.06)	.03	0.12 (-0.14 to 3.09)	.08
Education				
Middle school or below (ref)	—	—	—	—
High school	0.26 (0.23-1.23)	.005	0.11 (-0.13 to 1.01)	.25
College degree	0.36 (0.47-1.89)	.001	0.14 (0.01-1.60)	.04
Graduate degree	0.96 (0.46-4.24)	.02	0.12 (-0.05 to 3.92)	.07
Employment status				
Lost job or on temporary leave due to COVID-19 (ref)	—	—	—	—
Currently employed	0.08 (-0.24 to 1.03)	.22	—	.24
Unemployed currently and before COVID-19	-0.01 (-0.63 to 0.55)	.89	—	.57
Retired	-0.18 (-1.68 to -0.24)	.009	—	.53
Student	-0.06 (-4.13 to 1.27)	.30	—	.19
Previously tested positive for COVID-19				
No (ref)	—	—	—	—
Yes	0.29 (-0.56 to 0.90)	.69	—	—

^aRef: reference.

^bNot available (item was not accessed).

COVID-19 Attitudes

Among the 265 total participant, 104 (39.2%) strongly disagreed or disagreed that the government would help stop the spread of the virus; 198 (74.7%) strongly agreed or agreed that they felt nervous about how the COVID-19 pandemic would impact their future; 120 (45.3%) strongly agreed or agreed that they had felt

angry or frustrated because of the COVID-19 pandemic; and 147 (55.5%) strongly agreed or agreed that they had felt scared to leave their home because of COVID-19. However, a majority 72.5% (n=192) of the participants strongly agreed or agreed that they had felt hopeful about the future ([Table S2 in Multimedia Appendix 1](#)).

In the multivariate analysis, when adjusting for marital status and education, male gender had a positive association with COVID-19 attitude scores compared to female gender ($\beta=1.61$, 95% CI 0.50-2.72; $P=.005$; [Table 3](#)).

Table 3. Bivariate and multivariable analysis of factors associated with COVID-19 attitudes among Latinx individuals in Southern California (N=265).

Factor	Bivariate analysis, β (95% CI)	<i>P</i> value	Multivariate analysis, $a\beta$ (95% CI)	<i>P</i> value
Age	0.06 (–0.02 to 0.07)	.37	0.00 (–0.04 to 0.04)	.96
Gender				
Female (ref ^a)	— ^b	—	—	—
Male	1.65 (0.58-2.71)	.003	1.61 (0.50-2.72)	.005
Marital status				
Married (ref)	—	—	—	—
Single	–0.15 (–2.33 to –0.18)	.04	–0.13 (–2.31 to 0.08)	.07
Divorced	0.56 (–2.74 to 1.04)	.14	–0.03 (–2.45 to 1.44)	.61
Widowed	0.07 (–4.35 to 0.71)	.09	–0.07 (–3.99 to 1.09)	.26
Separated	–0.09 (–3.95 to 1.11)	.91	–0.07 (–4.00 to 1.06)	.25
Annual household income (US \$)				
<25,000 (ref)	—	—	—	—
25,000-49,999	–0.01 (–1.68 to 1.38)	.85	—	—
50,000-99,999	0.02 (–1.68 to 2.17)	.81	—	—
≥100,000	–0.01 (–3.09 to 2.93)	.96	—	—
Education				
Middle school or below (ref)	—	—	—	—
High school	–0.08 (–1.74 to 0.38)	.21	–0.06 (–1.65 to 0.73)	.45
College degree	–0.01 (–1.55 to 1.42)	.93	0.00 (–1.64 to 1.68)	.98
Graduate degree	0.01 (–3.85 to 4.07)	.96	–0.02 (–4.51 to 3.47)	.80
Employment status				
Lost job or on temporary leave due to COVID-19 (ref)	—	—	—	—
Currently employed	–0.09 (–1.99 to 0.46)	.96	—	—
Unemployed currently and before COVID-19	–0.01 (–1.34 to 1.28)	.22	—	—
Retired	0.12 (–0.21 to 2.74)	.09	—	—
Student	0.48 (–7.73 to 3.55)	.44	—	—
Previously tested positive for COVID-19				
No (ref)	—	—	—	—
Yes	–0.05 (–2.06 to 0.88)	.43	—	—

^aRef: reference.

^bNot available (item was not accessed).

COVID-19 Preventative Practices

Among the 265 participants, when asked about preventative practices to stay safe from COVID-19 transmission, 161 (60.8%) indicated that they washed their hands most of the time when entering their homes, whereas 92 (34.7%) indicated that they never engage in this practice. Interestingly, 248 (93.6%) indicated that they always wear a mask outside of their home,

whereas none indicated that they never wear a mask outside their home (Table S3 in [Multimedia Appendix 1](#)).

In the multivariable regression analysis, controlling for marital status, annual household income, and education, male gender was negatively associated with the COVID-19 practices score compared to female gender ($\beta=-0.16$, 95% CI –0.56 to –0.06; $P=.03$; [Table 4](#)).

Table 4. Bivariate and multivariable analysis of factors associated with COVID-19 attitudes among Latinx individuals in Southern California (N=265).

Factor	Bivariate analysis, β (95% CI)	<i>P</i> value	Multivariate analysis, $a\beta$ (95% CI)	<i>P</i> value
Age	0.04 (–0.01 to 0.01)	.54	—	—
Gender				
Female (ref ^a)	— ^b	—	—	—
Male	–0.65 (–0.56 to –0.08)	.008	–0.16 (–0.56 to –0.06)	.03
Marital status				
Married (ref)	—	—	—	—
Single	0.05 (–0.16 to 0.33)	.49	0.05 (–0.17 to 0.34)	.50
Divorced	0.07 (–0.18 to 0.67)	.26	0.05 (–0.28 to 0.60)	.47
Widowed	0.05 (–0.34 to 0.75)	.46	0.04 (–0.38 to 0.71)	.56
Separated	0.02 (–0.47 to 0.66)	.74	0.03 (–0.46 to 0.71)	.67
Annual household income (US \$)				
<25,000 (ref)	—	—	—	—
25,000–49,999	0.05 (–0.20 to 0.48)	.43	0.04 (–0.24 to 0.46)	.54
50,000–99,999	–0.08 (–0.69 to 0.16)	.22	–0.04 (–0.60 to 0.33)	.57
≥100,000	–0.01 (–0.72 to 0.62)	.88	–0.02 (–0.80 to 0.60)	.77
Education				
Middle school or below (ref)	—	—	—	—
High school	–0.01 (0.25–0.22)	.88	–0.01 (–1.65 to 0.73)	.89
College degree	–0.11 (–0.36 to 0.30)	.87	–0.00 (–1.64 to 1.68)	.90
Graduate degree	–0.00 (–0.90 to 0.86)	.96	0.01 (–4.51 to 3.47)	.84
Employment status				
Lost job or on temporary leave due to COVID-19 (ref)	—	—	—	—
Currently employed	0.07 (–0.15 to 0.44)	.32	—	—
Unemployed currently and before COVID-19	0.05 (–0.18 to 0.36)	.52	—	—
Retired	0.12 (–0.04 to 0.62)	.09	—	—
Student	–0.07 (–1.40 to 1.08)	.80	—	—
Previously tested positive for COVID-19				
No (ref)	—	—	—	—
Yes	0.05 (–0.19 to 0.46)	.43	—	—

^aRef: reference.

^bNot available (item was not accessed).

COVID-19 Vaccine Hesitancy

We asked a subset of 203 participants about their views on a potential COVID-19 vaccine before the COVID-19 vaccine was made available. Within this subset (N=203), 111 (54.7%) indicated that they would take a vaccine if it were available, but 54 (26.6%) indicated that they would not take a vaccine, and 38 (18.7%) indicated that they were unsure (ie, answered “maybe”). Of those who indicated they would not take a vaccine (n=54), 23 (43%) indicated that they were concerned with

possible side effects, 18 (33%) indicated that they didn’t think it was necessary, 8 (15%) indicated that they didn’t think it will work, and 1 (2%) indicated that they are worried about the cost and financial burden. Of those who indicated they were unsure (n=38), 27 (71%) indicated that they are concerned about possible side effects, 3 (8%) indicated that they didn’t think it will work, 2 (5%) indicated that they didn’t think it’s necessary, and none indicated that they are worried about cost and financial burden (Table 5).

Table 5. COVID-19 vaccine hesitancy before vaccine availability (N=203).

View on vaccine, reasons for hesitancy	Participants, n (%)
Willing to take the vaccine (n=111)	111 (100)
Unsure about taking the vaccine (n=38)	
Don't think it's necessary	2 (5)
Don't think it will work	3 (8)
Concerned about the possible side effects	27 (71)
Worried about the cost and financial burden	0 (0)
Refused to answer	6 (16)
Not willing to take the vaccine (n=54)	
Don't think it's necessary	18 (33)
Don't think it will work	8 (15)
Concerned about the possible side effects	23 (43)
Worried about the cost and financial burden	1 (2)
Refused to answer	4 (7)

Discussion

Principal Findings

Since the start of the COVID-19 pandemic in Southern California, the Latinx population has been disproportionately affected by disease incidence, morbidity, and mortality. Our data demonstrate that this population had good knowledge of COVID-19 transmission and spread; moderate knowledge of COVID-19 symptoms; overall negative attitudes including high pessimism in government public health efforts and high amounts fear, anxiety, and frustration due to COVID-19 pandemic; but high optimism about the future. Our data also show moderate participation in preventative practices and moderate vaccine hesitancy within a Southern California Latinx community during the first wave of the pandemic before the vaccine was available. In addition, our data show a significant association between college education and a higher COVID-19 knowledge score; male gender and a more optimistic attitude; and male gender and a lower practices score. We believe that observational data from this period are critical to identifying how a pandemic can initially affect vulnerable populations' understanding of disease, since knowledge helps form attitudes and practices that drive behavior change [36].

Comparison to Prior Works

Participants were particularly aware of the common physical symptoms of COVID-19 illness, such as cough, headache, and fever. Relatively few participants, however, identified loss of taste and smell as common COVID-19 symptoms. The lack of knowledge around these very specific symptoms may have been due to the unusual nature of the symptoms and the public health messaging at the time that was emphasizing "coughing" as an identifiable symptom to be aware of [37,38]. When participants were asked about their knowledge regarding COVID-19 transmission and susceptibility, most knew that transmission could happen when an infected person coughs, sneezes, or speaks and that the disease could be spread by touching contaminated surfaces and then touching the eyes or mouth.

Most also knew to stand 6 feet or more away from others to prevent disease transmission. However, our data show that over half of our participants felt that only older people were susceptible to COVID-19 infection.

Our findings also demonstrate that younger age was associated with lower knowledge scores, a finding supported by Alsan et al [39], which reported that people aged <55 years were less likely to know how the disease is spread and the symptoms of COVID-19. Higher education and income were associated with higher knowledge scores, which is supported by global COVID-19 studies from 2020 that showed higher education and income allowed for greater knowledge regarding the disease [34,40,41].

When participants were asked about their COVID-19 attitudes, only one-third agreed or strongly agreed that the government would stop the spread of the virus, whereas more than half disagreed or strongly disagreed. Focus groups among Latinx farmworkers in the central valley reported similar themes of mistrust in government institutions regarding COVID-19 vaccinations and testing [42]. This finding is in-line with the Latinx community's growing mistrust in the American government's medical and public health policies [43].

The participants also expressed feelings of fear, anxiety, and frustration. Widespread fear, anxiety, and depression related to COVID-19 has been well-documented in the United States, and recent research has shown that these feelings have been magnified in Latinx populations where the loss of employment has been widespread [44-46]. In our study, nearly one-third of the participants reported COVID-19-related "temporary leave" or lost jobs during the pandemic. This substantial change in employment status may have also contributed to the participants' reports of feeling angry or frustrated due to COVID-19. However, despite the negative attitudes toward COVID-19, over half of the participants indicated that they were still hopeful about the future. A positive outlook aligns with research that shows that specific Latinx populations have high resilience during stressful situations and carry optimism for the future

despite dissatisfaction with the present and the multiple obstacles and stressors they face [47].

Our data show that men had more COVID-19–related positive attitudes about government response and the pandemic’s effect on their lives compared to women. Our data differ from other European- and South American–based studies that have shown no significant association between gender and COVID-19–related positive attitudes in the Latinx community [48,49]. However, our results could be explained by women having reportedly higher levels of fear and stress and negative perceptions of government actions than men during the pandemic [50]. Multiple studies conducted globally and in the United States have indicated that women have been carrying high burdens of care (eg, caring for and teaching children in the absence of in-person learning environments) and emotional labor [51–53]. Consequently, this gendered division of labor could potentially have contributed to the gender differences in positive attitudes found in our study.

Additionally, when asked about COVID-19 preventative practices, almost all participants indicated that they always wore a mask when they went outside of their home. This strong knowledge base and the corresponding safety practices regarding COVID-19 may indicate that there was effective public health messaging regarding transmission and preventative practices that had penetrated the community. In addition, local laws possibly contributed to higher compliance with COVID-19 preventative practices, such as wearing masks [54]. Our data indicate that men had decreased preventative practices compared to women. This aligns with a study by Alsharawy et al [50] indicating that women engaged in more preventative practices during the pandemic and were more risk averse.

Our data captured vaccine attitudes and acceptability between July and October 2020—a period before COVID-19 vaccines were approved for essential workers in December 2020. The most common reasons given for an expressed reluctance to accept vaccination in our study were concern about possible side effects, thinking it was not necessary, and thinking it would not work. After the vaccine was released, studies documented mass vaccine hesitancy in Latinx and Black communities across the United States who had historically faced government oppression and had mistrust in the intentions of public health medical interventions [55,56]. Our findings have built upon these studies and provided further evidence of relatively high vaccine hesitancy in marginalized populations, and we suggest that in future pandemics, more focused effort should be expended on both vaccine education and interventions that are targeted toward combatting medical mistrust in marginalized communities prior to vaccine distribution.

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Limitations

Our study had several limitations. First, due to the cross-sectional nature of the study, we are unable to report whether the KAP was casually associated with the covariates examined. In addition, we had a limited set of questions due to time constraints in the clinical setting. Lastly, the reliance on self-reporting may have introduced response bias due to participants’ fear of judgement from health care providers regarding COVID-19 practices. To mitigate these challenges, we made sure that our survey administrators were not health care providers, were well-trained, and approached surveys in a nonjudgmental manner and that the participants were informed of the confidential nature of the study and allowed to terminate the survey at any time. Additionally, our vaccine acceptance questions were asked before a vaccine was approved, hence we recognize that these findings may not reflect current attitudes toward vaccines for our population. Additionally, the cross-sectional nature of our study did not allow us to track data over time but rather enabled us to capture data at one point in time. We acknowledge that the situation with COVID-19 has changed rapidly, and therefore, KAP in populations can change over time.

We believe, however, that our data capture important information related to symptom awareness, knowledge, attitudes, and practice, in addition to vaccine hesitancy during a critical time in the history of the COVID-19 pandemic; this data might provide important insights into the future implementation of critical public health interventions and policies serving Latinx populations.

Conclusion

We found high knowledge regarding transmission and spread; moderate knowledge regarding symptoms awareness; overall negative attitudes which included high pessimism in government public health efforts and high amounts of fear, anxiety, and frustration due to the COVID-19 pandemic; and moderate participation in preventive practices. We also found moderate vaccine hesitancy in the Latinx community in Southern California during the first wave of the pandemic. Good knowledge and preventative practices in the population may be a reflection of effective public health messaging and the implementation of public health laws during the first wave of the pandemic; however, the overall fear and anxiety may have been a reflection of the negative impact that the pandemic had on vulnerable populations such as the Latinx community. We believe it would be useful to examine KAP in larger populations during this time period and potentially use the data to inform public health approaches in Latinx communities amid the potential arrival of new pandemics.

Authors' Contributions

SNM led the project coordination, data analysis, and writing of the manuscript. SAMP and RSG also led the data analysis. ZCB, SNM, and TR led the proposal and protocol development. DOO, PKM, SBK, JK, and MM contributed to the clinical and logistical aspects of protocol development. All authors have approved the final manuscript and agreed to publication.

Conflicts of Interest

TR is a University of California, San Diego coinventor of a COVID-19 rapid test—patent pending. All other authors declared no additional conflicts of interest.

Multimedia Appendix 1

Additional knowledge, attitude, and practices survey results.

[[DOCX File, 17 KB - formative_v6i8e38351_app1.docx](#)]

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Abbreviations

KAP: knowledge, attitude, and practices

WHO: World Health Organization

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Original Paper

Sleep Patterns and Affect Dynamics Among College Students During the COVID-19 Pandemic: Intensive Longitudinal Study

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Abstract

Background: Sleep disturbance is a transdiagnostic risk factor that is so prevalent among young adults that it is considered a public health epidemic, which has been exacerbated by the COVID-19 pandemic. Sleep may contribute to mental health via affect dynamics. Prior literature on the contribution of sleep to affect is largely based on correlational studies or experiments that do not generalize to the daily lives of young adults. Furthermore, the literature examining the associations between sleep variability and affect dynamics remains scant.

Objective: In an ecologically valid context, using an intensive longitudinal design, we aimed to assess the daily and long-term associations between sleep patterns and affect dynamics among young adults during the COVID-19 pandemic.

Methods: College student participants (N=20; female: 13/20, 65%) wore an Oura ring (Oura Health Ltd) continuously for 3 months to measure sleep patterns, such as average and variability in total sleep time (TST), wake after sleep onset (WASO), sleep efficiency, and sleep onset latency (SOL), resulting in 1173 unique observations. We administered a daily ecological momentary assessment by using a mobile health app to evaluate positive affect (PA), negative affect (NA), and COVID-19 worry once per day.

Results: Participants with a higher sleep onset latency ($b=-1.09$, SE 0.36; $P=.006$) and TST ($b=-0.15$, SE 0.05; $P=.008$) on the prior day had lower PA on the next day. Further, higher average TST across the 3-month period predicted lower average PA ($b=-0.36$, SE 0.12; $P=.009$). TST variability predicted higher affect variability across all affect domains. Specifically, higher variability in TST was associated higher PA variability ($b=0.09$, SE 0.03; $P=.007$), higher negative affect variability ($b=0.12$, SE 0.05; $P=.03$), and higher COVID-19 worry variability ($b=0.16$, SE 0.07; $P=.04$).

Conclusions: Fluctuating sleep patterns are associated with affect dynamics at the daily and long-term scales. Low PA and affect variability may be potential pathways through which sleep has implications for mental health.

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KEYWORDS

sleep; objective sleep outcomes; COVID-19; affect variability; affect dynamics

Introduction

Sleep is a robust and transdiagnostic risk factor for various physical and mental health problems, including mood disorders [1-3]. Indeed, sleep disorders, such as insomnia and circadian misalignment, contribute to the development or recurrence of mood disorders, particularly depression and anxiety [4]. Variability in sleep duration, as measured by day-to-day changes in nightly sleep, is as important a predictor for psychological well-being as the average total amount of sleep [5]. Sleep problems, such as chronic sleep restriction and irregular sleep patterns, are common among college students [6]. For emerging adults who are already at greater risk for psychopathology [7,8], the COVID-19 pandemic has disrupted daily routines [9,10], thereby potentially exacerbating variable sleep patterns and contributing to further insufficient sleep and greater variability in sleep duration. Given the prevalence of sleep disturbances as well as the impact of the pandemic on young adults, it may be important to examine the associations between sleep and affect in young adults during the COVID-19 pandemic.

Insufficient sleep and sleep variability may contribute to physical and mental health via affect dynamics. Positive affect (PA) and negative affect (NA)—broadband indices of emotion—are well-established predictors of well-being [11]. Blunted PA and increased NA are risk factors for and significant predictors of the development and recurrence of mental disorders, such as depression. COVID-19 worry, or concern over SARS-CoV-2 infection, is another relevant affect construct that has arisen during the pandemic [12,13]. COVID-19 worry has been discussed at length by psychologists during the COVID-19 pandemic [12-14] and is a distinct psychological factor that uniquely contributes to general anxiety and persistent pessimism [12]. Affect, however, is dynamic; the trajectory of emotional experiences often fluctuates across time [15]. Beyond average affect, daily affect dynamics, such as affect variability, may contribute to explaining individual differences in psychological functioning. Affect variability—a measure of the extent to which individuals experience frequent PA, NA, and COVID-19 worry fluctuations—is known to play a prominent role in psychopathologies, such as mood disturbances [16,17].

Prior literature has mainly focused on the negative consequences that sleep deprivation has for average PA and NA, finding that sleep duration significantly predicts dampened PA and elevated NA [18-22]. Experimental studies have also confirmed the similar effects of sleep loss on changes in PA and NA [23,24]. Specifically, 1 night of sleep deprivation and/or sleep restriction (ie, 4 hours of sleep), when compared to idealized sleep (ie, the opportunity of sleeping for 9.5-10 hours), decreases PAs such as vigor and increases NAs such as anger [23,24]. Yet, this knowledge is largely based on correlational studies or sleep deprivation experiments that do not generalize to the daily lives of young adults with chronic sleep restriction. Additional studies on the relation between affect and sleep problems in young adults that are conducted in a more ecologically valid context (eg, daily life) may help to elucidate these associations. Furthermore, to date, the literature examining the associations between daily sleep variability and affect dynamics remains scant. Daily sleep variability contributes to psychological

well-being [5,25], but more studies that use newer methods to examine objective sleep are needed. Studies with intensive longitudinal designs that are conducted over longer periods of time to assess both subjective and objective sleep outcomes are poised to accomplish these goals. Considering the important contribution of poor sleep to mood disorders, particularly depression and anxiety [4,19], it is important to examine the nuanced characterizations of the consequences that daily sleep disturbances have for affect dynamics. Examining the association between daily sleep and affect will allow for a better understanding of the development of comorbid sleep and mood disorders and how to design prevention programs for at-risk individuals.

The aim of this study was therefore to assess (1) the daily associations between sleep and affect and (2) the long-term associations between sleep patterns (ie, average and variability in total sleep time [TST], wake after sleep onset [WASO], sleep efficiency, sleep onset latency [SOL]) and affect dynamics (ie, mean levels of PA and NA, PA and NA variability, and COVID-19 worry) dynamics among young adults during the COVID-19 pandemic across a 3-month period. Examining these associations at the between- and within-person levels will allow for an improved understanding of the development of comorbid sleep and mood disorders and support the identification of early intervention windows for at-risk individuals. This study was designed to examine sleep among young adults in a 3-month period; however, the period of assessment varied from 1 month to 3 months due to retention. The majority of previous studies have assessed subjective and objective sleep outcomes in a 14-day period [5,25], meaning that our study examined a longer period of time. Further, multilevel modeling is a powerful analytic approach to analyzing intensive longitudinal data with missing values for both between-subject research questions and, especially, within-subject research questions.

Methods

Participants

College student participants (N=20; female: 13/20, 65%; age: mean 19.80, SD 1.0 years) were assessed daily across a 3-month period during the 2020 COVID-19 pandemic (June to November), resulting in 1173 unique observations. Participants were eligible if they met the following criteria: participants must be unmarried, be English speakers, be full-time undergraduate students aged between 18 and 22 years, and own a primary Android smartphone that is compatible with the ecological momentary assessment (EMA) phone-based survey apps and study wearable devices.

Ethics Approval

This study was part of a larger intensive longitudinal study for examining student mental health that included physiological assessments, sleep tracking, and daily emotional and behavioral reports. The procedures of this study were approved by the institutional review board (approval number: 2019-5153) at University of California, Irvine. All individuals provided written informed consent prior to participation.

Procedure

Herein, we describe the procedures that are relevant to the purposes of our investigation. Participants were first instructed on how to wear the noninvasive device (ie, Oura ring [Oura Health Ltd]) that continuously assessed sleep, activity, and physiology throughout the day and during sleep [26]. Participants completed daily surveys on affect by using a smartphone app. To maintain high adherence, participants received reminders via text message, email, or phone call if there were more than 2 days of inactivity.

Measures

Sleep

By using the Oura ring (specifications: 2 infrared light-emitting diode heart rate sensors, 2 negative thermal coefficient body temperature sensors, a 3-axis accelerometer, and a gyroscope), TST, WASO, sleep efficiency, and SOL were calculated through the detection and interpretation of physiological measures, including heart rate, heart rate variability, and pulse wave variability amplitude. Previous studies have compared the Oura ring to polysomnography—the gold standard of sleep measurement—and research-grade actigraphy (Philips Respironics). A study by Chee et al [27] shows that, based on an epoch-by-epoch analysis, the Oura ring yields sleep assessments that are comparable to those of actigraphy [27] but underestimates TST when compared to polysomnography. However, other studies, such as one by de Zambotti et al [28], have shown that summary variables for SOL, TST, and WASO are not different between the Oura ring and polysomnography. The validation study by de Zambotti et al [28] was conducted among healthy adolescents and young adults and showed that “the differences for TST and WASO between PSG and Oura are within the ≤ 30 min a-priori-set clinically satisfactory ranges for 87.8% and 85.4% of the sample, respectively.” Their study also showed that the Oura ring is able to categorize sleep, with an accuracy of $>81.3\%$, based on polysomnography-defined TST ranges (eg, <6 hours, 6-7 hour, and >7 hours). However, there are some concerns regarding detecting the stages of sleep (eg, light sleep, deep sleep, and rapid eye movement sleep); therefore, sleep stages were not included in this study.

Affect and COVID-19 Worry

As part of the EMA phone-based surveys, participants reported daily PA and NA by using the Positive and Negative Affect Schedule (PANAS) [29] each evening. On the PANAS, 10 positive (eg, inspired) items and 10 negative (eg, nervous) items were rated on a 0 to 100 scale (0=“Very Slightly”; 100=“Extremely”). Total scores for PA and NA were calculated by using the average across each 10-item subscale (PA: mean 45.27, SD 20.22; $\alpha=.85$; NA: mean 21.79, SD 12.28; $\alpha=.91$). As a separate item (“How worried were you about contracting COVID today?”), participants reported their COVID-19 worry on a 0 to 100 scale (mean 17.41, SD 19.15).

Sleep and Affect Variability

To determine the variability of each sleep and affect variable, we first created a series of successive differences by calculating the difference between 2 successive observations within the same subject (eg, night 2 – night 1; night 3 – night 2; etc). Next,

these values were squared. We used the square successive differences to compute a mean square successive difference score. Finally, we calculated the root mean square successive difference score for each participant. The root mean square successive difference is considered an index of variability that is similar to the intraindividual variance of a series of observations but is more sensitive to fluctuations across successive observations [30].

Data Analysis

We first examined variables for normality and heteroscedasticity. To examine the association between sleep (TST, sleep efficiency, and SOL) and affect variables (PA, NA, and COVID-19 worry), we first conducted multilevel models by using the restricted maximum likelihood approach. This approach improves estimates of variance components and fixed effect SE estimates in smaller samples by separating the estimates of the fixed effects from the variance components [31]. We predicted PA, NA, and COVID-19 worry as a function of the fixed effects of time and between- and within-subject sleep variables while controlling for previous-day affect. Next, we examined the association between sleep and affect variables by using multiple regression models. Previous studies have found that sex is linked with sleep outcomes [32-34]. Therefore, sex was included as a covariate in these regression models. Finally, we conducted hierarchical linear regressions to examine whether sleep variability variables contribute to affect dynamics above and beyond the average sleep variables.

Results

Descriptive Statistics

A total of 20 college students (female: 13/20, 65%) completed this study, providing 1623 (mean 43.49, SD 25.51 days/person) nights of usable Oura ring sleep data. Completion rates for EMA studies were high (83%).

Table S1 in [Multimedia Appendix 1](#) provides descriptive statistics and the bivariate correlations between the key variables. The averages for participants' TST and TST variability were 6.84 and 1.8 hours, respectively. Participants also experienced an average of 65.04 and 12.01 minutes of WASO and SOL, respectively, with a sleep efficiency of 86.52% across the study. Further, on average, participants reported low levels of NA (mean 21.79), moderate levels of PA (mean 45.27), and low levels of COVID-19 worry (mean 17.41) across the study. We assessed the bivariate correlations between the COVID-19 worry mean and PA and NA means (between-person level) and found no significant correlations between these constructs. Specifically, the correlation between the COVID-19 worry mean and PA mean was -0.19 ($P=.43$), and the correlation between the COVID-19 worry mean and NA mean was 0.43 ($P=.06$).

Daily Sleep and Daily Affect

The multilevel models of the relation between sleep and affect revealed that participants with a higher SOL ($b=-1.09$, SE 0.36; $P=.006$) and TST on the prior day ($b=-0.15$, SE 0.05; $P=.008$) had lower PA on the next day, while controlling for previous-day PA. No within-subject differences were observed in predictions

for next-day PA. No associations between daily sleep and NA and between daily sleep and COVID-19 worry were found. Table S2 in [Multimedia Appendix 2](#) shows more details.

Main Effects of Sleep on Average Affect

The regression model for predicting PA from average TST accounted for 34% of the variance in average PA (adjusted $R^2=0.26$; $F_{2,17}=4.24$; $P=.03$). Specifically, higher TST was associated with lower PA ($b=-0.36$, SE 0.12; $P=.009$). Other sleep variables were not associated with average PA. Sleep was not associated with average NA or COVID-19 worry. Table S3 in [Multimedia Appendix 3](#) shows more details.

Main Effects of Sleep on Affect Variability

Sleep Averages and Affect Variability

SOL and sleep efficiency predicted COVID-19 worry variability. The multiple regression model for predicting COVID-19 worry variability from the average SOL and sex accounted for 38% of the variance in COVID-19 worry variability (adjusted $R^2=0.31$; $F_{2,17}=5.29$; $P=.02$), and the model for predicting COVID-19 worry variability from average sleep efficiency and sex accounted for 38% of the variance in COVID-19 worry variability (adjusted $R^2=0.31$; $F_{2,17}=5.24$; $P=.02$). Specifically, higher average SOL predicted higher COVID-19 worry variability ($b=1.87$, SE 0.89; $P=.05$), and higher sleep efficiency predicted lower COVID-19 worry variability ($b=-2.02$, SE 0.97; $P=.05$). Table S4 in [Multimedia Appendix 4](#) shows more details.

Sleep Variability and Affect Variability

The multiple regression models for predicting affect variability from TST variability, while controlling for sex, accounted for 36% of the variance in PA variability (adjusted $R^2=0.29$; $F_{2,17}=4.82$; $P=.02$), 34% of the variance in NA variability (adjusted $R^2=0.27$; $F_{2,17}=4.44$; $P=.03$), and 40% of the variance in COVID-19 worry variability (adjusted $R^2=0.33$; $F_{2,17}=5.70$; $P=.01$). Specifically, higher variability in TST was associated with higher PA variability ($b=0.09$, SE 0.03; $P=.007$), higher NA variability ($b=0.12$, SE 0.05; $P=.03$), and higher COVID-19 worry variability ($b=0.16$, SE 0.07; $P=.04$). Table S4 in [Multimedia Appendix 4](#) shows more details.

The hierarchical regression models showed that TST variability predicted PA variability above and beyond the average TST (adjusted $R^2=0.26$; $F_{3,16}=3.20$; $P=.05$). However, the models for predicting NA variability and COVID-19 worry variability were not statistically significant after adding average TST to the models (adjusted $R^2=0.22$; $F_{3,16}=2.82$; $P=.07$ and adjusted $R^2=0.22$; $F_{3,16}=2.82$; $P=.07$, respectively).

Discussion

Principal Findings

Sleep patterns across the daily and long-term scales were associated with daily and average affect and affect variability, which were assessed over a 3-month period. These findings are

consistent with those of prior work suggesting that poor sleep confers a heightened risk for affective disturbances that are prevalent in mood disorders, such as depression [4]. The link between sleep variability and affect variability may provide a window into how such patterns develop over time.

Individuals with longer sleep times on the previous night experienced lower PA on the next day. Similarly, individuals with longer average TSTs over the study period reported lower PA. Previous studies however have suggested a positive association between sleep duration and greater PA (eg, a study by Galambos et al [25]). During the COVID-19 pandemic, young adults' lives have changed dramatically [35], and it is possible that they have been sleeping for longer than the recommended hours; therefore, there may be a curvilinear association between TST and PA. Future studies may benefit from examining this curvilinear association in a larger sample. Notably, consistent with prior studies [36], sleep did not predict NA. Low PA may be a potential pathway through which sleep duration has implications for mental health. Low PA is both a significant predictor of the onset of depression and a characteristic of depressive disorders. When low PA is directly treated, symptoms of anxiety and depression, as well as other disorders with anhedonic features, are known to improve [37]. Thus, improving daily sleep may be particularly important for preventing PA decline, thereby potentially interrupting the pathogenesis of illness states, such as mood disorders.

TST variability predicted higher affect variability across all affect domains (ie, PA, NA, COVID-19 worry); thus, it may be a proximal predictor of mood disturbances. Affect variability is prevalent in various mood-related disorders, such as depression, bipolar disorder, and anxiety disorders [38]. Our findings have important implications. First, interventions that support sleep stability may indirectly reduce affect variability and therefore prevent clinically significant mood disturbances. For example, in bipolar disorder, variable sleep and affect during euthymia predict worse long-term outcomes, including episodic relapses [39]. Second, our findings suggest that the stabilization of affect may be an early marker or predictor of the efficacy of transdiagnostic sleep interventions that target mood disorders with anhedonic features [39]. Future research may benefit from experimentally investigating the effect of regulating sleep time on affect dynamics in clinical populations.

Our findings also provide specific relevance to the COVID-19 context. Individuals with a higher SOL experienced higher COVID-19 worry variability, and individuals with a higher sleep efficiency reported lower COVID-19 worry variability. The specificity of the associations between SOL and sleep efficiency, and COVID-19 worry variability (ie, not NA in general) may suggest that the association between sleep and arousal-related affect is unique. Sleep disturbances may contribute to the lower capacity to adaptively overcome stress and therefore may be associated with higher stress-related sleep reactivity and cognitive presleep hyperarousal [40]. Future research may benefit from experimentally investigating the association between sleep and specific subtypes of affect.

Limitations

Our findings carry some limitations. First, whether sleep causally predicts affect remains unclear. Daily affect may also predict multiple sleep indices [36]. The bidirectional link between sleep and affect may result in a cyclical pattern of sleep disturbance impacting affect, which in turn may contribute to greater sleep disturbances. Second, the small sample size of this study was not diverse in terms of age, which limits the generalizability of our findings to other age groups. However, the peak prevalence of affect variability is among adolescents and young adults (ie, individuals aged 16-24 years) and gradually declines with age [38]. Considering the small sample size of this study, future studies may benefit from examining

the association between sleep patterns and affect dynamics in a larger sample.

Conclusion

Fluctuating sleep patterns are associated with affect dynamics, such as average PA and affect variability, across all affect domains (ie, PA, NA, COVID-19 worry) at the daily and long-term scales. Low PA and affect variability may be potential pathways through which sleep has implications for mental health. Interventions that target sleep stability may indirectly reduce affect variability and therefore prevent mood disorders. The stabilization of affect may be an early marker or predictor of the efficacy of transdiagnostic sleep interventions that target mood disorders with anhedonic features.

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Authors' Contributions

ZAM was responsible for study conceptualization and design, conducted the data analysis, and drafted the manuscript. JL assisted with study conceptualization and design, edited the manuscript, and contributed to the analytic plan. KS contributed to study conceptualization, to contextualizing the contribution of the study within the literature, and to manuscript editing. APR, AY, and SH assisted with data preparation and manuscript writing. SL and SJ created computing models that enabled data collection and assisted with data preparation and manuscript writing. NDD, RCJ, and AMR assisted with study conceptualization and design, created computing models that enabled data collection, and assisted with data preparation and manuscript writing. JLB assisted with study conceptualization and design, edited the manuscript, and contributed to the analytic plan. All authors edited and approved the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Means, SDs, and correlations between sleep and affect variables.

[[DOCX File, 23 KB - formative_v6i8e33964_app1.docx](#)]

Multimedia Appendix 2

Adjusted estimates for predicting average affect from objective sleep, gender, and age.

[[DOCX File, 25 KB - formative_v6i8e33964_app2.docx](#)]

Multimedia Appendix 3

Adjusted estimates for predicting affect variability from objective sleep, gender, and age.

[[DOCX File, 29 KB - formative_v6i8e33964_app3.docx](#)]

Multimedia Appendix 4

Unstandardized coefficient estimates in models for predicting daily sleep by daily affect.

[[DOCX File, 29 KB - formative_v6i8e33964_app4.docx](#)]

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Abbreviations

- EMA:** ecological momentary assessment
NA: negative affect
PA: positive affect
PANAS: Positive and Negative Affect Schedule
SOL: sleep onset latency
TST: total sleep time
WASO: wake after sleep onset

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Original Paper

Programmatic Adoption and Implementation of Video-Observed Therapy in Minnesota: Prospective Observational Cohort Study

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Abstract

Background: In-person directly observed therapy (DOT) is standard of care for tuberculosis (TB) treatment adherence monitoring in the US, with increasing use of video-DOT (vDOT). In Minneapolis, vDOT became available in 2019.

Objective: In this paper, we aimed to evaluate the use and effectiveness of vDOT in a program setting, including comparison of verified adherence among those receiving vDOT and in-person DOT. We also sought to understand the impact of COVID-19 on TB treatment adherence and technology adoption.

Methods: We abstracted routinely collected data on individuals receiving therapy for TB in Minneapolis, MN, between September 2019 and June 2021. Our primary outcomes were to assess vDOT use and treatment adherence, defined as the proportion of prescribed doses (7 days per week) verified by observation (in person versus video-DOT), and to compare individuals receiving therapy in the pre-COVID-19 (before March 2020), and post-COVID-19 (after March 2020) periods; within the post-COVID-19 period, we evaluated early COVID-19 (March-August 2020), and intra-COVID-19 (after August 2020) periods.

Results: Among 49 patients with TB (mean age 41, SD 19; n=27, 55% female and n=47, 96% non-US born), 18 (36.7%) received treatment during the post-COVID-19 period. Overall, verified adherence (proportion of observed doses) was significantly higher when using vDOT (mean 81%, SD 17.4) compared to in-person DOT (mean 54.5%, SD 10.9; $P=.001$). The adoption of vDOT increased significantly from 35% (11/31) of patients with TB in the pre-COVID-19 period to 67% (12/18) in the post-COVID-19 period ($P=.04$). Consequently, overall verified (ie, observed) adherence among all patients with TB in the clinic improved across the study periods (56%, 67%, and 79%, $P=.001$ for the pre-, early, and intra-COVID-19 periods, respectively).

Conclusions: vDOT use increased after the COVID-19 period, was more effective than in-person DOT at verifying ingestion of prescribed treatment, and led to overall increased verified adherence in the clinic despite the onset of the COVID-19 pandemic.

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KEYWORDS

video directly observed therapy; vDOT; mobile health; mHealth; tuberculosis; medication adherence; telemedicine; treatment; telehealth; observed therapy; COVID-19; primary outcome; treatment adherence; technology adoption; virtual health

Introduction

Tuberculosis (TB) remains a leading cause of infectious disease death globally and a contributor to morbidity and mortality in the United States [1-3]. Adherence to a TB therapeutic regimen can be difficult, owing in part to its long treatment course over several months [1,4-6]. Incomplete treatment adherence can result in treatment failure, development of multidrug resistant strains, and poor clinical outcomes [7,8].

Directly observed therapy (DOT) has historically been regarded as the standard of care to document treatment adherence in most US public health TB clinics and involves a health care provider observing a patient take their TB medication [4,9-11]. It should be acknowledged that DOT is a multifaceted intervention that has heterogeneous implementation globally, with mixed data on effectiveness [12-14]. Nonetheless, in 2016, the US Centers for Disease Control and Prevention, American Thoracic Society, and Infectious Diseases Society of America guideline update suggested using DOT over self-administered therapy for routine treatment of TB [4].

While DOT offers the ability to document medication ingestion and couple adherence interventions (eg, psychological support and case management), implementation may carry substantial inconvenience, cost, or stigma for patients and service providers [15-17]. Furthermore, although current US and international guidance advocate for daily, 7-day TB treatment regimens, logistical constraints result in only partial documentation of adherence—DOT is commonly implemented only during weekdays, with self-report on weekends (ie, nearly one-third of all prescribed doses) [4,16]. New strategies to document TB treatment adherence using digital adherence technologies may allow more comprehensive ascertainment of adherence estimates in a more patient-centered manner [18-20].

Recent World Health Organization guidance has suggested that video directly observed therapy (vDOT) may replace DOT when video communication technology is available and can be appropriately administered, and its use has increased in US settings [9,16]. vDOT uses computer and other mobile devices to either synchronously (real time) or asynchronously (recorded) monitor a patient taking their TB medication and promote treatment adherence remotely [16,21,22]. Other benefits include facilitating adherence monitoring 7 days per week, being less resource intensive, and allowing flexibility in the timing of medication use for patients [16,20-23].

Previous studies, including randomized trials, demonstrated either noninferiority of vDOT to DOT for verifying scheduled weekday doses, or found that a greater proportion of prescribed doses can be verified using vDOT under study conditions [18,24-27]. Our group has previously assessed vDOT implementation under routine programmatic circumstances in a large urban clinic in the United States after an initial pilot period, and similarly found that vDOT led to higher proportions of verified prescribed doses than in person [20]. However, there are limited data on vDOT effectiveness and technology adoption in programs without prior experience with the technology.

We sought to evaluate vDOT use and effectiveness in a clinic with no prior vDOT experience and to understand patterns of technology adoption since the onset of the COVID-19 pandemic. In the Hennepin County Minnesota Public Health Department, the standard of care for TB treatment monitoring before Sept 2019 involved in-person DOT, Monday to Friday; vDOT technology was subsequently made available for routine use at the discretion of the TB clinic. We assessed the initial implementation of vDOT into the clinic and characterized technology effectiveness and adoption over time through a prospective pragmatic implementation study, beginning in 2019 when vDOT became available.

Methods

Overview

We conducted a pragmatic, prospective observational cohort study of TB treatment monitoring measured by self-report, in-person DOT, and asynchronous vDOT under routine conditions at the Hennepin County Public Health Clinic's Tuberculosis Program in Minneapolis Minnesota, a setting without prior vDOT use or experience [22].

Ethical Considerations

Patients with signed disclosures and authorization for release of records in accordance with the Minnesota Health Records Act were included. Protocols were approved by the ethics committees at Johns Hopkins University, with reliance agreements established with Hennepin Healthcare Research Institute (IRB00174219).

Study Population

We abstracted routinely collected clinical data from electronic medical records for patients receiving treatment for active TB, who had signed disclosures and authorization for release of records in accordance with the Minnesota Health Records Act, from Sept 2019 to March 2021, with treatment follow-up available until June 2021 [28]. We only included patients who were ≥ 18 years of age, as pediatric patients may have different considerations for using DOT and vDOT warranting a dedicated study [29]. In addition, we only included patients with ≥ 2 months of therapy remaining to ensure participants had sufficient follow-up time to measure adherence. vDOT (emocha Mobile health) became available for use within the Hennepin County Public Health Clinic TB program beginning Sept 2019 (Figure S1 in [Multimedia Appendix 1](#)).

Tuberculosis Care

As part of routine care, the TB program individualizes the modality of TB treatment monitoring (ie, self-report, vDOT, and in-person DOT) using locally developed protocols and in accordance with Hennepin County Public Health Clinic guidelines, following a shared decision-making paradigm with patients [30]. Local protocols excluded vDOT initiation in patients with current positive sputum acid-fast bacillus (AFB) smears; vDOT initiation was considered once patients were smear negative. There were no exclusion criteria for patients with drug-resistant TB or prior treatment adherence when determining modality for TB treatment monitoring. Providers

and patients are allowed to switch from treatment modalities as deemed necessary based on individual circumstances.

Most patients with active TB were treated with standard therapy (rifampin, isoniazid, pyrazinamide, and ethambutol) 7 days per week. Routine treatment monitoring for in-person DOT included a health care worker observing treatment ingestion at the patient's home or agreed location during weekdays (ie, Monday to Friday), with the exception of government holidays; other doses were self-administered, and adherence was determined by self-report.

Patients using vDOT were instructed to submit videos documenting ingestion of medications according to their prescribed schedule (ie, 7 days per week), and were given initial training into the vDOT software including demonstrations and instructions [31]. Patients received SMS reminders twice per day on days a video was expected, and the software allowed for secure chat between the patient and health care team in the case of questions or issues; the software was available in multiple languages. Videos were reviewed by either a nurse case manager or community health worker, typically the next business day. Patient inquiries were triaged and answered by either nurse case managers or community health workers during business hours.

Statistical Analysis

The “reach” or use of vDOT was defined as the proportion of patients in whom vDOT was used for treatment monitoring. We calculated effectiveness based on the *verified adherence*, defined as the proportion of total prescribed doses that were verified by in-person DOT or vDOT. Unobserved doses were considered either missed or “self-administered” if reported to be taken by the patient and documented as self-reported adherence in clinical charts (ie, doses during the weekend, holidays, or other occasions during a period of in-person DOT monitoring) [18,20,24]. We assessed observation time periods as “in-person” or “vDOT” based on the scheduled modality for treatment monitoring. We used 2-sample, 2-tailed *t* tests and chi-square tests to quantify the differences in clinical and demographic characteristics comparing in-person DOT and

vDOT, at an alpha of .05 to determine statistical significance. We assessed the association of potentially relevant clinical and demographic factors with the receipt of vDOT using a multivariable logistic regression; covariates were included in the model based on clinical relevance to the outcome of interest (age, sex, race, English proficiency, alcohol use, resistance, initial AFB smear status, site of TB, and COVID-19 period). To evaluate vDOT use over time due to increased experience with the tool and to assess the impact of COVID-19, we divided the observation period into approximately 6-month increments: September 2019-February 2020 (ie, pre-COVID-19 period), March 2020-August 2020 (early COVID-19 period), and September 2020-March 2021 (intra-COVID-19 period); periods after March 2020 were the considered post-COVID-19 period. All analyses were conducted in STATA 16 (StataCorp).

Results

Participant Characteristics

A total of 96 patients received treatment for active TB during the study period in the health department TB clinic, of which 49 (51%) signed disclosures allowing their charts to be abstracted for this study (n=31, 32% in the pre-COVID-19, n=11, 11% in the early COVID-19, and n=7, 7% in the intra-COVID-19 periods). Moreover, 96% (47/49) of the studied patients were non-US born, with the most commonly reported primary languages being English (28/49, 57%), Somali (11/49, 22%), Spanish (4/49, 8%), and Hmong (3/49, 6%; Table 1). Patients were classified as having pulmonary TB (n=20, 41%), extrapulmonary TB (n=22, 45%), or both (n=7, 14%; Table 1). Additionally, 7 (14%) patients had drug resistant disease, and 22 (45%) patients had AFB smear-positive disease at treatment onset (Table 1). The median treatment duration was 29.7 weeks (IQR 26-43), and it was longer in patients with exclusively pulmonary TB (median 38 weeks, IQR 29-66) compared to those with some extrapulmonary TB (median 27.5 weeks, IQR 26-39; $P=.02$). Additional patient characteristics are shown in Table 1.

Table 1. Patient characteristics.

Baseline characteristics ^a	All patients (n=49)	Any vDOT ^b (n=23)	No vDOT ^c (n=26)	P value
Age (years), mean (SD) ^d	40.9 (19)	35.0 (17)	46.2 (19)	.04
Patient sex, n (%)				.01
Male	22 (45)	6 (26)	16 (62)	
Female	27 (55)	17 (74)	10 (38)	
Non-US born, n (%)				.93
No	2 (4)	1 (4)	1 (4)	
Yes	47 (96)	22 (96)	25 (96)	
Ethnicity, n (%)				.99
Not Hispanic	43 (88)	20 (87)	23 (88)	
Hispanic	4 (8)	2 (9)	2 (8)	
Unknown or not reported	2 (4)	1 (4)	1 (4)	
Race, n (%)				.42
Asian	12 (25)	8 (35)	4 (15)	
Black or African American	29 (59)	11 (48)	18 (69)	
White	2 (4)	1 (4)	1 (4)	
Unknown or not reported	6 (12)	3 (13)	3 (12)	
English proficient, n (%)				.62
No	21 (43)	9 (39)	12 (46)	
Yes	28 (57)	14 (61)	14 (54)	
Experiencing homelessness, n (%)				.34
No	48 (98)	23 (100)	25 (96)	
Yes	1 (2)	0 (0)	1 (4)	
HIV infected, n (%)				.09
No	46 (94)	23 (10)	23 (88)	
Yes	3 (6)	0 (0)	3 (12)	
Any alcohol use, n (%)				.04
No	37 (76)	15 (65)	22 (85)	
Yes	4 (8)	1 (5)	3 (11)	
Unknown or not reported	8 (16)	7 (30)	1 (4)	
TB^e drug resistance,^f n (%)				.53
No	35 (72)	17 (74)	18 (69)	
Yes	7 (14)	2 (9)	5 (19)	
Unknown or not reported	7 (14)	4 (17)	3 (12)	
Initial AFB^g smear, n (%)				.98
No	25 (51)	12 (52)	13 (50)	
Yes	22 (45)	10 (44)	12 (46)	
Unknown or not reported	2 (4)	1 (4)	1 (4)	
Site of TB				.27
PTB ^h	20 (41)	8 (35)	12 (46)	
EPTB ⁱ	22 (45)	13 (56)	9 (35)	
PTB and EPTB	7 (14)	2 (9)	5 (19)	

^aThere were no significant differences in age, ethnicity, birth country, English proficiency, employment, homelessness, HIV, drug resistance, initial acid-fast bacillus smear status, or site of tuberculosis (TB) across the study periods. There were significantly more females with TB in the post-COVID-19 period (14/18, 78%) compared with the pre-COVID-19 period (13/31, 42%; $P=.02$).

^bvDOT: video directly observed therapy.

^cNo vDOT represents a combination of patients with self-administered and in-person directly observed therapy.

^dAge as of TB treatment start date.

^eTB: tuberculosis.

^fNo patients at the clinic were treated with injectable medications during the study period.

^gAFB: acid-fast bacillus.

^hPTB: pulmonary tuberculosis.

ⁱEPTB: extrapulmonary tuberculosis.

Reach of vDOT Compared to In-Person DOT

All patients had treatment monitored using in-person DOT, video-DOT, or some combination. vDOT was used for some portion of care in 47% (23/49) of patients, while the remainder (26/49, 53%) were monitored exclusively through in-person DOT (with self-administration during weekends, holidays, and per-clinic discretion; [Table 1](#)).

Overall, there was a trend toward increasing vDOT use when comparing each 6-month period, with 35% (11/31) using vDOT in the first 6 months after the technology became available (ie, pre-COVID-19), 64% (7/11) in the second 6 month (early COVID-19 period), and 71% (5/7) in the final

(intra-COVID-19) period (ie, 1 year after vDOT became available; $P=.10$; [Table 2](#)). When comparing the pre-COVID-19 period to after the onset of COVID-19 (ie, early and intra-COVID-19 periods combined), significantly more patients used vDOT in the post-COVID-19 period (12/18, 67%) compared to the pre-COVID-19 period (11/31, 35%; $P=.04$). Among individuals initiating therapy after vDOT was available, the median time to start vDOT relative to TB treatment initiation date was 7 days (IQR 0-78). In-person DOT was initiated at the same time as treatment in the clinic (median 0 days, IQR 0-26). There was no difference in the overall treatment duration among those receiving vDOT (median 29.7 weeks, IQR 26-39.4) and those who did not receive vDOT (median 31, IQR 26.1-52; $P=.67$).

Table 2. Primary outcomes by study period.

Variable	Overall (n=49)	Study period 1 ^a (n=31)	Study period 2 ^a (n=11)	Study period 3 ^a (n=7)	P value ^b
vDOT ^c use, n (%)	23 (47)	11 (35)	7 (64)	5 (71)	.10
Verified adherence (%), mean (SD)^d					
vDOT ^c	81 (17.4) ^f	76.1 (19.9)	81.9 (16.6)	90.7 (9.0)	.31
In-person DOT ^{e,g}	54.5 (10.9) ^f	54.6 (9.8)	47.7 (13.3)	65.4 (6.7)	.03
Overall (irrespective of monitoring modality)	61.7 (16.6)	56.1 (10.0)	66.6 (24.2)	79 (13.3)	.001
Self-administered therapy (%), mean (SD)^h					
During vDOT	10.8 (12.9)	15.6 (15.6)	6.6 (9.3)	6.1 (7.5)	.24
During in-person DOT	44.1 (10.9)	44.2 (10.1)	49.1 (14.0)	34.6 (6.7)	.11
Overall (irrespective of monitoring modality)	35.6 (17.2)	41.9 (10.2)	28.6 (24.5)	18.8 (14.9)	<.001

^aStudy period 1 is defined as the first 6 months of the study period from September 2019 to February 2020. Study period 2 is defined as the second 6 months of the study period from March 2020 to August 2020. Study period 3 is defined as the final study period from September 2020 to March 2021.

^bP values represent comparisons across study periods (by row).

^cvDOT: video directly observed therapy.

^dVerified adherence is defined as doses that were observed by either in-person or vDOT divided by the total number of prescribed doses.

^eComparing verified adherence between those receiving vDOT and in-person DOT, adherence was higher in all study periods when using vDOT ($P<.001$, $P=.001$, $P=.002$, for periods 1, 2, and 3, respectively).

^fThe overall verified adherence from vDOT (median 86%, IQR 71-99), was significantly greater than the overall verified adherence from in-person DOT (median 57%, IQR 47-63, $P=.001$).

^gDOT: directly observed therapy.

^hA greater proportion of doses was self-administered when using in-person DOT compared to vDOT overall and in each study period ($P<.001$ for all comparisons).

In univariate analysis ([Table 1](#)), mean age of individuals receiving vDOT was lower (35) compared to those not receiving vDOT (46; $P=.04$); a larger proportion of women (17/27, 63%)

received vDOT compared to men (6/22, 27%; $P=.01$; [Table 1](#)). However, in multivariate analysis adjusting for other covariates, the adjusted odds ratios (AORs) revealed that neither sex (AOR

0.23, 95% CI 0.29-1.83) nor age category (AOR 0.27, 95% CI 0.03-2.5; AOR 3.0, 95% CI 0.02-455; and AOR 0.06, 95% CI 0.01-2.4 for individuals 30-50, 50-65, and >65 years old compared to those <30 years old, respectively) was associated with vDOT use. There was a trend toward increased vDOT use after the onset of COVID-19 (AOR 10.1, 95% CI 0.57-176; $P=.11$), but it was not statistically significant; no other clinical or demographic features, including race, English proficiency, alcohol use, site of TB disease, initial smear status, or drug resistance, were found to be associated with vDOT use. All patients successfully completed treatment irrespective of adherence monitoring modality (or were censored at the end of the study period).

Effectiveness of vDOT Compared to In-Person DOT

Overall, the mean *verified adherence* (proportion of prescribed doses verified through observation) was significantly higher when using vDOT (mean 81%, SD 17.4; median 86%, IQR 71-99), compared to in-person DOT (mean 54.5%, SD 10.9; median 57%, IQR 47-63; $P=.001$; Table 2).

These findings were driven by the high proportion of “self-administered” doses when using in-person DOT (mean 44.1%, SD 10.9; median 41%, IQR 36-47) compared to periods when patients were using vDOT (mean 10.8%, SD 12.9; median 5%, IQR 0-16; $P<.001$). By contrast, few doses were documented as missed (median <1%, IQR 0-1.2) when using in-person DOT; overall, among prescribed doses (7 days per week), a median of 1% (IQR 0-11) was documented as missed when using vDOT ($P=.11$).

Effectiveness of vDOT Compared to In-Person DOT by Study Period

We found a trend toward greater verified adherence using vDOT over the time period of implementation, but it was not statistically significant (mean 76%, 82%, and 91%, in the pre-COVID-19, early COVID-19, and intra-COVID-19 study periods, respectively; $P=.31$; Table 2). In all time periods, adherence was higher when using vDOT compared to in-person DOT ($P<.01$ for each period; Table 2).

As a result of an increasing proportion of patients in whom vDOT was used for adherence monitoring, we found that overall adherence increased in the population across successive periods of observation (mean 56%, 67%, and 79% for each study period, respectively; $P=.001$; Table 2). We also found that the overall proportion of treatment doses documented as self-administered declined across study periods (42%, 29%, and 19%, respectively; $P<.001$; Table 2), which is attributable to the increasing vDOT use.

Discussion

Principal Results

Paradigms for documenting TB treatment adherence are evolving given the logistical constraints with in-person DOT since the onset of the COVID-19 pandemic and with the prioritization of daily TB therapy 7 days per week [4,9]. Several clinical trials have reported that video-observed therapy is effective at documenting TB treatment under study conditions,

but data to inform programmatic implementation are limited [25,27]. We previously reported that vDOT use was high under routine conditions in a clinic with established prior vDOT experience. In this prospective cohort study, at a vDOT naïve clinic (ie, no prior experience) in Minnesota, we found progressively increasing adoption of vDOT for patients with active TB disease [20]. Unsurprisingly, initial use of vDOT was slow ($n=11$, 35% of patients; Table 2); however, 1 year after vDOT availability, we found the TB program used vDOT preferentially in nearly three-quarters of patients. The shift toward monitoring treatment for all prescribed doses has clinical implications; vDOT was more effective than in-person DOT for verifying ingestion of prescribed TB treatment, allowing median documentation of adherence for 86% of the prescribed doses; by contrast, median in-person DOT verified adherence was 57%, owing to a large proportion of self-reported doses (Table 2). These data are consistent with findings in other study conditions [18,20,24,25]. With increasing vDOT use over time, we consequently found that the overall verified adherence among all patients in the clinic increased from 56% in the first 6 months of vDOT availability (pre-COVID-19 period) to 79% in the last 6 months of the study, despite programmatic disruptions and diminished staff during the COVID-19 pandemic (Table 2).

Several factors likely influenced our results and the observed “digital transformation” of health care. The adoption of vDOT in the Hennepin County Public Health Clinic TB program follows the “technology-push” paradigm, in which health care workers are in the process of implementing a tool foreign to them [32]. Commonly, the novelty of new tools and disruption to well-established routines often lead to lower initial use, as seen in our study [32]. Furthermore, health care providers’ perception of telemedicine may be negatively influenced by concerns surrounding telemedicine project funding, ease of use, and patient preferences [33].

The onset of the COVID-19 pandemic in March 2020 significantly impacted the TB clinic as well. The program staff of 4 full-time outreach Community Health Workers was reduced to 1.5 to 2 full-time equivalent workers at various times throughout the pandemic. Consequently, the reduction of in-person services caused by the COVID-19 pandemic likely accelerated the adoption of vDOT, along with growing comfort and experience with the technology. More generally, expansion of telemedicine and digitally enabled communication during the pandemic may also have contributed to greater acceptance of using digital adherence technologies among health care providers and patients [33,34].

In addition to these reasons, the continued use of vDOT technology over the course of the study period may also be partially due to the significantly larger proportion of prescribed doses that were verifiable using vDOT compared to in-person DOT. These findings are largely attributable to the reduction in the number of self-administered doses over weekends and holidays offered by vDOT compared to in-person DOT and is consistent with findings from other programmatic studies. Additionally, prior concerns within the Hennepin County TB program regarding costs and lost revenue associated with

reimbursements were mitigated by the program's ability to bill for vDOT visits based on local practices.

Limitations

Our study has several limitations. Due to local regulatory requirements, we were only able to abstract data from patients who had signed a disclosure and authorization for release of information; alternatively, this patient decision was independent of our specific study, and is unlikely to have led to significant selection biases as related to choice of treatment monitoring modality or adherence. We also were unable to differentiate the impact of COVID-19 (eg, staffing changes and lockdowns) and the natural process of technology adoption as staff became more familiar and comfortable with the platform. Our study setting implemented vDOT 7 days per week to allow the assessment of adherence to daily prescribed therapy; our study results may not be generalizable to clinics that prescribe treatment according to alternative dosing schedules (eg, 5 days per week or thrice weekly).

Comparison With Prior Works

While self-report or pill counts, in-person DOT, vDOT, and other digital technologies (eg, smart pill boxes) each provide a different level of certainty related to medication ingestion, they each broadly provide a measure of adherence. Our results add to the growing literature on the feasibility, acceptability, and effectiveness of video-DOT [18,20,24,25] for adherence measurements, but they also raise important considerations for the reevaluation of current paradigms in documenting TB treatment adherence. Recently, a large randomized trial found that electronic DOT was noninferior to in-person DOT at monitoring "scheduled" doses (Monday-Friday) but did not report adherence to all prescribed doses [27]. Our study highlights the limitations of this approach. Existing protocols for determining adherence used by many TB clinics offers incomplete assessments of true adherence by monitoring only a fraction of prescribed doses; for example, achieving 80%

documentation of Monday-Friday doses (with limited certainty of ingestion of prescribed weekend doses) represents documentation of only 57% of prescribed doses. We acknowledge that there are currently limited data on the optimal thresholds for determining the proportion of prescribed treatment that should be verified. Moreover, correlation of treatment verification and specifically added weekend treatment verification with clinical outcomes is also limited. Nonetheless, our results show that adoption of vDOT in a large urban clinic allowed verification of true adherence to above 80%, including weekend doses, and offered more comprehensive categorization of all treatment doses. Previously, we have also found that vDOT may reduce stigma and increase logistical convenience, while also allowing TB programs to reduce costs and reallocate resources more efficiently [18]. Notably, treatment adherence improved during the course of the study despite reductions in staff.

Conclusions

Our results should be interpreted in the context of individualized decision-making as is advocated by current guidelines. Some individuals continued to receive in-person DOT based on tailored individual considerations; while our prior work has suggested that older age may be associated with a lower likelihood of initiating vDOT in other settings, we did not find specific clinical or demographic factors associated with vDOT selection in this clinic [24]. We also note that provisions for adherence support (eg, psychological support, nursing support, and other incentives and enablers) were made in conjunction with decisions on deciding treatment modality for monitoring; in this manner, adherence support interventions should be viewed adjunctively and are not synonymous with DOT or vDOT. Other elements of adherence support built into the chosen vDOT system included electronic reminders, secure chat, and ability to document symptoms and side effects, which may have also impacted the results.

Acknowledgments

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Conflicts of Interest

MS is among the inventors of the video directly observed therapy technology licensed to emocha Mobile Health Inc. Under a license agreement between emocha Mobile Health Inc and the Johns Hopkins University (JHU), MS and JHU are entitled to royalties related to the technology described in this study. Specific to this study, MS did not and will not receive royalties or compensation from emocha Mobile Health Inc. Additionally, JHU owns equity in emocha. This arrangement has been reviewed and approved by JHU in accordance with its conflict-of-interest policies. As per JHU's Institutional Review Board (IRB) and Conflicts of Interest (COI) office, conflicted study team members (MS) were excluded from accessing the original data set. Oversight of data management, including primary analyses and audit of all data analyses, were carried out by nonconflicted designees (GM, EM, and CKL), as approved by the JHU IRB and COI office.

Multimedia Appendix 1

Description of emocha platform for video-observed therapy: (a) Video directly observed therapy (DOT) application schematic; (b) Video DOT application user interface.

[DOCX File , 1399 KB - [formative_v6i8e38247_appl.docx](#)]

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Abbreviations

AFB: acid-fast bacillus

AOR: adjusted odds ratio

DOT: directly observed therapy

TB: tuberculosis

vDOT: video directly observed therapy

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Original Paper

The Prevalence of Psychotic Symptoms, Violent Ideation, and Disruptive Behavior in a Population With SARS-CoV-2 Infection: Preliminary Study

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Abstract

Background: The COVID-19 disease results from infection by the SARS-CoV-2 virus to produce a range of mild to severe physical, neurological, and mental health symptoms. The COVID-19 pandemic has indirectly caused significant emotional distress, triggering the emergence of mental health symptoms in individuals who were not previously affected or exacerbating symptoms in those with existing mental health conditions. Emotional distress and certain mental health conditions can lead to violent ideation and disruptive behavior, including aggression, threatening acts, deliberate harm toward other people or animals, and inattention to or noncompliance with education or workplace rules. Of the many mental health conditions that can be associated with violent ideation and disruptive behavior, psychosis can evidence greater vulnerability to unpredictable changes and being at a greater risk for them. Individuals with psychosis can also be more susceptible to contracting COVID-19 disease.

Objective: This study aimed to investigate whether violent ideation, disruptive behavior, or psychotic symptoms were more prevalent in a population with COVID-19 and did not precede the pandemic.

Methods: In this preliminary study, we analyzed questionnaire responses from a population sample (N=366), received between the end of February 2021 and the start of March 2021 (1 year into the COVID-19 pandemic), regarding COVID-19 illness, violent ideation, disruptive behavior, and psychotic symptoms. Using the Wilcoxon rank sum test followed by multiple comparisons correction, we compared the self-reported frequency of these variables for 3 time windows related to the past 1 month, past 1 month to 1 year, and >1 year ago among the distributions of people who answered whether they tested positive or were diagnosed with COVID-19 by a clinician. We also used multivariable logistic regression with iterative resampling to investigate the relationship between these variables occurring >1 year ago (ie, before the pandemic) and the likelihood of contracting COVID-19.

Results: We observed a significantly higher frequency of self-reported violent ideation, disruptive behavior, and psychotic symptoms, for all 3 time windows of people who tested positive or were diagnosed with COVID-19 by a clinician. Using multivariable logistic regression, we observed 72% to 94% model accuracy for an increased incidence of COVID-19 in participants who reported violent ideation, disruptive behavior, or psychotic symptoms >1 year ago.

Conclusions: This preliminary study found that people who reported a test or clinician diagnosis of COVID-19 also reported higher frequencies of violent ideation, disruptive behavior, or psychotic symptoms across multiple time windows, indicating that they were not likely to be the result of COVID-19. In parallel, participants who reported these behaviors >1 year ago (ie, before

the pandemic) were more likely to be diagnosed with COVID-19, suggesting that violent ideation, disruptive behavior, in addition to psychotic symptoms, were associated with COVID-19 with an approximately 70% to 90% likelihood.

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KEYWORDS

COVID-19; paranoia; delusions; disruptive behavior; violent ideation; psychotic symptoms; pandemic; mental health; distress; stress; psychological health; psychosis; risk; machine learning

Introduction

Background

The COVID-19 disease results from infection by the single-stranded RNA virus SARS-CoV-2. Physically, COVID-19 can produce a range of mild symptoms, including fever, cough, shortness of breath, fatigue, muscle aches, headache, and new loss of taste or smell [1], to severe symptoms requiring ventilation in an intensive care unit because of respiratory failure, septic shock, and multiple organ dysfunction [1]. In the context of mental function, COVID-19 has been linked to significant cognitive and attention deficits, brain fog, anxiety, depression, and sleep problems [2,3]—all of which can affect mental health and well-being.

The COVID-19 pandemic has burdened the mental health of both those infected with SARS-CoV-2 and those who have been living through the pandemic without infection. The pandemic has indirectly caused worldwide emotional distress that has triggered the development of mental conditions in persons not previously affected and exacerbated symptoms in those with existing conditions [4-7]. Numerous COVID-19 research reviews have reported the adverse psychological effects brought on by pandemic-related stressors, including posttraumatic stress symptoms, confusion, and anger [8]. The management of behavioral symptoms in patients with COVID-19 (eg, agitation) has become a unique challenge for health care workers in emergency departments [9]. COVID-19 can be particularly distressing to individuals with pre-existing mental health conditions such as autism spectrum disorders and other neurodevelopmental disorders, leading to more intense and frequent behavior problems, including disruptive behavior [10] or increased externalizing and aggressive behavior [11].

Many mental health conditions can lead to violent ideation and disruptive behavior (VIDB), which is defined by aggression, threatening acts, or deliberate harm toward other people or animals, as well as inattention and noncompliance in education or workplace settings [12,13]. For instance, people with substance use disorders [14,15], mania [16,17], psychosis [18,19], and personality disorders [20,21] can all evidence VIDB or be at an increased risk for adverse psychosocial outcomes during pandemic-related periods of stress. Individuals with mild to severe symptoms of psychosis (eg, delusions, paranoia, and hallucinations) have been reported to be susceptible to pandemic-related emotional distress [18,19]. The 12-month prevalence of psychosis is 3.89 to 4.03 per 1000 individuals, and the median lifetime prevalence is 7.49 per 1000 individuals [22]. Prior research has shown that people with psychosis are less likely to take precautionary measures such as receiving vaccination or isolating during the influenza pandemic [23],

thereby increasing their potential risk for COVID-19 infection. As with autism spectrum disorder, individuals with psychosis can show greater vulnerability to unpredictable changes, such as COVID-19, and are thus at greater risk for VIDB [24,25].

Objective

In this preliminary study, we assessed potential relationships among COVID-19 infection, VIDB, and symptoms related to psychosis, which may increase the risk of infection and VIDB. Psychotic symptoms and VIDB increase the potential for engagement in riskier-than-average behaviors, potentially including nonadherence to COVID-19 precautions. Individuals exhibiting VIDB and psychotic symptoms could thus be at a greater risk of contracting and spreading the virus. Although these associations are not directional, any findings between VIDB and psychotic symptoms with COVID-19 would permit hypothesis framing for two scenarios: (1) COVID-19 infection increases the likelihood of psychosis and VIDB or (2) psychotic symptoms and VIDB increase the possibility of COVID-19 infections. Other viral infections, including influenza and HIV, have led to similar hypotheses [26-34]. To do this, we analyzed questionnaire responses regarding COVID-19 history along with historical questions regarding VIDB and psychotic symptoms over 3 time windows in a small but representative internet sample that followed the US Census (ie, 300 < n < 500). The questionnaire was distributed between the end of February 2021 and the start of March 2021 and was timed to overlap with the onset of the COVID-19 pandemic 1 year earlier. We assessed the frequency of self-reported VIDB and symptoms of psychosis from the past 1 month, 1 month to 1 year ago, and >1 year ago among participants with and without self-reported COVID-19. Given the existing case reports of an increased incidence of VIDB and psychotic symptoms during the pandemic, we hypothesized that participants with COVID-19 would exhibit an increase in VIDB and psychotic symptoms. We also investigated the relationship between these behaviors occurring >1 year ago and the likelihood of contracting SARS-CoV-2 with the hypothesis that people with these behaviors were more likely to experience COVID-19 infection. We used multivariable logistic regression (MVLRL) with iterative resampling to investigate how accurately VIDB and psychotic symptoms from before the pandemic discriminated between participants with and without self-reported COVID-19.

Altogether, the results of this study show that individuals with VIDB and psychotic symptoms have an increased risk for SARS-CoV-2, although long-term longitudinal data will be needed to assess causal relationships.

Methods

Participant Recruitment

Study participants were recruited by Gold Research Inc from multiple vendors. Gold Research vendors recruit the emails of willing participants in multiple ways. Some are recruited *by invitation only* from customer databases of large companies in revenue-sharing agreements, some are recruited from social media, some through direct mail, and others sign up voluntarily to participate in research studies in lieu of monetary or other incentives such as coupons for everyday household purchases. During recruitment, all survey respondents also go through a double opt-in process to indicate the types of research studies they would like to participate in, in addition to providing their profiles on different demographic attributes such as age, race, and sex. This information is then used to reflect representation against US Census metrics. In this process, respondents are also asked multiple test questions to screen out those providing random and illogical responses or showing flatline or speeder behavior. In addition to having cohort demographics balanced to meet the demographic criteria established by the US Census, Gold Research also oversampled 15% (7500/50,000) of the sample for mental health conditions. Gold Research reported that >50,000 respondents were contacted for questionnaire completion. They estimated that of the 50,000 participants, >37,500 (75%) either did not respond or said no. Of the remaining 25% (12,500/50,000) of participants who clicked on the survey link, >50% did not complete the questionnaire. Of the ≥6000 participants who completed the survey, those who did not clear the data integrity assessments were omitted to achieve the final number of completed surveys. Participants meeting quality assurance procedures (including completion of the survey) were studied, with a limit of 500-520 participants. All participants provided informed consent following oversight from the Northwestern University Institutional Review Board, and a double opt-in methodology was used for consenting (shown later in the following section).

This study assessed multiple mental health conditions, including psychotic symptoms, violent ideation, and disruptive behavior. For this paper, we focused only on psychotic symptoms, violent ideation, and disruptive behavior. All participants provided informed consent following oversight from the Northwestern University Institutional Review Board, which reviewed and approved the project procedures, including the use of a double opt-in methodology for consenting. Participants were guaranteed anonymity and confidentiality, and the researchers did not possess any protected health information. Questionnaire responses were collected between the end of February 2021 and the beginning of March 2021, approximately 1 year after the official pandemic declaration in the United States (March 11, 2020) [35] (Figure 1). Data integrity assessment (see the *Data Quality Assurance* section) reduced the final sample size to 366 participants.

Participants reported their age, sex, ethnicity, handedness, annual household income, employment status, level of education, and years of schooling. A total of 506 participants (mean age 47, SD 15 years) completed the study by Gold Research Inc. After quality assurance, participants were found to be 57.9% (212/366) female, 68% (249/366) White, 82% (300/366) right-handed, 42.6% (156/366) employed full-time, and 28.7% (105/366) with some college education (mean years of schooling 13, SD 5 years), approximating the national averages for these measures. A complete summary of the demographic variables is provided in Table 1.

Participants were asked questions related to COVID-19, as shown in Textbox 1. They were asked to report whether they had ever had a positive COVID-19 test (yes or no; *test+*), whether they were ever diagnosed with COVID-19 by a medical professional (yes or no; *diagnosis*), and whether a family member or close friend had experienced serious symptoms or died of COVID-19 (yes or no; *family*). Of the 366 participants, 36 (9.8%) reported a positive COVID-19 *test+*, and 34 (9.3%) reported a COVID-19 *diagnosis*; 26 (7.1%) participants answered *yes* to both the COVID-19 *test+* and *diagnosis*. Of the 366 participants, 95 (26%) reported that a family member or close friend had serious symptoms or had died of COVID-19.

Figure 1. Timeline for survey data collection.

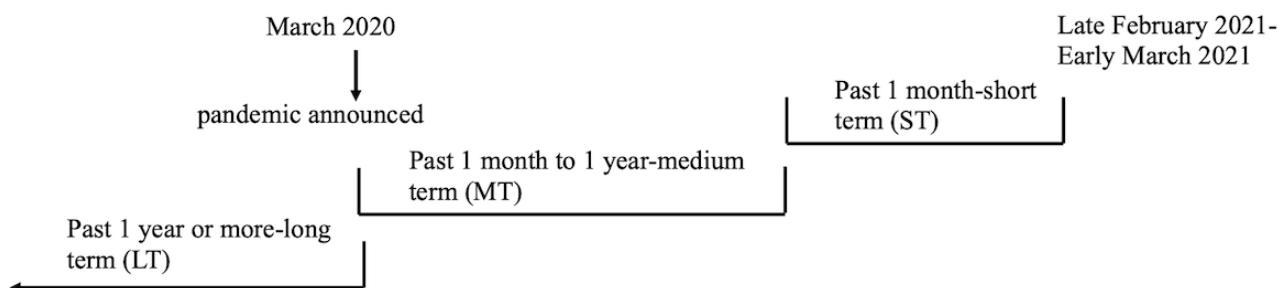


Table 1. Summary statistics of the demographic variables reported by the participants, including age, gender, ethnicity, handedness, annual household income, employment status, level of education, and years of schooling (N=366).

Variable	Values
Age (years)	
Participants, n (%)	366 (100)
Value, mean (SD; range)	46.67 (15.40; 18-70)
Years of schooling	
Participants, n (%)	366 (100)
Value, mean (SD; range)	13.29 (5.04; 1-30)
Sex, n (%)	
Male	153 (41.8)
Female	212 (57.9)
Other	1 (0.3)
Ethnicity, n (%)	
White	249 (68)
African American	48 (13.1)
Hispanic	29 (7.9)
Asian American or Pacific Islander	13 (3.6)
Native American or Alaskan Native	18 (4.9)
Mixed race	3 (0.8)
Other	3 (0.8)
Prefer not to answer	3 (0.8)
Handedness, n (%)	
Right	300 (82)
Left	52 (14.2)
Both	14 (3.8)
Level of education, n (%)	
Some high school	6 (1.6)
High school graduate	95 (26)
Some college	105 (28.7)
Bachelor degree	83 (22.7)
Some graduate school	12 (3.3)
Graduate degree	27 (7.4)
Postgraduate or doctorate	38 (10.4)
Employment status, n (%)	
Unemployed	58 (15.8)
Full-time	156 (42.6)
Part-time	41 (11.2)
Self-employed	24 (6.6)
>1 job	3 (0.8)
Retired	61 (16.7)
Other	23 (6.3)
Annual household income (US \$), n (%)	
<25,000	86 (23.5)

Variable	Values
25,000-50,000	92 (25.1)
50,000-75,000	70 (19.1)
75,000-100,000	47 (12.8)
100,000-150,000	37 (10.1)
150,000-300,000	26 (7.1)
>300,000	8 (2.2)

Textbox 1. COVID-19–related questions from the survey and their abbreviations used in this study.

Abbreviations used and COVID-19 questions (yes or no)

- Test+
 - Have you ever tested positive for COVID-19?
- Diagnosis
 - Have you ever been diagnosed with COVID-19 by a medical clinician?
- Family
 - Has anyone in your family or group of friends had serious symptoms or died of COVID-19?

Power analysis for a 2-sample Wilcoxon rank sum test revealed an estimated power of >0.80 for the experimental conditions based on *test+* (sample size for *test+* was 36 and sample size for no *test+* was 330; $\alpha=.05$) and an estimated power >0.9 for experimental conditions based on *diagnosis* (sample size for *diagnosis* was 34 and sample size for no *diagnosis* was 332; $\alpha=.05$). This power suggests that we had statistically adequate sample sizes for the analysis that follows.

For initial recruitment, participants received the following communication:

Gold Research Inc., a national market research firm and its client, Northwestern University, request your participation in this study of emotional health. We will be evaluating how different emotions and experiences are connected and may relate to our emotional health. The information you provide will be kept confidential, coded to be anonymous so it cannot be connected back to you and will be used only for research purposes. Researchers will not be able to contact you or restudy you after this survey. We will not share your information with any other third party. We will also not use your information to identify you individually or use your responses to market or sell other services or products to you. As part of this effort, you will not be asked to provide any personal identifiers such as your name, email, phone number, address or social media handles. A unique identifier will be generated for you and each survey participant to enhance privacy. As part of the survey process, we will be able to tell if you completed the survey, but we will not be able to tell which answers were yours. For this study, we are going to ask you some questions about yourself and how much

you like or dislike a set of pictures. You may discontinue this study at any time. We appreciate your help with this study, given the serious challenges facing many people regarding emotional health at this time. We thank you in advance.

1. Accept
2. Decline

If participants responded with “Accept,” they were sent a further communication with the following:

Thank you for participating in our survey. All responses during this survey are anonymous and confidential. We will be able to tell if you completed the survey, but we will not be able to tell which answers were yours. In this study, we aim to understand how different emotions and experiences relate to visual processing.

We are going to:

**Ask you some questions about yourself*

**Have you rate how much you like or dislike a set of pictures*

For this study, your identity is protected and your answers are anonymous and confidential. Press “Next” to proceed.

The survey would then begin if participants pressed “Next.”

Ethics Approval

Participants were offered notice that Gold Research administered an emotional health questionnaire on behalf of Northwestern University, with the following phrasing: “We will be evaluating how different emotions and experiences are connected and may relate to our emotional health.” The complete text related to the solicitation, study description, and opt-in procedures can be

found in the *Methods under Participant Recruitment*. All participants provided informed consent following oversight from the Northwestern University Institutional Review Board (approval number STU00213665), which reviewed and approved the project proposal. Participants were guaranteed anonymity and confidentiality, and the researchers did not possess any protected health information.

Survey Questions and Scoring

The survey comprised several blocks of questions from existing questionnaires on depression, anxiety, suicidality, addiction, psychosis, VIDB, and COVID-19 infection, in addition to demographic and historical diagnoses of mental health disorders. A picture-rating task was also administered; however, it is not the focus of this study. This study assessed the relationships among psychotic symptoms, VIDB, and COVID-19 infection. Questions about VIDB and 4 positive psychotic symptoms were taken from the behavioral neurology screening questions in the Massachusetts General Hospital Subjective Question (MGH SQ) Screener from the Phenotype Genotype Project in Addiction and Mood Disorder [36]. The MGH SQ has been used in several studies [37-43]. Of the 13 questions used here, 4 were related to positive psychotic symptoms (auditory and visual hallucinations, paranoia, and delusions), which had originally been adapted to the MGH SQ from a clinical textbook on emergency psychiatry (Textbox 2, Psych1-Psych4) [44]. A total

of 9 other questions were related to VIDB (eg, wanting to hurt others, prior attempts to hurt others or animals, wanting to start fires, being disruptive, or breaking rules) and were similarly adapted to the MGH SQ using the same clinical textbook on emergency psychiatry (Textbox 2, Disruption1-Disruption9) [44]. Participants rated the questions based on how often they experienced these behaviors as follows: (1) *past ≥1 year* (long term), (2) *past 1 month to 1 year* (medium term), and (3) *past 1 month* (short term; Figure 1 provides the timeline) on a 1 to 7 Likert scale (1=never; 2-3=rarely; 4-5=sometimes; 6=often; 7=always; Figure 2). The data were collected regarding psychotic symptoms and VIDB from the past 1 month (short term) and between 1 month and 1 year (medium term) to assess and relate these symptoms and behaviors during the recent past to COVID-19 infection. We chose a 1-month cutoff to obtain the most recent history, similar to what is done for timeline follow-back methods with substance use or menstrual cycle assessments. The data from >1 year ago (long term) were collected to assess these behaviors before the pandemic and to determine whether a history of psychosis and VIDB before the pandemic influenced a person's likelihood of COVID-19 infection. This would provide insight into the participants' current state and how COVID-19 infection or the pandemic, in general, has affected the general population. All 13 questions are listed in Textbox 2 as they appeared in the survey.

Textbox 2. The 13 questions from the larger survey related to psychosis and violent ideation and disruptive behavior that was used in this study for 3 time windows (long term, medium term, and short term) for which participants answered each question.

Questions and time windows

- Psych1-LT
 - Hallucinations/Hearing voices others cannot past ≥ 1 year
- Psych1-MT
 - Hallucinations/Hearing voices others cannot past 1 month to 1 year
- Psych1-ST
 - Hallucinations/Hearing voices others cannot past 1 month
- Psych2-LT
 - Hallucinations/Seeing things others cannot see past ≥ 1 year
- Psych 2-MT
 - Hallucinations/Seeing things others cannot see past 1 month to 1 year
- Psych2-ST
 - Hallucinations/Seeing things others cannot see past 1 month
- Psych3-LT
 - Worries that others are out to get you or to get people close to you (these might resemble paranoia) past ≥ 1 year
- Psych 3-MT
 - Worries that others are out to get you or to get people close to you (these might resemble paranoia) past 1 month to 1 year
- Psych3-ST
 - Worries that others are out to get you or to get people close to you (these might resemble paranoia) past 1 month
- Psych4-LT
 - Having one or more unique beliefs or impressions that are strong despite being contradicted by others (these might resemble delusions) past ≥ 1 year
- Psych 4-MT
 - Having one or more unique belief or impression that is strong despite being contradicted by others (these might resemble delusions) past 1 month to 1 year
- Psych4-ST
 - Having one or more unique belief or impression that is strong despite being contradicted by others (these might resemble delusions) past 1 month
- Disruption1-LT
 - Wanting to hurt others past ≥ 1 year
- Disruption 1-MT
 - Wanting to hurt others past 1 month to 1 year
- Disruption1-ST
 - Wanting to hurt others past 1 month
- Disruption2-LT
 - Prior attempts at hurting others past ≥ 1 year
- Disruption 2-MT

- Prior attempts at hurting others past 1 year to 1 month
- Disruption2-ST
 - Prior attempts at hurting others past 1 month
- Disruption3-LT
 - Having a plan for not hurting others when these feelings arise past ≥ 1 year
- Disruption3-MT
 - Having a plan for not hurting others when these feelings arise past 1 year to 1 month
- Disruption3-ST
 - Having a plan for not hurting others when these feelings arise past 1 month
- Disruption4-LT
 - Prior attempts at hurting insects or small animals past ≥ 1 year
- Disruption4-MT
 - Prior attempts at hurting insects or small animals past 1 year to 1 month
- Disruption4-ST
 - Prior attempts at hurting insects or small animals past 1 month
- Disruption5-LT
 - Intrusive thoughts that lead you to repetitive actions past ≥ 1 year
- Disruption5-MT
 - Intrusive thoughts that lead you to repetitive actions past 1 year to 1 month
- Disruption5-ST
 - Intrusive thoughts that lead you to repetitive actions past 1 month
- Disruption6-LT
 - Desire to start fires past ≥ 1 year
- Disruption6-MT
 - Desire to start fires past 1 year to 1 month
- Disruption6-ST
 - Desire to start fires past 1 month
- Disruption7-LT
 - Being disruptive in a social environment (eg, at school or elsewhere) past ≥ 1 year
- Disruption7-MT
 - Being disruptive in a social environment (eg, at school or elsewhere) past 1 year to 1 month
- Disruption7-ST
 - Being disruptive in a social environment (eg, at school or elsewhere) past 1 month
- Disruption8-LT
 - Attention problems past ≥ 1 year
- Disruption8-MT
 - Attention problems past 1 year to 1 month

- Disruption8-ST
 - Attention problems past 1 month
- Disruption9-LT
 - Breaking rules at school or elsewhere past ≥ 1 year
- Disruption9-MT
 - Breaking rules at school or elsewhere past 1 year to 1 month
- Disruption9-ST
 - Breaking rules at school or elsewhere past 1 month

Figure 2. The Likert scale on which participants rated the questions.

1	2	3	4	5	6	7
never	rarely		sometimes		often	always

Data Quality Assurance

Data quality used 4 exclusion criteria: (1) participants with the same responses throughout any section of the questionnaire (eg, “1” for all questions), (2) participants indicating they had been diagnosed by a clinician with ≥ 10 illnesses, (3) participants with minimal variance in a picture-rating task (all pictures were rated the same or varied only by 1 point; data not described here), (4) participants reporting inconsistent education level and years of education *and* participants who completed the questionnaire in < 500 seconds. From these procedures, 366 participants were cleared for statistical analysis.

Statistical Analyses

Analysis of Demographics and Survey Questions by Self-reported COVID-19 Infection

Demographic variables (Table 1) and survey question scores for all questions were divided into 2 distributions based on the *yes* and *no* responses from participants for each of the COVID-19 questions: *test+*, *diagnosis*, and *family*. Distributions of the demographic variables and survey question scores were assessed for differences using the Wilcoxon rank sum test [45]. Significant categorical demographic variables were further assessed for distribution equality using the Kolmogorov-Smirnov test ($\alpha=.05$) [46]. The resulting *P* values for the questions *Psych1-LT*, *Psych1-MT*, *Psych1-ST*, and *Psych2-LT* to *Psych4-ST* were corrected for multiple comparisons using the Benjamini-Hochberg procedure [47] (reported as *q*[FDR]) for each COVID-19 question. The same procedure was repeated for questions *Disruption1-LT* to *Disruption9-ST*. The normalized test statistic from the Wilcoxon rank sum test and *q*(FDR) are reported. Box plots were generated to display the *yes* or *no* distribution for all survey questions and are presented in the Multimedia Appendix 1.

MVLR and Iterative Resampling: Using Demographics and Survey Questions to Model COVID-19 Likelihood

MVLR was performed with the goal of modeling COVID-19 likelihood. The aim was to determine how psychotic symptoms and VIDB from before the pandemic made people more vulnerable to COVID-19 infection during the pandemic. The set of *past ≥ 1 year (long term)* survey responses for the psychotic symptoms and VIDB, which significantly differed (*q*[FDR]) between those responding *yes/no* to *test+*, *diagnosis*, and *family* questions for COVID-19, were used as *independent variables*. The demographic variables with significant differences across *yes* or *no* responses for COVID-19 *test+*, *diagnosis*, or *family* (*q*[FDR] < 0.05 ; Wilcoxon rank sum test) were used as *covariates* in the MVLR analyses. The COVID-19 question responses (*yes*=1 and *no*=0) were the binary *dependent variables*. However, the percentage of participants with a positive self-reported COVID-19 *test+* or *diagnosis* (*yes*=1; 9% to 10%) was much lower than the percentage of those without COVID-19 *test+* or *diagnosis* (*no*=0; approximately 90%), implying a class imbalance that could lead to model overfitting. To avoid overfitting the MVLR model to the majority class, data in the majority class (ie, participants in the COVID-19 *test+* *no* and *diagnosis* *no* groups) were randomly downsampled to match the sample size of those self-reporting COVID-19 (*yes*=0; 36/366, 9.8% for *test+* model, and 34/366, 9.3% for *diagnosis* model). Downsampling was iterated 1000 times, and MVLR was run at each iteration for the downsampled data to obtain the model accuracy, root mean square error (RMSE), and mean absolute error (MAE) of the model. The model accuracy was computed by comparing the number of times the model correctly determined the binary outcome divided by the size of the downsampled data. The average accuracy, SD of the accuracy, average RMSE, and average MAE across all iterations are reported.

Results

Overview

The demographic variables and the frequency of self-reported symptoms of psychosis and VIDB from the 3 time intervals were assessed for participants with and without self-reported COVID-19. For this assessment, we used a Wilcoxon rank sum test followed by multiple comparisons correction. The relationship between these behaviors occurring >1 year ago and the likelihood of contracting COVID-19 was investigated using MVLR with iterative resampling. Namely, we asked whether symptoms from >1 year ago could predict COVID-19 infection.

Demographic Variables and Survey Question Responses Varied by Self-reported COVID-19

In summary, of the 366 participants, 36 (9.8%) reported a positive COVID-19 *test+*, and 34 (9.3%) reported a COVID-19 *diagnosis*; 26 (7.1%) participants answered yes to both the COVID-19 *test+* and *diagnosis*. Of the 366 participants, 95 (26%) reported that a family member or close friend had serious COVID-19-related symptoms or died of COVID-19. We found that participants who self-reported yes to contracting COVID-19 were middle-aged and belonged to the higher-income and higher education groups. Participants who self-reported yes to contracting COVID-19 also reported a higher frequency of psychotic symptoms and VIDB across all 3 time windows of the past 1 month, 1 month to 1 year ago, >1 year ago.

Specifically, age and income significantly varied by *test+*, and age, income, and education level significantly varied by *diagnosis* (all $q[FDR] < 0.05$; Wilcoxon rank sum test; Table 2). Participants who responded yes to *test+* and *diagnosis* were, on average, younger than those who responded no (Table 3;

Figure 3A and 3B). Specifically, middle-aged adults more frequently reported yes to *test+* (IQR 25-47, median 37 years) and *diagnosis* (IQR 25-45, median 37.5 years) than those responding no (IQR 31-59, median 45). Participants responding no to *test+* or *diagnosis* showed a distribution with a higher percentage of low-income levels than those with COVID-19 ($P=.004$; $P=.001$; Kolmogorov-Smirnov test; Figure 3C and 3D). Participants responding yes to *test+* or *diagnosis* exhibited a bimodal distribution of education level, whereas the distribution for NO responses was skewed left ($P=.04$; $P=.01$; Kolmogorov-Smirnov test; Figure 3E and 3F) indicating a higher percentage of low education levels. None of the demographic variables exhibited significant differences based on *family* COVID-19 questions.

Furthermore, the survey questions for which responses significantly varied ($q[FDR] < 0.05$; Wilcoxon rank sum test) by COVID-19 status (*test+*, *diagnosis*, and *family*) have $q(FDR)$ highlighted in Tables 4 and 5. All 4 questions related to psychotic symptoms showed significant differences in medians across the yes and no distributions with respect to *test+* and *diagnosis* for COVID-19 across the three time windows: (1) *past ≥ 1 year (long term)*, (2) *past 1 month to 1 year (medium term)*, and (3) *past 1 month (short term)*; Table 4). All 9 questions related to VIDB also showed significantly different medians across the yes and no distributions with respect to *test+* and *diagnosis* for COVID-19 across the 3 time windows (Table 5). There were no significant response differences across the 13 psychotic symptoms and VIDB questions relative to the COVID-19 *family* questions. Box plots based on *test+* and *diagnosis* for yes distribution had higher scores than for those who answered no for all survey questions, as presented in the Multimedia Appendix 1.

Table 2. List of the demographic variables that significantly differed by COVID-19 questions (Wilcoxon rank sum test)^a.

Demographic	COVID-19 questions	<i>P</i> value	$q(FDR)$
Age	Test+ ^b	.006	0.024 ^b
Age	Diagnosed ^b	.004	0.02 ^b
Employment	Diagnosed	.04	0.20
Income	Test+ ^b	.004	0.02 ^b
Income	Diagnosed ^b	<.001	<0.001 ^b
Education level	Test+	.02	0.08
Education level	Diagnosed ^b	.009	0.04 ^b

^aUncorrected *P* values and $q(FDR)$ are reported.

^bDemographic variables with $q(FDR) < .05$.

Table 3. List of demographic variables that significantly differ by Kolmogorov-Smirnov test ($P < .05$).

Demographic	COVID-19 questions	<i>P</i> value (yes>no)	<i>P</i> value (no>yes)
Income	Test+	.004	>.99
Income	Diagnosis	.001	>.99
Education level	Test+	.64	.04
Education level	Diagnosis	.48	.01

Figure 3. Box plots for distributions of age for participants who answered yes or no for (A) COVID-19 test+ and (B) COVID-19 diagnosis. Histograms for distributions of annual household income (US dollars) for participants who answered yes or no for (C) COVID-19 test+ and (D) COVID-19 diagnosis. Histograms for distributions of education for participants who answered yes or no for (E) COVID-19 test+ and (F) COVID-19 diagnosis.

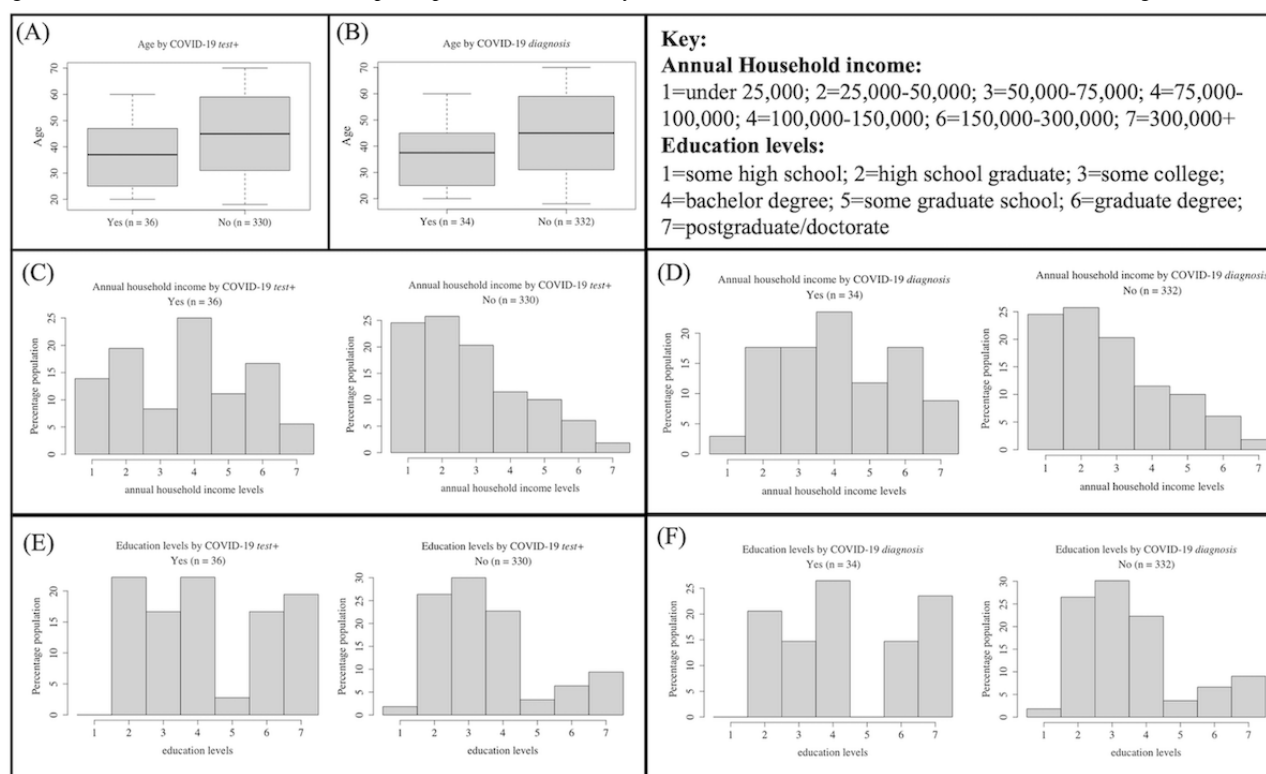


Table 4. Survey questions related to psychosis assessed by COVID-19 status (test+, diagnosis, and family) using the Wilcoxon rank sum test.

Questions	COVID-19 questions					
	Test+		Diagnosis		Family	
	Test statistic	q(FDR)	Test statistic	q(FDR)	Test statistic	q(FDR)
Hallucinations/Hearing voices others cannot						
Past ≥1 year	3.50	6.21×10^{-4}	4.78	2.33×10^{-6}	0.42	0.95
Past 1 month to 1 year	3.51	6.21×10^{-4}	4.93	1.21×10^{-6}	0.06	0.95
Past 1 month	4.17	1.42×10^{-4}	5.56	7.88×10^{-8}	0.08	0.95
Hallucinations/Seeing things others cannot see						
Past 1 ≥year	3.61	5.30×10^{-4}	4.94	1.21×10^{-6}	0.11	0.95
Past 1 month to 1 year	4.10	1.42×10^{-4}	5.92	1.90×10^{-8}	0.24	0.95
Past 1 month	4.07	1.42×10^{-4}	5.96	1.90×10^{-8}	0.26	0.95
Worries that others are out to get you, or to get people close to you (these might resemble paranoia)						
Past ≥1 year	3.82	3.25×10^{-4}	3.84	1.24×10^{-4}	1.09	0.95
Past 1 month to 1 year	3.29	1.08×10^{-3}	4.27	2.34×10^{-5}	0.38	0.95
Past 1 month	2.78	5.51×10^{-3}	3.88	1.14×10^{-4}	0.18	0.95
Having one or more unique beliefs or impressions that are strong despite being contradicted by others (these might resemble delusions)						
Past ≥1 year	3.44	6.95×10^{-4}	5.39	1.44×10^{-7}	0.44	0.95
Past 1 month to 1 year	3.66	5.05×10^{-4}	5.50	8.99×10^{-8}	0.67	0.95
Past 1 month	4.16	1.42×10^{-4}	5.86	1.90×10^{-8}	0.46	0.95

Table 5. Survey questions related to violent ideation and suicidal behavior assessed by COVID-19 status (test+, diagnosis, and family) using the Wilcoxon rank sum test.

Questions	COVID-19 questions					
	Test+		Diagnosis		Family	
	Test statistic	q(FDR)	Test statistic	q(FDR)	Test statistic	q(FDR)
Wanting to hurt others						
Past ≥1 year	4.13	1.62×10^{-4}	5.33	3.88×10^{-7}	0.61	0.72
Past 1 month to 1 year	4.34	1.42×10^{-4}	5.35	3.88×10^{-7}	1.07	0.67
Past 1 month	3.80	3.19×10^{-4}	4.77	3.09×10^{-6}	0.55	0.72
Prior attempts at hurting others						
Past 1 ≥year	4.18	1.58×10^{-4}	4.90	1.83×10^{-6}	0.34	0.83
Past 1 month to 1 year	3.77	3.19×10^{-4}	4.98	1.39×10^{-6}	0.81	0.67
Past 1 month	4.01	2.33×10^{-4}	5.35	3.88×10^{-7}	0.65	0.72
Having a plan for not hurting others when these feelings arise						
Past ≥1 year	2.21	2.84×10^{-2}	4.26	2.48×10^{-5}	1.16	0.67
Past 1 month to 1 year	2.76	6.43×10^{-3}	4.10	4.24×10^{-5}	1.46	0.55
Past 1 month	2.75	6.45×10^{-3}	4.20	3.01×10^{-5}	1.53	0.55
Prior attempts at hurting insects or small animals						
Past ≥1 year	3.75	3.24×10^{-4}	5.33	3.88×10^{-7}	0.58	0.72
Past 1 month to 1 year	3.87	3.15×10^{-4}	5.47	3.88×10^{-7}	0.87	0.67
Past 1 month	3.85	3.15×10^{-4}	5.12	7.32×10^{-7}	1.43	0.55
Intrusive thoughts that lead you to repetitive actions						
Past ≥1 year	3.40	9.65×10^{-4}	4.69	3.80×10^{-6}	0.26	0.86
Past 1 month to 1 year	3.31	1.27×10^{-3}	4.53	8.00×10^{-6}	0.14	0.92
Past 1 month	3.82	3.19×10^{-4}	5.15	7.01×10^{-7}	0.08	0.93
Desire to start fires						
Past ≥1 year	4.28	1.42×10^{-4}	5.18	6.98×10^{-7}	0.84	0.67
Past 1 month to 1 year	4.50	1.42×10^{-4}	5.57	3.88×10^{-7}	0.83	0.67
Past 1 month	4.25	1.42×10^{-4}	4.17	3.29×10^{-5}	0.63	0.72
Being disruptive in a social environment (eg, at school or elsewhere)						
Past ≥1 year	3.22	1.56×10^{-3}	4.36	1.69×10^{-5}	1.19	0.67
Past 1 month to 1 year	3.87	3.15×10^{-4}	5.17	6.98×10^{-7}	1.72	0.55
Past 1 month	3.77	3.19×10^{-4}	4.73	3.53×10^{-6}	1.78	0.55
Attention problem						
Past ≥1 year	3.28	1.34×10^{-3}	4.72	3.61×10^{-6}	1.40	0.55
Past 1 month to 1 year	2.87	4.83×10^{-3}	4.21	3.00×10^{-5}	1.60	0.55
Past 1 month	2.18	2.92×10^{-2}	3.76	1.70×10^{-4}	1.40	0.55
Breaking rules at school or elsewhere						
Past ≥1 year	3.45	8.36×10^{-4}	4.82	2.53×10^{-6}	1.03	0.67
Past 1 month to 1 year	3.63	4.84×10^{-4}	4.97	1.39×10^{-6}	0.89	0.67

Questions	COVID-19 questions					
	<i>Test+</i>		<i>Diagnosis</i>		<i>Family</i>	
	Test statistic	q(FDR)	Test statistic	q(FDR)	Test statistic	q(FDR)
Past 1 month	3.56	5.84×10^{-4}	5.37	3.88×10^{-7}	0.42	0.79

MVLR: Using Demographics and Survey Questions to Model COVID-19 Likelihood

In brief, using MVLR with iterative resampling, we observed a model accuracy of 72% to 94% for an increased incidence of COVID-19 in participants with psychotic symptoms or VIDB >1 year ago (ie, before the pandemic).

Specifically, MVLR with iterative resampling focused on the responses from the time window of *past* ≥ 1 year (*long term*) for the 13 survey questions that significantly varied by COVID-19 status (Table 4 and Table 5). Responses to these 13 questions were used as *primary predictors* to model COVID-19 *test+* and *diagnosis* using MVLR. Given that no significant differences were observed in the survey question responses when split by responses to the COVID-19 *family* question, no attempt was made to model COVID-19 *family* using MVLR. The significant demographic variables of age, income, and education level were used as *covariates* in the model. To avoid overfitting of the model to the majority class (ie, participants in COVID-19 *test+* no and *diagnosis* no groups), the majority

class was iteratively downsampled 1000 times, and the MVLR model was run each time. The average accuracy, SD of the accuracy, average RMSE, and average MAE across all iterations are reported. The null model with only the survey questions regarding psychosis with responses from >1 year ago (ie, Psych1-LT, Psych2-LT, Psych3-LT, and Psych4-LT) had an average accuracy of 72.08% for *test+* and 76.75% for *diagnosis*. The model with 4 survey questions as predictors along with demographic variables as covariates had an average accuracy of 85.45% for model *test+* and 89.43% for model *diagnosis* (Table 6). Similarly, the null model for 9 survey questions regarding VIDB with responses from more than a year ago (Disruption1-LT, Disruption2-LT..., Disruption9-LT) had average accuracies of 81.32% and 87.53% for *test+* and *diagnosis*, respectively. The 9 survey questions, along with covariates, had an average accuracy of 90.35% for the model *test+* and 94.39% for the model *diagnosis* (Table 6). Additional measures, including the SD of the accuracy, average RMSE, and average MAE for these models are also reported in Table 6.

Table 6. Multivariable logistic regression results^a.

COVID-19 question (dependent variable)	Independent variables	Covariates	Accuracy, mean (SD)	RMSE ^b , mean (SD)	MAE ^c , mean (SD)
Test+	Psych1-LT, Psych2-LT, Psych3-LT, and Psych4-LT	— ^d	72.08 (3.80)	0.53 (0.04)	0.28 (0.04)
Test+	Psych1-LT, Psych2-LT, Psych3-LT, and Psych4-LT	<ul style="list-style-type: none"> • Age • Income • Education level 	85.45 (4.60)	0.38 (0.06)	0.15 (0.04)
Diagnosis	Psych1-LT, Psych2-LT, Psych3-LT, and Psych4-LT	—	76.75 (3.67)	0.48 (0.04)	0.23 (0.04)
Diagnosis	Psych1-LT, Psych2-LT, Psych3-LT, and Psych4-LT	<ul style="list-style-type: none"> • Age • Income • Education level 	89.43 (4.44)	0.32 (0.08)	0.11 (0.04)
Test+	Disruption1-LT, Disruption2-LT, Disruption3-LT, Disruption4-LT, Disruption5-LT, Disruption6-LT, Disruption7-LT, Disruption8-LT, and Disruption9-LT	—	81.32 (1.09)	0.43 (0.01)	0.19 (0.01)
Test+	Disruption1-LT, Disruption2-LT, Disruption3-LT, Disruption4-LT, Disruption5-LT, Disruption6-LT, Disruption7-LT, Disruption8-LT, and Disruption9-LT	<ul style="list-style-type: none"> • Age • Income • Education level 	90.35 (3.20)	0.31 (0.05)	0.10 (0.03)
Diagnosis	Disruption1-LT, Disruption2-LT, Disruption3-LT, Disruption4-LT, Disruption5-LT, Disruption6-LT, Disruption7-LT, Disruption8-LT, and Disruption9-LT	—	87.53 (1.15)	0.35 (0.02)	0.12 (0.01)
Diagnosis	Disruption1-LT, Disruption2-LT, Disruption3-LT, Disruption4-LT, Disruption5-LT, Disruption6-LT, Disruption7-LT, Disruption8-LT, and Disruption9-LT	<ul style="list-style-type: none"> • Age • Income • Education level 	94.39 (3.51)	0.22 (0.09)	0.06 (0.03)

^aThe table lists the dependent variable, independent variables, and covariates for each multivariable logistic regression model and reports the average and SD of accuracy, RMSE, and MAE.

^bRMSE: root mean square error.

^cMAE: mean absolute error.

^dNo covariates were included in the model.

Discussion

Principal Findings

In a small population sample, we assessed the frequency of self-reported VIDB and psychotic symptoms among people with or proximate to someone with a COVID-19 diagnosis and further tested the potential for discriminating who might become infected by COVID-19 based on a preceding history of these behaviors. For all 3 time windows, we found that participants who answered yes to having COVID-19 (*test+* and *diagnosis*) experienced VIDB and psychotic symptoms more frequently than those who answered no. No significant differences were observed between the yes or no distributions for those who had a close friend or family contract COVID-19 (ie, *family*). Using MVLRL with iterative resampling to avoid model overfitting, we also found that participants who experienced psychotic symptoms and VIDB more frequently before the COVID-19 pandemic were more likely to subsequently contract COVID-19, suggesting that individuals experiencing psychotic symptoms and VIDB may (1) have comorbid conditions that increase their susceptibility to COVID-19 infection and (2) engage in

riskier-than-average behaviors, potentially including nonadherence to COVID-19 precautions and engaging with other people.

The 3 demographic variables (age, income, and educational level) were significantly different when divided into yes or no distributions for COVID-19. Regarding age, COVID-19 was more prevalent in middle-aged individuals, with *yes* distributions for both COVID-19 infection questions having a median age of 37 years. These results contrast with some reports of COVID-19 incidence, where it was reported that older adults were more likely to be hospitalized because of COVID-19 [48], but support the results of other studies, in which younger to middle-aged people were more likely to contract COVID-19 [49]. It should be noted that this study only asked about the diagnosis or testing positive for COVID-19, which is different from hospitalization.

Annual household income for participants who answered yes to COVID-19 questions was more equally distributed across all income levels, with a peak at higher-income households (>US \$75,000). In comparison, the income distribution of participants who answered no was skewed, with a higher concentration of

participants in lower-income households. However, the participants who answered yes were evenly distributed across all income levels. This demonstrates that people who answered no for COVID-19 *test+* and *diagnosis* were predominately from lower-income households and that people who answered yes to *test+* and *diagnosis* were evenly distributed across all household income levels. This suggests that COVID-19 occurred in people with a wide range of income levels and did not preferentially occur in those living in lower- or higher-income households. These findings are in line with those reported in the study by Alsan et al [49] but are in contrast with those in the study by Baena-Diéz et al [50]. This study [50] found that people belonging to lower-income level households had higher incidence rates of contracting COVID-19 infection in Barcelona, Spain. Education had bimodal distributions for participants who answered yes to COVID-19 questions, with a larger peak at higher education levels. For participants who responded no, the distribution was skewed to the left, suggesting that education level did not predispose individuals to COVID-19.

Responses to survey questions about VIDB and psychotic symptoms exhibited higher scores for participants who answered yes for COVID-19 than for people who responded no. This observation showed similar statistical effects regardless of the time window assessed (ie, in the past 1 month, 1 month to 1 year ago, and >1 year ago; Tables 4 and 5). Given these findings for all time windows in this specific study, including those before the pandemic, our observation of a higher frequency of psychotic episodes is less likely to be a direct consequence of COVID-19, which has been linked to cognitive and attention deficits, brain fog, and anxiety [2]. For the same reason, our findings are less likely to be because of higher doses of steroid treatment, which is known to complicate or trigger psychosis [51]. It should be noted that there have been multiple reports of subacute onset of psychotic episodes in healthy individuals with no prior history of mental illness after treatment for COVID-19 [52-55]. These psychotic episodes also led to aggressive, violent, and disruptive behavior and a preponderance of not following rules [53,55]. The psychological impacts of quarantine, temporary loss of employment, lack of livelihood, and financial insecurity have also been shown to trigger violent and disruptive behavior [8,56]. Owing to feelings of frustration and agitation associated with COVID-19, pandemic-related stressors may manifest as aggression and violence toward household members [57-59]. Fear surrounding the COVID-19 pandemic has also been associated with aggressive behavior on the web [60]. Although this is consistent with our results where participants who contracted SARS-CoV-2 reported higher incidences of psychotic symptoms and VIDB in the past 1 month and 1 month to 1 year, our observation of these symptoms, ideation, and behavior before the pandemic for these participants suggests that COVID-19 infection was not causal in the presentation of VIDB or psychotic symptoms. Our study did not find associations that were directional, namely, whether COVID-19 infection increases the likelihood of psychosis and VIDB or whether psychotic symptoms and VIDB increase the possibility of COVID-19 infection. Other viral infections, including influenza and HIV, have led to similar hypotheses [26-34]. Recently, a study by Douaud et al [61] observed a greater reduction in overall brain size, reduction in gray matter

thickness and tissue contrast in the orbitofrontal cortex and parahippocampal gyrus, and changes in markers of tissue damage in regions functionally connected to the primary olfactory cortex in people who tested positive for infection with SARS-CoV-2. Similar brain regions are known to be affected in the same way by psychosis and VIDB [62-66].

To assess whether self-reported VIDB or psychotic symptoms that occurred >1 year ago (ie, before the pandemic) modeled that individuals subsequently had COVID-19 infection, MVLR was performed with iterative downsampling of the majority class to reduce the possibility of model overfitting (Table 6). The demographic variables of age, income, and education level were used as covariates. The full model was not confounded by covariates as the highest accuracy without covariates (ie, null model) was 87.5%, whereas the highest accuracy for the full model was 94.4%. Across all the models, the accuracy of modeling COVID-19 by *diagnosis* was higher than that for *test+*. This might be because of the likelihood of false positives from COVID-19 testing and the fact that COVID-19 testing is an inherent component of clinical diagnosis, making clinical diagnosis more informed. There was also a lag at the beginning of the pandemic before testing was widely available. Overall, the highest accuracy for modeling COVID-19 infection from psychotic symptoms from >1 year ago was 89.4%, and for VIDB, it was 94.4%. These results may reflect comorbid conditions that increase susceptibility to COVID-19 infection or reflect engagement in riskier-than-average behaviors, potentially including nonadherence to COVID-19 precautions, as has been observed with other viral infections [30-32]. Conversely, there is another hypothesis that people with mental health conditions become more antisocial and are thus more distant from other people, potentially resulting in a reduced viral spread. Further work is needed to determine whether psychotic symptoms or VIDB increase the risk for, and the spread of, COVID-19.

This study has several limitations. First, this study involved a small sample size of participants responding yes to *test+* (36/366, 9.8%) and *diagnosis* (34/366, 9.3%) in our cohort. Although the percentage of studied participants infected with COVID-19 herein was consistent with the population estimates of COVID-19 in the United States at the time of data collection, future work needs to assess larger population samples. Another limitation is the bias arising from the false positives of self-reported COVID-19 test positives. It should be noted that the survey did not collect data when the respondents were infected with COVID-19 in the previous year; this is a limitation in estimating the precise time frame for an increase in behavioral symptoms associated with COVID-19. Recall bias is a well-known caveat for any study that uses survey methods [67]. Furthermore, it should also be noted that MVLR results do not represent true predictions, which would require adequately sized training and test sets, along with cross-validation of prediction outcomes. Future work will need to use larger sample sizes and perform better predictive analyses with more sophisticated machine learning algorithms. These caveats aside, it must be noted that this study used iterative resampling to overcome a major confounder that is common in current machine learning

papers with class imbalance in smaller data sets—model overfitting—supporting the generalizability of these results.

Conclusions

This preliminary study examined a population sample collected at the end of February 2021 and the beginning of March 2021 and found that people who reported a test and clinician diagnosis of COVID-19 also reported higher frequencies of VIDB or psychotic symptoms across multiple time windows (the past 1 month, 1 month to 1 year ago, and >1 year ago), including those before the pandemic started. We also found that participants

who experienced VIDB or psychotic symptoms >1 year ago (ie, before the pandemic) were more likely to contract SARS-CoV-2 or be diagnosed with COVID-19. A greater understanding of how COVID-19 may trigger these mental health issues is needed, given other literature on viral, carcinogenic, and toxic effects in changing mental status, including triggering psychotic symptoms and disruptive behavior [26-29,33,34,68-71]. It is also of utmost importance to understand which vulnerable populations are at a greater risk of contracting and spreading the virus to curb the viral spread, which includes vulnerable populations related to age, sex, and household income.

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Authors' Contributions

SB, NLV, NM, AKK, and HCB took part in the study concept and design and acquisition of original data. SB performed the coding of statistical tools (with guidance from NLV, AKK, and HCB). SB and NLV performed the analysis of data (with guidance from HCB and AKK). Interpretation of data was conducted by SB, NLV, AKK, and HCB (with input from KS, SW, SL, LS, B-WK, and NM). SB performed the statistical assessment (with input from NLV, AKK, and HCB), authored the original draft (with input from HCB), and generated figures. All authors were involved in the revision of the manuscript for content. All authors approved the final version of this manuscript for submission. Coauthorship is as follows: SB and NLV are joint first authors; KS, SW, LS, LS, BWK, and NM are joint second authors; and HCB and AKK are cosenior authors.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Survey questions and box plots of survey questions for yes or no distributions based on COVID-19 questions.

[\[DOCX File , 21265 KB - formative_v6i8e36444_app1.docx \]](#)

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Abbreviations

- MAE:** mean absolute error
- MGH SQ:** Massachusetts General Hospital Subjective Question
- MVLR:** multivariable logistic regression
- RMSE:** root mean square error
- VIDB:** violent ideation and disruptive behavior

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Original Paper

Virtual Care Prior to and During COVID-19: Cross-sectional Survey of Rural and Urban Adults

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Abstract

Background: To reduce person-to-person contact, the COVID-19 pandemic has driven a massive shift to virtual care. Defined as the use of technology (synchronous or asynchronous) to support communication between health care providers and patients, rural-urban differences in virtual care are relatively unexplored.

Objective: The 2-fold purpose of this study was to examine rural and urban virtual care access, use, and satisfaction during the pandemic and to identify any unmet needs.

Methods: This study was a cross-sectional online survey exploring virtual care among rural and urban adults in summer 2021 using a combination of fixed and open-ended response options. Quantitative data were analyzed using both descriptive and inferential statistics, and qualitative data were analyzed using inductive thematic content analysis.

Results: Overall, 501 (373, 74.4% female; age range 19-86 years; 237, 47.3% rural-living) Western Canadians completed the survey. Virtual care use was high among both rural (171/237, 72.2%) and urban (188/264, 71.2%) participants, with over one-half (279/501, 55.7%) reporting having only started to use virtual care since the pandemic. The self-reported need for mental health programs and services increased during the pandemic, compared with prior for both rural and urban participants. Among virtual care users, interest in its continuation was high. Our analysis also shows that internet quality (all $P < .05$) and eHealth literacy (all $P < .001$) were positively associated with participants' perceptions of virtual care usefulness, ease of use, and satisfaction, with no rural-urban differences. Rural participants were less likely to have used video in communicating with doctors or health care providers, compared with urban participants ($P < .001$). When describing unmet needs, participants described a (1) lack of access to care, (2) limited health promotion and prevention options, and (3) lack of mental health service options.

Conclusions: The increased demand for and use of virtual care may reflect increased availability and a lack of alternatives due to limited in-person services during the COVID-19 pandemic, so a balance between virtual care and in-person care is important to consider postpandemic. Further, ensuring availability of high-speed internet and education to support patients will be important for providing accessible and effective virtual care, especially for rural residents.

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KEYWORDS

virtual care; rural; urban; COVID-19; digital literacy; unmet needs

Introduction

The World Health Organization declared COVID-19 a pandemic and global health emergency on March 11, 2020 [1]. Respecting no geographic boundaries, the pandemic has impacted both rural and urban populations. However, the pandemic was superimposed on well known urban-rural health and health service disparities. Compared with their urban counterparts, rural dwellers experience poorer health and health behaviors, more chronic conditions, and shorter life expectancies and higher mortality rates [2]. These health inequities are systemic and avoidable differences in health that are caused by the unfair distribution of resources, wealth, and power in society [3] and reflect social and structural determinants of health, such as educational, financial, social, and geographical difficulties [4,5]. Moreover, rural communities have historically lacked access to health services and care, due to heightened health provider shortages, underdeveloped digital infrastructure, travel burdens, and costs [6,7].

Adding to the existing social-structural factors influencing rural health and health service use, the pandemic has contributed further to health care gaps [3]. The deferral of elective procedures and routine checkups [8,9] and patient avoidance of medical care for non-COVID-19 illness due to fear of contracting the virus [10] accounted for a massive global reduction in health care utilization (by one-third) during COVID-19 [8]. At the same time, a meta-analysis of 60 studies reported high levels of depression and anxiety worldwide [11], generating high demand for mental health services that have been disrupted by COVID-19 [12]. Few studies have considered the extent of unmet health and wellness needs as a result of these gaps and whether there are urban and rural differences. In their South Korean study [13], researchers found that demographics (eg, age, sex, educational level), chronic diseases, and stress and anxiety were associated with unmet care. To prevent or reduce exposure with the emergence of new variants coupled with the redirection of resources for COVID-19 patients, health care was drastically altered. COVID-19 catalyzed a massive shift to virtual care, with reported increases as much as 56-fold compared with prior to COVID-19 [14,15]. The term virtual care is often used interchangeably with telemedicine or telehealth; we are referring specifically to virtual care defined as the use of technology (synchronous or asynchronous) to support communication between health care providers and patients [16]. Virtual care technologies include video visits, email, text messaging, and telephone visits. In an online survey in summer 2020, 31% of rural adults reported using virtual care somewhat and far more often after March 2020 [17]. However, in a Canadian rural-urban comparison study using an administrative database, urban uptake of virtual care increased at a steeper rate than rural uptake at the start of the pandemic (220 vs 147 visits per 1000 patients) [18]. Similarly, 53% of US urban households, compared with 46% of rural households, used virtual care during the pandemic, though this difference was not statistically significant [19]. In their US study of rural

and urban living veterans, Hogan and colleagues [20] found higher use of virtual mental health care pre-COVID-19 among rural than among urban living veterans and increased use by both groups during the first 7 months into COVID-19 but with urban veterans surpassing rural veterans' usage. Researchers have suggested that barriers to a rapid transition to telehealth delivery may have affected rural areas more than urban areas particularly due to their lack of access to broadband internet, limited device ownership (smartphone, tablet, laptop), and lower digital literacy [20].

Despite lower uptake of virtual care, satisfaction with virtual care was high among rural-dwelling individuals both before [21] and during COVID-19 [22]. In a US study, virtual care satisfaction was higher in rural (88%) than in urban (84%) areas, though not significantly different [19]. Whether satisfaction translates into willingness to continue virtual care postpandemic deserves more research; however, in a recent COVID-19 study of 1059 US residents, 72% to 77% reported intentions to continue to use virtual care, at least for acute health conditions, with no rural-urban differences [23].

Another factor that impacts users' ability to use, and satisfaction with, virtual care is eHealth literacy, which is defined as the ability to find, use, and apply health information from electronic sources [24]. Although inextricably linked to rural challenges in access to high-speed internet, eHealth literacy is often reported to be lower among rural residents compared with their urban counterparts [25]. In a small US study (n=253), utilization of and satisfaction with virtual care were associated with higher eHealth literacy among rural-living adults [22]. Similarly, a significantly positive relationship was found between eHealth literacy and satisfaction with virtual care among people living peripherally to Israel [26].

Given the massive impact of COVID-19 on virtual care, a comprehensive examination of rural and urban virtual care access, use, satisfaction, and future intention to use, considering eHealth literacy and unmet needs, is needed. No such study has been conducted at the time of this study—a full year after COVID-19 was declared a pandemic [1]. The purpose of this study was to compare rural- and urban-living Canadian adults' access, use, satisfaction, and intentions to continue to use virtual care, as well as to explore unmet health and wellness needs 1 year after COVID-19 was declared a pandemic.

Methods**Study Design, Context, and Participant Recruitment**

This study employed a cross-sectional online survey open to adults (19 years or older) residing in urban, rural, and remote communities in a Western Canadian province where 18.44% live in rural communities [27]. The online survey was open to participants for a 6-week period (June 24, 2021, to August 9, 2021). During this time, the province was in a state of re-opening [28]. Step one of the provincial re-start plan began May 25, 2021; social restrictions were loosened, businesses re-opened,

and recreational activities resumed. Step two of the re-start (from June 15, 2021, to June 30, 2021) included additional lifting of travel restrictions and easing of restrictions for businesses and recreational activities (eg, liquor served until midnight, up to 50 spectators at outdoor sporting events allowed). The COVID-19 vaccine was available to everyone age 12 years and older during the time of this survey [29].

Recruitment efforts primarily involved Facebook posts targeting local community pages (n=35; eg, “What’s Up [community name]”) together totaling over 177,000 members as well as through 3 paid Facebook advertisements (“post boosts”) targeting adults living within a 25-mile radius of several rural and urban communities in the province. Email invitations with the survey link were also sent to rural-living participants who completed an online survey in 2020 [17] and consented to being contacted for a future survey. Advertisements were also posted on Twitter, Kijiji (Canadian Craigslist), Facebook, and rural websites and in the volunteer sections of classified web pages, as well as shared through targeted announcements in rural community association newsletters. Additionally, REACH BC, an online platform designed to connect individuals across British Columbia (BC) with research opportunities; Patient Voices Network, a partner platform of REACH BC; and a network aimed at engaging patients in their health care were used for advertisement and recruitment. Although we were unable to track how many potential respondents were reached in total, the 3 Facebook advertisements had a combined estimated audience reach of 5776 adults and engagement (link clicks) of 109 (1.9% response rate), and 56 of the 206 (27.2%) previous survey participants completed this survey. Due to more individuals residing in urban areas than in rural communities, it was anticipated that recruitment of urban participants would be more efficient. Accordingly, more recruitment efforts were focused on targeting participants in rural communities. To promote participation, 5 CAD \$100 (US \$77.61), 3 CAD \$200 (US \$155.22), and 1 CA \$400 (US \$310.43) draw prize incentives were advertised. The survey used a combination of fixed and open responses and an attention check question (“If you are a human reading this, please select strongly agree”) to detect survey bots and inattentive respondents [30,31].

Ethical Considerations

The study was conducted in accordance with the Declaration of Helsinki and with the Canadian Tri-Council Policy Statement. All participants provided informed consent online prior to completing the survey. Participants were provided a link to download the consent form and encouraged to keep a copy for their personal records. Consent was obtained by participants selecting “Yes” in response to the question “Do you consent to participate?” This study was reviewed and received ethics approval from the University of British Columbia—Okanagan Behavioural Research Ethics Board (H20-01166).

Measures

Rurality

Participants provided their community’s name, and based on the census subdivision of the community, a score was assigned from Statistics Canada’s Index of Remoteness [32]. Remoteness

index scores are based on population size and cost to travel to the nearest population center and range from 0 to 1, with scores closer to 1 indicating greater remoteness. Based on the manual method of classification into 5 categories of accessibility using predetermined cutoffs by Subedi et al [33], community scores categorized as easily accessible (<0.1500) or accessible (0.1500 to 0.2888) were classified as urban, and community scores categorized as less accessible (0.2889 to 0.3898), remote (0.3899 to 0.5532), or very remote (>0.5532) were classified as rural.

Demographic Characteristics of Participants

Demographic data collected from all participants included age in years (open response), gender (female, male, nonbinary, prefer not to answer, other), ethnicity/race (select all from options provided or enter under “other”), education (response options ranging from “some high school or less” to “university degree”), and occupation (working full-time, working part-time, going to school, retired, not employed, other).

General Health and Health Care Service Use

Participants were asked to rate their health on a scale ranging from poor (1) to excellent (5). They were also asked to indicate the frequency of contact with their doctor or health care provider in the last 12 months (never, once, 2-5 times, 6-11 times, or 12 or more times) and whether their communications with their doctor or health care provider during COVID-19 had included a series of video or nonvideo interfaces (select all that apply). Those who selected video alone or along with other modes of communication were grouped as having used video, and those who did not select video were grouped as having not used video.

Virtual Care Use and Satisfaction

Participants were provided with a definition of virtual care as using technology (including email, text messaging, video visits, and telephone visits) to communicate with clinicians. Participants were then asked about their engagement with virtual care, with the question “Have you used virtual care?” Response options included: “Yes, and I used virtual care prior to the COVID-19 pandemic,” “Yes, but I only began using virtual care since the COVID-19 pandemic began,” and “No.” Those who responded “Yes” were asked to complete modified 5-point (strongly disagree to strongly agree) subscales of the Telehealth Usability Questionnaire (TUQ) [34] related to Usefulness, Ease of use, and Satisfaction. The TUQ was modified to specifically refer to “virtual care” instead of “telehealth.” Mean subscale scores were calculated, with a higher score indicating greater usefulness, ease of use, and satisfaction with virtual care. The TUQ has strong content validity and good to excellent internal consistency [34]. In this study, Cronbach alphas were .82 for Usefulness, .84 for Ease of use, and .90 for Satisfaction subscales.

Intention to Use Virtual Care Postpandemic

The participants who reported using virtual care were also asked to answer a 4-item, 7-point (strongly disagree to strongly agree) scale about their intention to use virtual care postpandemic [23], modified to remove reference to “acute” conditions. Confirmatory factor analysis, internal reliability, and construct reliability have been reported [23]. In the present study, the

Cronbach alpha was .86 for the future intentions to use virtual care scale.

Health Service Need and Access

A series of questions asking participants about their health service needs and access both before and during COVID-19 were generated based on the expertise of the research team and a previous survey suggesting that mental health needs might be a focal area, given the impact of COVID-19 [35]. Health services included virtual care, online mental health programs, and video or phone mental health services (eg, connecting with someone). Participants were asked to indicate if they “needed and had access to,” “needed and did not have access to/not aware if available,” or “did not need” these services both before and during COVID-19. Responses were then grouped into “needed” versus “not needed” for comparison. In addition, an open-ended question, “Please describe any unmet health or wellness needs you have had since the start of the COVID-19 pandemic (March 2020),” explored unmet needs.

eHealth Literacy

Participants completed an 8-item, 5-point (strongly disagree to strongly agree; eg, “I know what health resources are available on the internet”) electronic Health Literacy Scale (eHEALS) [24] that measures “combined knowledge, comfort, and perceived skills at finding, evaluating, and applying electronic health information to health problems.” Summative scores range from 8 to 40. Previous research using the eHEALS has demonstrated moderate test-retest reliability, good internal consistency, and construct validity [24,35]. In this study, the Cronbach alpha was .92 for the eHEALS scale.

Internet Quality

Participants were asked to rate the adequacy of their internet access during their day-to-day life on a scale ranging from 1 to 7, where 1 represents poor/inadequate (minimal to no reliability and very poor quality) and 7 represents excellent/adequate (always reliable and high quality).

Analysis

Descriptive statistics (frequencies; means and SDs) were used to summarize the data. Chi-square tests were used to examine participant characteristics and virtual care use by rurality (rural or urban). Independent samples *t* tests were used to investigate differences in categorical variables (ie, rural vs urban and used video vs telephone only) on virtual care usefulness, ease of use, satisfaction, future use, eHealth literacy, and internet quality. Regression analyses were used to examine relationships between virtual care scale scores and age, general health, eHealth literacy, internet adequacy, and remoteness. Normality was examined using histograms and P-P plots. Internet adequacy and age were slightly skewed but considered acceptable given the large sample size. Multivariate outliers and influential cases were examined

using casewise diagnostics, Cooks distance, Mahalanobis distance, and leverage. Two cases consistently came up as outliers in each regression analysis; however, these were not consistently unusual on other variables, and regression results were the same with and without these cases, so they were retained. All regression analyses met assumptions of linearity, heteroscedasticity, and multicollinearity. Quantitative data were analyzed using SPSS version 27 (IBM Corp, Armonk, NY) [36]. Open-ended responses were analyzed by 2 research team members (CLS, KC), and inductive thematic analysis was used to code and determine central themes. Two research team members independently coded the responses. Once initial coding was completed, similar codes were clustered into derived themes using consensus. NVivo 12 (QSR International, Burlington, MA) was used to analyze the qualitative data.

Data Screening

Over the 6-week data collection period, 617 total responses were collected, 116 of which were excluded due to the participant selecting “under 19 years” or “not a resident of [Province]” in response to initial eligibility questions and exit survey (n=39), survey incompleteness beyond demographics (n=33), unidentified community name of residence (n=6), inattentive and inaccurate responses (n=8), or survey bots (n=30). An attention check question is a moderately effective strategy for survey bot detection, but other factors were considered (eg, repeating same response options across multiple questions, similar illogical responses to open-ended questions, unrealistic survey completion times) in determining the exclusion of potential survey bots [31]. After removing the exclusions, the final sample of 501 (373/501, 75.0% female) responses were retained for the current study and analyses.

Results

Participant Characteristics

In total, 237 (237/501, 47.3%) participants were classified as rural-living, and 264 (264/501, 52.7%) were urban-living. Characteristics of the sample are presented in Table 1. Urban participants (mean age 34.8 years) were, on average, younger than rural participants (mean age 48.8 years). Rural participants were more likely to have trades certification/diploma, while urban participants were more likely to be working or going to school and less likely to be retired or unemployed. Rural participants were more likely to be Indigenous or Caucasian (218/237, 92.0%), whereas urban participants were more likely to be Caucasian or Asian or mixed ethnicity (217/264, 82.2%). There were no rural/urban differences in general health or number of health care visits over the past year, though rural participants were less likely to have used video in communicating with health care providers, compared with urban participants.

Table 1. Characteristics of all (n=501), rural (n=237), and urban (n=264) participants.

Characteristics	All participants, n (%)	Rural, n (%)	Urban, n (%)	χ^2 (df)	P value ^a
Age (range: 19-86 years)					
19-35 years	238 (47.5)	64 (27.0)	174 (65.9)	78.5 (2)	<.001
36-54 years	117 (23.4)	69 (29.1)	48 (18.2)		
≥55 years	142 (28.3)	101 (42.6)	41 (15.5)		
Missing/prefer not to answer	4 (0.8)	3 (1.3)	1 (0.4)		
Gender					
Female	373 (74.5)	179 (75.5)	194 (73.5)	0.4 (1)	.52 ^b
Male	121 (24.2)	54 (22.8)	67 (25.4)		
Nonbinary	6 (1.2)	4 (1.7)	2 (0.8)		
Prefer not to answer	1 (0.2)	0 (0)	1 (0.4)		
Education					
Some high school or less	16 (3.2)	12 (5.1)	4 (1.5)	21.6 (3)	<.001
Completed high school	126 (25.1)	49 (20.7)	77 (29.2)		
Trades certification/diploma	124 (24.8)	77 (32.5)	47 (17.8)		
University degree	231 (46.1)	98 (41.4)	133 (50.4)		
Missing/prefer not to answer	4 (0.8)	1 (0.4)	3 (1.1)		
Ethnicity					
Indigenous (First Nation/Inuit/Metis)	26 (5.2)	19 (8.0)	7 (2.7)	92.1 (4)	<.001
Asian (including South/Southeast)	94 (18.8)	7 (3.0)	87 (33.0)		
Caucasian/White	321 (64.1)	191 (80.6)	130 (49.2)		
Indigenous and Caucasian	16 (3.2)	8 (3.4)	8 (3.0)		
Other/mixed ancestry	37 (3.2)	10 (4.2)	27 (10.2)		
Missing/prefer not to answer	7 (1.4)	2 (0.8)	5 (1.9)		
Occupation					
Working or going to school	356 (71.1)	155 (65.4)	201 (76.1)	8.8 (1)	.003
Retired or not employed	137 (27.3)	80 (33.8)	57 (21.6)		
Missing/prefer not to answer	8 (1.6)	2 (0.8)	6 (2.3)		
General health					
Poor	21 (4.2)	8 (3.4)	13 (4.9)	1.2 (4)	.88
Fair	70 (14.0)	33 (13.9)	37 (14.0)		
Good	173 (34.5)	81 (34.2)	92 (34.8)		
Very good	183 (36.5)	86 (36.3)	97 (36.7)		
Excellent	46 (9.2)	24 (10.1)	22 (8.3)		
Missing/prefer not to answer	8 (1.6)	5 (2.1)	3 (1.1)		
Health care provider visits (past 12 months)					
Never	34 (6.8)	15 (6.3)	19 (7.2)	2.6 (4)	.63
Once	61 (12.2)	27 (11.4)	34 (12.9)		
2-5 times	247 (49.3)	115 (48.5)	132 (50.0)		
6-11 times	98 (19.6)	53 (22.4)	45 (17.0)		
≥12 times	51 (10.2)	22 (9.3)	29 (11.0)		
Missing/prefer not to answer	10 (2.0)	5 (2.1)	5 (1.9)		
Communication with health care providers					

Characteristics	All participants, n (%)	Rural, n (%)	Urban, n (%)	χ^2 (df)	<i>P</i> value ^a
Used video	162 (32.3)	58 (24.5)	104 (39.4)	12.7 (1)	<.001
Did not use video	339 (67.7)	179 (75.5)	160 (60.6)		

^aChi-square tests comparing rural with urban participants.

^bChi-square for gender only compared men with women due to expected counts falling below 5 for the other categories.

Virtual Care

Virtual care use was high, with over one-half (279/501, 55.7%) of participants reporting having only started to use virtual care since the onset of the COVID-19 pandemic (see Table 2). The pattern of virtual care use was not different for rural versus urban participants ($\chi^2_2=1.03$, $P=.60$). There were more female users than male users of virtual care ($\chi^2_2=14.92$, $P=.002$). There were no age differences in virtual care use or nonuse.

The need for virtual health care and for mental health programs and services increased significantly during the COVID-19 pandemic compared with prior to COVID-19 (see Table 3). This pattern of increased need was similar in both rural and urban participants. A greater proportion of urban participants reported needing all mental health services both pre- and during COVID-19, though the only significant difference was that urban participants had a greater need for online mental health programming pre-COVID-19 ($\chi^2_1=5.08$, $P=.02$).

Table 2. Virtual care use among all (n=501), rural (n=237), and urban (n=264) participants.

Virtual care use	Total, n (%)	Rural, n (%)	Urban, n (%)
Has not used virtual care	142 (28.3)	66 (27.8)	76 (28.8)
Has used virtual care and used virtual care prior to COVID-19	80 (16.0)	42 (17.7)	38 (14.4)
Has used virtual care but only since the onset of COVID-19 (March 2020)	279 (55.7)	129 (54.4)	150 (56.8)

Table 3. Comparison of services needed versus not needed between rural (n=237) and urban (n=264) participants, pre-COVID-19 and post-COVID-19.

Services needed	Before COVID-19		During COVID-19		χ^2 (df)	<i>P</i> value ^a
	Rural, n (%)	Urban, n (%)	Rural, n (%)	Urban, n (%)		
Virtual care						
I needed	72 (30.4)	78 (29.5)	146 (61.6)	171 (64.8)	58.4 (1)	<.001
I did not need	134 (56.5)	160 (60.6)	54 (22.8)	56 (21.2)		
Missing	31 (13.1)	26 (9.8)	37 (15.6)	37 (14.0)		
Online mental health programs						
I needed	40 (16.9)	69 (26.1)	61 (25.8)	89 (33.8)	209.9 (1)	<.001
I did not need	163 (68.8)	169 (64.0)	134 (56.5)	138 (52.3)		
Missing	34 (14.3)	26 (9.8)	42 (17.7)	37 (14.0)		
Video or phone mental health services						
I needed	51 (21.3)	76 (28.9)	80 (33.7)	107 (40.5)	163.1 (1)	<.001
I did not need	154 (65.0)	162 (61.4)	115 (48.5)	118 (44.7)		
Missing	32 (13.5)	26 (9.8)	42 (17.7)	39 (14.8)		

^aChi-square tests comparing needed versus not needed before versus during COVID-19 (ie, collapsed across rural and urban participants).

Among those who “needed” virtual care, online mental health programs and phone or video mental health services, we also explored the proportion who either did not have access to the services or were not sure if the services were available (see Table 4). There were no differences in the pattern of results by rural versus urban, so combined data are presented for simplicity. Before COVID-19, for both rural and urban participants, there was a higher percentage who needed the services or programs and did not have access compared with those who needed them but did have access to all services or programs. Then, during COVID-19, the numbers evened out or

even reversed—where a significantly higher percentage needed and had access, compared with needed and did not have access, across both rural and urban participants.

There were no rural-urban differences in virtual care usefulness, ease of use, satisfaction, intention to use in future, or eHealth literacy; however, internet quality was reported to be significantly worse among rural participants than among urban participants (see Table 5). There were no gender differences on virtual care scale scores, eHealth literacy, or internet adequacy. Those who had used video had significantly higher scores for

virtual care usefulness, ease of use, satisfaction, intention to use in future, eHealth literacy, and internet adequacy scores compared with those who had not used video (see Table 6). There was a great deal of interest in continuing to use virtual care postpandemic (see Figure 1), with no significant rural-urban differences.

When controlling for age and general health, eHealth literacy and internet adequacy were positively associated with all virtual care usefulness, ease of use, and satisfaction scores (see Table 7). Only eHealth literacy individually contributed to future intentions to use virtual care when all predictors were entered in the model simultaneously.

Table 4. Comparison of access versus no access pre- to post-COVID-19 among those who needed virtual care, online mental health programs, and phone or video mental health services.

Services needed	Before COVID-19, n (%)	During COVID-19, n (%)	χ^2 (df)	P value ^a
Virtual care				
Needed and had access to	63 (12.6)	290 (57.9)	5.5 (1)	.03
Needed but did not have access or was unaware	87 (17.4)	27 (5.4)		
Online mental health programs				
Needed and had access to	31 (6.2)	71 (14.2)	25.0 (1)	<.001
Needed but did not have access or was unaware	78 (15.6)	79 (15.8)		
Video or phone mental health services				
Needed and had access to	55 (11.0)	136 (27.1)	28.9 (1)	<.001
Needed but did not have access or was unaware	72 (14.4)	51 (10.2)		

^aChi-square tests comparing pre- with during COVID-19.

Table 5. Rural and urban participant scores on virtual care scales, eHealth literacy, and internet adequacy.

Scores	Rural (n=171), mean (SD)	Urban (n=188), mean (SD)	t test (df)	2-sided P value ^a
Virtual care				
Usefulness (range 1-5)	3.8 (0.87)	3.89 (0.82)	1.00 (357)	.32
Ease of use (range 1-5)	3.79 (0.74)	3.90 (0.77)	1.48 (357)	.14
Satisfaction (range 1-5)	3.83 (0.86)	3.88 (0.82)	0.47 (356)	.64
Future intentions to use (range 1-7)	5.03 (1.38)	5.23 (1.37)	1.36 (350)	.17
eHealth literacy (range 1-5)	3.91 (0.72)	3.91 (0.96)	0.04 (485)	.97
Internet adequacy (range 1-7)	5.47 (1.57)	5.98 (0.07)	4.01 (485)	<.001

^at tests comparing rural with urban.

Table 6. Virtual care scale, eHealth literacy, and internet adequacy scores of those who had used video versus those who had not.

Scores	Used video (n=203), mean (SD)	Had not used video (n=156), mean (SD)	t test (df)	2-sided P value ^a
Virtual care				
Usefulness (range 1-5)	4.08 (0.73)	3.67 (0.89)	4.64 (357)	<.001
Ease of use (range 1-5)	4.04 (0.75)	3.70 (0.73)	4.39 (357)	<.001
Satisfaction (range 1-5)	4.10 (0.76)	3.67 (0.85)	5.03 (356)	<.001
Future intentions to use (range 1-7)	5.53 (1.35)	4.82 (1.33)	4.90 (350)	<.001
eHealth literacy (range 1-5)	4.08 (0.65)	3.83 (0.71)	3.82 (485)	<.001
Internet adequacy (range 1-7)	5.96 (1.34)	5.64 (1.41)	2.43 (485)	.02

^at tests comparing video users with non-video users.

Figure 1. Proportion of rural versus urban participants who agreed, somewhat agreed, or strongly agreed with the intention to continue to use virtual care items. This is the proportion among only those who had used virtual care previously. About 28% (142/501) of the sample had not used virtual care and therefore did not answer these questions.

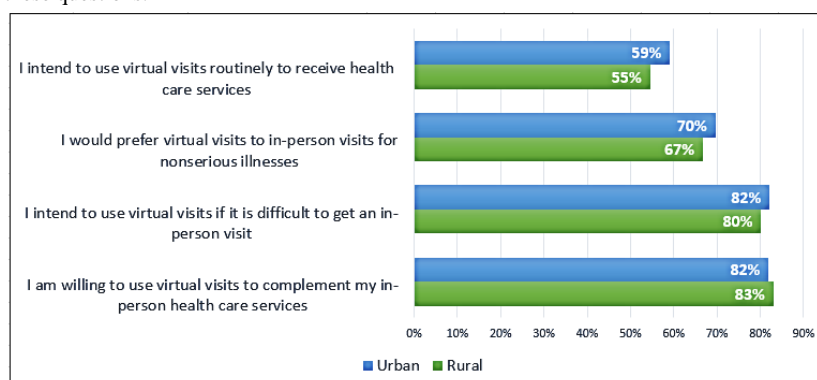


Table 7. Regression analyses examining the association between predictors age, general health, eHealth literacy, internet adequacy, and remoteness with virtual care scale scores (outcomes).

Scores	B ^a	Coefficient P value	Overall R ²	F test (df)	Model P value ^b
VC^c usefulness					
Age	-.13	.03	0.11	8.55 (5,336)	<.001
General health	.03	.59			
eHealth literacy	.24	<.001			
Internet adequacy	.12	.04			
Remoteness (RI ^d)	.05	.37			
VC ease of use					
Age	-.10	.07	0.15	11.80 (5,336)	<.001
General health	.05	.32			
eHealth literacy	.29	<.001			
Internet adequacy	.12	.03			
Remoteness (RI)	.02	.71			
VC satisfaction					
Age	-.02	.77	0.09	6.70 (5,335)	<.001
General health	.01	.86			
eHealth literacy	.24	<.001			
Internet adequacy	.12	.047			
Remoteness (RI)	.03	.66			
Future intentions to use VC					
Age	-.06	.29	0.10	7.53 (5,330)	<.001
General health	-.03	.57			
eHealth literacy	.30	<.001			
Internet adequacy	.06	.27			
Remoteness (RI)	.01	.89			

^aStandardized beta coefficients (β) are reported.

^bAll 5 predictors were entered simultaneously in separate regression analyses for each virtual care outcome.

^cVC: virtual care.

^dRI: remoteness index.

Unmet Needs

Themes

Of the 501 participants, 294 (58.7%) responded to the unmet needs open-ended question. The proportion of the rural participants who responded to the question and reported “no unmet needs” (53/132, 40.2%) was similar to the proportion of the urban participants with “no unmet needs” (58/162, 35.8%). For the comments reporting unmet needs, thematic analysis was used to construct 3 inter-related main themes: (1) lack of access to desired care, (2) limited health promotion and prevention options, and (3) mental health impacts and service adequacy or options.

Lack of Access to Desired Care

Among those describing unmet health or wellness needs, both rural and urban participants described reduced or limited access to desired care due to restricted or delayed in-person care (appointments, services), lack of virtual communication options to accommodate disability, and care avoidance from personal fears of viral exposure. Underlying their desire for different care were participants’ concerns or anxieties about aspects of their care being missed. A 30-year-old rural participant described her response to delayed in-person care:

Being pregnant, I was unable to see a health care provider in person before 20 weeks. This led to a lot of anxiety and I felt I didn’t have proper prenatal care.

In some cases, participants reported serious consequences, such as a 51-year-old urban participant’s “ruptured appendix was undiagnosed and ended up in emergency; lucky to be alive.” Other participants were unwilling or afraid to access care (delaying care), as an urban participant described: “Visiting doctor or hospital involves risk of exposure to virus.”

Participants also expressed that new virtual care platforms did not address the needs of individuals with disabilities. One 48-year-old urban participant shared her challenges in using virtual care due to the temporary loss of her voice:

I lost my voice during the pandemic and have difficulty speaking, due to what we now know are post-acute Covid-19 syndrome neurologic issues. I needed access to texting, emailing, chatting communication options with medical providers because I could not speak, or be understood when calling. I literally could not call 911 for help because at times I could not communicate using speech. My primary care physician refuses to use virtual meetings, whereby I would have been able to at least use the chat function to communicate. This situation has caused me panic attacks, isolation from medical care, and other mental health issues rooted in hopelessness and fear.

Limited Health Promotion and Prevention Options

Participants also reported that less critical health promotion and prevention options had been greatly reduced, such as delays in routine health checking, cancer screenings, and dental appointments. A 58-year-old rural participant explained:

I have not been able to schedule my routine cancer screening exam (due every 3 years) with my physician. I also have not had a massage in over 18 months, and it was over a year before I went in to get my teeth cleaned.

The mandatory shutdown of health centers and gyms also impacted some urban participants’ exercise routines:

I’ve been less able to attend the gym facility [that] I used to use multiple times per week, especially with the most recent wave, and likely lost strength in my muscle groups. I’ve recently injured my knee and suspect this is the reason. As well, I’ve gained weight, likely in part for the same reason.

Mental Health Impacts and Service Adequacy

Finally, unmet mental health needs were indicated in response to this open-ended question. Participants described the negative socioemotional impacts of the pandemic, such as depression, anxiety, stress, and social isolation, and the corresponding lack of adequate mental health services to meet their needs. For example, one 59-year-old rural participant stated, “I have suffered from depression since the start of the pandemic,” whereas an urban participant expressed having “More anxiety and stress due to concerns about the pandemic. Especially safety of my loved ones.” Similarly, many participants expressed unmet social needs, restrictions on social gatherings, and the ever-changing COVID-19 safety protocols at work that had detrimental impacts on their mental health. One urban participant stated that “[their] mental health, specifically depression and anxiety, has deteriorated [gotten worse] since [their] ability to engage with others and make connections was limited to virtual options.”

Some participants also expressed unmet needs related to barriers to accessing mental health services, including affordable and ongoing versus crisis-oriented mental health services, and privacy concerns. One 24-year-old urban participant described her challenge with virtual privacy:

It is difficult to do online [mental health] sessions even from home when there are other people in the house (which is very often due to the pandemic).

Others felt like there were limited mental health services available, especially affordable options, as one 22-year-old urban participant explained:

Although there were mental health [services] available, I find that the majority of the free ones are crisis support, but not ongoing mental health support. I wish there were more low-cost or free ongoing counselling supports that were available, as I wasn’t necessarily always in crisis but I still needed help with my mental health.

One 27-year-old urban participant expressed that there is a need for more government-provided mental health programs:

My overall mental health took a decline with the increased expectations of my workplace and level of stress living in a small apartment with my partner. I wish that I could have more access to

government-provided mental health counselling with a human, either in-person or visually [virtually]

Discussion

Principal Findings and Comparison With Prior Work

The purpose of this study was to examine rural and urban virtual care access, use, and satisfaction during the COVID-19 pandemic, as well as to explore future intentions to use virtual care and understand participants' unmet health and wellness needs. Virtual care use, satisfaction, and future intentions to use were all high, with no rural-urban differences. Several unmet needs were identified.

Our finding that virtual care satisfaction was high among both rural and urban participants mirrors other research [19,22] and is consistent with participants' high levels of interest in continuing virtual care. However, it contrasts with participants in a peripheral/outlying area of Israel who had low levels of interest in continuing virtual sessions postpandemic in December 2020 [26], reflecting their low levels of satisfaction with virtual sessions (only 36%). Noteworthy were significantly higher future intentions to use virtual care among those study participants who had used video compared with those who had not. Prior to the pandemic, Ghaddar et al [37] found 78.9% of participants from an underserved Hispanic (Texas-Mexico) border community were somewhat or very likely to use telehealth services if offered. It may be that patients in underserved areas will continue to be willing to use virtual care, but the extent to which urban-dwelling patients and providers will be willing to continue virtual care may depend on the ongoing risk of exposure to the virus [38]. Yet, contrary to this notion, in a survey of South Korean urban virtual care users, fear of COVID-19 exposure was not associated with virtual care acceptance [39]. More research is needed on the role COVID-19 anxiety plays in willingness to use virtual care among both rural and urban adults.

Similar to our findings, higher use of and satisfaction with virtual care were associated with higher eHealth literacy among rural Virginians [22] and residents in peripheral areas of Israel [26]. Unlike other research that has found lower health literacy in rural populations [25], there were no rural and urban differences in eHealth literacy scores in our study population. However, the online survey was not available to those without internet or device access, and it is not clear if lack of access to internet or devices is associated with lower eHealth literacy levels. Indeed, our findings support the notion that challenges with internet quality, even among a connected sample, play a role in virtual care satisfaction in addition to eHealth literacy. Regular access to the internet was associated with higher satisfaction among rural US adults [22]. Virtual care used to its full capacity (eg, video) requires adequate broadband access [40], and more urban than rural participants in the present study reported using video virtual care. In a telephone survey of a nationally representative US sample, only 36% of rural US households without high-speed internet had used telehealth compared with 53% of households with it [19]. By including measures of not only eHealth literacy but also internet quality

and rurality, we were able to discern the unique contribution of each of these characteristics to virtual care satisfaction.

The need for virtual mental health programming and services increased among both rural and urban participants during the pandemic compared with before the pandemic, but encouragingly, a higher percentage of those who needed virtual mental health programs and services had access to these during the pandemic compared with before the pandemic. However, the need for online mental health programs and services in this study was higher among urban participants than among rural participants, with urban participants' needs significantly higher pre-COVID-19. This is consistent with pre-COVID-19 evidence indicating that risk for mental health problems was higher in urban than rural communities [41]. Urbanization and increased population density during a viral pandemic may exacerbate mental health needs and provoke greater anxiety; indeed, in a study from China, urban participants reported more severe anxiety and depression during the COVID-19 pandemic compared with rural participants [42]. It is also possible that urban participants were previously more reliant on in-person services that were less available to rural participants. Even so, mental health services and programs for special needs (eg, autism, youths, seniors, physical disabilities) are not accessible to many rural residents; therefore, it is crucial to ensure continuous mental health support to these populations. How rural and urban-dwelling adults access mental health services is a topic that requires continuing study.

Open-ended survey responses revealed that one-third or more of rural (79/237, 33.3%) and urban (104/264, 39.4%) participants in our study had a variety of unmet health and health service needs. Among these were lack of access to desired care (eg, obstetrics and gynecology visits, specialty care), delayed preventive care (eg, health checks, cancer screenings), limited health promotion and prevention options (eg, access to gyms), and lack of affordable and ongoing versus crisis-oriented mental health services. Similarly, Czeisler et al [43] found that, during the pandemic, 12% and 32% of US residents delayed or avoided urgent or ED care and routine care, respectively, because of concerns about COVID-19. Whether system- or patient-initiated, delayed care can have detrimental health consequences [44]. Additionally, a survey of 400,000 BC residents showed decreases in health-promoting behaviors (eg, exercise, healthy eating) and increases in alcohol and cannabis consumption during the pandemic [45], with likely longer-term negative population health impacts. Delayed access to care, including routine health checks and cancer screenings, has been documented. Furthermore, despite increased need for counselling, many BC residents reported an unwillingness to use virtual mental health services, viewing these as only for crisis situations [45], a notion that also surfaced in our findings. Although these themes relate to unmet needs specifically during COVID-19, a unique time of reduced service options, they provide valuable learnings for future virtual health delivery when service reductions are no longer a public health requirement.

Limitations and Future Research

The online nature of the survey and recruitment efforts excluded the perspectives of those without access to the internet. Despite this, we had participants from very remote locations, suggesting approximation of a representative sample with respect to rurality. Further, our results were consistent with comparative evidence from both online and telephone surveys [19]. Still, the primarily social media recruitment limits the generalizability of the results. The survey was conducted during the summer months when the province was in a state of re-opening (eg, recreational activities were resuming) when a vaccine was widely available and prior to announcements of a fourth wave (Delta variant) and vaccine passports and mandates, which may have influenced responses; yet, the timing of the survey during a phase of lower risk might mean that the finding that over two-thirds of participants were willing to continue virtual care use is a conservative estimate. It should also be noted, that during the time of the survey, significant climate hazard events in the province may have impacted participation and participant mental health; for example, during June 25, 2021, through July 1, 2021, a record-breaking heat wave swept the province [46], and the subsequent wildfire season was one of the worst on record [47].

More research is needed to explore why the pattern of access among those who needed virtual mental health services might

have changed; it is possible that increased programming and advertising has contributed to greater availability and awareness and perhaps less stigma. Furthermore, although this study explored virtual care access, satisfaction, and intentions, more research is needed to explore unmet in-person health care needs. The present results reinforce the notion that some things (eg, surgeries) cannot be done virtually. The trade-off between reducing exposure and delaying care will be important to consider for future research and care.

Conclusions

Overall, findings from this study suggest that eHealth literacy and internet quality play important roles in virtual care satisfaction and future intentions to use virtual care. Yet, despite high levels of satisfaction with virtual care among both rural and urban participants, open-ended responses highlighted many unmet needs, reinforcing the notion that virtual care can supplement, but not replace, in-person care. Understanding not only use of but also rural and urban patient satisfaction with virtual care and whether patient demand will continue post-COVID-19 are important considerations for providers and policy makers. If virtual care is to be incorporated into ongoing practice following COVID-19, it is important that equitable access is addressed.

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Authors' Contributions

All authors contributed to the conceptualization of the project and contributed to the study design. KC and NH contributed to the online questionnaire construction, participant recruitment, coding of open-ended data, and description of the methods. CLS oversaw the data collection and completed the data analyses. All authors contributed to manuscript drafts and reviewed the final manuscript.

Conflicts of Interest

None declared.

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Abbreviations

- BC:** British Columbia
- eHEALS:** electronic Health Literacy Scale
- TUQ:** Telehealth Usability Questionnaire
- UBC:** University of British Columbia

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Original Paper

Accessibility of Virtual Primary Care for Adults With Intellectual and Developmental Disabilities During the COVID-19 Pandemic: Qualitative Study

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Abstract

Background: The COVID-19 pandemic has led to an unprecedented increase in the delivery of virtual primary care. Adults with intellectual and developmental disabilities (IDDs) have complex health care needs, and little is known about the value and appropriateness of virtual care for this patient population.

Objective: The aim of this study was to explore the accessibility of virtual primary care for patients with IDDs during the pandemic.

Methods: We conducted semistructured interviews with 38 participants in Ontario, Canada between March and November 2021. A maximum variation sampling strategy was used to achieve a diverse sample including 11 adults with IDDs, 13 family caregivers, 5 IDD support staff members, and 9 primary care physicians. An iterative mixed inductive and deductive thematic analysis approach was used to code the data and synthesize higher-level themes. The analysis was informed by the Levesque Patient-Centered Access to Health Care Framework.

Results: We identified themes related to 4 of 5 access-to-care dimensions that highlighted both the benefits and challenges of virtual care for adults with IDDs. The benefits included saving time spent traveling and waiting; avoiding anxiety and challenging behavior for patients who struggle to attend in-person visits; allowing caregivers who live far away from their loved ones to participate; reducing illness transmission; and allowing health care providers to see patients in their home environments. The challenges included lack of access to necessary technology, lack of comfort or skill using technology, and lack of nonverbal communication; difficulty engaging and establishing rapport; patient exclusion from the health care encounter; and concerns about privacy and confidentiality. An overarching theme was that “one size does not fit all,” and the accessibility of virtual care was dependent on the interaction between the following 5 categories of factors: patient characteristics, patient context, caregiver characteristics, service context, and reason for a particular primary care visit. Though virtual care was not always appropriate, in some cases, it dramatically improved patients’ abilities to access necessary health care.

Conclusions: This study suggests that a flexible patient-centered system including multiple delivery modalities is needed to ensure all patients have access to primary care. Implementing this system will require improved virtual care platforms, access to technology for patients and caregivers, training for primary care providers, and appropriately aligned primary care funding models.

KEYWORDS

COVID-19; intellectual disability; developmental disability; qualitative; telemedicine; virtual care; primary care

Introduction

In March 2020, the COVID-19 pandemic led to an unprecedented increase in the delivery of virtual primary care in countries around the world [1-6]. In Ontario, Canada, virtual care increased 56-fold to comprise over 70% of primary care in the first 4 months of the pandemic [2]. Though virtual care is sometimes defined broadly to refer to any use of technology to improve health care, this study focuses on technology-supported interactions between health care providers and patients in different locations. This includes synchronous and asynchronous interactions using video, telephone, and text-based technologies [7]. The rapid expansion of virtual care during the pandemic has raised questions about the quality and accessibility of virtual care for different patient groups [8,9]. Primary care is often the first point of access to the health care system and plays an important role in improving health outcomes, reducing health inequities, and reducing health care costs [10]. Considering the ongoing role of virtual care, it is critical to ensure that primary care remains accessible for all patients.

Adults with intellectual and developmental disabilities (IDDs) are a group that may require additional consideration to ensure that the increased use of virtual modalities does not compromise their access to care. The term IDDs is an umbrella term that includes a wide range of conditions of childhood onset that impact cognitive and adaptive functioning across the lifespan [11]. The conditions include, for example, intellectual disabilities, autism, Down syndrome, and fetal alcohol spectrum disorders. People with IDDs are more likely to live in poverty [12] and may therefore have greater challenges accessing technology. Some adults with IDDs live in congregate settings where there is limited access to technology and limited private space to use that technology, and where support staff may have limited skills to support technology use [13,14]. Other adults with IDDs may be supported by older parents with limited technology skills [15,16]. Additionally, some people with IDDs rely on facial expressions, lip reading, sign language, or communication devices for effective communication, which may be more difficult to use in virtual interactions [17,18]. Conversely, some people with IDDs find travelling to the health care appointment and waiting in the waiting room to be extremely stressful [19-22], and the ability to access care from the comfort of their own home may improve accessibility.

There is currently limited research on the accessibility of virtual primary care for adults with IDDs. A recent scoping review [23] on virtual health care for adults with IDDs identified 12 studies on access to virtual care, none of which focused on primary care. The review found that study participants generally reported high acceptability of virtual care, though the studies conducted during the pandemic reported more mixed feedback. The main challenges reported were related to participant skill and comfort using technology, and poor internet quality. The review

concluded that the limited available literature suggests that virtual care can be accessible for adults with IDDs, but a better understanding is needed of when and for whom virtual care is appropriate. It is important to note that many of these studies were conducted prior to the pandemic. In these studies, patients typically opted for virtual care, care was usually provided by video, and access to technology was a requirement for participation. During the pandemic, virtual care was sometimes the only option, and it was much more likely to be delivered by telephone than video [24,25]. Additionally, in some studies, patients received virtual care in supported settings (eg, a telemedicine clinic) versus the typical experience during the pandemic where patients participated in virtual care from their homes.

We identified one study focused on video-based virtual primary care for autistic adults during the pandemic [26]. The study identified benefits to virtual care, including increased patient comfort and reduced risk of COVID exposure, and challenges, including technology issues, lack of a physical examination, and reduced patient engagement (eg, distracted and wandered away from the visit). Participants in this study reported that they found communication via virtual care to be the same or better than in-person communication, though the sample did not include individuals with intellectual disabilities. In contrast, other studies on virtual interactions for people with IDDs during COVID-19 found that effective virtual communication could be challenging [27,28].

The aim of this study was to explore the accessibility of virtual primary care for patients with IDDs. Our intention was to understand the experiences of virtual primary care in Ontario, Canada during the pandemic to help inform the potential ongoing role of virtual care within an accessible primary care system.

Methods

Access to Care Framework

We conceptualized access to care based on the Patient-Centered Access to Care Framework developed by Levesque et al [29]. In this framework, access is defined as the fit between the characteristics of the service and the needs and abilities of the individual. The Access to Care Framework identifies 5 dimensions of service accessibility with 5 corresponding dimensions reflecting the patient's ability to access the service as follows: (1) *approachability*, how easy the service is to identify or be aware of, and *ability to perceive*, the patient's awareness of their need for services; (2) *acceptability*, whether the service is perceived to meet patient needs, and *ability to seek*, the patient's capacity to seek care; (3) *availability and accommodation*, how, when, and where services are offered, and *ability to reach*, the patient's ability to use the service; (4) *affordability*, the cost of the service, and *ability to pay*, the patient's financial resources; and (5) *appropriateness*, the quality

of the service, and *ability to engage*, the patient's motivation to engage in care.

Methodology

Qualitative description methodology was used to guide the overall study design. Qualitative description focuses on describing and understanding participant experiences with the goal of achieving descriptive and interpretive validity [30-32]. This pragmatic participant-centered approach is recommended for applied health services research aimed at informing policy and practice [33] and for studies focused on addressing health disparities for vulnerable populations [34].

Sampling and Recruitment

This study included adults with IDD, caregivers (including family members and IDD support staff members), and primary care providers. The study was restricted to participants living in Ontario, Canada who had experience participating in at least one virtual primary care visit for an adult with an IDD over 18 years of age and had the capacity to provide informed consent. Adults with IDD were included if they self-identified as having an IDD. Given the limited prior research on this topic, we used a maximum variation sampling strategy to achieve a diverse study sample with the intention of capturing a wide range of experiences [35,36].

Efforts were made to recruit a demographically diverse set of participants based on age, gender, and geographic location across the province. Efforts were also made to recruit primary care providers from different practice models, as they may have different resources available to support virtual care, and adults with IDD living independently, with family, and in supported settings. To achieve these aims, we used broad recruitment strategies. A study flyer was developed and shared widely using existing health care provider networks (eg, the Alliance for Healthier Communities, the Association of Family Health Teams of Ontario, and Developmental Disabilities Primary Care Program), community agencies (eg, Vita Community Living Services, Community Living Ontario, and Surrey Place Centre), caregiver and self-advocate networks (eg, the Azrieli Adult Neurodevelopmental Centre self-advocate and caregiver advisories), social media, and other relevant newsletters (eg, Health Care Access Research and Developmental Disabilities newsletter and Developmental Services Ontario newsletter). All participants and recruitment contacts were encouraged to share the flyer widely. Additional targeted recruitment was conducted as needed to improve representation across participant groups.

Data Collection

Semistructured interviews were conducted with participants by phone or the Webex video conference platform (Cisco) according to participant preference. Participants also had the option of typing their responses through the chat function on the Webex platform. All interviews were conducted by the first author (AS) who has 10 years of qualitative research experience, including prior experience conducting interviews with adults with IDD.

Tailored interview guides were developed for each participant group informed by a previous scoping review of the literature [23] and the Levesque Access to Care Framework [29]. Questions focused on the experience of receiving, supporting, or delivering virtual care; preferences related to the future role of virtual care; and supports needed for successful virtual care. Virtual care was defined as including any care provided remotely including by phone, video, or written communication (eg, email). Demographic information on age, gender, disability, and geographic location was also collected. Interview questions for adults with IDD were developed recognizing the unique considerations in interviewing this population, including the need to adapt language based on individual capacity, potential difficulty with abstract concepts and recalling past events, and risk of suggestibility or acquiescence [37-39]. If helpful, interview questions were sent in advance. Patients with IDD had the option of being interviewed independently or with a support person. If both the patient with an IDD and their caregiver choose to participate in the study, dyadic interview techniques were used to elicit both the patient perspective, using caregiver-mediated communication if appropriate, and the caregiver's own perspective [40].

Interviews lasted approximately 20-60 minutes and were audio recorded and transcribed. Field notes were taken during and immediately following each interview to document interviewer impressions and nuances that may not be captured in the recording [41]. An honorarium was provided to all participants.

Interviews were conducted between March and November 2021. In Ontario, temporary billing codes were implemented in March 2020 to reimburse physicians for virtual health care, and physicians were encouraged to take a "virtual first" approach [42,43]. The proportion of care delivered virtually in Ontario has fluctuated throughout the pandemic in accordance with each wave of COVID, but early data suggest that it consistently accounted for a substantial proportion of patient visits throughout the study period [43,44]. A recent Ontario study using population-level administrative data found that about 62% of adults with IDD in Ontario used virtual care during the first year of the pandemic, similar to the proportion of adults without IDD [45].

Ethics Approval

This study received approval from the research ethics board at the Centre for Addiction and Mental Health (REB # 160/2020) and the University of Toronto (Protocol # 40483). All participants provided informed consent prior to participating in the study.

Analysis

A mixed inductive and deductive thematic analysis approach was used to guide the analysis [46-48]. Though the study was informed by a pre-existing Access to Care Framework [29], the framework was being applied in a novel context, and it was important that it should not restrict or limit initial coding. Therefore, initial coding was guided by the research question, but remained relatively open and data driven. The first author (AS) developed an initial codebook based on a review of all transcripts and field notes. A subset of transcripts from each

stakeholder group was reviewed and discussed with 2 additional authors (JD and YL) to identify key ideas and patterns of ideas, and to refine the initial codebook. The first author (AS) then coded all transcripts, iteratively updating and refining the codebook throughout the process. Coding was conducted using NVivo 12 software (QSR International).

A multi-stage process was used to synthesize the collated data and generate themes. First, an open data mapping exercise was conducted to explore relationships and patterns across all codes. Codes were then mapped onto the Access to Care Framework, considering fit with existing framework domains. These initial maps were reviewed and discussed by all the study authors, and key themes were identified. These initial themes were then reviewed, discussed, and refined with members of each stakeholder group (ie, self-advocates, caregivers, and primary care physicians) as part of a peer debriefing process [49]. Results are reported by access to care domain. Quotations are included to illustrate the findings.

Rigor

This study was conducted as part of the doctoral thesis of the first author and was supported by a team that included researchers working in both the health care and IDD sectors, including health services researchers, a psychologist, an occupational therapist, and family members of people with IDDs. Our team engaged in ongoing critically reflexive dialogues to reflect on our positionalities and assumptions in relation to this work and to consider how they shaped the study findings [49,50]. The collective experiences and perspectives of this team guided and informed the study design, analysis, and interpretation.

Several strategies were used to support trustworthiness in this study [32,49]. Credibility was supported by promoting an open and safe interview process, using clear and easy-to-understand interview questions, and conducting a peer debriefing process to support data interpretation. Dependability was supported through the use of an audit trail to clearly document each step of the analysis process, and through detailed and transparent reporting of the findings. Transferability was supported by providing detailed descriptions of the sample and the recruitment process, and contextualizing findings through thick descriptions so readers can gauge the applicability to different settings. Confirmability was supported through the use of field notes to

contextualize the data, an iterative coding process based on multiple re-readings of the data, and inclusion of quotations to illustrate the findings.

Results

Participants

In total, 38 individuals participated in this study, including 11 adults with IDDs, 13 family members, 5 IDD support staff members, and 9 primary care physicians. Participants included 25 women and 13 men (between 23 and 69 years old) living across the province (Greater Toronto Area, 19; Eastern Ontario, 9; Western Ontario, 8; Northern Ontario, 2). The study included adults with IDDs or the caregivers of adults with IDDs, who live with their family (n=18), independently (n=5), or in supported settings (n=6). Primary care physicians participated from all 4 primary care delivery models in Ontario: family health teams (n=3), community health centers (n=2), physician group practices (n=3), and solo practitioners (n=1). Seven of the nine physicians reported having practices with a particular focus on patients with IDDs. Participants had or supported people with a range of IDDs including autism, intellectual disabilities, and Down syndrome. Many of these individuals also had co-occurring health issues, including mental illness, vision and hearing impairments, physical disabilities, and chronic illnesses.

Main Findings

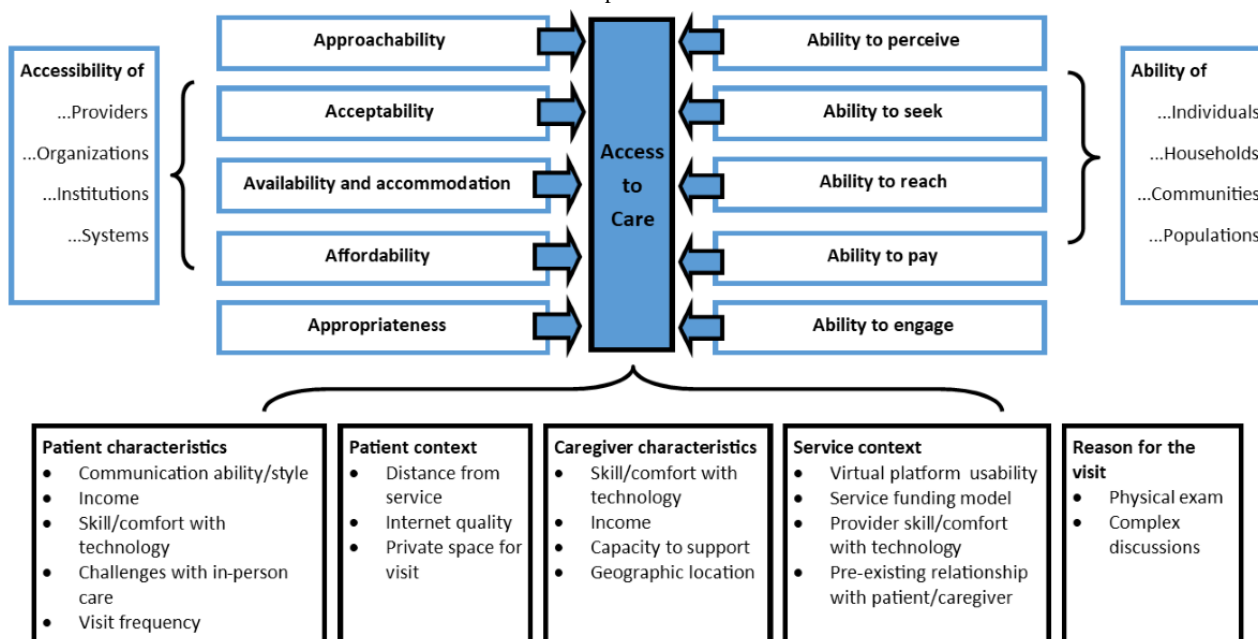
All study participants reported receiving or delivering synchronous virtual primary care by telephone or video. These synchronous appointments were sometimes supported by asynchronous communication by email or text message to schedule appointments; ask questions; and send documentation, photographs, and videos. Across the 38 interviews, we identified themes that aligned with each of the access-to-care dimensions, with the exception of approachability/ability to perceive (see [Table 1](#)). This is likely due to the data source used for this study. Interview participants could only speak about services they had used (ie, you do not know what you do not know). These themes were informed by mutable and immutable variables related to the patient's characteristics, the patient's context, the caregiver's characteristics, the service context, and the reason for a particular primary care visit (see [Figure 1](#)). Each of these themes is described in more detail below.

Table 1. Access to care dimensions and themes.

Dimensions and themes	Description
Acceptability/ability to seek (patient/caregiver comfort or satisfaction with the services)	
Convenience	<ul style="list-style-type: none"> Virtual care saved time and could be more convenient than in-person care. Phone was seen as quick and easy; video could be more difficult and time-consuming.
Change is hard	<ul style="list-style-type: none"> Virtual care was new, and change can be challenging.
Health care visits as a valuable outing	<ul style="list-style-type: none"> For some patients, in-person visits were enjoyable outings and important opportunities to practice social skills that were lost with virtual care. Some patients had important rituals or reward systems to facilitate health care visits that were disrupted by virtual care.
Caregiver distress	<ul style="list-style-type: none"> Virtual care sometimes put additional responsibility on the caregiver to negotiate health care interactions.
Availability and accommodation/ability to reach (patient/caregiver ability to use the service)	
Technology quality, access, and skill	<ul style="list-style-type: none"> Patients and caregivers did not always have access to necessary technology. Patients, caregivers, and primary care providers sometimes lacked skill and comfort using technology. Switching between multiple virtual platforms was confusing for some patients and caregivers.
Difficulty travelling and waiting	<ul style="list-style-type: none"> Virtual care facilitated access to care for patients unable or challenged to attend in-person visits.
Participation in the visit	<ul style="list-style-type: none"> Virtual care facilitated participation of multiple care providers and caregivers in the visit. Patients were less likely to be included in virtual visits, especially by phone.
Patient independence	<ul style="list-style-type: none"> Virtual care supported independence for patients unable to travel by themselves. However, it reduced independence for patients who could travel but required support to use technology.
Affordability/ability to pay (affordability of the service for patients/caregivers)	
Travel and parking costs	<ul style="list-style-type: none"> Virtual care saved costs related to travel and parking.
Staff time	<ul style="list-style-type: none"> Supported settings saved costs due to fewer staff required to accompany patients to their health care visits.
Technology costs	<ul style="list-style-type: none"> Costs were incurred to purchase high-speed internet and internet-enabled devices. Residential settings incurred costs for technical support staff.
Appropriateness/ability to engage (quality of care received by the patient)	
Communication and rapport	<ul style="list-style-type: none"> Nonverbal communication was lost in phone interactions and was more challenging in video interactions for patients, caregivers, and primary care providers. Communicating via phone could be more challenging for people with hearing impairments. It was sometimes difficult to manage conversations with multiple participants. The ability to use chat functions supported improved communication for some patients. Video was sometimes a better option to see facial expressions or read lips while masks were required for in-person visits. Some participants found it difficult to develop rapport virtually, especially with new primary care providers.
Seeing patients at home	<ul style="list-style-type: none"> Participating in visits from their home made some patients more comfortable and less anxious, leading to more effective visits. Video visits allowed primary care providers to see patients in their home environment.
Importance of physical examination	<ul style="list-style-type: none"> Physical examinations are sometimes a necessary component of care and were particularly important for some people with IDD^a who could not describe their symptoms.
Privacy/confidentiality	<ul style="list-style-type: none"> Patients did not always have a private space from which to participate in the visit. Some patients were concerned about cyber security. Some caregivers were concerned that people with IDDs may be more vulnerable to online scams and may disclose medical information inappropriately.
Safety	<ul style="list-style-type: none"> Virtual care reduced the transmission of COVID-19 and other illnesses. Some patients felt safer in-person when discussing potentially triggering topics.

^aIDD: intellectual and developmental disability.

Figure 1. Access to virtual care for adults with intellectual and developmental disabilities.



Acceptability/Ability to Seek

Acceptability of virtual care varied widely across participants. There were those who preferred their health care appointments to take place by phone, by video, or in-person and some who had no strong preferences. The following 4 themes related to acceptability/ability to perceive were identified: convenience, change is hard, health care visits as a valuable outing, and caregiver distress.

Convenience

Some patients and caregivers appreciated the convenience of participating in care from home. Virtual visits allowed them to avoid sometimes lengthy travel time to appointments, potentially requiring missed work or school. Instead of waiting in waiting rooms, they could go about their normal day until the primary care provider called. A 29-year-old autistic woman shared:

It's so convenient...I think it's great that they can kind of assess you on the phone and then say, "OK, well, I think you need to come in or you don't need to come in." [...] It saves so much time for everyone- getting ready to go, finding my stuff, getting it together, taking the subway, waiting in the waiting room.

This was particularly important in cases where the patient or caregiver lived far away from the provider, or if the caregiver had other responsibilities (eg, multiple care recipients). Phone visits were seen as particularly fast and easy, while video calls could be more complicated and time-consuming for patients, caregivers, and primary care providers.

Change is Hard

Some patients, caregivers, and primary care providers disliked virtual care because it was new and different. Participants also reported that change is always challenging, but can be particularly challenging for some people with IDD. A 48-year-old autistic man explained:

[Virtual care] is not something that I think should be encouraged for people on the spectrum because it's, yeah it's another change.

Participants noted that it is possible that some of the resistance or dislike of virtual care will change as people grow more accustomed to it.

Health Care Visits as a Valuable Outing

Some participants highlighted the experiences they or the person they support missed out on due to virtual care. Some people with IDDs enjoyed travelling for their health care visits and felt that virtual care deprived them of an enjoyable outing. For some people with IDDs, health care visits were an important opportunity to socialize and practice skills. A staff member at a group home in eastern Ontario explained:

Another big downfall [of virtual care] is just that so much of what we do here for these individuals is supporting that socialization and those social skills and it's one less opportunity for us to teach that in person. [...] So for these individuals, speaking with the receptionist and having that opportunity to practice with the nurse and then the doctor, it was a lot of opportunities for them to practice that social interaction.

There was also concern that some people with IDDs will find it very challenging to return to in-person visits, and it may require significant work to rebuild tolerance and comfort with health care settings.

Some people with IDDs had important rituals or reward systems surrounding the health care visit that served as motivation and positive reinforcement to support the health care visit, which were disrupted by the shift to virtual care. The mother of a 26-year-old autistic woman with multiple chronic health issues shared:

[My daughter] geared herself to these appointments by, you know, deciding what she's going to wear and

how she's going to get there. She's going to have a Starbucks latte afterwards or she's going to going into a special place after the appointment [...]. She makes it a special outing.

Without these rituals, some people with IDD were less motivated or willing to participate in the visit.

Caregiver Distress

Some caregivers felt that virtual care placed additional pressure on the caregiver to make medical decisions, conduct assessments, and communicate on behalf of the person they support. While the provider could conduct a physical examination during an in-person visit, virtual care required the caregiver to relay the relevant information to the provider to the best of their ability, and in some cases, they needed to conduct elements of the examination themselves (eg, monitoring blood pressure). This caused some caregivers a great deal of additional stress. The mother of a 28-year-old man with Down syndrome explained:

I have enough on my plate trying to parent him, trying to help him [...] manage every day, especially during COVID. To ask me to be the person that has to communicate all that to the medical person at the other end [...] can get to be extremely overwhelming. [...] For a family that has a child or an adult with intellectual disabilities who may or may not be able to communicate their needs, you're asking those parents to make even more decisions or communicate more things. And what if I mess up? What if I miss something?

Availability and Accommodation/Ability to Reach

This domain includes themes focused on the benefits or challenges of virtual care in facilitating the patient's and caregiver's abilities to attend a primary care visit. The following 4 themes were identified: technology quality, access, and skill; difficulty travelling and waiting; participation in the visit; and patient independence.

Technology Quality, Access, and Skill

A number of technology-related challenges were raised by participants as barriers to video-based care. Internet or technology failure (eg, internet cuts out or camera stops working) interrupted appointments. This was particularly challenging in more rural areas where internet quality is poor. Some patients, caregivers, and primary care providers also lacked skills or comfort using technology. This was further complicated by the fact that currently there are a number of approved secure video platforms used for health care in Ontario, which was confusing for some participants. The concern was also raised that not all patients and caregivers have access to internet-enabled devices or high-speed internet necessary to conduct video-based appointments. For these reasons, phone was sometimes preferred to video, which could appear to be too challenging and time-consuming to use. One physician shared:

I don't think the video worked very well at all. It was a challenge to set it up, you had to give a lot of

instructions on how to connect and turn it on. [...] And I found that even if I have a [video] visit, I still have to call them on the phone to see what was going on. 'Where are you?' 'Is it working?' So it's just frustrating. And then there were also technical glitches, screen freezes, no sound. [...] And also the quality, some people just don't have the Wi-Fi or Internet to have a great video quality so it's just a blurry picture. It's not helpful anyway.

Participants also shared, however, that they have become more skilled and comfortable using technology during the pandemic. In particular, it was noted that the pandemic has demonstrated that people with IDD are in many cases far more capable of using technology than was previously assumed. The mother of a 34-year-old woman with Down syndrome shared:

She is totally engaged [in virtual programs] and she's never done that before. She's never had the opportunity to try it this way. So this is a gift of COVID. All this came about because of COVID and people are seeing the benefits.

Difficulty Travelling and Waiting

There are some people with IDD for whom getting to an in-person visit or waiting in the waiting room is prohibitively difficult due to physical, mental, or behavioral challenges. Participants highlighted that for these individuals, virtual care is not only convenient, but also critical to enable them to access care. One physician shared:

It's not just that their needs are convenience, their needs are accessibility needs. It is very difficult to get a patient that requires, you know, an hour and a half of transitioning and then can't manage the sensory overload experience of the waiting room and, you know, other complex issues and is brought to the appointment by someone who isn't even their main caregiver and doesn't know them. Those aren't convenience issues, those are accessibility, accommodation needs.

Participation in the Visit

Participants noted that virtual care also impacted the extent to which patients, caregivers, and other health care providers can participate in the primary care visit. Virtual care allowed multiple caregivers, especially family members who live far away from the person they support, to all attend the visit, thus improving lines of communication and supporting appropriate decision-making. The brother of a 55-year-old man with Down syndrome described the benefits of everyone being in the same virtual room as follows:

Everything is transparent and there's no miscommunications. The group home staff are hearing the same thing that we are hearing.

Virtual care also supported case conferencing with multiple health care providers, improving care quality and coordination.

Patients, however, were less likely to be included in virtual primary care visits, particularly if they took place by phone. Sometimes it did not occur to the caregiver or provider that the

patient could or should be included. The mother of a 24-year-old autistic man explained:

Because it was a phone consult, I don't even think we thought of it to be honest.

Sometimes the patient was uninterested or harder to engage in the interaction. The sister of a 38-year-old autistic man shared:

He's not a part of it, no. He's nonverbal and he doesn't really communicate. We tried video [...] and he would sit down for maybe two minutes and then he just wants to bolt away. It doesn't keep his attention.

On the other hand, it was noted that a benefit of virtual care is that patients have the flexibility to come and go as they wish. A physician explained:

Even with the video calls, it's very rare that the patient will stay on the call the entire time. But I think that's OK, too. In some ways it's nice if I can see them and then the parents can give me the history and tell me more about what's been going on.

It was also suggested that it may be appropriate in some cases for the patient not to be included in the virtual visit. Examples were shared of successful hybrid approaches where an initial phone call with the caregiver was used to gather information, and then, a shorter in-person appointment was conducted with the patient, which was easier for them to tolerate.

Patient Independence

Participants appreciated that virtual care can support independence for some people with IDD who may need help with transportation but could participate in a virtual visit independently. A 30-year-old autistic man shared:

I don't drive, [my mom] drives. So it's basically on her to get me to the [clinic]. So it's better for me and her when I have an appointment and I don't have to physically go there.

Conversely, there were some people with IDD who could attend in-person appointments by themselves but required support for virtual encounters.

Affordability/Ability to Pay

This domain includes the following 3 themes related to the additional costs or costs saved due to virtual care: travel and parking costs, staff time, and technology costs. This domain received less focus in the interviews, potentially due to the challenges of isolating costs of virtual health care from the general increase in virtual interaction during the pandemic.

Travel and Parking Costs

Participants appreciated costs saved with virtual care due to avoided travel and parking costs. This is especially relevant for people who live further away from their primary care provider or in large urban centers with high parking costs.

Staff Time

Participants suggested that group homes or other supported settings may save costs due to fewer staff members needed to support in-person appointments.

Technology Costs

Participants reported that video appointments required increased spending on high-speed internet and internet-enabled devices and on information technology support in group home settings. However, it was noted that the increased spending on technology was not solely due to virtual health care. Some patients also incurred costs for medical equipment needed to support at-home monitoring (eg, blood pressure monitor, pulse oximeter, and scale).

Appropriateness/Ability to Engage

This domain includes findings related to service quality and effectiveness. The following 5 themes related to this domain were identified: communication and rapport, seeing patients at home, importance of the physical examination, privacy and confidentiality, and safety.

Communication and Rapport

In some cases, virtual care can be a barrier to effective communication. Some people with IDD were more reliant on nonverbal cues or body language for communication, which was lost entirely in phone interactions and was still sometimes challenging over video. The father of a 22-year-old autistic man explained:

Because of the autism, he doesn't pick up on the behavior cues as well virtually. [...] There's definitely a disconnect between what's... what he's able to process, and I don't think he gets as good cues. You need a full body to see what people are doing.

Similarly, physicians also missed important nonverbal information, such as lack of eye contact, repetitive movements, or hygiene issues, which may have impacted their ability to accurately diagnose and gauge patient comprehension. For those with hearing impairments, it was sometimes more difficult to understand the providers, especially if they had a heavy accent or if there was no visual component. Conversely, the chat function, if available, can offer a valuable alternative way to communicate for some individuals. Additionally, despite the limitations of video, it was sometimes a better option to see faces while mask requirements were in effect for in-person visits.

Despite the value of having multiple people participate in the visit, it sometimes made it more challenging to manage the conversation, especially by phone. One physician shared:

It's almost impossible on the phone to capture both voices. [...] Very, very difficult to really get that triadic relationship and back and forth on the speakerphone just because everyone struggles to know when to talk and [we] have no visual cues.

Participants also reported that it can be more difficult to develop rapport over virtual interactions, particularly when the visit is with a new primary care provider. People with IDD can have more difficulty engaging in virtual interactions and may be easily distracted when in their own homes. Without good communication and rapport, patients may be less interested in participating and less likely to disclose health issues, and important health issues may be missed.

Seeing Patients at Home

In-person visits can be an overwhelming and stressful experience for some people with IDD, causing distress for the individual and leading to a less effective appointment. Allowing the patient to participate from their home where they are calm and comfortable can improve the quality of the visit. One physician explained:

For my patients who don't enjoy coming into clinic, it's very stressful for them in terms of the sensory stimuli [and] in terms of the social interaction. I found that being on video, or just by phone even, I'm able to get a lot more history from them and a lot more engagement in that discussion than if they were in office because they're so overwhelmed and so just preoccupied with being in the office that there really isn't that much bandwidth to engage.

Participants shared that in some cases, virtual care allowed them to reduce or eliminate use of medications that were previously needed to get the patient to the appointment. Video visits have the additional benefit of allowing primary care providers to see how patients act in their home environments, which can be important to inform appropriate treatment.

Importance of the Physical Examination

Participants stressed that in-person physical examinations will always be a necessary component of care. It was suggested that for some adults with IDDs, the physical examination is even more important because they are unable to describe their symptoms. One physician shared:

I think what ended up happening was I just, I really wasn't trusting my virtual assessments in the same way that I might in someone in the general population. So I was often bringing them into clinic, just feeling like I had to do the clinical exam to complete my assessment and honestly, just to reassure myself of my virtual assessment.

There are some types of primary care visits that must be conducted in-person but others that may be possible to conduct virtually depending on a range of factors, including the capacity of the caregiver to support an examination or administer treatment, the feasibility of a quality video visit, the patient's level of insight into their physical health, and the patient's ability to communicate virtually.

Privacy and Confidentiality

Patients who lived with the family or in supported settings did not always have a private space from which to participate in the primary care visit. Primary care providers expressed concern that they did not always know who else was in the room or able to listen to the visit. There were also concerns about cyber security for medical information shared online. It was noted that this patient population may be particularly vulnerable to scams and may end up disclosing medical information to predators.

Safety

Participants highlighted that an important benefit of virtual care was infection control. This was critical during COVID-19 but

could also be an important ongoing benefit beyond the pandemic. This was also particularly relevant for some people with IDDs who could not tolerate wearing masks. There were some circumstances, however, when participants felt that in-person care was safer, such as when discussing topics that might trigger thoughts of self-harm. The father of a 22-year-old autistic man with complex mental health needs shared:

In person, there's the safety factor. If there's something that's been triggering for [my son], I think he feels safer if there's somebody else physically there.

Contextual Factors

Across the 4 access-to-care dimensions, we found that virtual care can be accessible for some individuals under certain circumstances. The success or appropriateness of a virtual care encounter is dependent on the interaction between 5 categories of factors. First, the characteristics of the individual patient, including their communication ability or style, income, skill and comfort using technology, difficulty attending in-person appointments, and visit frequency. Second, the patient's context, including their distance from the health care service, the local internet quality, and access to a private space to conduct the appointment. Third, the characteristics of the caregiver, including their skill and comfort using technology, income, distance from the patient, and other responsibilities (eg, multiple caregiving roles). Fourth, the service context, including the usability of the virtual platform, the provider reimbursement model, the provider's skill and comfort using technology, and whether the provider has a pre-existing relationship with the patient. Fifth, the specific reason for a particular health care visit, for example, if the visit requires a physical examination or a more complex or triggering discussion. Some of these variables are fixed, but many may change over time or per individual health care visit.

Discussion

Principal Findings

This qualitative study explored the accessibility of virtual primary care for patients with IDDs during the COVID-19 pandemic. A key finding was that one size does not fit all. We identified themes across 4 dimensions of accessibility that highlighted both the benefits and challenges of virtual care. For some patients, virtual delivery was critical to accessing necessary health care; for other patients, virtual delivery posed a barrier to accessing high-quality care. Whether virtual care was accessible was dependent on a combination of factors, including the characteristics of the patient, the patient's context, the characteristics of the caregiver, the service context, and the reason for the specific health care visit. Some of these variables may be relatively constant (eg, patient's communication style), some may change over time (eg, comfort with technology, distance from the provider, and private space), and some may change per appointment (eg, need for a physical examination).

Many of the themes identified in this study align with those identified in previous studies focused on the general patient population. Virtual care had many benefits, especially for simple issues or follow-up care. The benefits included greater

convenience for patients, lower risk of COVID-19 transmission, and the value of seeing patients in their home environment [1,6,44,51]. Virtual care was not appropriate for issues that required a physical examination, and while some issues could be diagnosed via photographs or video observations, this could be challenging due to technology failures, lack of nonverbal communication, privacy concerns, and difficulties establishing rapport with new patients [1,6,44,51].

This study showed, however, that these same issues may look different or require different accommodations for patients with IDD. One important difference for patients with IDD is that there is often a caregiver involved, leading to additional considerations for virtual care, such as the caregiver's comfort using technology, the value of facilitating the caregiver's participation if they live far away, and difficulties managing calls with multiple participants. Communication and rapport in virtual care may be challenging for many individuals but can be additionally challenging for individuals with IDD who are nonverbal, use communication devices, or have trouble engaging in virtual interactions. The physical examination is a critical component of care for all patients, but it can play a larger role in the care of people with IDD if they are unable to identify or articulate their symptoms. Privacy may be a concern for anyone participating in a health care visit from their home, but it can be a particular concern for people with IDD who live in congregate settings. Virtual care may be convenient for many patients, but for some people with IDD, it is a necessary accommodation to support access to care.

The fifth access dimension, approachability, was not identified in this study but is nonetheless important to consider in designing accessible primary care systems. There has been a great deal of inconsistency in how primary care has been delivered during COVID-19, and patients and caregivers are likely unaware that it is possible to receive care in different ways than offered by their primary care provider. Direct education is needed for patients and caregivers to ensure they know what is available, what they are entitled to, and how to advocate for it.

It is important to note that some of the challenges and benefits of virtual care identified in this study are specific to the current context and may be less relevant moving forward. Some of the benefits of virtual care are related to COVID-19, including reducing the risk of COVID-19 transmission and accommodating patients who cannot tolerate wearing masks. Additionally, some of the challenges are because virtual care was implemented abruptly, with little existing infrastructure to deliver it effectively, for patients with little experience participating in virtual care. In this study, some participants noted that at the time of their interview, at least 1 year into the pandemic, they already felt more comfortable and proficient using technology and participating in virtual care than they did at the start of the pandemic. People will likely continue to become more comfortable with virtual care as technology infrastructure improves and everyone becomes more accustomed to virtual interactions.

Implementing Accessible Virtual Care

It is clear from the study findings that the relevant question is not whether virtual care is accessible, but how it can be implemented in a way that will promote and not hinder health care accessibility. This study suggests that an optimal system should include multiple modalities depending on patient need and preference, including in-person, telephone, video, and written communication options. Achieving this type of flexible patient-centered system requires policies and supports considering both care delivery and use.

From an implementation lens, the largest hurdle seems to be supporting video-based care. The vast majority of virtual care in Ontario has been delivered by telephone, with only a relatively small proportion of virtual care delivered by video [24,25]. This study suggested that while telephone care can be very effective in some cases, it also has a number of limitations, including communication for individuals with hearing impairments or who are reliant on nonverbal communication, developing rapport between patients and providers, and managing conversations with multiple participants. These limitations can lead to health issues being missed and patients with IDD being less engaged or excluded entirely from the visit. While telephone and in-person options may be sufficient in many cases, this study suggests that video can play an important role in supporting accessible care and should be part of the basket of services available.

To support greater implementation of video-based care, it is important that patients and their caregivers have access to high-speed internet and video-enabled devices. During the pandemic, some health care organizations provided tablets and smartphones to low-income patients [52]. With appropriate funding, this is a practice that could be expanded across primary care practices. High-speed internet continues to be a challenge in parts of the province, and public investment is needed to build capacity [53]. Currently, multiple virtual platforms are used in the health care system, many of which are not user friendly. Ideally, a common virtual platform should be implemented across the system that is easy for patients, caregivers, and primary care providers to use; has built-in accessibility features (eg, chat box and captioning); and can be integrated into electronic medical record systems. Given that primary care providers may themselves struggle to use technology and do not have the time or expertise to provide technical support to patients and families, primary care practices would benefit from including a dedicated staff role to provide technical support [54,55]. This could include meeting patients at the beginning of the appointment to orient them to the platform and troubleshooting technical issues before the provider joins the session or even offering in-person practice sessions to teach patients and family members how to use the virtual platform.

Beyond building capacity for video-based care, we also need health care funding structures that facilitate and incentivize delivery of both in-person and virtual care options according to patient need and preference. There are unintended consequences with any reimbursement model, but it has been recommended that the best strategy to avoid incentivizing a

particular modality to the detriment of patients is shifting from a fee-for-service model to capitation or salary-based payment models [44].

Primary care providers also need training on how to deliver care virtually. Currently, most providers have received little if any training on when virtual care is appropriate, how to work with patients to determine the most appropriate type of care per visit, and how to effectively deliver care using virtual modalities [56]. There is starting to be more focus on the importance of this topic in medical education [57-59], and it is critical that these programs include considerations for different patient groups, including patients with IDD. It is important to also highlight that primary care providers generally receive little specific training on how to care for patients with IDDs [60-62]. Any virtual care-specific training should be situated within general competencies to provide high-quality care to patients with IDDs.

Efforts to support the implementation of high-quality accessible virtual care should be informed by the large body of literature on implementation and health technology. Frameworks, such as the nonadoption, abandonment, scale-up, spread, and sustainability (NASSS) framework developed by Greenhalgh et al [63], can help outline the many considerations, including but not limited to those identified above, required for successful adoption of virtual care.

Strengths and Limitations

This is one of the few studies we are aware of that looks at the accessibility of virtual primary care for adults with IDDs. A strength of the study is the inclusion of a diverse sample, including patients, family members, IDD support staff members, and physicians, to elicit perspectives from a range of different experiences. However, this study only collected limited demographic data on participants, and we cannot speak about the diversity of participants in terms of race or other important intersectional identities. This study was conducted in English, and it would be important for future work to look at the impact of virtual care for non-English speakers who may have different experiences. The study was limited to individuals who had participated in at least one virtual primary care visit. Therefore, individuals unable, unwilling, or lacking the opportunity to participate in virtual care were not included. Most participating physicians had practices that included a focus on patients with IDDs, and their perspectives may differ from the perspectives

of physicians less experienced in caring for this patient population.

The study was also limited to one Canadian province, and people in jurisdictions with different pandemic restrictions or different health care delivery systems may have had different experiences. This study reflects a single interview conducted with each participant during the second year of the pandemic. Though some participants described how their perspectives changed, we did not assess this directly. This study included perspectives from all members of the health care triad (patients, caregivers, and providers) but not related to the same encounter. It would be important for future studies to compare perspectives from the same encounter to understand how they may be similar or different.

All interviews were conducted virtually due to pandemic restrictions. Based on the interviewer's observations, good rapport was developed with participants, and they generally provided positive feedback on the interview experience. However, some interviews were disrupted due to technical challenges. In 6 cases, these challenges were severe enough to require the interview to be completed by phone. It is possible that these challenges or other issues not immediately apparent to the interviewer (eg, lack of rapport or participant discomfort) may have impacted the quality of the information gathered.

Conclusions

The COVID-19 pandemic has provided a unique opportunity to learn about the accessibility of virtual primary care for adults with IDDs. This study found that virtual care can increase the accessibility of primary care for some individuals with IDDs under some circumstances and decrease accessibility for others. To meet the needs of all patients, a flexible patient-centered approach is needed that includes in-person, phone, and video options. This system must be supported by the necessary infrastructure, resources, and supports to ensure that the potential benefits of virtual care can be fully realized. This includes training for patients, caregivers, and primary care providers; universal access to the technology necessary to participate in virtual care; implementation of accessible virtual care platforms; and a primary care funding structure that can facilitate and incentivize delivery of both in-person and virtual care. While virtual care is not appropriate or desirable for all patients, there is a subset of patients with IDDs for whom virtual care is not just convenient but can enable access to necessary health care.

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Conflicts of Interest

None declared.

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Abbreviations

IDD: intellectual and developmental disability

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Original Paper

Methodological Issues in Using a Common Data Model of COVID-19 Vaccine Uptake and Important Adverse Events of Interest: Feasibility Study of Data and Connectivity COVID-19 Vaccines Pharmacovigilance in the United Kingdom

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Abstract

Background: The Data and Connectivity COVID-19 Vaccines Pharmacovigilance (DaC-VaP) UK-wide collaboration was created to monitor vaccine uptake and effectiveness and provide pharmacovigilance using routine clinical and administrative data. To monitor these, pooled analyses may be needed. However, variation in terminologies present a barrier as England uses the Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT), while the rest of the United Kingdom uses the Read v2 terminology in primary care. The availability of data sources is not uniform across the United Kingdom.

Objective: This study aims to use the concept mappings in the Observational Medical Outcomes Partnership (OMOP) common data model (CDM) to identify common concepts recorded and to report these in a repeated cross-sectional study. We planned to do this for vaccine coverage and 2 adverse events of interest (AEIs), cerebral venous sinus thrombosis (CVST) and anaphylaxis. We identified concept mappings to SNOMED CT, Read v2, the World Health Organization's *International Classification of Disease Tenth Revision* (ICD-10) terminology, and the UK Dictionary of Medicines and Devices (dm+d).

Methods: Exposures and outcomes of interest to DaC-VaP for pharmacovigilance studies were selected. Mappings of these variables to different terminologies used across the United Kingdom's devolved nations' health services were identified from the Observational Health Data Sciences and Informatics (OHDSI) Automated Terminology Harmonization, Extraction, and Normalization for Analytics (ATHENA) online browser. Lead analysts from each nation then confirmed or added to the mappings identified. These mappings were then used to report AEIs in a common format. We reported rates for windows of 0-2 and 3-28 days postvaccine every 28 days.

Results: We listed the mappings between Read v2, SNOMED CT, ICD-10, and dm+d. For vaccine exposure, we found clear mapping from OMOP to our clinical terminologies, though dm+d had codes not listed by OMOP at the time of searching. We

found a list of CVST and anaphylaxis codes. For CVST, we had to use a broader cerebral venous thrombosis conceptual approach to include Read v2. We identified 56 SNOMED CT codes, of which we selected 47 (84%), and 15 Read v2 codes. For anaphylaxis, our refined search identified 60 SNOMED CT codes and 9 Read v2 codes, of which we selected 10 (17%) and 4 (44%), respectively, to include in our repeated cross-sectional studies.

Conclusions: This approach enables the use of mappings to different terminologies within the OMOP CDM without the need to catalogue an entire database. However, Read v2 has less granular concepts than some terminologies, such as SNOMED CT. Additionally, the OMOP CDM cannot compensate for limitations in the clinical coding system. Neither Read v2 nor ICD-10 is sufficiently granular to enable CVST to be specifically flagged. Hence, any pooled analysis will have to be at the less specific level of cerebrovascular venous thrombosis. Overall, the mappings within this CDM are useful, and our method could be used for rapid collaborations where there are only a limited number of concepts to pool.

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KEYWORDS

Systematized Nomenclature of Medicine; COVID-19 vaccines; COVID-19; sinus thrombosis; anaphylaxis; pharmacovigilance; vaccine uptake; medical outcome; clinical coding system; health database; health information; clinical outcome; vaccine effect; data model

Introduction

COVID-19 vaccination is the best option for controlling the current pandemic, with data about uptake and pharmacovigilance (the science and activities relating to the detection, assessment, understanding, and prevention of any side effects of a vaccine or drug) therefore essential for monitoring its progress. Since COVID-19 was first identified in Wuhan, China, at the end of 2019, the virus has spread worldwide, with more than 190 million confirmed cases and over 5.9 million COVID-19-related deaths as of February 28, 2022 [1,2]. Worldwide, most health care systems have opted for a vaccination strategy to protect public health by reducing the incidence but, most importantly, serious outcomes leading to hospitalization and death. Five vaccines have been approved for use in the United Kingdom by the Medicines and Healthcare products Regulatory Agency (MHRA). The first 2, Pfizer-BioNTech and Oxford-AstraZeneca, have been used since December 2020 and January 2021, respectively [3,4]. Real-world data (RWD) suggest that these vaccines are effective [5,6] in preventing severe disease and death; RWD in medicine are data derived from any number of sources that are associated with outcomes in a heterogeneous patient population in real-world settings, such as patient surveys, clinical trials, and observational cohort studies. However, there has been concern about the risk of adverse effects, such as thrombotic thrombocytopenia and anaphylaxis [7,8]. It is important to be able to monitor these at scale to give power to detect potential associations with rare adverse events of interest (AEIs). AEIs are medical conditions arising after the administration of a vaccine, not necessarily causally linked.

Medical record systems enable information flow beyond organizational boundaries. General practices with their own information technology (IT) systems record millions of patient interactions daily. A challenge for this partnership is the heterogeneity of routine primary care data due to variation in the clinical terminologies used across the 4 UK nations. The Data and Connectivity COVID-19 Vaccines Pharmacovigilance (DaC-VaP) collaboration was formed to explore vaccine effectiveness, uptake, and safety across the United Kingdom.

England has transitioned to the Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT) and has not updated Read v2 since April 2016 [9]. Read v2 is a clinical terminology system (5-byte version) that was developed by Dr. James Read. However, the devolved nations (Scotland, Wales, and Northern Ireland) still use the Read terminology. In addition, the levels of granularity and hierarchy of the 2 are incompatible, making comparison of the results of any analysis a challenge. Primary care data have not been included in the Northern Ireland component of the study because systems to make anonymized primary care data available for research are under development.

The use of a common data model (CDM) could provide a solution faced by many looking to aggregate data from different sources [10,11]. CDMs use logic and semantics (in the case of the OMOP CDM, having 1 standard reference vocabulary per domain so that everyone is “speaking the same language”) to standardize data and enable data from different sources to be used in pooled analyses. The use of CDMs is common within clinical research, and at present, 3 are cited in many studies: (1) the Observational Medical Outcomes Partnership CDM (OMOP; used to be a partnership project but now only designates a type of a CDM for RWD/evidence in clinical research), (2) the US Food and Drug Administration (FDA) Sentinel CDM (the Sentinel Operations Center [SOC] coordinates the network of Sentinel data partners and leads the development of the Sentinel common data model [SCDM], a standard data structure that allows the data partners to quickly execute distributed programs against local data), and (3) the Patient-Centered Outcomes Research Institute (PCORI) CDM (PCORnet; facilitates the sharing of information across PCORI's wider network and is based on the mini-SCDM) [12]. The OMOP CDM, the most cited of the 3, enables the transformation of data from diverse observational databases into a common format using a standardized vocabulary [13]. The OMOP CDM includes different data domains required for observational studies, including demographics, vaccine exposure, and AEIs relevant to this study [14].

Other groups, including the National COVID Cohort Collaborative (N3C) in the United States, have faced challenges in how to achieve harmonization between data sources. Although

this was customized and drew together data from different sources and CDMs, the N3C also extensively used OMOP [15]. We carried out this study, therefore, to test the feasibility of using the OMOP CDM for comparisons of vaccine uptake and AEs across the 4 UK nations.

Our primary aim is to assess the feasibility of using the OMOP CDM to report the incidence of exemplar AEs following COVID-19 vaccination across the DaC-VaP collaboration and report these as repeated cross-sectional analyses. The objectives of the study include the following:

- To test the validity of the mappings within the OMOP Automated Terminology Harmonization, Extraction, and Normalization for Analytics (ATHENA) online browser to our exemplar AEs. ATHENA is a repository of all the latest OMOP CDM vocabularies and mappings are hosted and can be searched and downloaded.
- To report the vaccine uptake rate across the United Kingdom, stratified by age group, sex, vaccine type, and ethnicity, with the goal of reporting a UK-wide vaccination uptake rate. We differentiated people who have had their first and second doses.
- To report the rates for England, Scotland, Wales, and Northern Ireland and overall for the 2 exemplar AEs, cerebral venous sinus thrombosis (CVST) and anaphylaxis.

Methods

Overview

We used the OMOP ATHENA online browser to identify mappings to SNOMED CT, Read v2 terminology, and the *International Classification of Disease Tenth Revision* (ICD-10). We reported vaccine exposure using SNOMED CT for vaccine administration and *Dictionary of Medicines and Devices* (dm+d; National Health Service [NHS]) codes for vaccine prescriptions; dm+d is a dictionary of descriptions and codes which represent medicines and devices in use across the NHS. Each national team validated these mappings and any differences between the terms they would use to represent each concept discussed with a decision made by consensus. We then used to create monthly reports of vaccine coverage and AEs. We elected to use CVST and anaphylaxis as demonstration AEs [16].

Settings

The data were drawn from the data sources of the 4 DaC-VaP partners.

English Data

The data from England are from the Oxford Royal College of General Practitioners (RCGP) Research and Surveillance Centre (RSC), 1 of Europe's oldest surveillance networks. It is now in its 53rd season of operation, working alongside Public Health England (PHE) [17]. The RSC has been involved in monitoring studies of influenza vaccine safety. This network is active in COVID-19 research, including the PRINCIPLE (Platform Randomized Trial of Treatments in the Community for Epidemic and Pandemic Illnesses) trial [18]. The RSC is the surveillance platform of the Oxford RCGP Clinical Informatics Digital Hub (ORCHID, a secure data processing environment) [19,20].

Scottish Data

The EAVE II data of 5.4 million people registered in general practices in Scotland track COVID-19 within the Scottish population. This effort has led to impactful findings used by the Scottish and UK governments to respond to the COVID-19 pandemic.

Welsh Data

The Secure Anonymised Information Linkage (SAIL) databank is a trusted research environment (TRE), a Wales-wide research resource focused on improving health, well-being, and services, which includes primary care general practitioner (GP) records, secondary care hospital data, and emergency services data, along with a range of administrative, governmental, education, social care, and specialist audit, register, and services data. These data are also used by the National Institute for Health and Care Excellence (NICE) to shape policies that cover England and Wales. SAIL is powered by the Secure e-Research Platform (SeRP, a technology platform and service that enables the SAIL databank and other TREs and platforms in the United Kingdom and worldwide).

Northern Ireland Data

Data are accessed through the Business Services Organisation Honest Broker Service (HBS), which also uses SeRP. It has available GP registration (but not primary care clinical records), the enhanced prescribing database, emergency department attendances, hospital admissions, COVID-19 testing, and the vaccine management system.

Study Design

We performed repeated cross-sectional reports of the incidence of the AEs in the vaccinated population in a single time interval postvaccination.

Phase 1: Validating OMOP Mapping and Creating Searches for Distributed Analyses

We searched the OMOP CDM for the concepts of interest using the ATHENA online browser. These concepts were demographic details, COVID-19 vaccine uptake, and the AEs. The demographic and socioeconomic status (SES) data of interest were age and sex, and the SES was divided into quintiles (quintile 5 being the most deprived). We also collected data on obesity (defined as the latest BMI \geq 30 or coded as obesity; the BMI is a measure that uses your height and weight to work out whether your weight is healthy) and smoking status (current, ex-, or never smoked).

We compared the linkages flagged by the OMOP ATHENA online browser with those currently used across the 4 nations. We reported any differences and achieved a consensus as to which terms/codes will be used in each nation.

OMOP also maps to the *Medical Dictionary for Regulatory Activities* (MedDRA), and if the method in this protocol became established, considerations for enabling reporting of pharmacovigilance study findings mapped to MedDRA.

Each DaC-VaP partner nation will restrict its ATHENA search using the VOCAB (vocabulary) tool to SNOMED CT or Read v2, as relevant, and dm+d.

The medication dictionary dm+d is made up of a hierarchy of generic terms (termed “virtual”) and real prescribable items (termed “actual”). The dm+d use case for the COVID-19 vaccine is set out below:

- Virtual therapeutic moiety (VTM): top of the hierarchy (type of therapy indicator, eg, COVID-19 vaccine); in this use case, this is the COVID-19 vaccine.
- Virtual medicinal product (VMP): This is the next level of notional product and allows vaccine types (COVID-19 vaccine type: mRNA or vector); in our use case, messenger RNA (mRNA) vaccines and their manufacturers were to be distinguished from recombinant vaccines.
- Virtual medicinal product pack (VMPP): This is the notional product pack for the medical VMP, for example, a 6-dose multidose vial.
- Actual medicinal products (AMPs): These are the medicinal products prescribed to an individual; for example, vaccine brands (Pfizer-BioNTech, Moderna).
- Actual medicinal product packs (AMPPs): These are the distribution packs of medicinal products.

The analyst team from each nation reported whether they included all the terms identified from their search of OMOP for mapping to their terminology using ATHENA and whether they added others they routinely use.

Phase 2: Monthly Reports and Aggregation of Results

We ran these searches monthly to produce a monthly output of vaccine coverage by demographic group and reported the incidence of our AEs.

Vaccine uptake was reported as the percentage of adults vaccinated per nation and stratified by age, sex, smoking status, and obesity. We reported 2 exemplars of AEs following vaccination using 2 time windows (0-2 and 3-28 days).

Cross Sections, Exposures, and Outcomes

DaC-VaP partners ran cross-sectional studies for the previous 28 days.

The first search started on December 8, 2020 (first dose of the Pfizer vaccine given in the United Kingdom), and the second search on January 5, 2021. These ran in 28-day intervals (February 2, March 2, March 30, April 27-August 17, 2021).

The cross sections included all individuals registered with general practices on the date of vaccination and remained registered for 28 days. The outputs were reported in the following age bands: <16 years old, 16-39 years, 40-64 years, and 65 years and older. Mortality in the postvaccination period were also reported for those with AEs.

We reported by vaccine brand, including reporting unknown vaccines. We presumed that the unknown vaccine brand for December 2020 was Pfizer-BioNTech, as Oxford-AstraZeneca was unavailable until January 2021 and other vaccine types later.

We aimed to include statistical reporting and disproportional analysis metrics, a proportional reporting ratio (PRR), and a reporting odds ratio (ROR). We used a Bayesian method that provided a framework to combine prior information/knowledge

and data to account for conceptual transparency. Our aim was to use $IC = \log_2(\text{observed} + 1/2)/(\text{expected} + 1/2)$.

Ethical Considerations

The DaC-VaP collaborators had individual ethical control of their data. No data were reported that might risk identifying individuals. Where less than 5 individuals were in a group, this was reported as <5. This study aims to demonstrate the potential of the DaC-VaP collaboration to report outcomes of interest.

English Data

The University of Oxford complies with the General Data Protection Regulation and the NHS Digital Data Security and Protection Policy [21]. This study was approved by the Health Research Authority Research Ethics Committee (21/HRA/2786; (Integrated Research Application ID 301740). ORCHID meets the NHS Digital Data Security and Protection Toolkit requirements. [22].

Scottish Data

Ethical permission for this study was granted by the South-East Scotland Research Ethics Committee (#314 02; 12/SS/0201). The Public Benefit and Privacy Panel Committee of Public Health Scotland (#315) approved the linkage and analysis of the de-identified data sets for this project (#1920-0279).

Welsh Data

This study made use of anonymized data held in the SAIL databank. We used data provided by patients and collected by the NHS as part of their care and support. All research conducted was completed after the permission and approval of the SAIL independent Information Governance Review Panel (IGRP; project number 0911).

Northern Ireland Data

Northern Irish data were accessed from the Business Services Organization HBS, which provided de-identified linked data via SeRP. All research conducted was approved by the HBS Governance Board (HBSGB; project number 064).

Results

Study Concepts Within the OMOP CDM

We initially reported whether the data items or clinical concepts required for the study existed within the OMOP CDM and whether there were mappings to SNOMED CT, Read v2, or dm+d (Table 1).

We then reported the components by terminology (Table 2). Age did not map to the Read v2 terminology, but this is of no practical significance. We noted that the SES only exists as a generic concept in OMOP and that a custom mapping would be required. There was no mapping of vaccine dose (first or second) to Read v2. However, like age, this would not be practically important as these data are well ordered in the DaC-VaP collaborators' data sources.

Of most importance are the AEs. For CVST, the specific concept exists within OMOP, and it also exists in SNOMED CT: SNOMED concept IDs 95455008 and 19522900 from CVST

(concept ID 195229008). For anaphylaxis, SNOMED CT and the ATHENA online browser showed 130 and 161 items, respectively. SNOMED CT and OMOP had 16 and 15 items, respectively. Read v2 codes were generic for CVST and

anaphylaxis. Of these, those relevant to vaccination are shown in Tables 2, 3, 4, and 5 for England, Wales, Scotland, and Northern Ireland, respectively.

Table 1. Variables included in the CDM^a conceptual mapping exercise, with counts subsequently reported monthly.

Data item	OMOP ^b (Y=yes, N=no)	Data source
Demographics		
Gender	Y	Standardized sex (gender) codes are used in OMOP CDM mapping. Date of birth and age concepts also exist.
Age band	Y	Date of birth and age concepts exist in OMOP.
SES^c quintile		
The Index of Multiple Deprivation (IMD, a set of relative measures of deprivation for small areas [lower-layer super-output areas] across England, based on 7 domains of deprivation), in England, the Scottish Index of Multiple Deprivation (SIMD), the Welsh Index of Multiple Deprivation (WIMD), and the Northern Ireland Multiple Deprivation Measure (NIMDM)	N	Does not exist in the OMOP CDM. It can be introduced as a custom mapping in all UK databases within OMOP. It is to be harmonized across the DaC-VaP ^d data partners (quintile 5 most deprived, quintile 1 least deprived).
Other characteristics		
BMI>30/obesity	Y	Will be found in the measurement table or from a diagnosis of obesity.
Smoking status	Y	Will be found in the observation table.
Vaccination		
Vaccine type	Y	Will be found in the drug, procedure, and event tables. For England, the source codes are dm+d ^e or SNOMED CT ^f .
Vaccine dose	Y	In vaccine administration.
Vaccination date	Y	Date of event when the event is COVID-19 vaccination.
Exemplar AEs^g		
CVST ^h	Y	Will be found in the condition table. It is mapped to SNOMED CT or Read v2. We did not include medications in this feasibility study.
Anaphylaxis	Y	Will be found in the condition table. It is mapped to SNOMED CT or Read v2. We did not include medications in this feasibility study.

^aCDM: common data model.

^bOMOP: Observational Medical Outcomes Partnership.

^cSES: socioeconomic status.

^dDaC-VaP: Data and Connectivity COVID-19 Vaccines Pharmacovigila.

^edm+d: Dictionary of Medicines and Devices.

^fSNOMED CT: Systematized Nomenclature of Medicine Clinical Trials.

^gAEI: adverse event of interest.

^hCVST: cerebral venous sinus thrombosis.

Table 2. Study concepts identified within OMOP^a and ICD-10^b, and any mapping to SNOMED CT^c, Read v2, and dm+d^d.

Primary term	OMOP ATHENA ^c concept ID	ICD-10	dm+d	SNOMED CT	Read v2
CVST ^f (nonstandard to standard map)	10083037	I63.6, I67.6, U07.7 (vaccine caused adverse effects) and P3.344 (CVST in hospitalized adults)	N/A ^g	4102202	N/A
CVST (standard to nonstandard map)	10083037	I63.6, I67.6, U07.7 (vaccine caused adverse effects)	N/A	4102202	N/A
Anaphylaxis (localized)	4034658	T78.2 (anaphylactic shock unspecified)	N/A	40316757 (systemic), 42536383 (anaphylactic shock), 4294049 (sudden onset), 2084167 (allergic), 4084167 (acute allergic reaction), 441202 (nonstandard to standard OMOP map), 441202, 40640468 (generalized)	N/A
Anaphylaxis	441202	45537000 (anaphylactic shock unspecified)	N/A	40316757 (systemic), 40640468 (generalized)	N/A
Anaphylaxis (anaphylactic shock due to adverse effect of correct medicinal substance properly administered)	45376003	45537000 (anaphylactic shock unspecified), 19746	N/A	4254051 (drug or medicament), 441297 (adverse reaction to drug)	N/A
Anaphylaxis (drug induced)	241937000	45537000 (anaphylactic shock unspecified)	N/A	46274027, 4084168 (nonstandard OMOP)	N/A
Anaphylaxis (procedure)	42537947	45537000 (anaphylactic shock unspecified)	N/A	44807057 (anaphylaxis care), 4021200 (care of patient states), 42537947 (nonstandard to standard OMOP map), 44807057 (standard to nonstandard OMOP map)	N/A
Anaphylaxis (due to substance)	4221182	45537000 (anaphylactic shock unspecified)	N/A	4022675 (substance), 4294049 (sudden onset), 441202 (anaphylaxis), 4221182 (nonstandard to standard OMOP map), 4083868 (standard to nonstandard OMOP map)	N/A

^aOMOP: Observational Medical Outcomes Partnership.

^bICD-10: *International Classification of Disease Tenth Revision*.

^cSNOMED CT: Systematized Nomenclature of Medicine Clinical Trials.

^ddm+d: Dictionary of Medicines and Devices.

^eATHENA: Automated Terminology Harmonization, Extraction, and Normalization for Analytics.

^fCVST: cerebral venous sinus thrombosis.

^gN/A: not applicable.

Table 3. Study concepts identified within OMOP^a and any mapping to ICD-10^b, dm+d^c, SNOMED CT^d, or Read v2 in Scotland.

Primary term	OMOP ATHENA ^c concept ID	ICD-10	dm+d	SNOMED CT	Read v2
CVST ^f (nonstandard to standard map)	10083037	I63.6, I67.6, UO7.7 (vaccine caused adverse effects) and P3.344 (CVST in hospitalized adults)	N/A ^g	N/A	N/A
CVST (standard to nonstandard map)	10083037	I63.6, I67.6, UO7.7 (vaccine caused adverse effects)	N/A	N/A	N/A
Cerebral vein thrombosis	45446702	I63.6, I67.6, UO7.7 (vaccine caused adverse effects)	N/A	N/A	G67A
Thrombosis of central nervous system venous sinus NOS	3534267	I63.6, I67.6, UO7.7 (vaccine caused adverse effects)	N/A	N/A	F051z
Thrombophlebitis of central nervous system venous sinuses	4100223	I63.6, I67.6, UO7.7 (vaccine caused adverse effects)	N/A	N/A	F053
Nonpyogenic venous sinus thrombosis	45456755	I63.6, I67.6, UO7.7 (vaccine caused adverse effects)	N/A	N/A	G676
Anaphylaxis (localized)	4034658	45537000 (anaphylactic shock unspecified)	N/A	N/A	N/A
Anaphylaxis	441202	45537000 (anaphylactic shock unspecified)	N/A	N/A	N/A
Anaphylaxis (anaphylactic shock due to adverse effect of correct medicinal substance properly administered)	45376003	45537000 (anaphylactic shock unspecified), 19746	N/A	N/A	N/A
Anaphylaxis (drug induced)	241937000	45537000 (anaphylactic shock unspecified)	N/A	N/A	N/A
Anaphylaxis (procedure)	42537947	45537000 (anaphylactic shock unspecified)	N/A	N/A	N/A
Anaphylaxis (due to substance)	4221182	45537000 (anaphylactic shock unspecified)	N/A	N/A	N/A

^aOMOP: Observational Medical Outcomes Partnership.

^bICD-10: *International Classification of Disease Tenth Revision*.

^cdm+d: *Dictionary of Medicines and Devices*.

^dSNOMED CT: *Systematized Nomenclature of Medicine Clinical Trials*.

^eATHENA: Automated Terminology Harmonization, Extraction, and Normalization for Analytics.

^fCVST: cerebral venous sinus thrombosis.

^gN/A: not applicable.

Table 4. Study concepts identified within OMOP^a and any mapping to ICD-10^b, dm+d^c, SNOMED CT^d, or Read v2 in Wales.

Primary term	OMOP ATHENA ^e concept ID	ICD-10	dm+d	SNOMED CT	Read v2
CVST ^f (nonstandard to standard map)	10083037	I63.6, I67.6, U07.7 (vaccine caused adverse effects) and P3.344 (CVST in hospitalized adults)	N/A ^g	N/A	N/A
CVST (standard to nonstandard map)	10083037	I63.6, I67.6, UO7.7 (vaccine caused adverse effects)	N/A	N/A	N/A
Anaphylaxis (localized)	4034658	T78.2 (anaphylactic shock unspecified)	N/A	N/A	N/A
Anaphylaxis	441202	45537000 (anaphylactic shock unspecified)	N/A	N/A	SN50.11
Anaphylaxis (anaphylactic shock due to adverse effect of correct medicinal substance properly administered)	45376003	45537000 (anaphylactic shock unspecified), 19746	N/A	N/A	SN50110
Anaphylaxis (drug induced)	241937000	45537000 (anaphylactic shock unspecified)	N/A	N/A	SN50.00, 14M5.00
Anaphylaxis (procedure)	42537947	45537000 (anaphylactic shock unspecified)	N/A	N/A	SN50.11, SN50.00, 14M5.00
Anaphylaxis (due to substance)	4221182	45537000 (anaphylactic shock unspecified)	N/A	N/A	SN50.11, SN50.00, 14M5.00

^aOMOP: Observational Medical Outcomes Partnership.

^bICD-10: *International Classification of Disease Tenth Revision*.

^cdm+d: *Dictionary of Medicines and Devices*.

^dSNOMED CT: Systematized Nomenclature of Medicine Clinical Trials.

^eATHENA: Automated Terminology Harmonization, Extraction, and Normalization for Analytics.

^fCVST: cerebral venous sinus thrombosis.

^gN/A: not applicable.

Table 5. Study concepts identified within OMOP^a and any mapping to ICD-10^b, dm+d^c, SNOMED CT^d, or Read v2 in Northern Ireland.

Primary term	OMOP ATHENA ^e concept ID	ICD-10	dm+d	SNOMED CT	Read v2
CVST ^f (nonstandard to standard map)	10083037	I63.6, I67.6, UO7.7 (vaccine caused adverse effects) and P3.344 (CVST in hospitalized adults)	N/A ^g	N/A	N/A
CVST (standard to nonstandard map)	10083037	I63.6, I67.6, UO7.7 (vaccine caused adverse effects)	N/A	N/A	N/A
Anaphylaxis (localized)	4034658	45537000 (anaphylactic shock unspecified)	N/A	N/A	N/A
Anaphylaxis	441202	45537000 (anaphylactic shock unspecified)	N/A	N/A	N/A
Anaphylaxis (anaphylactic shock due to adverse effect of correct medicinal substance properly administered)	45376003	45537000 (anaphylactic shock unspecified), 19746	N/A	N/A	N/A
Anaphylaxis (drug induced)	241937000	45537000 (anaphylactic shock unspecified)	N/A	N/A	N/A
Anaphylaxis (procedure)	42537947	45537000 (anaphylactic shock unspecified)	N/A	N/A	N/A
Anaphylaxis (due to substance)	4221182	45537000 (anaphylactic shock unspecified)	N/A	N/A	N/A

^aOMOP: Observational Medical Outcomes Partnership.

^bICD-10: *International Classification of Disease Tenth Revision*.

^cdm+d: *Dictionary of Medicines and Devices*.

^dSNOMED CT: Systematized Nomenclature of Medicine Clinical Trials.

^eATHENA: Automated Terminology Harmonization, Extraction, and Normalization for Analytics.

^fCVST: cerebral venous sinus thrombosis.

^gN/A: not applicable.

Vaccine Exposure

COVID-19 vaccine exposure was well recorded with dm+d and SNOMED CT. The vaccine unsurprisingly was listed as a VTM at the top of the drug dictionary hierarchy, with VMPs created for each vaccine type. There were virtual and actual packs and

products to match the vaccines available. Additional administration and vaccine-type clinical terms were also within SNOMED CT (Table 6). Finally, we found a small number of vaccine administration codes within dm+d that were not mapped to OMOP.

Table 6. COVID-19 vaccine concepts.

Vaccine brand/generic/administration	Administration, n	Number of dm+d ^a or SNOMED CT ^b codes, n					Ingredients, n
		VTM ^c	VMP ^d	VMPP ^e	AMPP ^f	AMP ^g	
Generic COVID-19	N/A ^h	1	N/A	N/A	N/A	N/A	N/A
Generic mRNA ⁱ	3	N/A	N/A	N/A	N/A	N/A	N/A
Generic recombinant	N/A	N/A	N/A	N/A	N/A	N/A	3
Vaccine administration	1	N/A	N/A	N/A	N/A	N/A	N/A
COVID-19 vaccine administration	6	N/A	N/A	N/A	N/A	N/A	N/A
COVID-19 1st dose vaccine administration	2	N/A	N/A	N/A	N/A	N/A	N/A
COVID-19 2nd dose vaccine administration	2	N/A	N/A	N/A	N/A	N/A	N/A
Oxford-AstraZeneca(N/A	N/A	1	4	4	1	N/A
Moderna	N/A	N/A	1	2	2	1	N/A
Pfizer-BioNTech	N/A	N/A	1	2	2	1	N/A

^adm+d: Dictionary of Medicines and Devices.

^bSNOMED CT: Systematized Nomenclature of Medicine Clinical Trials.

^cVTM: virtual therapeutic moiety.

^dVMP: virtual medicinal product.

^eVMPP: virtual medicinal product pack.

^fAMPP: actual medicinal product pack.

^gAMP: actual medicinal product.

^hN/A: not applicable.

Discussion

Principle Findings

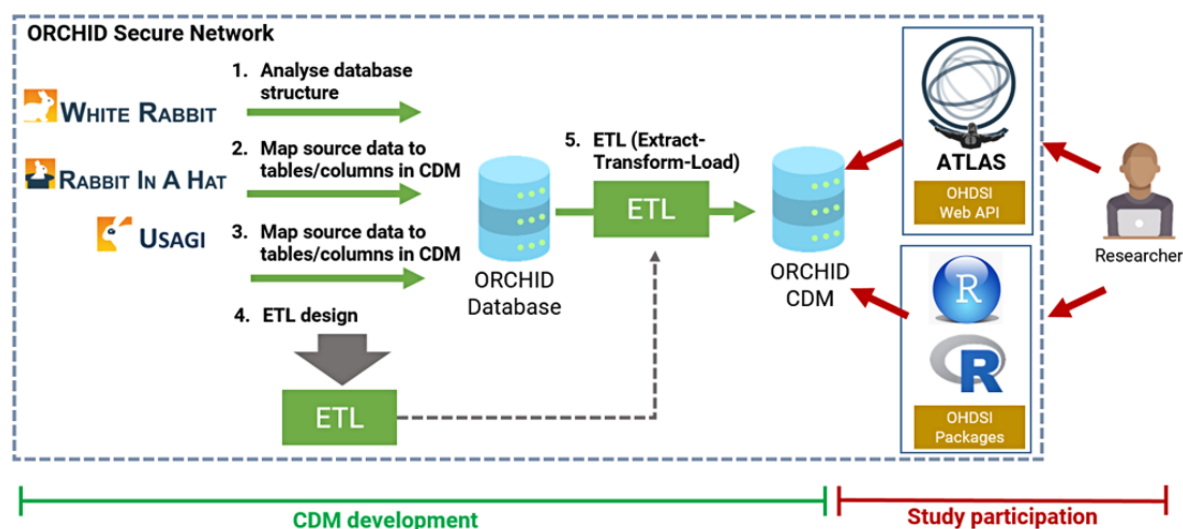
This study shows a mapping method to identify codes relevant to CVST and anaphylaxis using the OMOP CDM to link common concepts required for COVID-19 vaccine pharmacovigilance to different terminologies relevant to the United Kingdom. All our predefined concepts were represented in the OMOP CDM. However, some, such as SES, did not have specific mappings and, thus, custom mappings would need development. We noted that local codes and curation of variables may be used to enable specificity where the concepts are less granular, especially for CVST.

Comparison With Prior Work

The OMOP CDM may be suboptimal to overcome the limitation in the granularity of the coding systems used for AEs. As well as being less granular, the Read v2 terminology has not been updated formally since April 2016, so local adaptations have been undertaken in the developed UK nations to enable new conditions and treatments, such as COVID-19 and vaccination, to be recorded.

Conventionally, CDMs, such as OMOP, are used by each database, mapping data and querying them using the script created by 1 of the teams. The cataloguing is carried out using applications such as White Rabbit and Rabbit in a Hat (Figure 1).

Figure 1. Formal mapping of a database (in this case ORCHID) to the OMOP CDM. We used 3 steps to develop the extract, transform, and load (ETL) design. We tested this specifically in relation to the SQL environment of the ORCHID database. CDM: common data model; OHDSI: Observational Health Data Sciences and Informatics; OMOP: Observational Medical Outcomes Partnership; ORCHID: Oxford RCGP Clinical Informatics Digital Hub.



Limitations

The OMOP CDM provides a framework for capturing patient demographic and socioeconomic characteristics, varying vaccine exposure [23], and AEI data. Although others could replicate our approach, avoiding the need to map whole databases, initial findings reflect the relative size of the terminologies we use, and their granularity needs improvement. Therefore, to conduct future research, concepts will require localization to evaluate COVID-19 vaccination associated with CVST and anaphylaxis. We selected dm+d rather than the better-known British National Formulary (BNF), although the latter is mapped to SNOMED CT. Its limitations are that it only lists prescribable drugs. Its chapter headings change from time to time, and it is not mapped to the ATHENA OMOP hierarchy. We considered MedDRA with clinically validated medical terminologies for clinical conditions, medical devices, and medicines that is commonly used to share AEIs mainly with regulators. MedDRA is primarily

used to report pharmacovigilance using acute care and clinical trial data. This approach cannot be directly used within primary care but will be considered for future studies.

Conclusion

Concept mapping to a large number of terminologies, such as within OMOP and its ATHENA online browser, are usable and valuable for those conducting studies that draw together heterogeneous data to perform pooled analyses. Comprehensive mappings have to set a level of granularity that may be more or less specific than the terminologies they map to. Clinical variable curation at a local database level would prove useful to address issues around granularity. This would allow local expert refinement of the mappings that could be used by others looking to do a limited pooled analysis of a small number of clinical concepts. The interconnectivity of the pooled analysis may also support the MHRA's Spontaneous Report System used for optimizing patient safety.

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Authors' Contributions

SdeL conceived the approach in collaboration with FDRH and A Sheikh. SdeL, GD, and A Stipanac drafted versions of the protocol, with input from all authors who have read and approved the paper.

Conflicts of Interest

SdeL reports that through his university, he has had grants from AstraZeneca, GSK, Sanofi, Seqirus, and Takeda for vaccine-related research and membership of advisory boards for AstraZeneca, Sanofi, and Seqirus. FDRH acknowledges part support as director of the National Institute for Health and Care Research (NIHR) Applied Research Collaboration (ARC) Oxford Thames Valley, and theme lead of the NIHR Oxford University Hospitals (OUH) Biomedical Research Centre (BRC). FDRH also received occasional fees or expenses for speaking or consultancy from AstraZeneca, Boehringer Ingelheim (BI), Bayer, Bristol Myers Squibb (BMS)/Pfizer, and Novartis. A Sheikh serves as an adviser to the UK and the Scottish Governments. He is also a member of Astra-Zeneca's Thrombotic Thrombocytopenic TaskForce. All these roles are unremunerated. RO is a member of the National Institute for Health and Care Excellence (NICE) Technology Appraisal Committee, member of the NICE Decision Support Unit (DSU), and associate member of the NICE Technical Support Unit (TSU). She has served as a paid consultant to the pharmaceutical industry, providing unrelated methodological advice. She reports teaching fees from the Association of British Pharmaceutical Industry (ABPI) and the University of Bristol. RAL is an unremunerated member of the Welsh Government COVID-19 Technical Advisory Group. All other authors declare no conflicts of interest.

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Abbreviations

AEI: adverse event of interest
AMP: actual medicinal product
AMPP: actual medicinal product pack
ATHENA: Automated Terminology Harmonization, Extraction, and Normalization for Analytics
CDM: common data model
CVST: cerebral venous sinus thrombosis
DaC-VaP: Data and Connectivity COVID-19 Vaccines Pharmacovigila
dm+d: Dictionary of Medicines and Devices
FDA: Food and Drug Administration
GP: general practitioner
HBS: Honest Broker Service
IC: *information component*
ICD-10: *International Classification of Disease Tenth Revision*
MedDRA: Medical Dictionary for Regulatory Activities
MHRA: Medicines and Healthcare products Regulatory Agency
N3C: National COVID Cohort Collaborative
NHS: National Health Service
OHDSI: Observational Health Data Sciences and Informatics
OMOP: Observational Medical Outcomes Partnership
ORCHID: Oxford RCGP Clinical Informatics Digital Hub
PCORI: Patient-Centered Outcomes Research Institute
PCORnet: Patient-Centred Outcomes Research Network
RCGP: Royal College of General Practitioners
RSC: Research and Surveillance Centre
RWD: real-world data
SAIL: Secure Anonymised Information Linkage
SCDM: Sentinel common data model
SeRP: Secure e-Research Platform
SES: socioeconomic status
SNOMED CT: Systematized Nomenclature of Medicine Clinical Terms
TRE: trusted research environment
VMP: virtual medicinal product
VMPP: virtual medicinal product pack
VTM: virtual therapeutic moiety

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Original Paper

An Observational Report of Screen Time Use Among Young Adults (Ages 18-28 Years) During the COVID-19 Pandemic and Correlations With Mental Health and Wellness: International, Online, Cross-sectional Study

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Abstract

Background: Screen time (ST) drastically increased during the COVID-19 pandemic, but there is little research on the specific type of ST use, degree of change from before COVID-19, and possible associations with other factors. Young adults are a particular interest since previous studies have shown the detriment ST has on a young person's health. With the combination of a life-changing pandemic, there are unreached depths regarding ST and young adults. This study aims to provide insight into these unknowns.

Objective: This study aims to assess ST in 3 domains (entertainment, social media [SM], and educational/professional) in young adults early in the COVID-19 pandemic; identify trends; and identify any correlations with demographics, mental health, substance abuse, and overall wellness.

Methods: An online, cross-sectional observational study was performed from September 2020 to January 2021 with 183 eligible respondents. Data were collected on ST, trauma from COVID-19, anxiety, depression, substance use, BMI, and sleep.

Results: The average total ST during COVID-19 was 23.26 hours/week, entertainment ST was 7.98 hours/week, SM ST was 6.79 hours/week, and ST for educational or professional purposes was 8.49 hours/week. For all categories, the average ST during COVID-19 was higher than before COVID-19 ($P < .001$). We found ST differences between genders, student status, and continent of location. Increased well-being scores during COVID-19 were correlated with greater change in total ST ($P = .01$). Poorer sleep quality ($P = .01$) and longer sleep duration ($P = .03$) were associated with a greater change in entertainment ST ($P = .01$). More severe depression and more severe anxiety was associated with the amount of entertainment ST ($P = .047$, $P = .03$, respectively) and greater percent change in SM ($P = .007$, $P = .002$, respectively). Greater stress from COVID-19 was associated with the amount of ST for educational/professional purposes ($P = .05$), change in total ST ($P = .006$), change in entertainment ST ($P = .01$), and change in ST for educational/professional purposes ($P = .02$). Higher Alcohol, Smoking, and Substance Involvement Screening Test (ASSIST) tobacco scores were associated with greater change in total ST ($P = .004$), and higher pack-years were associated with greater change in SM ST ($P = .003$). Higher alcohol scores ($P = .004$) and servings of alcohol per week ($P = .003$) were associated with greater change in entertainment ST. Quarantining did not negatively impact these variables.

Conclusions: There is no doubt ST and worsening mental health increased during COVID-19 in young adults. However, these findings indicate there are many significant associations between ST use and mental health. These associations are more complex than originally thought, especially since we found quarantining is not associated with mental health. Although other factors need to be further investigated, this study emphasizes different types of ST and degree of change in ST affect various groups of people in discrete ways. Acknowledging these findings can help young adults optimize their mental health during pandemics.

KEYWORDS

coronavirus; COVID-19; pandemic; mental health; depression; anxiety; screen-time usage; young adults; students; international study; observational study; cross-sectional study; smoking

Introduction

Background

COVID-19, a novel disease, wreaked havoc on the world and caused an international public health emergency. Thus, quarantine and social distancing measures were implemented to decrease viral transmission and, in turn, resulted in dire consequences, including posttraumatic stress, fear, and anger [1,2]. These self-isolation measures caused work and education to move online, naturally increasing screen time (ST) use among groups [3]. Because ST was a controversial and well-studied topic prior to the pandemic, the interest revolving around ST and ST behaviors and the correlations they may have with various wellness variables became a popular target for mental health and public health researchers. Since the inception of the worldwide pandemic, many studies have demonstrated the harmful effects of ST on different population groups, particularly from mental and physical health perspectives [3]. Increased ST use during the pandemic has been linked to addictive behaviors, like alcohol, smoking, and sugar intake in adults [4].

It is obvious that ST use during the pandemic and the relationship to mental health are quite complex and multifactorial. For example, researchers have found shocking findings regarding ST in adolescents, pinpointing various demographic disparities and acknowledging mixed findings of ST depending upon modalities (ie, smartphone vs television), signifying that device ST may be an important factor to consider [5]. These findings indicate that the focus on ST should not solely be on time spent doing a particular activity on the screen, but it is important to further quantify activities in a way that might be meaningful to a person's overall wellness. For instance, there has been a significant increase in online gaming during the pandemic associated with the need for individuals to socially connect due to stay-at-home mandates, which can either be beneficial or detrimental to a person's well-being [6]. Understanding these complex associations can not only help improve future generations but also provide insight on novel treatment systems to potentially help others in the future during similar situations.

ST use during the COVID-19 pandemic largely focuses on its effects in children and adolescents, and there is little research on the young adult population (ages 18-30 years), which is of particular interest as this is the age of people attending college or university, developing their careers, and connecting with peers. Furthermore, specific ST use (ie, ST for studying vs ST for social media [SM] use) has not been looked at during the COVID-19 pandemic, and most of the focus is on total ST, as opposed to evaluating ST spent on specific activities without focusing on modality. Lastly, there is little analysis comparing the current use of ST to before the COVID-19 pandemic, as the degree of change could potentially hold vital insights and add

information upon the complex relationship with ST and psychological state.

Aim of This Study

Due to the emergence of the impact of specified ST use during the COVID-19 pandemic on declining mental health in younger generations around the world, this study originally aimed to collect information on ST patterns in young adults ages 18 years to 28 years, as well as additional wellness measures, like mental health, substance use, and overall well-being. The study not only collected data on 3 different ST uses (entertainment, SM, and educational or professional uses) but also aimed to assess ST changes between the pre-COVID-19 era and ongoing COVID-19 pandemic to expand the literature on ST patterns amid the pandemic.

Methods

Study Design and Sample Size

Data were collected via an online, international, cross-sectional, observational study that was conducted using the SurveyMonkey online survey platform (SurveyMonkey, San Mateo, CA) from September 2020 to January 2021. The research utilized convenience sampling to recruit participants in the targeted age range of 18 years to 28 years from the group's medical institution in Saint Vincent and the Grenadines via word of mouth and school-wide emails. The study was publicized on popular SM websites (ie, Facebook, Twitter, LinkedIn) and research platforms (ie, SurveyCircle and SurveySwap) to collect additional responses on an international scale. The collection of responses was generated positively by the local campus (11/174, 6.3%), SM (55/174, 31.6%), and online research participant platforms (108/174, 62.1%).

A total of 294 respondents completed the questionnaire. Inclusion and exclusion criteria were added to validate all collected responses due to the structure of the research study. The inclusion criteria required all participants to be between the ages of 18 years and 28 years at the time of survey administration, which was verified by birth date. If a participant was outside of this age group, they were excluded from data analysis. Three validated questions were implemented within the survey to minimize random selection of choices. Respondents who incorrectly answered questions such as "Click to continue the survey" and "Please select agree/disagree for this answer" were excluded from data analysis. A total of 183 responses were validated, where 35 respondents were ineligible because they were out of the age range (ie, less than 18 years of age or greater than 28 years of age) and 76 respondents did not correctly answer the validation questions.

Ethics Approval

An online consent form was presented to every participant to confirm their voluntary participation, allowing them to withdraw

at any point or skip or refuse any questions they felt uncomfortable answering. All participants included in the study participated in the informed consent process with an additional informed consent for all individual participants for whom identifying information is included in this article. Participants did not receive any risks or reimbursements for their participation except the benefit of allowing this research group to gain more information on how mass pandemics can affect an individual's mental health, which might help public health expand mental health options in the future. For the mental health section, we included an international mental health number and website the participant could go to should they experience distress from answering any of the questions. The research was approved by the Institutional Research Committee of the Saint James School of Medicine Saint Vincent and the Grenadines campus (Research Study #119). All procedures performed in studies involving human participants were per the ethical standards of the institutional or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Research Instruments

The pre-COVID-19 period was from October 2019 to December 2019, while the current COVID-19 period was from March 2020 to the day the participant participated in the survey. All questionnaires were tailored to specify assessment during the COVID-19 pandemic.

Social Demographics

The first section of the questionnaire collected general demographic information, like gender, age in 2020, ethnicity, race, employment status, country of residency in the past 6 months, income, and student status. Those who were students and not employed selected "unemployed, not looking for work." Due to low sample sizes, the country of residence was categorized into continents during data analysis.

COVID-19-Related Questions

Participants were also asked a series of COVID-19 medically related questions. They answered questions ("Yes," "No," "Don't know/unsure," or "Refuse to answer") regarding whether they had been tested for the virus and whether they were infected by SARS-CoV-2. Participants also answered questions regarding whether they quarantined and, if they quarantined, to specify if the quarantine time was past or current. Lastly, if they did quarantine (past or present), they were required to include the number of days they quarantined.

Screen Time Data

A validated questionnaire quantified the use of ST but was modified by asking participants for average ST use (hours/week) in the past 7 days during the COVID-19 pandemic for a particular category (entertainment, SM, and educational or professional purposes) [7]. "Thinking of an average week BEFORE the COVID-19 pandemic (October 2019-December 2019) and DURING (March 2020-Present Day), how much time do you spend using each of the following types of screens as the primary activity?" ST for the pre-COVID-19 era was retrospectively collected. Each category had examples listed. Entertainment included streaming websites, television, movies,

music, and video games. SM included all major SM networks (ie, Facebook, Twitter, Snapchat) and related activities (eg, chatting, sharing information or pictures). Educational and professional ST included online lectures, webinars, business meetings, and video tutorials. If no time was spent, respondents were instructed to use "0" as their answer.

Mental Health (Depression, Anxiety, Psychological Impact of COVID-19, Substance Use, and Fear of COVID-19)

We used the Patient Health Questionnaire (PHQ-9) to assess depression, scoring each of the 9 DSM-IV criteria on a 4-point Likert-scale ranging from "not at all" (0), "several days" (1), "more than half the days" (2), and "nearly every day" (3), with a total sum ranging from 0 to 27 and scores equal to or greater than 10 indicating possible depression [8-10].

We used the Generalized Anxiety Disorder 7-item (GAD-7) to assess anxiety on a 4-point Likert scale from "not at all" (0) to "nearly every day" (3), where anxiety symptoms are classified as minimum (0-4), mild to moderate (5-14), and severe (15-21) [11,12].

The Impact of Events Scale-Revised (IES-R) is a 22-item measure, where scores over 24 indicate potential posttraumatic stress disorder (PTSD) [13-16]. The assessment for COVID-19 distress required calculating the overall IES-R scores, consisting of 22 items that include 7 items for intrusion, 8 for avoidance, and 7 for hyperarousal. The amount of difficulty experienced for each item is scaled as not at all "0," a little bit "1," moderately "2," quite a bit "3," and extremely "4." Overall scores can point to a potential diagnosis of PTSD based on the range. A score from 24 to 32 indicates partial PTSD symptoms, a score from 33 to 38 indicates a probable diagnosis of PTSD, and a score above 39 suggests suppression of the immune system's functioning. The means of each subset (intrusion, avoidance, hyperarousal) were also computed and used in the data analysis.

Illicit substance use was assessed using the World Health Organization's (WHO's) Alcohol, Smoking, and Substance Involvement Screening Test (ASSIST V3.0), which was modified to focus only on tobacco, alcohol, cannabis, amphetamine, and opioid use. The responses to each question are rated on a 5-point scale that ranges from "never," "once or twice," "monthly," "weekly," to "daily or almost daily." Substance scores under 3 indicate no treatment needed, scores from 4 to 26 require brief treatment, and scores of 27 and higher require intensive treatment [17]. Additional questions evaluated pack-years and the average amount of alcohol consumed per week, with a guideline for serving size of alcohol (1 can/glass of beer = 1 glass of wine = 1 shot of liquor [eg, rum, tequila, vodka]). Due to low sample sizes, cocaine, amphetamine, and opioid ASSIST scores were dropped from the data analysis.

We used the Fear of COVID-19 Scale (FCV-19S) to assess an individual's stress, anxiety, and fear over the virus. The questionnaire uses the Likert scale, ranging from 1 (strongly disagree) to 5 (strongly agree), to calculate the total score, with an overall sum score from 7 to 35: the higher the score, the greater the level of fear of COVID-19 [18].

Overall Well-being

The WHO's Five Well-Being Index (WHO-5) was used to measure subjective well-being, where 0 signifies the lowest quality of well-being and 100 indicates the highest quality of well-being [19]. Like the ST questions, these questions were asked twice—before and during the COVID-19 pandemic.

BMI

Each respondent was asked for their current height and their specific weight before and during the pandemic, along with dates of the weight recordings. The survey accepted each respondent's weight and height depending on whether they chose the US measurement system (pounds and feet/inches) or the universal metric system (kilograms and centimeters).

Sleep Quality

The Pittsburgh Sleep Quality Index (PSQI) was used to assess sleep quality in the past month (ie, during the COVID-19 pandemic) [20]. The sum score for each of the 7 subareas (subjective quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, sleep medication use, and daytime dysfunction) yields a total score, which can be used to categorize sleep quality. Scores less than 5 indicate “good” sleep quality, whereas scores 5 or more indicate “poor” sleep quality.

Data Analysis

Data analysis was conducted at the 95% significance level with SPSS version 25.0 (IBM Corp, Armonk, NY). Data analysis included paired and independent *t* tests, Levene test for equality

of variances, Pearson correlation, chi-square tests, ANOVA tests, and Tukey post-hoc tests. Missing data and those who answered with “don't know” or “refuse to answer” were removed, as were small sample size numbers ($n < 15$), like in the case of ASSIST cocaine, amphetamine, and opioid scores. If a participant had missing data for a scored section (ie, GAD-7, IES-R), that participant did not receive a score.

The dependent variables for analysis included demographic information (age in 2020, gender, ethnicity, race, student status, employment status, and continent of residence), alcohol weekly servings, pack-years, FCV-19S scores, past and current WHO-5 scores, past and current BMI, change in BMI, sleep duration, PSQI scores, PHQ-9 scores, GAD-7 scores, IES-R total, IES-R intrusion, IES-R avoidance, IES-R hyperarousal scores, and ASSIST scores for tobacco, alcohol, and cannabis.

Most participants were female ($n=128$), White ($n=142$), not Hispanic/Latinx ($n=128$), and from Europe ($n=124$). The average age in 2020 for all 183 participants was 23.43 (SD 2.54) years. Of the participants, 58.2% (106/183) were unemployed, and most participants were students (162/183, 88.5%). Over 70% (98/136, 72.1%) reported an income of less than US \$50,000. Income was not associated with any of the dependent variables.

Results

Demographic Information

A comprehensive summary of demographics is in [Table 1](#).

Table 1. Summary of demographic characteristics (n=183).

Individual-level variables	Results
Age in 2020 (years), mean (SD)	23.43 (2.54)
Gender, n (%)	
Male	52 (28.9)
Female	128 (69.9)
Race, n (%)	
Caucasian/White	142 (77.6)
Black/African American	3 (1.6)
Asian	25 (13.7)
American Indian	1 (0.5)
Mixed	7 (3.8)
Ethnicity, n (%)	
Hispanic/Latinx	52 (28.9)
Not Hispanic/Latinx	128 (71.1)
Continent, n (%)	
Europe	124 (67.8)
North America	42 (23.0)
Asia	11 (6.0)
Africa	4 (2.2)
Australia	2 (1.1)
Employment status, n (%)	
Full-time	24 (13.2)
Part-time	47 (25.8)
Currently unemployed/student	106 (58.2)
Other	5 (2.7)
Income (US \$), n (%)	
<50,000	98 (72.1)
50,000-99,999	22 (16.2)
100,000-149,999	8 (5.9)
≥150,000	8 (5.9)
Student status, n (%)	
Current student	162 (89.0)
Not a student	20 (11.0)

COVID-19–Specific Statistics and Associations

A breakdown of statistics on COVID-19 testing, diagnosis, and quarantine is provided in [Table 2](#).

Only 40.3% (74/183) of the sample took a COVID-19 test, which was not associated with any of dependent variables. Of the participants, 6.7% (12/183) were diagnosed with a COVID-19 infection, which was only associated with ASSIST cannabis scores ($t_{33}=2.299$, $P=.004$), 9.3% (17/183) were currently quarantining with an average quarantine time of 15.18

(SD 23.50) days, and 33.9% (62/183) quarantined in the past with an average quarantine time of 20.07 (SD 20.87) days. The Student t test analysis did not detect differences between groups quarantining or not quarantining for any of the dependent variables. The Pearson correlation analysis did not detect significant correlations between length of past quarantine and the dependent variables. However, the Pearson correlation did detect a positive correlation between length of current quarantine and current WHO-5 well-being scores ($r_{17}=0.531$, $P=.03$) and past WHO-5 well-being scores ($r_{17}=0.626$, $P=.007$).

Table 2. Summary of COVID-19 statistics (n=183).

Category	Results
Took a COVID-19 test ^a , n (%)	74 (40.4)
Had COVID-19 ^b , n (%)	12 (6.7)
Currently in quarantine ^a , n (%)	17 (9.3)
Length of current quarantine (days) ^c , mean (SD)	15.18 (23.50)
Quarantined in the past ^a , n (%)	62 (33.9)
Length of quarantine in the past (days) ^d , mean (SD)	20.07 (20.87)

^an=183.^bn=180.^cn=17.^dn=61.

Summary of ST Statistics

The average use of ST before and during COVID-19 for all domains is provided in [Table 3](#).

Table 3. Comparison of screen time (ST) before and during the COVID-19 pandemic.

Type of ST	Before the COVID-19 pandemic	During the COVID-19 pandemic	<i>t</i> statistic (<i>df</i>)	<i>P</i> value
Total ST (hours/week), mean (SD)	14.26 (11.24)	23.26 (16.19)	-12.08 (178)	<.001
Entertainment ST (hours/week), mean (SD)	5.08 (4.85)	7.98 (6.45)	-10.11 (179)	<.001
Social media ST (hours/week), mean (SD)	4.49 (4.47)	6.79 (6.41)	-8.14 (179)	<.001
ST for educational or professional purposes (hours/week), mean (SD)	4.69 (5.54)	8.49 (7.05)	-8.63 (178)	<.001

Before and During COVID-19 ST Comparisons

The paired *t* tests indicated that the mean ST for all domains significantly increased ($P<.001$; [Table 3](#)).

Categorical Analysis of ST

For total ST during COVID-19, 20.7% (37/183) of participants used ST 0 hours to 10 hours per week, 38.0% (68/138) used ST 10 hours to 20 hours per week, and 41.3% (74/183) used ST at least 20 hours per week. There was a significant association with student status ($P=.002$; [Table 4](#)).

For entertainment ST during COVID-19, most participants (108/183, 60.0%) used ST 0 hours to 7 hours per week ([Table](#)

[5](#)). There was a significant association with student status ($P=.02$; [Table 4](#)), as well as between groups for PHQ-9 scores ($P=.047$; [Table 6](#)).

For SM ST during COVID-19, 70.0% (126/183) of participants used ST 0 hours to 7 hours per week ([Table 5](#)).

Regarding ST for educational or professional purposes during COVID-19, 54.7% (98/183) of participants used ST 0 hours to 7 hours per week, and 45.3% (81/183) used ST more than 7 hours per week ([Table 5](#)). There was a significant difference between groups for total IES-R scores ($P=.05$) and for IES-R intrusion scores ($P=.004$; [Table 6](#)).

Table 4. Significant associations between screen time (ST) data and demographic information.

Characteristics	Age in 2020		Gender		Ethnicity		Student status		Employment status		Continent of residence			
	Statistic	<i>P</i> value	Statistic	<i>P</i> value	Statistic	<i>P</i> value	Students, mean (SD)	Nonstudents, mean (SD)	Statistic	<i>P</i> value	Statistic	<i>P</i> value		
Total ST (0-10, 10-20, >20 hours/week)	— ^a	—	—	—	—	—	—	—	$\chi^2_{2,178} = 12.123$.002	—	—	—	—
Entertainment ST (0-7, >7 hours/week)	—	—	—	—	—	—	—	—	$\chi^2_{2,179} = 5.958$.02	—	—	—	—
Change in total ST (hours)	—	—	—	—	—	—	—	—	$t_{176} = -2.774$.006	—	—	—	—
Change in entertainment ST (hours)	—	—	—	—	$F_{2,162} = 4.676$.01	3.10 (4.98) ^b	1.20 (1.61) ^c	$t_{177} = -3.960$	<.001	—	—	—	—
Change in SM ^d ST (hours)	—	—	—	—	—	—	2.55 (3.86) ^b	0.25 (2.40) ^c	$t_{177} = -2.594$.01	$F_{3,175} = 2.714$.046	—	—
Percent change in total ST	—	—	—	—	—	—	96.08 (172.15) ^e	16.49 (86.74) ^c	$t_{175} = -2.031$.04	—	—	—	—
Percent change in entertainment ST	—	—	—	—	$F_{2,152} = 4.127$.02	—	—	—	—	—	—	—	—
Percent change in SM ST	—	—	—	—	—	—	62.67 (81.75) ^f	8.08 (78.55) ^c	$t_{172} = -2.833$.005	$F_{3,170} = 3.192$.025	—	—
Percent change in educational or professional ST	—	—	—	—	—	—	163.18 (276.30) ^g	12.14 (121.97) ^h	$t_{141} = -2.019$.045	—	—	$F_{4,139} = 3.634$.008
Percent change in total ST (-200% to 0%, 0% to 100%, >100%)	—	—	—	—	—	—	—	—	$\chi^2_{2,177} = 12.235$.002	—	—	—	—
Percent change in entertainment ST (-200% to 0%, 0% to 100%, >100%)	—	—	$\chi^2_{2,167} = 8.462$.02	$\chi^2_{4,155} = 17.371$.002	—	—	—	—	—	—	—	—
Percent SM ST (-200% to 0%, 0% to 100%, >100%)	$F_{2,172} = 3.744$.03	$\chi^2_{2,172} = 6.694$.04	—	—	—	—	$\chi^2_{2,174} = 7.155$.03	—	—	—	—

^aNot applicable.

^b_n=159.^c_n=200.^dSM: social media.^e_n=157.^f_n=154.^g_n=129.^h_n=14.**Table 5.** Overview of categorical screen time (ST) during the COVID-19 pandemic (n=183).

Characteristics	0-7 hours/week, n (%)	>7 hours/week, n (%)
Entertainment	108 (60.0)	72 (40.0)
Social media	126 (70.0)	54 (30.0)
Educational or professional purposes	98 (54.7)	81 (45.3)

Table 6. Significant findings between screen time (ST) during the COVID-19 pandemic and secondary variables.

Characteristics	Entertainment ST		<i>F</i> statistic (<i>df</i>)	<i>P</i> value	Educational or professional ST		<i>F</i> statistic (<i>df</i>)	<i>P</i> value
	0-7 hours/week	>7 hours/week			0-7 hours/week	>7 hours/week		
PHQ-9 ^a , mean (SD)	0.97 (0.62) ^b	1.19 (0.76) ^c	3.987 (1,166)	.047	— ^d	—	—	—
IES-R ^e total, mean (SD)	—	—	—	—	17.58 (12.95) ^f	22.23 (15.96) ^g	3.918 (1,150)	.05
IES-R intrusion, mean (SD)	—	—	—	—	0.67 (0.59) ^h	0.99 (0.78) ⁱ	8.765 (1,163)	.004

^aPHQ-9: Patient Health Questionnaire 9-item.^b_n=101.^c_n=67.^dNot applicable.^eIES-R: Impact of Events Scale-Revised.^f_n=79.^g_n=73.^h_n=89.ⁱ_n=76.

Average Change in ST

The calculation for the average ST change was the difference between the ST during and the ST before the COVID-19 pandemic.

For total ST, the average change in ST was 9.00 hours per week (SD 9.97, *n*=179; [Table 7](#)). There was a significant difference in student status (*P*=.002; [Table 4](#)). There were also correlations with WHO-5 scores before COVID-19 (*P*=.04), IES-R total (*P*=.006) and intrusion scores (*P*=.003), and tobacco scores (*P*=.03; [Table 8](#)).

For entertainment, the average change in ST (*n*=180) was 2.90 (SD 3.85) hours per week ([Table 7](#)). Students were significantly different from nonstudents (*P*<.001; [Table 4](#)). There were associations with WHO-5 scores before COVID-19 (*P*=.045); GAD-7 scores (*P*=.03); IES-R total (*P*=.01), intrusion (*P*=.02), and hyperarousal scores (*P*=.045); sleep duration (*P*=.03); PSQI

scores (*P*=.01); alcohol servings per week (*P*=.004); and alcohol scores (*P*=.003; [Table 8](#)).

For SM, the average change in ST (*n*=180) was 2.29 (SD 3.78) hours per week ([Table 7](#)). There was a significant difference between groups for student status (*P*=.001) and employment status (*P*=.046; [Table 4](#)). The Tukey post-hoc analysis showed full-time employees (mean 0.22, SD 1.95; *n*=23) were significantly different than part-time employees (mean 2.68, SD 3.19; *n*=47; *P*=.05; 95% CI -4.93 to 0.0005) and unemployed individuals (mean 2.56, SD 4.20; *n*=104; *P*=.04; 95% CI -4.57 to -0.11). There was also a correlation with pack years (*P*=.007; [Table 8](#)).

For educational or professional uses, the average change in ST (*n*=179) was 3.80 (SD 5.89) hours per week ([Table 7](#)). There were correlations with IES-R total (*P*=.02) and intrusion (*P*=.02) scores ([Table 8](#)).

Table 7. Summary of change and percent change in screen time (ST) statistics.

Individual-level variables	Results, mean (SD)
Change in total ST (hours)	9.00 (9.97) ^a
Change in entertainment ST (hours)	2.90 (3.85) ^b
Change in SM ST (hours)	2.29 (3.78) ^b
Change in educational or professional ST (hours)	3.80 (5.89) ^a
Percent change in total ST (%)	88.28 (166.79) ^c
Percent change in entertainment ST (%)	93.29 (159.10) ^d
Percent change in SM ST (%)	56.94 (83.08) ^e
Percent change in educational or professional ST (%)	150.14 (268.59) ^f

^an=179.^bn=180.^cn=178.^dn=169^en=175.^fn=144.**Table 8.** Significant associations between change in screen time (ST) between the before COVID-19 and during COVID-19 periods and secondary variables.

Characteristics	Change in total ST (hours)		Change in entertainment ST (hours)		Change in SM ^a ST (hours)		Change in educational or professional ST (hours)	
	Statistic	P value	Statistic	P value	Statistic	P value	Statistic	P value
WHO-5 ^b scores prior to COVID-19	$r_{179}=0.155$.04	$r_{180}=0.149$.045	— ^c	—	—	—
PSQI ^d	—	—	$r_{99}=0.256$.01	—	—	—	—
Sleep duration	—	—	$r_{180}=0.164$.03	—	—	—	—
GAD-7 ^e	—	—	$r_{175}=0.169$.03	—	—	—	—
IES-R ^f total	$r_{152}=0.221$.006	$r_{153}=0.204$.01	—	—	$r_{152}=0.185$.02
IES-R intrusion	$r_{165}=0.234$.003	$r_{166}=0.181$.02	—	—	$r_{165}=0.187$.02
IES-R hyperarousal	—	—	$r_{176}=0.151$.045	—	—	—	—
ASSIST ^g tobacco scores	$r_{32}=0.387$.03	—	—	—	—	—	—
Pack-years (smoking)	—	—	—	—	$r_{33}=0.460$.007	—	—
ASSIST alcohol scores	—	—	$r_{114}=0.264$.004	—	—	—	—
Servings of alcohol per week	—	—	$r_{117}=0.269$.003	—	—	—	—

^aSM: social media.^bWHO-5: World Health Organization Well-Being Index 5-item.^cNot applicable.^dPSQI: Pittsburg Sleep Quality Index.^eGAD-7: Generalized Anxiety Disorder 7-item.^fIES-R: Impact of Events Scale-Revised.^gASSIST: Alcohol, Smoking, and Substance Involvement Screening Test.

Average Percent Change in ST

The average percent change in ST was calculated by dividing the change number by the amount of ST before COVID-19 and multiplying it by 100.

The average percent change in total ST (n=178) was 88.28% (SD 166.79%; Table 7). Students had statistically significant higher percent changes in total ST than nonstudents ($P=.04$; Table 4). There were also correlations with WHO-5 past and current scores ($P=.004$ and $P=.001$, respectively; Table 9).

For entertainment, the average percent change in ST (n=169) was 93.29% (SD 159.10%; Table 7). There is a positive correlation with alcohol weekly servings ($P<.001$; Table 9).

The average percent change in SM ST (n=175) was 56.94% (SD 83.08%; Table 7). Students had statistically significant higher percent changes in SM ST than nonstudents ($P=.005$; Table 4). There was a significant difference between groups for

employment status ($P=.03$; Table 4). The Tukey post-hoc analysis showed full-time employees were statistically significant from unemployed individuals ($P=.049$; 95% CI -97.85 to -0.20). There are correlations with GAD-7 scores ($P=.007$), PHQ-9 scores ($P=.002$), and IES-R intrusion scores ($P=.02$; Table 9).

For educational or professional uses, the average percent change in ST (n=144) was 150.14% (SD 268.59%; Table 7). Students had statistically significant higher percent changes in educational or professional ST than nonstudents ($P=.045$; Table 4). In addition, there was a significant difference between groups for continent of residence ($F_{4,139}=3.634$, $P=.008$; Table 4). The Tukey post-hoc analysis showed those who lived in Europe (mean 154.35, SD 236.61; n=100; $P=.01$; 95% CI -794.30 to -63.67) and North America (mean 68.52, SD 183.52; n=30; $P=.003$; 95% CI -896.16 to -133.45) had less change than those in Africa (mean 583.33, SD 141.42; n=4).

Table 9. Significant associations between percent change in screen time (ST) between the before COVID-19 and during COVID-19 periods and secondary variables.

Characteristics	Percent change in total ST (%)		Percent change in entertainment ST (%)		Percent change in SM ^a ST (%)	
	Statistic	P value	Statistic	P value	Statistic	P value
WHO-5 ^b scores prior to COVID-19	$r_{178}=0.217$.004	— ^c	—	—	—
WHO-5 scores during COVID-19	$r_{175}=0.191$.01	—	—	—	—
PHQ-9 ^d	—	—	—	—	$r_{163}=0.212$.007
GAD-7 ^e	—	—	—	—	$r_{170}=0.235$.002
IES-R ^f intrusion	—	—	—	—	$r_{161}=0.184$.02
Servings of alcohol per week	—	—	$r_{112}=0.356$	<.001	—	—

^aSM: social media.

^bWHO-5: World Health Organization Well-Being Index 5-item.

^cNot applicable.

^dPSQI: Pittsburg Sleep Quality Index.

^eGAD-7: Generalized Anxiety Disorder 7-item.

^fIES-R: Impact of Events Scale-Revised.

Categorical Analysis of Percent Change in ST

For the percent change in total ST, less than one-quarter of participants (27/178, 15.2%) decreased ST use, but more than three-quarters (151/178, 84.0%) increased it (Table 10). There was a significant association with student status ($P=.002$; Table 4). There was a significant difference between groups for total IES-R scores ($P=.01$) and IES-R intrusion ($P=.03$; Table 11).

For percent change in entertainment, more than one-quarter of participants (44/169, 26.0%) decreased ST use, and almost three-quarters (125/169, 74.0%) increased it (Table 10). There was a significant association with gender ($P=.02$; Table 4). There was a significant difference between groups for WHO-5 scores during the pandemic ($P=.01$), GAD-7 scores ($P=.047$), IES-R total scores ($P=.03$), IES-R intrusion scores ($P=.01$), and IES-R hyperarousal scores ($P=.01$; Table 12).

For percent change in SM ST, 29.7% (52/175) of participants decreased SM use, but over 70% (123/175, 70.3%) increased it (Table 10). There was a significant association with gender ($P=.04$), student status ($P=.03$), and average age in 2020 ($P=.03$; Table 4). For average age, the Tukey post-hoc analysis found the mean value for the -200% to 0% category (mean 23.01, SD 2.49 years; n=97) was significantly different from the mean value for the 0% to 100% category (mean 23.38, SD 2.16 years; n=26; $P=.02$; 95% CI -2.20 to -0.16). There was a significant difference between groups for PHQ-9 scores ($P=.03$) and IES-R total ($P=.006$), intrusion ($P=.001$), and avoidance ($P=.02$) scores (Table 13).

For percent change in ST for educational or professional purposes, 41.0% (59/183) of participants decreased ST for educational or professional purposes, and over one-half (124/183, 59.0%) increased (Table 10). There was a significant difference between groups for BMI during COVID-19 ($P=.03$; Table 14).

Table 10. Overview of percent change in screen time (ST) during the COVID-19 pandemic.

Characteristics	-200% to 0%, n (%)	0% to 100%, n (%)	>100%, n (%)
Total ST	27 (15.2)	96 (53.9)	55 (30.1)
Entertainment ST	44 (26.0)	86 (50.9)	39 (23.1)
Social media ST	52 (29.7)	97 (55.4)	26 (14.9)
ST for educational or professional purposes	59 (41.0)	36 (25.0)	49 (34.0)

Table 11. Significant associations between total percent change in screen time (ST) categories and secondary variables.

Characteristics	Percent change in total ST			<i>F</i> statistic (<i>df</i>)	<i>P</i> value
	-200% to 0%	0% to 100%	>100%		
IES-R ^a total, mean (SD)	11.43 (9.97) ^b	20.45 (12.72) ^c	22.25 (18.04) ^d	4.370 (2,148)	.01
IES-R intrusion, mean (SD)	0.48 (0.45) ^e	0.84 (0.66) ^f	0.92 (0.82) ^g	3.629 (2,161)	.03

^aIES-R: Impact of Events Scale-Revised.

^bn=21.

^cn=82

^dn=48.

^en=25.

^fn=87.

^gn=52.

Table 12. Significant associations between percent change in entertainment screen time (ST) categories and secondary variables.

Characteristics	Percent change in entertainment ST			<i>F</i> statistic (<i>df</i>)	<i>P</i> value
	-200% to 0%	0% to 100%	>100%		
WHO-5 ^a scores during COVID-19, mean (SD)	48.93 (22.29) ^b	46.64 (18.45) ^c	36.53 (20.04) ^d	4.586 (2,163)	.01
GAD-7 ^e , mean (SD)	6.67 (5.03) ^f	8.40 (5.26) ^g	9.62 (5.93) ^h	3.122 (2,162)	.047
IES-R ⁱ total, mean (SD)	16.84 (11.06) ^j	19.28 (12.55) ^k	25.69 (20.52) ^l	3.486 (2,140)	.03
IES-R intrusion, mean (SD)	0.63 (0.55) ^m	0.81 (0.62) ⁿ	1.10 (0.94) ^o	4.525 (2,152)	.01
IES-R hyperarousal, mean (SD)	0.94 (0.75) ^b	0.93 (0.62) ^c	1.36 (0.94) ^j	4.737 (2,162)	.01

^aWHO-5: World Health Organization Well-Being Index 5-item.

^bn=43.

^cn=85.

^dn=38.

^eGAD-7: Generalized Anxiety Disorder 7-item.

^fn=42.

^gn=84.

^hn=39.

ⁱIES-R: Impact of Events Scale-Revised.

^jn=37.

^kn=74.

^ln=32.

^mn=40.

ⁿn=78.

^on=35.

Table 13. Significant associations between percent change for social media (SM) screen time (ST) categories and secondary variables.

Characteristics	Percent change in SM ST			<i>F</i> statistic (<i>df</i>)	<i>P</i> value
	-200% to 0%	0% to 100%	>100%		
PHQ-9 ^a , mean (SD)	8.35 (6.28) ^b	10.80 (5.43) ^c	11.70 (7.63) ^d	3.467 (2,160)	.03
IES-R ^e total, mean (SD)	14.17 (9.92) ^f	22.64 (13.82) ^g	20.36 (20.88) ^h	5.352 (2,146)	.006
IES-R intrusion, mean (SD)	0.51 (0.46) ^b	0.95 (0.68) ⁱ	0.93 (0.98) ^j	7.083 (2,158)	.001
IES-R avoidance, mean (SD)	0.70 (0.62) ^k	1.10 (0.79) ^l	1.01 (1.15) ^d	3.934 (2,157)	.02

^aPHQ-9: Patient Health Questionnaire 9-item.

^bn=49.

^cn=91.

^dn=23.

^eIES-R: Impact of Events Scale-Revised.

^fn=46.

^gn=81.

^hn=22.

ⁱn=88.

^jn=24.

^kn=48.

^ln=89.

Table 14. Significant associations between percent change for educational or professional screen time (ST) categories and secondary variables.

Characteristics	Percent change in educational/professional ST			<i>F</i> statistic (<i>df</i>)	<i>P</i> value
	-200% to 0%	0% to 100%	>100%		
BMI during COVID-19, mean (SD)	24.73 (6.74) ^a	23.00 (3.53) ^b	22.18 (3.49) ^c	3.517 (2,141)	.03

^an=59.

^bn=36.

^cn=40.

Discussion

Main Findings

Overall, our findings corroborate with those of other studies indicating that ST increased significantly during COVID-19 in all domains compared with before COVID-19 (all $P < .001$; Table 2) [3,5,21]. Since most of our sample consisted of students, it is expected that the change and percent change in ST for educational and professional purposes had the greatest increase (Table 7). Yet, we found the percent change in ST for SM increased by around 57% compared with entertainment, at 93% (Table 7), indicating our sample drastically increased their time spent on entertainment and only somewhat increased time spent on SM. Higher ST levels for SM were associated with higher social connectedness in high school students, which would be expected during quarantine situations in students, as they might use SM networks to keep in touch with friends during remote schooling [22]. Discovering that entertainment had a higher increase in ST sheds light onto the patterns of young adults who are primarily students during the pandemic and how this population sought more time on entertainment and less on social networking. Even evaluating categorical breakdowns, more participants spent ≥ 7 hours per week (72/180, 40.0%) on entertainment than SM (54/180, 30.0%; Table 5), and more

participants increased their ST time $\geq 100\%$ for entertainment compared with before the pandemic (39/169, 23.1%) than for SM (26/175, 14.9%; Table 10). This could potentially be explained by the fact that researchers are now finding that playing video games, which was included as an example of entertainment ST, is now a new form of social contact for people during COVID-19 and could even have a positive impact on people, which may indicate why quarantine was not associated with negative mental health findings [23].

The differences between SM and entertainment ST variables are stark and emphasize discrete characteristics. For one, we found that there were no significant findings for the dependent variables and SM ST between the 0-7 hours/week and ≥ 7 hours/week groups, but there were differences between the groups for entertainment ST and depression scores ($P = .047$; Table 6). Furthermore, greater change in SM ST compared with before the pandemic was only associated with higher pack-years ($P = .007$), but greater changes in entertainment were associated with higher well-being scores ($P = .045$), poorer sleep quality ($P = .01$), longer sleep duration ($P = .03$), more severe anxiety ($P = .03$), greater stress from the pandemic ($P = .02$), higher levels of alcohol abuse ($P = .004$), and more servings of alcohol per week ($P = .003$; Table 8). However, the greater degree of change compared with before the pandemic is critical, as the greater

the percent change in SM has associations with more severe depression ($P=.007$), more severe anxiety ($P=.002$), and more stress from the pandemic ($P=.02$), whereas a greater degree of change in entertainment ST was only associated with higher servings of alcohol per week ($P<.001$; [Table 9](#)). Once these degrees of change are broken down into decreased percent change, mild to moderate percent change (0%-100% compared with before), and extreme percent change ($\geq 100\%$ compared with before), more correlations become apparent and reiterate that degree of change compared with before does play a role in areas of well-being, anxiety, depression, and stress from the pandemic ([Tables 12 and 13](#)). These findings suggest a complex relationship between type of ST and increase compared with before, especially since this study found that total ST did not have any associations with the dependent variables outside of gender.

Current research emphasizes that quarantine affects a person's mental health, yet we did not find that in our sample size [24]. However, a recent meta-analysis did suggest that quarantine affects varying groups of people differently, and our population might possess a quality or multiple qualities that affects them less than others [25]. A study in Ecuador did mention that, although students express discontent in self-isolation, many students are happy with remote learning, and only 16% have clinical depression [26]. Since our sample is primarily students, this also might be a reason for these findings, especially since we found that, if people were quarantining at the time of taking the survey, longer time spent quarantining was associated with higher well-being scores ($P=.03$). Another reason behind this could be due to increased levels of entertainment ST, and despite finding associations with negative mental health consequences, gaming can be a positive impact. Future studies need to assess ST, entertainment ST, gaming-specific ST, and types of games played with these factors to provide more concrete explanations [23]. In addition, although a COVID-19 diagnosis was not found to be associated with mental health or wellness in this sample, we did find that there was an association with ASSIST cannabis scores ($P=.004$), potentially indicating an association between COVID-19 diagnosis and cannabis use, which could be explained by the fact that researchers postulate that regular cannabis users may be more vulnerable to COVID-19 infections [27].

Although our study did show some demographic differences, the most significant demographic grouping difference was seen between students and nonstudents. There were significant differences ($P<.05$) for all but 2 ST characteristics—percent change in total ST and categorical analysis percent change for entertainment ST ([Table 4](#)). Although it is well-known that students have increased ST during the pandemic due to remote learning [28], a noteworthy finding is that students were more likely to have a higher degree of percent change for entertainment and SM ST compared with nonstudents. This further reiterates the point that total ST only provides minimal information and detailing the type of ST and the amount spent will provide greater insights into ST behaviors and patterns. Aside from students, we also found that full-time employees were less likely to have a drastic change in ST for SM and average percent change in SM than part-time employees or

unemployed individuals ($P=.046$ and $P=.03$, respectively; [Table 4](#)), indicating employment may play a role in the amount of SM usage during a pandemic. A similar finding was recently found, associating it with increased sedentary time [29]. Furthermore, percent change in SM ST may have a generational link, as those who had a general percent decrease in SM were younger than those who had an increase ($P=.03$; [Table 4](#)). Although we did not find any differences between races in our sample, we did find differences between ethnicities for change in entertainment ST ($P=.01$) and percent change in entertainment ST ($P=.02$; [Table 4](#)), which has been postulated to be due to structural and systemic racism-driven factors proposed by a recently published study [5]. These discrepancies encourage race and ethnicity-specific studies to learn more about these patterns to help benefit these minority populations who have largely struggled during the COVID-19 pandemic. Lastly, one of the more unique findings is the difference between groups for the continent of residence for the average percent change in ST for educational and professional purposes ($P=.001$; [Table 4](#)). On average, those who lived in Africa had a more remarkable change than the participants who lived in Europe or North America. This finding implies participants who live in Africa drastically increased their time devoted to education and profession during the pandemic than before the pandemic. This discrepancy can be due to multiple factors, from cultural to structural ones.

There was substantial evidence linking ST to multiple adverse wellness factors, especially with psychological distress from the pandemic. IES-R total scores were more significant for those who spent ≥ 7 hours per week on ST for educational or professional reasons ($P=.05$; [Table 6](#)) but not for other ST variables. This unique finding suggests a correlation between educational or professional ST and psychological distress. Furthermore, like studies before, we found an association between depression and entertainment ST ($P=.047$; [Table 6](#)) [30], not to mention the various post-hoc tests for percent change and IES-R indicate how the IES-R scores were notably increased when the percent change in ST increased; this was seen for all but educational or professional ST. It is critical to note depression scores were not correlated with total ST use, indicating certain types of ST do not influence depression, but others, like entertainment, might. In addition, we found associations with anxiety and average change in entertainment ST ($P=.03$; [Table 8](#)), something sparse in current literature. This finding is novel because, like depression, it is not linked with total ST but rather a specific type of ST.

Since the literature is lacking in information about substance use and ST, our findings add insight into multiple substances. For one, we reiterated the link between increased entertainment ST and alcohol drinking during COVID-19 [4]. We also found ASSIST tobacco scores increased with greater change in total ST use, similar to other studies' scores ($P=.03$; [Table 8](#)) [31]. This could be due to stress, as increased academic stressors can increase smoking behaviors [32]. Our research also found links between the number of pack-years and change in SM ST ($P=.007$; [Table 8](#)), the first mentioned in current literature.

We did not find many associations between sleep quality and ST despite literature indicating otherwise [33,34]. Physiotherapy

students with excessive ST had poor sleep quality, yet our data suggest this is only the case for a significant change in ST for entertainment ($P=.01$; [Table 8](#)) [33]. We also expected to find significant associations with ST and BMI [35] but found those who decreased their ST had a significantly higher BMI than those who increased their ST ($P=.03$; [Table 14](#)). Aside from this association, there were no significant findings regarding BMI, indicating ST was not an impactful factor on BMI scores during COVID-19 in our sample.

Limitations

This study has multiple limitations. Some variables had small sample sizes and needed to be removed from the data analysis. The study was conducted online, and participants were recruited online, thus providing an amount of bias in reporting since these participants may have more ST than others. We were unable to stratify by country due to low sample sizes; thus, we grouped participants into continents, which generalizes and takes away from the discrete culture within one country. For one, we did not collect information on psychiatric history. In addition, calculating ST was focused on hours per week and did not scientifically measure time spent on each device, nor did we

collect information on modalities. Furthermore, the inability to recall could influence and provide a degree of bias in the pre-COVID-19 variables. Lastly, our population did not properly mimic the overall young adult population, as most were White, students, and female.

Conclusion

This study is the first in the current literature to focus on ST behaviors and patterns during the COVID-19 pandemic in young adults and to identify various correlations in ST and demographics, mental health, substance use, and wellness factors. Our findings show that total ST alone is not enough to predict mental health of young adults during the pandemic and that certain types of ST, in particular for entertainment and SM, provide more insight into psychological health and other wellness factors. Furthermore, the amount and degree of change of ST compared with before the pandemic are more telling of psychological impact and wellness. These insights provide a baseline for future researchers to continue to explore these untouched depths in hopes to find personalized solutions to benefit young adults and their mental health and wellness in the future with similar pandemics.

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Data Availability

The raw data presented in this study are not publicly available, but senior author MTW can provide additional statistical analysis in response to a reasonable request. Participants received assurance that all responses would remain confidential within the research team with limited access to databases except for the listed co-authors.

Conflicts of Interest

None declared.

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Abbreviations

ASSIST: Alcohol, Smoking, and Substance Involvement Screening Test

FCV-19S: Fear of COVID-19 Scale

GAD-7: Generalized Anxiety Disorder 7-item

IES-R: Impact of Events Scale-Revised

PHQ-9: Patient Health Questionnaire 9-item

PSQI: Pittsburg Sleep Quality Index

PTSD: posttraumatic stress disorder

SM: social media

ST: screen time

WHO: World Health Organization

WHO-5: World Health Organization Well-Being Index 5-item

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Original Paper

Feasibility of a Novel COVID-19 Telehealth Care Management Program Among Individuals Receiving Treatment for Opioid Use Disorder: Analysis of a Pilot Program

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Abstract

Background: The emergence of COVID-19 exacerbated the existing epidemic of opioid use disorder (OUD) across the United States due to the disruption of in-person treatment and support services. Increased use of technology including telehealth and the development of new partnerships may facilitate coordinated treatment interventions that comprehensively address the health and well-being of individuals with OUD.

Objective: The analysis of this pilot program aimed to determine the feasibility of delivering a COVID-19 telehealth care management program using SMS text messages for patients receiving OUD treatment.

Methods: Eligible individuals were identified from a statewide opioid treatment program (OTP) network. Those who screened positive for COVID-19 symptoms were invited to connect to care management through a secure SMS text message that was compliant with Health Insurance Portability and Accountability Act standards. Care management monitoring for COVID-19 was provided for a period of up to 14 days. Monitoring services consisted of daily SMS text messages from the care manager inquiring about the participant's physical health in relation to COVID-19 symptoms by confirming their temperature, if the participant was feeling worse since the prior day, and if the participant was experiencing symptoms such as coughing or shortness of breath. If COVID-19 symptoms worsened during this observation period, the care manager was instructed to refer participants to the hospital for acute care services. The feasibility of the telehealth care management intervention was assessed by the rates of adoption in terms of program enrollment, engagement as measured by the number of SMS text message responses per participant, and retention in terms of the number of days participants remained in the program.

Results: Between January and April 2021, OTP staff members referred 21 patients with COVID-19 symptoms, and 18 (82%) agreed to be contacted by a care manager. Participants ranged in age from 27 to 65 years and primarily identified as female (n=12, 67%) and White (n=15, 83%). The majority of participants were Medicaid recipients (n=14, 78%). There were no statistically significant differences in the demographic characteristics between those enrolled and not enrolled in the program. A total of 12 (67%) patients were enrolled in the program, with 2 (11%) opting out of SMS text message communication and choosing instead to speak with a care manager verbally by telephone. The remaining 10 participants answered a median of 7 (IQR 4-10) SMS text messages and were enrolled in the program for a median of 9 (IQR 7.5-12) days. No participants were referred for acute care services or hospitalized during program enrollment.

Conclusions: These results demonstrate the feasibility of a novel telehealth intervention to monitor COVID-19 symptoms among OTP patients in treatment for OUD. Further research is needed to determine the applicability of this intervention to monitor patients with comorbid chronic conditions in addition to the acceptability among patients and providers using the SMS text messaging modality.

KEYWORDS

opioid use disorder; substance use; drug addiction; opioid treatment program; COVID-19; telehealth; telemedicine; eHealth; Short Message Service; SMS; text messaging; text message; opioid use; opioid; care management; patient care management; health intervention; telehealth intervention

Introduction

When the COVID-19 *pandemic* began in the United States, it collided with a multidecade opioid *epidemic*. Following the emergence of the pandemic in March 2020, drug overdoses spiked by 28.5% between April 2020 and April 2021 [1]. Provisional data reported that approximately 75% of drug overdose deaths in 2020 were due to opioids including potent synthetic opioids such as fentanyl [2].

As overdose deaths continue to increase, improving access to evidence-based treatment for opioid use disorder (OUD) is a key tertiary prevention strategy [3]. This necessitates coordinating efforts with treatment settings including opioid treatment programs (OTPs). However, patients face challenges in meeting recovery and other health goals while adhering to COVID-19 safety precautions. Specifically, calls for increased social distancing to reduce disease spread may impede access to OUD treatment services [4]. Thus, there are concerns that the COVID-19 pandemic may exacerbate the current opioid crisis [5]. People with OUD may also be at higher risk for contracting COVID-19 and experiencing more severe outcomes in terms of mortality and morbidity [4,6-9].

To address these concerns, experts recommend increased use of technology, including telehealth, and the development of new partnerships to facilitate coordinated treatment interventions that comprehensively address individual health and well-being [10,11]. While this could help manage the needs associated with co-occurring OUD and COVID-19, there is limited evidence on how to best engage and retain patients with OUD in telehealth care management services. This retrospective study aimed to determine the feasibility of a COVID-19 telehealth care management program using a standardized protocol of SMS text messaging for patients receiving OUD treatment in a statewide OTP network.

Methods

Pilot Program Setting and Participants

An OTP network based in the state of Delaware recruited patients to participate in this telehealth care management program where eligible patients are invited to connect with a care manager to monitor their COVID-19 symptoms through daily SMS text messaging communications. The overall COVID-19 telehealth care management program has been in place since the beginning of the pandemic and provides COVID-19 resources and support to businesses and their employees. It consists of 10 care managers who are all licensed registered nurses. This study focuses on the feasibility of enrolling patients with OUD into this established telehealth program.

OTP staff conducted universal COVID-19 symptom screenings for their patients during OTP appointments and referred patients with symptoms to community sites for a COVID-19 test to confirm diagnosis. The Delaware Department of Public Health reviewed and verified diagnostic test samples, and notified the testing facility if patients were positive for COVID-19.

Eligible patients who screened positive for COVID-19 symptoms were invited by OTP staff to participate in the telehealth care management program. Eligibility criteria included patients 18 years or older; with confirmed COVID-19 symptoms; currently receiving OUD treatment; who owned a cell phone with SMS text messaging capabilities; and able to understand, speak, and read English.

Program Procedures

Beginning January 2021, OTP staff invited patients who met eligibility criteria to receive a SMS text message from a care manager using Twistle software [12]. This enabled a 2-way communication between the care managers and program participants that was compliant with Health Insurance Portability and Accountability Act standards. Program monitoring services consist of a standardized protocol for daily SMS text messages sent from care managers to patient participants inquiring about the following: the participant's physical health status in relation to COVID-19 symptoms by confirming their current temperature, if the participant is feeling worse since the prior day, and if the participant is experiencing symptoms such as coughing or shortness of breath. Individuals with OUD participating in the pilot program were monitored up to 14 days while continuing OUD treatment at the OTP. The length of the monitoring period during this pilot program was based on the Centers for Disease Control and Prevention (CDC) COVID-19 quarantine and isolation guidelines that were in place for the general population as of January 2021. These guidelines were later updated by the CDC in December 2021 [13]. If any participants reported worsening COVID-19 symptoms during this monitoring period, the care manager would conduct a standardized assessment to obtain additional details about their symptoms. This assessment included a brief survey asking participants to select their current temperature in terms of Fahrenheit degree categories: 103 °F (39.4 °C) or greater, 101.6 °F to 102.9 °F (38.7 °C to 39.4 °C), 100.4 °F to 101.5 °F (38 °C to 38.6 °C), 97 °F to 100.3 °F (36.1 °C to 37.9 °C), or less than 97 °F (36.1 °C). Participants were also asked to confirm if they were experiencing any coughing or shortness of breath. Care managers would use this clinical information to help determine when patients needed a referral to a local health care provider for acute care services or hospitalization.

Data Sources and Measures

This pilot program was conducted between January 11 and April 30, 2021. We assessed the feasibility of the program intervention

by focusing on three process measures: (1) adoption, which was measured by the number of patients who were invited versus the number who agreed to participate and enrolled in the program; (2) engagement, as measured by the overall number of SMS text messages sent by participants; and (3) program retention, as measured by the number of days participants remained active in the program by continuing to respond to the daily SMS text messages. OTP staff provided a count of patients screened for COVID-19 symptoms and program referrals. The lead care manager tallied the number of patients who screened positive for COVID-19, received a SMS text message program invitation, were lost to follow-up or declined participation, and were enrolled in the program. They also reported the number of days participants were monitored and if any were referred for acute care services during the program. The Twistle data provided the number of messages sent by participants to care managers. Demographic data including age, sex, race, and insurance type were obtained from the electronic health record (EHR). An EHR review confirmed if participants were locally hospitalized while in the program.

Analysis

Descriptive statistics summarized the characteristics of patients approached to participate in the telehealth care management

pilot program and process metrics for program enrollment. Mann-Whitney *U* and Fisher exact tests calculated differences in the demographic characteristics for age, sex, race, and insurance type between those enrolled and not enrolled in the program. Data were analyzed using Stata/SE version 16.1 (StataCorp).

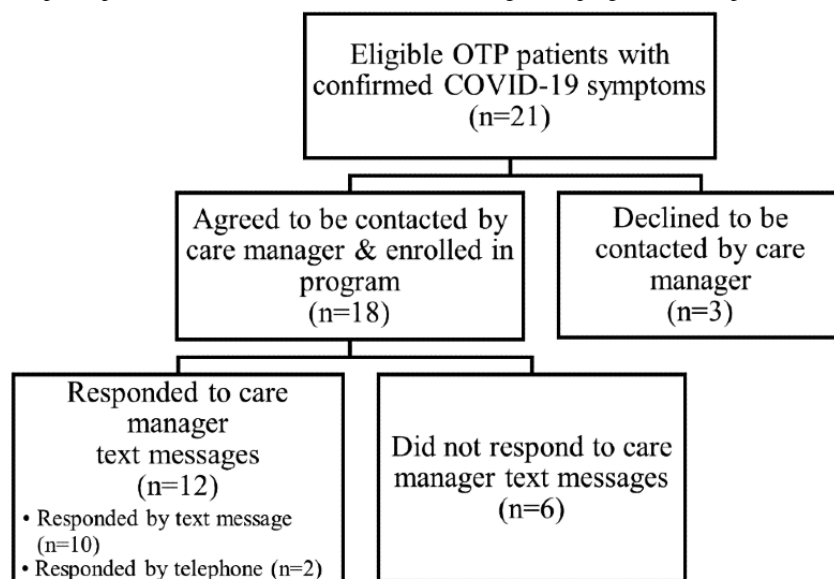
Ethics Approval

We received approval from the ChristianaCare Institutional Review Board (IRB00000480) to evaluate the feasibility of this program.

Results

Figure 1 provides a flow diagram of the participation of OTP patients in the COVID-19 telehealth care management program. Of the 21 eligible patients with COVID-19 symptoms, 18 (82%) agreed to be contacted by a care manager. Of those, 6 (33%) did not enroll in the program, including 4 not responding to care manager messages, 1 opting out, and 1 being withdrawn after confirming a negative COVID-19 diagnostic test. This left 12 (67%) individuals who participated in the telehealth care management program.

Figure 1. Flow diagram of OTP participants in the COVID-19 telehealth care management program. OTP: opioid treatment program.



Characteristics of patients enrolled in the program (n=12) and those not enrolled (n=6) are shown in Table 1. Overall, participants ranged in age from 27 to 65 years and primarily identified as female (n=12, 67%) and White (n=15, 83%). The majority of participants were Medicaid recipients (n=14, 78%) with the remaining participants enrolled in either a Medicare, private, or dual Medicaid/Medicare plan (n=3, 17%). There were no statistically significant differences in demographic characteristics between those enrolled and not enrolled in the program (Table 1).

Of the 12 individuals enrolled, 2 opted-out of SMS text message communication and instead spoke with the care manager verbally by telephone. The remaining 10 participants answered a median of 7 (IQR 4-10) messages. The median time in the program was 9 (IQR 7.5-12) days. Of the 12 participants, 10 were monitored for less than 14 days because of improvement in COVID-19 symptoms, and 2 were monitored for the maximum 14-day period. No participants were referred for acute care services or hospitalized while being monitored by the care manager.

Table 1. Characteristics of opioid treatment program patients enrolled and not enrolled in the COVID-19 telehealth care management program.

	All patients (N=18)	Enrolled (n=12)	Not enrolled ^a (n=6)	P value
Age (years), mean (SD)	41.47 (11.43) ^b	43.0 (11.60)	37.80 (11.34) ^b	.41
Sex, n (%)				.10
Female	12 (67)	7 (58)	5 (83)	
Male	5 (28)	5 (42)	0 (0)	
Unknown, not reported	1 (6)	0 (0)	1 (17)	
Race, n (%)				.25
White	15 (83)	11 (92)	4 (67)	
Other ^c	2 (11)	1 (8)	1 (17)	
Unknown, not reported	1 (6)	0 (0)	1 (17)	
Insurance type, n (%)				.19
Medicaid	14 (78)	9 (75)	5 (83)	
Other ^d	3 (17)	3 (25)	0 (0)	
Unknown, not reported	1 (6)	0 (0)	1 (17)	

^aPatients that were not enrolled either declined participation or were lost to follow-up after agreeing to be contacted by a telehealth care manager.

^bAge for 1 participant not reported.

^cOther race: due to the small sample size, participants with race identified as “Black/African American” or “Other” were combined into one category.

^dOther insurance type: due to the small sample size, participants with insurance type identified as “Medicare,” “Private” plan, or “dual Medicaid/Medicare” plan were combined into one category.

Discussion

Principal Results

In this study, we assessed the feasibility of using SMS text messaging to manage COVID-19 symptoms of OTP patients receiving treatment for OUD. We evaluated the feasibility using three criteria: adoption measured by the ratio of enrolled participants over eligible patients, engagement measured by the number of participant responses to the care managers, and retention measured by the days participants remained in the program. Although a small number of individuals were eligible, the majority of those approached about the program agreed to be contacted and monitored by a care manager via SMS text message. Only a few then opted for verbal telephone communication as opposed to SMS text message communication. Our findings are consistent with the literature documenting the acceptability of SMS text message interventions among individuals seeking OUD treatment following emergency department discharge [14]. Adherence with our SMS text message protocol was high, with the majority of participants responding multiple times to the care manager messages during the monitoring period.

Telehealth is considered safe and effective for a variety of conditions, and research has demonstrated its ability to manage health care needs while maintaining social distancing to reduce infectious disease transmission [15-17]. Current research involving individuals with substance use disorders (SUDs), including OUD, primarily address the provision of telehealth services for SUD treatment including medication management and counseling [18-20]. Little is known about telehealth’s ability to manage co-occurring medical concerns while receiving SUD

treatment. The convenience of offering telehealth-based care management for COVID-19 could ease the burden of managing multiple conditions and potentially improve retention in SUD treatment programs.

Telehealth care management through secure SMS text messaging is a promising tool that offers a convenient, private, and low-maintenance approach to promote patient engagement. SMS text messaging does not require broadband internet access, a smartphone data plan, or downloading a smartphone app, thereby avoiding barriers that exist for many individuals including those in rural areas [21]. Though care management delivered through SMS text messaging is acknowledged to be cost-effective and a relatively simple telehealth modality, few studies have explored its application among individuals receiving treatment for SUDs including OUD [20].

Our study shows that OTP patients may be comfortable communicating through SMS text messages. Though 2 participants preferred to communicate verbally by phone, we believe SMS text messaging remains a feasible telehealth modality. Further research is needed to explore telehealth preferences including concerns related to privacy, security, and other potential barriers. This is consistent with a recent review identifying that only a limited number of studies to date have explored telehealth *acceptability* among patients and providers [22]. Consequently, more participatory research on telehealth use is necessary to better address patient engagement needs and ensure sustained telehealth use among patients and providers [22,23].

Limitations

The small sample size of this pilot study limits the generalizability of our findings to the broader population of OTP patients. Because of the small sample size, we could not assess other feasibility criteria such as estimating the appropriate workload for the care manager or the referral rate to acute care. The program focused on patients from a single OTP network within Delaware, which restricts the validity of our findings to this local region. The feasibility of this program may vary depending on contextual factors such as geography. Fortunately, our OTP network included multiple community-based sites in urban, suburban, and rural settings throughout the state.

Conclusions

This study identified the feasibility of a novel telehealth program intervention delivering COVID-19 care management services for OTP patients. Further research is needed to determine the impact of this intervention on managing other comorbid chronic conditions within this patient population, the association between telehealth outcomes and use of health care services, and telehealth acceptability among patients treated for OUD and providers to ensure engagement and sustainability of services through this evolving modality using SMS text messaging for telehealth purposes.

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Conflicts of Interest

None declared.

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Abbreviations

CDC: Centers for Disease Control and Prevention

EHR: electronic health record

OTP: opioid treatment program

OD: opioid use disorder

SUD: substance use disorder

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Original Paper

Local Community Response to Mass Asymptomatic COVID-19 Testing in Liverpool, England: Social Media Analysis

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Abstract

Background: Mass asymptomatic testing for COVID-19 was piloted for the first time in the United Kingdom in Liverpool in November 2020. There is limited evidence on uptake of mass testing, and previously where surge testing has been deployed, uptake has been low.

Objective: There was an urgent need to rapidly evaluate acceptance of asymptomatic testing, specifically identifying barriers and facilitators to taking part.

Methods: As part of the wider evaluation, we conducted a rapid thematic analysis of local community narratives on social media to provide insights from people unlikely to engage in testing or other standard evaluation techniques, such as surveys or interviews. We identified 3 publicly available data sources: the comments section of a local online newspaper, the city council Facebook page, and Twitter. Data were collected between November 2, 2020, and November 8, 2020, to cover the period between announcement of mass testing in Liverpool and the first week of testing. Overall, 1096 comments were sampled: 219 newspaper comments, 472 Facebook comments, and 405 tweets. Data were analyzed using an inductive thematic approach.

Results: Key barriers were accessibility, including site access and concerns over queuing. Queues were also highlighted as a concern due to risk of transmission. Consequences of testing, including an increase in cases leading to further restrictions and financial impact of the requirement for self-isolation, were also identified as barriers. In addition, a lack of trust in authorities and the test (including test accuracy and purpose of testing) was identified. Comments coded as indicative of lack of trust were coded in some cases as indicative of strong collective identity with the city of Liverpool and marginalization due to feeling like test subjects. However, other comments coded as identification with Liverpool were coded as indicative of motivation to engage in testing and encourage others to do so; for this group, being part of a pilot was seen as a positive experience and an opportunity to demonstrate the city could successfully manage the virus.

Conclusions: Our analysis highlights the importance of promoting honest and open communication to encourage and harness existing community identities to enhance the legitimacy of asymptomatic testing as a policy. In addition, adequate and accessible financial support needs to be in place prior to the implementation of community asymptomatic testing to mitigate any concerns surrounding financial hardship. Rapid thematic analysis of social media is a pragmatic method to gather insights from communities around acceptability of public health interventions, such as mass testing or vaccination uptake.

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KEYWORDS

COVID-19; asymptomatic testing; social media; attitude; behavioral science; testing; behavior; community; England; acceptance; barrier; motivator; hesitancy; communication

Introduction

As part of the United Kingdom's response to COVID-19, in September 2020, the government announced a large-scale expansion of the national testing program, with the intention of regular testing of the entire UK population on a weekly basis, regardless of symptoms [1]. This strategy was known as "Operation Moonshot" and involved using lateral flow antigen tests, which aim to provide results within 30 minutes.

To pilot the operationalization and effectiveness of mass testing, on November 2, 2020, it was announced that Liverpool City would be offered asymptomatic testing for everyone who lived or worked in the city, before the rest of the country. The pilot was a collaboration between the National Health Service (NHS) Test & Trace, Liverpool City Council (LCC), NHS Liverpool Clinical Commissioning Group, the Army (8 Engineer Brigade), Cheshire & Merseyside Health & Care Partnership, and Liverpool Charity and Voluntary Services.

A similar mass asymptomatic testing pilot in Slovakia resulted in extremely high uptake of testing, with 97% of eligible people taking part in the mass testing pilot, resulting in 38,000 new cases being identified within 2 days [2]. In the United Kingdom, research suggests that, although intentions to take a test if asymptomatic were quite high at the time [3], actual engagement with mass asymptomatic testing during the Liverpool pilot was much lower (25%) [4]. There was an urgent need to rapidly gather local insights in the Liverpool city community, to understand barriers and facilitators to engaging with mass asymptomatic testing and to inform ongoing engagement and communication strategies to increase uptake of mass asymptomatic testing. To address this and to supplement self-report survey data, we carried out rapid thematic analysis of local narratives from local community media and social media sites in Liverpool. This work was part of a wider evaluation of the Liverpool mass testing pilot, known as MAST (mass, asymptomatic, serial testing), that was led by The University of Liverpool with NHS Test and Trace, Public Health England (PHE), the Joint Biosecurity Centre, and Office for National Statistics [4]. The pilot resulted in 25% of residents taking part in testing using lateral flow tests and the identification of 897 COVID-19 cases. The aim of this study was to identify barriers and facilitators to engaging in mass asymptomatic testing and to generate recommendations for improving uptake of mass asymptomatic testing in future.

Methods

Aim

As part of the wider evaluation work undertaken by the Evaluation Steering Group, we conducted a rapid thematic analysis of local narratives from local community media and social media sites in Liverpool. The aims of this analysis were to provide insights into local narratives surrounding MAST, particularly from people who may not engage in testing or other standard evaluation techniques such as surveys and interviews; to inform a broader understanding of public test-seeking behaviors, including facilitators and barriers to accessing testing;

and to optimize management of mass testing as part of the national COVID-19 response.

Population

Liverpool is a city in the northwest of England, with a population of around 500,000. The average age of the population is 37.6 years [5], and in 2019, it was ranked the third most deprived local authority area in England based on the overall Indices of Multiple Deprivation score [6]. In week 41 2020 (October 5 to October 11), just before the end of a national lockdown and prior to the implementation of a new tiering system for COVID-19 restrictions, Liverpool had one of the highest rates of COVID-19 in England (659 per 100,000) [7] and was the first area of England to be placed under very high alert (Tier 3) restrictions on October 14, 2020. A strong sense of identity and belonging exists in Liverpool communities, reinforced by experiences with racism, stigma, and marginalization [8,9].

Ethics Approval

In line with British Psychological Society guidelines [10] for conducting internet-mediated research, this research did not require ethical approval because only publicly available data (comments posted in response to public Facebook posts, Twitter posts, or comments posted in relation to online media articles) were used. The PHE Research Ethics and Governance Group was consulted and confirmed that ethical approval was not required for this research.

Sampling

Data were collected from publicly accessible sources of community narratives, including social and online media sites. These included online comments sections from the local online newspaper for Liverpool City, which has a large circulation, the LCC Facebook page, and Twitter. Sampling captured comments posted from November 2, 2020 (when Liverpool was announced as the city to pilot mass testing) to November 8, 2020, to cover the period before and during the first week of the pilot. All publicly accessible comments on identified posts or articles were copied and pasted to text documents for coding.

Articles from the local online newspaper about the mass testing pilot were identified using the search terms "testing" and "mass testing" between November 2, 2020, and November 8, 2020. The searches resulted in the identification of 11 articles, and all comments from these articles were sampled for analysis.

All posts made by the council on the LCC Facebook page related to the mass testing pilot were identified between November 2, 2020, and November 8, 2020. Overall, 16 posts were identified, and all comments from other Facebook users on these posts were sampled for analysis.

The following search string was used to search Twitter to identify tweets with the hashtags #liverpooltesting and/or #masstesting between November 2, 2020, and November 8, 2020, sent in the Liverpool area: *near:liverpool (#liverpooltesting OR #masstesting) until:2020-11-08 since:2020-11-02*.

The search included replies to tweets (which may not necessarily have originated in or near Liverpool) and tweets containing links. In addition to the hashtag search outlined in the previous paragraph, all replies to 2 tweets announcing the mass testing pilot (1 from the local newspaper and 1 from LCC) before 00:00 on November 8, 2020, were collected. Replies to tweets from official accounts (eg, LCC and news media sources) were included in Twitter data collection, but the original tweets were excluded from analysis as they reflected official, organizational perspectives, rather than lay, public perspectives.

Overall, 1096 comments were sampled: 219 newspaper comments, 472 Facebook comments, and 405 tweets.

Analysis

Data were depersonalized by removing any identifiable data (including names and locations) and divided and analyzed separately by 2 authors in NVivo or Microsoft Word. An inductive approach using open coding [11] identified key themes

of interest and was used to develop the initial coding framework. During this stage, meetings were held to discuss coding and reach consensus. Through this process, the authors developed a final coding framework using the framework approach, a type of thematic analysis that is commonly used in research that has implications for policy [12]. This coding framework was then applied to the remaining data. Data were categorized into 2 broad themes of interest (facilitators to testing and barriers to testing), each of which was then divided into relevant subthemes.

Results

Facilitators to Getting Tested

For those motivated to get tested, key drivers were a desire to protect the community, a belief that mass testing could help the city return to normality, and a belief that testing would be (or experience that testing was) convenient and efficient. Some example quotes are included in the following sections, and further examples are shown in [Table 1](#).

Table 1. Facilitator and barriers to engagement with mass asymptomatic testing in Liverpool (2020)—results of the thematic analysis of social media.

Theme	Example quote	Source	Date
Facilitator: protecting the community			
	“No symptoms just want to do my bit!”	Facebook	November 7, 2020
	“Get in and get it done. Save a life maybe?”	Online newspaper	November 6, 2020
	“I actually got tested so I can be sure I’m not a carrier infecting others! It’s a bit insulting to assume every person from Liverpool is just getting tested so they don’t have to work.”	Facebook	November 7, 2020
	“If it saves lives and gets this city back to some semblance of normality then I am all for it.”	Online newspaper	November 3, 2020
	“I think it’s perfectly reasonable to be careful in Liverpool when 1 in 250 people currently have the virus (many of whom will not know about it) and the risks for vulnerable people are much greater. Why wouldn’t you follow the advice from people who’ve dedicated careers to this?”	Twitter	November 3, 2020
	“I will be taking part in #MassTesting #Liverpool to break the chain of transmission and protect the people I love.”	Twitter	November 7, 2020
	“Protecting or vulnerable is most important. With regular testing, we can get tested on a Friday after work, if negative go see, spend time with vulnerable loved ones, and then return to work and school etc, repeat until necessary.”	Facebook	November 5, 2020
Facilitator: return to normality			
	“It’s important we get this testing and tracing working effectively so that we can go back to ‘normal’ life. People need to recognise their own responsibility though and self-isolate when appropriate.”	Facebook	November 6, 2020
	“The more tests, the more people that will be diagnosed, the quicker we can put a cap on it in LIVERPOOL, the more likely WE (not London, not the Tories) but WE, will get out before [Christmas].”	Online newspaper	November 3, 2020
	“If everyone gets tested 2 or 3 times a week we’d potentially have very very few cases in a matter of weeks.”	Online newspaper	November 5, 2020
	“Just get yourself tested, and then we can all start to think about getting back to normal. You can’t be anti-lockdown and anti-testing.”	Twitter	November 2, 2020
Facilitator: positive experience			
	“Hand it in, results back in 40 mins #covid #Liverpooltesting”	Twitter	November 6, 2020
	“Arrived at the test centre, got tested, and received results through all within one hour. Well done to all the Army and NHS staff involved”	Twitter	November 7, 2020
	“...once I had the test it took under an hour for the result to come through ...so this test could be a game changer ...test wait and if negative fly or entry to a theatre etc”	Facebook	November 6, 2020
Facilitator: shared social identity with others in Liverpool and with authorities			
	“Let’s support them. What I have always loved about Liverpool is the community spirit, warmth and the way we pull together in a crisis...If it works it will have positive effects not just in Liverpool but across the whole country. All eyes are on us. Let’s show the country that Liverpool can beat covid 19, and they can too.”	Online newspaper	November 3, 2020
	“Really great to see such a huge positive response to this - together we will do this. Well done Liverpool [thumbs up emoji].”	Facebook	November 6, 2020
	“Absolutely, come on Liverpool we have got this!”	Twitter	November 4, 2020
	“We are the test bunnies, but this isn’t a negative thing, in fact, if we get this sorted, we’ll be the first back to normal.”	Online newspaper	November 3, 2020
Barriers: practical barriers			
	“I wouldn’t bother booking, having a time slot doesn’t make any difference, you have to queue up with everyone else, it’s a joke. [In response] Might not bother at all then if it’s not organized.”	Facebook	November 6, 2020

Theme	Example quote	Source	Date
	"3 1/2 hour wait at [<i>location</i>] even though I booked! Didn't bother waiting, won't bother again! [angry face emoji]."	Facebook	November 6, 2020
	"I am in a family of 6, can only order 4 home tests. Why?"	Facebook	November 6, 2020
	"Tried to book a test, via http://gov.uk link but only allowing me to go for a test in [<i>location</i>]? As a key worker in Liverpool this doesn't make sense... not sure this system is ready to be rolled out yet..."	Twitter	November 6, 2020
	"...they will never help us all. I won't be getting tested unless I'm unwell as I don't get paid for being off and not entitled to those payments. I am sure lots won't. Hopefully mass testing certain groups will. Pin point the problem anyway [thumbs up emoji]"	Facebook	November 4, 2020
	"...Not just the self employed. I don't earn enough to qualify for sick pay but my wages are needed to keep us afloat. And because we don't claim benefits, we can't get that payment from the council. I've already had to isolate through track and trace and lost 2 weeks wages. Like you, no help available anywhere. I want to participate because I believe testing is the only way out of this hole but, yet again, it's the people who actually work who lose out."	Facebook	November 4, 2020
	"Well I went wrong one. Still had test but the normal one. I have to make sure I do the right one next time [eye roll, laughing face emoji]."	Facebook	November 6, 2020
	"Queues for booked appointments at [<i>location</i>] are hours long. There is no signage there are people leaving the queue having waited over 2 hours."	Facebook	November 6, 2020
Barrier: risk of transmission			
	"How do we know these test centers aren't spreading 'it'?"	Facebook	November 2, 2020
	"I just wouldn't do that wait in a queue like that it's pathetic and more to the point riskier"	Facebook	November 6, 2020
	"It infuriates me that the PM positively encouraged these awful tests where you are more likely to get pneumonia stood in a queue, in the cold, without a mask"	Facebook	November 6, 2020
	"Being at the testing site today it would seem that there are two 'sites' in the same car park (one for invited people with symptoms and one for asymptomatic people who booked a test) and I was in a single queue of both groups mixed because of no direction from staff or signs"	Twitter	November 6, 2020
	"What a shambles! Wouldn't let me book a drive in test so I booked a walk in test for 1pm. The que [sic] is absolutely huge, nobody knows what's going on. No managers just car park assistants to ask. Why give so many people the same time? No social distancing. I've walked away" "More chance of me getting covid with that system. Please look at the numbers you are allowing to book in the half hour slots #farcical"	Twitter	November 6, 2020
Barrier: perceived ineffectiveness of testing			
	"Don't see the point you could get tested today and all clear and then catch it tomorrow."	Online newspaper	November 6, 2020
	"How does a Covid test help you get better from the virus? We are in Lockdown so we are all isolating anyway."	Online newspaper	November 6, 2020
	"What's the point? They can't cure it!!!"	Online newspaper	November 3, 2020
Barrier: lack of trust			
	"The tests are not accurate & not fit for purpose, giving up to 85% false positives, they do not isolate Covid, so what's the point in getting tested, just doesn't make sense to me?"	Online newspaper	November 6, 2020
	"I won't be getting tested or using the so-called NHS app whilst Serco are involved."	Twitter	November 2, 2020
	"Forced tests today, forced vaccines tomorrow."	Twitter	November 2, 2020
	"Not a chance in hell would I get one of these tests.... corrupt government!"	Twitter	November 2, 2020

Theme	Example quote	Source	Date
	“Precisely that...every dog on the street know the tests are wholly unreliable, and the possibility of false negatives high, and yet everything that even meekly questions the narrative is a conspiracy theory!! Dismal!!”	Twitter	November 3, 2020
	“I wonder if that will increase the so-called number of cases They can use those false cases to justify their lockdown #WakeUp”	Twitter	November 2, 2020
	“Liverpool are being played for mugs. The disease rate is falling by itself. They are going to find a lot of “cases” to justify the lockdown.”	Twitter	November 2, 2020
	“More tests = More False Positives More false positives = More False ‘cases’ More cases = More lockdown restrictions More lockdowns = More power to the government More government power = Less rights & less liberty for the UK people STOP GETTING TESTED”	Twitter	November 3, 2020
	“Don’t get tested. Dodgy test = false positives = further lockdown”	Twitter	November 6, 2020
	“The will make the R rate rise and we won’t get out of lockdown”	Facebook	November 5, 2020
	“Imagine how many old criminal cases that will be solved with the mass DNA harvest.”	Twitter	November 3, 2020
	“Can Liverpool City Council explain why they are taking peoples DNA. That’s what the test is isn’t it?”	Facebook	November 7, 2020
Barrier: shared social identity with others in Liverpool but not with authorities			
	“Surprise Surprise, we are just one big test case.”	Online newspaper	November 7, 2020
	“Mass testing should be in London, not Liverpool. The Greater Manchester mayor said no to our area being treated like a canary in a coal mine.”	Facebook	November 6, 2020
	“The guinea pigs are staying in their cages”	Twitter	November 6, 2020
	“Why not do this in London first.”	Twitter	November 2, 2020
	“We are the Guinea Pigs for everything”	Twitter	November 2, 2020
	“Operation Scouse Guinea pigs is a go.”	Twitter	November 2, 2020
	“Do you really think they want Liverpool out of tier 3?? If they wanted anyone out of tier 3 Liverpool would be bottom of the pile.”	Facebook	November 6, 2020
	“There’s an agenda behind this and obviously us being the guinea pigs isn’t a coincidence. That toffee nosed slob hates Liverpool and would love to bring the city to its knees. If he’d moved his backside in before March and locked down sooner, maybe we wouldn’t be at this point- unless this was all by design, I don’t know anymore.”	Online newspaper	November 3, 2020
	“There [sic] blaggin ya eds [your heads] big time, look if you do what we say we can save [Christmas] for you!!!”	Online newspaper	November 2, 2020
	“Don’t comply, we’re being scapegoated again, you will gain nothing by being tested apart from losing your jobs and having your kids barred from school, it’s just another money spinner for the old school tie network of the Eton set”	Online newspaper	November 3, 2020
	“Obedient biodrones’ couldn’t agree more.”	Online newspaper	November 6, 2020
	“People who don’t question what’s going on just play into the hands of the greedy politicians and snearing [sic] middle classes. The problem is the rest of us are left to protest and fight for their rights as well. Come on people, please wake up.”	Online newspaper	November 5, 2020
	“Won’t be testing me anytime soon, I’m no government clone, bring them swabs anywhere near me and they’ll be inserted where the sun don’t shine”	Twitter	November 2, 2020
	“The car park was full of SERCO workers who told me they had been drafted from London and the South and knew nothing about local details. Couldn’t you get local Test & Trace workers?”	Facebook	November 6, 2020

Protecting the Community

Wanting to protect their community was a key motivator for those who engaged with the testing program. This included a motivation to protect their loved ones, which in turn would have wider implications for public health:

I will be taking part in #MassTesting #Liverpool to break the chain of transmission and protect the people I love. [Twitter, November 7, 2020]

There was also a wider understanding of community, beyond immediate family and friends. For example, people wanted to protect vulnerable people, both within their family and elsewhere. Within this, they fulfilled a sense of duty and felt, by engaging with the asymptomatic testing, they were contributing to saving lives:

Get in and get it done. Save a life maybe? [Online newspaper, November 6, 2020]

Return to Normality

Tied in with wanting to protect the community was the anticipation of being able to return to “normal”:

If it saves lives and gets this city back to some semblance of normality then I am all for it. [Online newspaper, November 3, 2020]

There was an understanding that pulling together as a community would not only help protect others and save lives but would also help the city recover quicker, specifically reducing the number of cases and entering a lower tier following the national lockdown:

The more tests, the more people that will be diagnosed, the quicker we can put a cap on it in LIVERPOOL, the more likely WE (not London, not the Tories) but WE, will get out before [Christmas]. [Online newspaper, November 3, 2020]

Positive Experience

Among commenters who did get tested, some discussed positive experiences of the testing process itself. These positive experiences were noted throughout the testing process, including ordering tests or booking test slots. Positive experiences were also shared for the time spent at the test site, specifically how organized the process was:

Arrived at the test centre, got tested, and received results through all within one hour. Well done to all the Army and NHS staff involved. [Twitter, November 7, 2020]

In addition, the kindness of the staff working at the test centers was noted as part of their positive experience of the end-to-end test experience.

Shared Social Identity With Others in Liverpool and With Authorities

There is a strong sense of social identity associated with the city of Liverpool; the city is who people are and where they belong. Where people identified with others in the city, as well as with authorities managing the response, shared identity

operated not only as an individual motivator to get tested but also to encourage others to do the same:

Absolutely, come on Liverpool we have got this! [Twitter, November 4, 2020]

There was a sense of wanting to come together as a community, to help not only the city but also the rest of the country. Rather than seeing this as a sacrifice on behalf of the rest of the country, it was seen as an opportunity to demonstrate that Liverpool can successfully manage the virus, setting an example for everyone else:

Let's support them. What I have always loved about Liverpool is the community spirit, warmth and the way we pull together in a crisis...If it works it will have positive effects not just in Liverpool but across the whole country. All eyes are on us. Let's show the country that Liverpool can beat covid 19, and they can too. [Online newspaper, November 3, 2020]

Rather than being chosen as the city to pilot test being viewed as negative, the feeling of social identity and an emotional connection with the city helped people understand the pilot as an opportunity and privilege for the city, for example being the first place out of lockdown or into a lower tier following the end of the national lockdown.

Barriers to Getting Tested

Analysis of the data highlighted several barriers to people getting tested. The key barriers identified were practical barriers to testing, concern over the risk of transmission at the testing sites, and lack of trust in the mass testing program and in the government.

Practical Barriers

A key practical barrier to getting tested was inconvenience associated with attending testing sites. Various factors associated with inconvenience were identified, including long queues at testing sites and poor organization of the testing process:

3 1/2 hour wait at [location] even though I booked! Didn't bother waiting, won't bother again! [angry face emoji]. [Facebook, November 6, 2020]

In addition, there was frustration that the booking system did not help to reduce queue length on attending the testing site—those who experienced long queues despite advanced booking were less motivated to try again. In some cases, people shared their negative experiences on social media, for example around queues, disorganization, or delays in getting results; this may have influenced others' decisions in regard to getting a test.

The uncertainty surrounding the pilot, particularly in the first few days of launch, led to questions being raised in local narratives. These were predominantly related to access to testing, how to book, where the test sites were, whether there were separate sites for asymptomatic testing, and who would be conducting the tests. Uncertainty around how to access testing sometimes resulted in people attending the wrong test centers and having the wrong test or being unable to book tests at all:

Well I went wrong one. Still had test but the normal one. I have to make sure I do the right one next time [eye roll, laughing face emoji]. [Facebook, November 6, 2020]

Another practical barrier to getting tested related to concerns about the consequences of someone testing positive. For example, some individuals raised lack of compensation if required to self-isolate following a positive test as a reason for not getting tested.

Risk of Transmission

As well as long queues being a barrier to accessing testing because of the inconvenience, they also contributed to concerns over the risk of transmission. For some, the risk of catching COVID-19 while queuing was cited as a reason for not wanting to get tested:

I just wouldn't do that wait in a queue like that it's pathetic and more to the point riskier. [Facebook, November 6, 2020]

In some cases, commenters who had participated in testing reported lack of distancing at test sites, with symptomatic people having to queue alongside asymptomatic people.

Perceived Ineffectiveness of Testing

There was also confusion surrounding the purpose of mass testing and how it would help the overall COVID-19 response. In addition, there was the perception that there was no practical purpose for getting tested because there would be no individual benefit to knowing your disease status, particularly if asymptomatic:

What's the point? They can't cure it!!! [Online newspaper, November 3, 2020]

Lack of Trust

In addition to the more passive barriers outlined in the previous sections, there was a motivation to actively avoid participation in mass testing, sometimes expressed alongside discouragement to others or criticism of fellow residents who had been or were planning to get tested. A key factor motivating people to not get tested was lack of trust. This included lack of trust in the accuracy of the test and lack of trust in stakeholders involved in the delivery of mass testing, such as national and local government, scientists, and Test and Trace:

Not a chance in hell would I get one of these tests.... corrupt government! [Twitter, November 2, 2020]

Those who displayed low trust in the mass testing process, and in government response generally, raised potential illegitimate bases on which testing was implemented or highlighted potential adverse consequences of mass testing for Liverpool. These potential consequences focused on 2 main concerns: coercion by the state during mass testing and further restrictions following mass testing due to the rise in the number of known cases. The latter concern was related to the aforementioned lack of trust in the accuracy of the test, with commentators predicting an anticipated high number of false positive cases (sometimes referred to as a “casedemic”) that would lead to further restrictions in Liverpool only, including a prolonged lockdown:

More tests = More False Positives. More false positives = More False “cases”. More cases = More lockdown restrictions. More lockdowns = More power to the government. [Twitter, November 3, 2020]

Other drivers for not getting tested were concern about the use of mass testing for surveillance or DNA gathering:

Can Liverpool City Council explain why they are taking peoples DNA. That's what the test is isn't it?” [Facebook, November 7, 2020]

Shared Social Identity With Others in Liverpool But Not With Authorities

Analysis highlighted how social identity can have a dual role in understanding responses to testing. For those who identified with authorities managing the response, as well as with others in the city, this operated as a facilitator to getting tested (as described in the previous sections). However, for those who did not trust the government response and for whom there was no shared identity with authorities, shared identity with others in the city contributed to motivations not to get tested. In this instance, people felt that mass testing was something being imposed on them rather than something they could engage with as a community:

Surprise Surprise, we are just one big test case. [Online newspaper, November 7, 2020]

This led to a sense of marginalization; local communities felt disconnected from those making the decisions, particularly central government. Feeling disenfranchised from local and central government resulted in discussions around ulterior motives, highlighting a breakdown in trust between the local community in Liverpool and those in power:

Do you really think they want Liverpool out of tier 3?? If they wanted anyone out of tier 3 Liverpool would be bottom of the pile. [Facebook, November 6, 2020]

In addition, the role of social identity in local narratives around testing resulted in some members of the community not wanting to conform with what others were doing. For this group, people who were participating in testing were viewed negatively; they had lost their identity and become “other” and therefore outsiders in the local community, which resulted in criticism for “conforming”:

‘Obedient biodrones’ couldn't agree more. [Online newspaper, November 6, 2020]

Social identity also played a part in concern over “outsiders” coming to the city to deliver the testing program and highlighted a lack of trust in central government.

Discussion

Principal Findings

Findings from this study have implications for the management of mass testing in the future, both in terms of practical management of setting up and running testing sites and communication with members of communities in which mass testing will be provided. Our analysis identified that facilitators

for engaging in mass asymptomatic testing included a sense of community, a desire to return to normality, positive experiences of others, and having a shared identity with Liverpool authorities. Barriers included practical barriers (access to test sites, long queues), concern over risk of transmission, perceived ineffectiveness of testing, lack of trust, and a shared social identity with the Liverpool community but not those in authority.

Findings showed that one of the key motivators to engaging with the pilot in Liverpool was a strong sense of community identity and belonging, both with city residents and local authorities. However, when a strong sense of identity was not shared with authorities (for example, where local and central governments were not seen as trusted organizations), community identity acted as a barrier to engagement with testing. Furthermore, it actively motivated people to disengage from the pilot. To ensure that shared community identity acts as a facilitator rather than a barrier, it is important that members of the community identify with the authorities managing the testing, as well as identifying with each other. This is in line with previous research that emphasized that shared identity is a crucial part of promoting community resilience in response to mass disasters and emergencies [13] and can provide a basis for understanding of the relationship between communities and authorities [14]. Harnessing and working with existing shared identities, such as the identity shared by Liverpool city residents, can help build and maintain trust in authorities and the information they provide [14]. Authorities should communicate openly and honestly and demonstrate respect for public needs in order to enhance legitimacy of the response and facilitate the development of shared identity between communities and authorities, subsequently promoting increased adherence to recommended behaviors, for example mass testing [15,16].

Identity also plays a role in the sense of responsibility duty that was frequently cited by Liverpool residents for reasons why they were engaging in testing. This response is not unique to Liverpool residents; in a recent survey of university students taking part in asymptomatic testing, the majority of students stated they took part in testing because they wanted to protect others (91%) and because it was the right thing to do (82%). A smaller proportion (63%) also stated they took part to help fight the virus [17]. Return to normality was also identified as a key motivator to engage in testing. This has also been identified elsewhere; for example, in the pilot in Slovakia, a relaxation of restrictions was offered as an incentive to participate and increased willingness to take part in the pilot.

However, it is not enough that people are willing to take part in mass testing; they must also be able to do so. Our analysis of local narratives in Liverpool identified several structural barriers, which made it more challenging to access testing, even for those willing to engage in the pilot. These were primarily access to testing sites and queues, for example not wanting to spend time traveling to a test site or waiting in a queue. Clear guidance about how to access testing and test sites would help negate concerns over access, for example dedicated websites or booking systems for asymptomatic testing where applicable; maps of where testing sites are located, including directions for how to access them (for example bus routes, nearest available public car park); and clear signage at the site.

In addition to being identified as an access barrier, queues were also cited as a barrier due to concern over risk of transmission. This was particularly early on in the pilot, where there was confusion between how to access asymptomatic testing opposed to the symptomatic testing to which the community had become accustomed. Requesting people to queue in proximity to others is contra to the basic public health guidance on protective behaviors that has become the pervasive narrative throughout the pandemic response: social distancing. To address concerns about being unable to social distance while waiting for testing, communicating what measures have been put in place to ensure safe queuing is an essential part of the communications for asymptomatic testing.

Financial concerns around the requirement to self-isolate if a test was positive were also highlighted as a barrier to testing. Several people stated that they would be reluctant to take a test because they would not receive any financial support and would therefore struggle to self-isolate if they received a positive result. It is essential that everyone required to self-isolate has the financial support to do so without encountering financial hardship, in order to improve adherence both to self-isolation [18,19] and to related behaviors (eg, testing) and to mitigate against adverse effects on mental health [20]. It is essential that people are aware of support available to them if they are self-isolating (eg, financial support scheme for people required to self-isolate), as this will remove some of the financial barriers associated with undergoing mass testing.

It is currently unclear the extent to which mass asymptomatic testing had an impact on cases or hospitalizations in Liverpool. As of December 9, 2020, one-quarter of the city's residents engaged in the pilot and took a lateral flow test. During this time, nearly 900 people were identified as positive [4]. Interestingly, the uptake of testing in Liverpool was considerably lower than a similar pilot in Slovakia, where nearly all eligible people engaged in testing [2]. This highlights the importance of evaluating acceptance of asymptomatic testing, specifically identifying barriers and motivators to undergoing mass testing. The work presented here could therefore provide valuable insights into barriers and facilitators to mass testing that could be used to inform the way in which these processes are managed in future and could potentially increase uptake with mass testing programs.

Recommendations

Based on the findings presented here, we suggest that, in order to promote good uptake of mass testing, authorities should communicate openly and honestly with communities, particularly about the nature and purpose of mass testing; provide clear instructions around practical aspects of testing (eg, details of site locations, how to access testing); provide financial support for self-isolation; listen to and address public concerns; engage with communities in order to understand their experiences; and ensure that communities know that their views are being taken into account (eg, where community engagement is taking place and being used to inform the response, this should be communicated).

Limitations

Although analysis of social media data and other online media can facilitate access to the perspectives of those who do not necessarily choose to participate in other types of research, there is the potential that the demographic composition of digital media users may differ from that of the wider population [21]. The first limitation of this study is therefore that we only collected the perspectives of people who opted to publish their thoughts online; consequently, the sample may not be representative of the wider population.

The pragmatic thematic analysis of a targeted sample of social and online media sites presented in this paper was carried out to provide rapid insights into public perceptions of mass testing. A second limitation of the study is therefore that the rapid nature of the research meant that there was no time to carry out checks of interrater reliability. We recommend that future studies employ web scraping tools to capture a greater quantity of data and that checks of interrater reliability are carried out wherever possible. While every effort was taken to increase the likelihood that comments collected in the data set were all expressed by Liverpool residents, there is no guarantee that the data set was entirely limited to Liverpool residents.

Conclusion

This study has highlighted several key barriers and facilitators to engaging in asymptomatic testing in residents in Liverpool city, including concerns over access, risk of transmission, and financial hardship. These structural barriers are amenable to mitigation and should be considered when rolling out similar testing programs elsewhere. We also identified psychosocial barriers, including lack of trust in authorities, which was associated with a sense of marginalization and disengagement with the testing program. This emphasizes the importance of recognizing and engaging with local community identity when implementing asymptomatic testing programs. We suggest that future implementation of mass testing programs should include honest and open communication to encourage and harness existing community identities, thereby enhancing the legitimacy of asymptomatic testing as a policy. In addition, adequate and accessible financial support needs to be in place prior to the implementation of community asymptomatic testing to mitigate any concerns surrounding financial hardship. Rapid thematic analysis of digital media is a pragmatic method to gather insights from communities around acceptability of public health interventions, such as mass testing or vaccination uptake. This methodological approach can complement other, more established approaches to ascertaining insights, such as surveys, interviews, and focus group discussions.

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Conflicts of Interest

None declared.

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Abbreviations

LCC: Liverpool City Council

MAST: mass, asymptomatic, serial testing

NHS: National Health Service

NIHR HPRU: National Institute for Health Research Health Protection Research Unit

PHE: Public Health England

UKHSA: United Kingdom Health Security Agency

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Original Paper

Analyzing Suicide Risk From Linguistic Features in Social Media: Evaluation Study

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Abstract

Background: Effective suicide risk assessments and interventions are vital for suicide prevention. Although assessing such risks is best done by health care professionals, people experiencing suicidal ideation may not seek help. Hence, machine learning (ML) and computational linguistics can provide analytical tools for understanding and analyzing risks. This, therefore, facilitates suicide intervention and prevention.

Objective: This study aims to explore, using statistical analyses and ML, whether computerized language analysis could be applied to assess and better understand a person's suicide risk on social media.

Methods: We used the University of Maryland Suicidality Dataset comprising text posts written by users (N=866) of mental health-related forums on Reddit. Each user was classified with a suicide risk rating (no, low, moderate, or severe) by either medical experts or crowdsourced annotators, denoting their estimated likelihood of dying by suicide. In language analysis, the Linguistic Inquiry and Word Count lexicon assessed sentiment, thinking styles, and part of speech, whereas readability was explored using the *TextStat* library. The Mann-Whitney *U* test identified differences between at-risk (low, moderate, and severe risk) and no-risk users. Meanwhile, the Kruskal-Wallis test and Spearman correlation coefficient were used for granular analysis between risk levels and to identify redundancy, respectively. In the ML experiments, gradient boost, random forest, and support vector machine models were trained using 10-fold cross validation. The area under the receiver operator curve and F_1 -score were the primary measures. Finally, permutation importance uncovered the features that contributed the most to each model's decision-making.

Results: Statistically significant differences ($P<.05$) were identified between the at-risk (671/866, 77.5%) and no-risk groups (195/866, 22.5%). This was true for both the crowd- and expert-annotated samples. Overall, at-risk users had higher median values for most variables (*authenticity*, *first-person pronouns*, and *negation*), with a notable exception of *clout*, which indicated that at-risk users were less likely to engage in social posturing. A high positive correlation ($\rho>0.84$) was present between the part of speech variables, which implied redundancy and demonstrated the utility of aggregate features. All ML models performed similarly in their area under the curve (0.66-0.68); however, the random forest and gradient boost models were noticeably better in their F_1 -score (0.65 and 0.62) than the support vector machine (0.52). The features that contributed the most to the ML models were *authenticity*, *clout*, and *negative emotions*.

Conclusions: In summary, our statistical analyses found linguistic features associated with suicide risk, such as social posturing (eg, *authenticity* and *clout*), *first-person singular pronouns*, and *negation*. This increased our understanding of the behavioral and thought patterns of social media users and provided insights into the mechanisms behind ML models. We also demonstrated the applicative potential of ML in assisting health care professionals to assess and manage individuals experiencing suicide risk.

KEYWORDS

evaluation study; interdisciplinary research; linguistics; machine learning; mental health; natural language processing; social media; suicide risk

Introduction

Background

Suicide is one of the leading causes of death worldwide [1] and is an international public health problem. The World Health Organization estimates that approximately 800,000 people die because of suicide every year, and global targets to reduce suicide mortality are unlikely to be met [2].

Effective suicide risk assessment screening methods are key to reducing this preventable cause of death [3,4]. Traditional approaches to suicide risk assessment include a comprehensive clinical evaluation and the use of self-reported measures, including the Columbia Suicide Severity Rating Scale, Patient Health Questionnaire, and other measures that screen for depression and psychological distress [1,5,6]. Although these approaches provide the best practice for suicide risk assessment, not all people experiencing thoughts of suicide or suicidal ideation disclose their risk or have access to health care professionals.

In addition, people experiencing suicide risk may not seek mental health support [7,8], and for those who do, the demand for clinicians often exceeds the supply, especially in remote areas where access to health care professionals is limited [9]. Therefore, an automated risk detection tool, or a deeper understanding of the linguistic features associated with suicide risk, could allow individuals to assess their own risk of suicide. This may prompt them to seek support and, in turn, increase suicide prevention.

Social Media and Suicide Risk Detection

Suicidal ideation has been widely documented on social media [10]. As these platforms provide individuals with an outlet to express their innermost thoughts [10], social media data offer new ways of understanding and assessing suicide risk. Hence, this creates novel possibilities for suicide assessment, intervention, and prevention [11].

Reddit, a web-based forum with >52 million daily users, offers particularly rich data. This is because of several reasons. First, it has a high character limit of 40,000 per post, which is a notable increase from other social media sites such as Twitter (280 characters), allowing users to write linguistically richer posts. Second, the website has the potential to be anonymous. Users can make *throwaway* accounts—temporary identities separate from their main accounts—to uninhibitedly discuss sensitive topics and emotions. This feature has been proven to promote open conversations and emotionally engaging feedback [12], thus making it ideal for suicide risk detection studies. Finally, Reddit's structure is advantageous. The website is made up of subforums (subreddits) that are topic specific. This allows researchers to preselect data from mental health-related

subreddits, identifying users who potentially express suicide risk.

Machine Learning for Mental Health

In recent years, there has been increased interest in using machine learning (ML) to detect mental health conditions, including depression [13]. However, such studies often focus primarily on the performance of the classifier rather than on processes that underpin or explain its classification decisions [14].

This raises a key problem. ML models are often opaque, with *black box* models such as neural networks being largely uninterpretable [15]. This highlights a clear need for increased interpretability and understanding of the features themselves. Model-agnostic methods for understanding the feature importance include permutation importance [16] and Shapley Additive Explanations [17]. Such techniques are beneficial as they help us understand not only the outcomes but also the mechanisms behind the models themselves.

Research Objectives

This study aimed to examine the relationship between linguistic features and indicators of users' suicide risk on Reddit, thereby increasing interpretability. In addition to identifying statistically significant relationships, this study explored the contributions of the features to classifications by constructing ML models and permutation importance analysis.

Our main contributions are as follows: (1) we conducted nonparametric statistical analysis to identify linguistic features significantly associated with suicide risk; (2) we performed correlation analysis to identify relationships between significant features, thus identifying redundancies; (3) we built several ML models using linguistic features, highlighting the potential for future application; and (4) we measured the features that contributed the most to each model's decision-making through permutation importance analysis.

Methods

Data Selection and Access

In this work, we used the existing University of Maryland Suicidality Dataset [9,18]. This comprised social media posts annotated by mental health experts and crowdsourced annotators with respect to the author's suicide risk.

We chose this source for the following 3 main reasons.

First, it was extracted from the web-based Reddit forum. As stated earlier, Reddit has a generous character limit that allows greater linguistic complexity. Thus, it would be ideal to explore our first research question.

Second, another benefit of this data set was its high-quality annotations. A prevalent problem with social media data is the

reliability of ground truth labels; it is difficult to determine whether a web user is actually at risk in real life. Annotators are often inaccurate, even when label definitions are shown [19]. The Maryland data set alleviated this issue in several ways. To begin with, the researchers preselected at-risk (low-, moderate-, and severe-risk) users by identifying people who posted on mental health-related forums (eg, SuicideWatch). Furthermore, the annotation process was completed by mental health experts and crowdsourced annotators. Consensus mechanisms (eg, multiple annotators for each user) were also used.

Ethics Approval

The University of Maryland Suicidality Dataset [9,18] was approved for use by the Australian National University Human Research Ethics Committee (protocol number 2021/047). This was followed by obtaining proper permission to access and use it for the purposes of this study from the University of Maryland.

Data Overview

Reddit is a web-based forum designed to help people “detach from their real-world identities” [20]. The Maryland data set comprises text posts written by 934 unique users of this website—specifically, posts published on the SuicideWatch subforum from January 1, 2008, to August 31, 2015. It includes posts from both SuicideWatch and users’ other non-mental health-related posts. In addition, users who did not post on any mental health-related forum [21] were included as a control group.

Although Reddit is intended to be anonymous, users may provide personal identifying information. Thus, this data set was further anonymized by replacing each username with a token, as well as by replacing all URLs [9,18].

Annotation Process

The Maryland researchers annotated the data set as follows. First, posts written by a given user were temporally organized and split into annotation units. These contained up to 5 posts each. Each unit was then annotated with a suicide risk rating by either medical experts or crowdsourced contributors. Experts were given *short* instructions asking them to follow their formal training in assessing patients at risk of suicide. Meanwhile, the crowdsourced annotators were given *long* instructions that asked

them to focus on risk factors such as thoughts (eg, suicide ideation and feeling like a burden), thought patterns (eg, sense of agitation), logistics (eg, talking about methods of attempting suicide), and context (eg, previous attempts and isolation from family and friends) [9,18].

Ratings were on a 4-point risk scale as follows [9]: (1) no risk (“I don’t see evidence that this person is at risk for suicide”), (2) low risk (“There may be some factors here that could suggest risk, but I don’t really think this person is at much risk of suicide”), (3) moderate risk (“I see indications that there could be a genuine risk of this person making a suicide attempt”), and (4) severe risk (“I believe this person is at high risk of attempting suicide in the near future”).

Users with <10 posts and users whose posts had <3 annotators were eliminated from the data set by the Maryland researchers. This resulted in a final sample size of 866 unique users who posted on SuicideWatch, which is described by Reddit as a peer support forum for anyone struggling with suicidal thoughts. There was also an equal number of unannotated control users (n=866). Of the 866 annotated users, 245 (28.3%) were labeled by experts, whereas 621 (71.7%) were disjointly labeled by crowdsourced contributors.

The expert annotators included multiple mental health professionals. These included a cochair of the National Suicide Prevention Lifelines Standards, Training and Practices Sub-Committee, and a clinician in the Department of Emergency Psychiatry at Boston Children’s Hospital [9,18]. To generate user-level annotations, maximum likelihood estimation was used [22,23]. Overall, the average Krippendorff interannotator agreeability α was .812.

In contrast, the crowdsourced task was completed on the web-based platform, CrowdFlower. The website’s inbuilt consensus mechanism was used to resolve disagreements among crowdsourced annotations [18]. Each user was assigned a *trust score*, which indicated their reliability. Annotations were then weighted by this trust score and aggregated into a *confidence score* for each label. The label with the highest confidence score was chosen. This resulted in a Krippendorff α of .554.

An example of a typical post is presented in (Table 1). To preserve user privacy, the post body was an aggregate of several existing posts, and the subreddit was randomly chosen.

Table 1. Example of a typical Reddit post from the data set and the suicide rating.

Features	Value
Post ID	1a2b3c
User ID	45678
Time stamp (Unix epoch)	1.4E+09
Subreddit	r/self-harm
Post body	“I’ve been feeling depressed for a while. I don’t know how to deal with it anymore...”
Label	Severe risk

Data Preprocessing and Linguistic Feature Engineering

In our research, we randomly split the data into an 80:20 training-test ratio following the Pareto principle [24]. This was

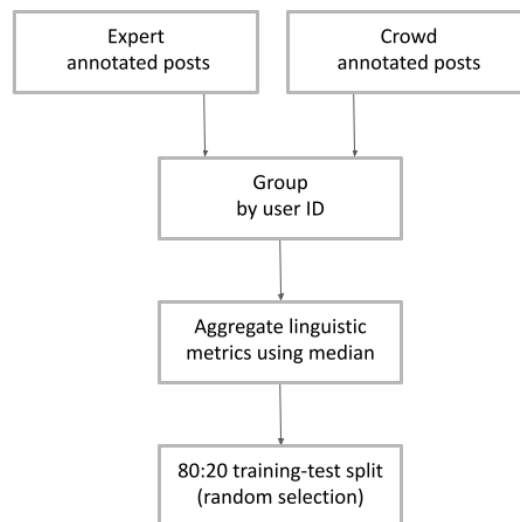
achieved by randomly selecting 80% of the user IDs from both the crowd- and expert-annotated data sets. All posts associated with the users were then retrieved. In addition, unannotated

control users and posts without any text were discarded. For the ML models, expert- and crowd-annotated users were combined into singular training and test sets to maximize the available data. Meanwhile, the statistical analysis was performed on the expert and crowd data sets separately to compare the distributions of the different groups.

Linguistic features for users were aggregated by taking the average of all the posts (Figure 1). The median rating was used instead of the mean rating to reduce the influence of outliers. Overall, we chose to group according to users to reflect the annotation process, as ratings were attached to a user rather than an individual post.

Linguistic Inquiry and Word Count (LIWC) 2015 and the *TextStat* Python library were used to extract linguistic features from posts. All the LIWC and *TextStat* features are listed in Multimedia Appendix 1 and Multimedia Appendix 2, respectively.

Figure 1. Flowchart detailing the data preprocessing stages.



Statistical and Correlation Analyses

Statistical and correlation analyses were designed and reported in consultation with the Australian National University Statistical Consultation Unit.

Statistical errors because of the assumption of normality are common in quantitative studies [33]. To mitigate this, we used the Shapiro-Wilk test [34] from *scipy.stats*. The analysis revealed that none of the features were normally distributed. Hence, nonparametric tests were used to compare the distributions of different risk groups.

First, a 2-sided Mann-Whitney *U* test was used to compare at-risk and no-risk users. This test was chosen because of its nonparametric nature and previous applications in medical studies [35]. To form this binary grouping, users who received either a severe-, moderate-, or low-risk rating were considered at risk. Meanwhile, users who received a no-risk rating formed their own group.

To supplement these results, we used the Kruskal-Wallis test. This compared the distribution of features within different risk

LIWC is a lexicon [25] that groups words into psychologically meaningful categories. Aside from aggregate features such as *authenticity*, the scores for most features were the percentage of total words in a text that belonged to a specific category. Prior studies have demonstrated the capacity of LIWC to detect emotionality [26,27], thinking styles [28], and individual differences [29,30]. Moreover, it has been used to detect self-reported symptoms of depression and other mental health conditions [31,32]. In this study, all the categories were used to ensure comprehensive coverage.

In juxtaposition, *TextStat* is a computerized analysis tool that measures linguistic complexity. This package was selected because it contains both simple features such as word count and widely used linguistic readability metrics such as the Gunning Fog Index, Simple Measure of Gobbledygook, and Flesch-Kincaid scores.

levels. This analysis allowed us to determine whether the severe-, moderate-, and low-risk groups behaved differently.

For both tests, we used an α value of $P < .05$. To correct for multiple comparisons, we applied the Benjamini-Hochberg procedure [36] to the *P* values. We calculated 95% CIs to estimate the difference between medians using the Mann-Whitney *U* test. In addition, although post hoc methods (eg, Dunn test) for the Kruskal-Wallis test can be calculated to determine which specific medians are different, these were not computed in this work, as this was largely observed through the use of comparative box plots. Python (*scipy.stats* and *scipy.statsmodels*) and R (*wilcox* and *kruskal*) libraries were used for the implementation.

To reach a consensus between the expert- and crowd-annotated data sets, the features needed to have *P* values of $< .05$ and the same directionality to be labeled as *significant* in the Mann-Whitney *U* and Kruskal-Wallis tests. In addition, features with 95% CIs that included 0 were eliminated. This was because of 2 main reasons.

First, crowdsourced annotators were less reliable than experts. As they had less training, they had a lower macro F_1 -score, with

a tendency to misclassify lower-risk users as having higher risk [9].

Second, the distribution of features could be different because of random variation. Although this does not necessarily mean that features that are only significant in one data set are not significant overall, it does suggest that the distributions are noticeably different. Therefore, it would be inappropriate to compare them.

A correlation analysis was also used to identify redundancies. This was because, in a practical context, having too many features limits interpretability and increases the computational complexity. For instance, if there are thousands of features, even if we know the weighted contribution of each feature, it is still extremely difficult to fully understand ML models and their classifications [37]. Hence, we identified relationships between significant features to determine potential proxies on both the expert- and crowd-annotated data sets, with P values corrected using the Benjamini-Hochberg procedure. We selected the Spearman correlation coefficient because of its nonparametric nature [38] and established use in medical research [39].

ML Models, Their Performance Evaluation, and Feature Importance Analysis

To determine whether the features would prove useful for risk assessment, we constructed several preliminary ML models that classified whether a user was at risk or had no risk. For this project, we used random forest (RF) [40], gradient boost (GB) [41], and support vector machines (SVMs) [42]. These techniques were selected because of their application in mental health research [43]. All LIWC and *TextStat* features were used to train the models.

An SVM is a supervised ML algorithm. It classifies data by representing each data point as a vector and fitting a hyperplane that separates the different classes [42]. In a 2D context, this is equivalent to fitting a dividing line through the data. Intuitively, an optimal hyperplane in such a fitting should be approximately at the center of the 2 classes. For SVMs, this is determined by calculating the distance between the hyperplane and the closest data points from each class. The hyperplane that maximizes this distance, or the maximum-margin hyperplane, is selected [42]. As not all data are linearly separable [44], SVMs use a kernel function in classification problems, a mathematical operation that performs the equivalent of mapping a lower-dimensional space to a higher dimension [45]. Ideally, this higher-dimensional projection should help make the data separable and, therefore, classifiable.

Decision trees are nonparametric and supervised learning methods. They work by splitting the root node, which represents the entire data set, into branch-like segments based on the values of their features. This continues until all the data are matched to a leaf node, which represents a class label [46]. Splitting is determined by the *purity* of the split, which is measured by metrics such as the information gain, gini index, and gain ratio [47].

Fundamentally, the algorithm tries to split the data so that the data points in each branch belong to the same class. However,

a problem with decision trees is that they are prone to overfitting [48]. Hence, a common way of addressing this problem is through ensemble methods that combine multiple smaller classifiers into a single classifier [49].

The RF method is a prime example of an ensemble method. It works by drawing k random subsamples of the data and fitting decision trees to each subsample. When presented with a new data point, each of the k decision trees casts a vote for the class label. The final label is determined by the results of the majority vote [40].

GB is another decision tree-based ensemble method. However, in contrast to RF, GB functions in an additive manner [50]. Fundamentally, this implies that each of the k decision trees is iteratively trained. The first decision tree is fitted to the training data, and the error is calculated. Following this, data points that were incorrectly classified will be given a higher weight, so that the following model can address the deficiencies of the previous model [41]. After all the weak learners have been trained, the final class label is determined by a weighted majority vote, with votes from more successful learners being more important.

As noted above, an 80:20 training-test split was used. The class distribution was as follows. In the training set, there were 63% (546/866) at-risk and 16.4% (142/866) no-risk users. A similar distribution was observed in the test set, with 14.4% (125/866) at-risk and 6.1% (53/866) no-risk users. To find the optimal hyperparameters and reduce overfitting [51], we used 10-fold cross validation [52] on the training set. The area under the receiving operator curve (AUC) was used as the primary scoring metric for validation because of increased discrimination and consistency [53,54]. To evaluate the performance on the test set, a more diverse range of metrics, including the AUC and accuracy, as well as the precision, recall, and F_1 -score, were used to balance the trade-off between sensitivity and specificity [55]. Finally, confusion matrices [56] provided visualizations of true and false positives, as well as negatives on the test set.

Although univariate statistical tests can uncover relationships between linguistic variables and suicide risk, they might not indicate the importance of features in a given ML model. Hence, to better understand our models' decision-making process, we analyzed the permutation importance of each feature [16]. This examined the decrease in an existing model's score over a given number of iterations when the values of a single feature were randomly reordered. We implemented this using the Python *sklearn* library.

Features were considered important for a given model if a large decrease was observed and vice versa. For the purposes of this research, we calculated the permutation importance over 100 iterations on a holdout test set and used AUC, precision, and recall as the scoring mechanisms. Only variables with mean permutation importance values >1 SD away from 0 were considered significant.

Results

Mann-Whitney U Test

At-risk (low-, moderate-, and severe-risk) users had, on average, a greater use of *authenticity*, *first-person singular pronouns*, and *negation* (Multimedia Appendices 3 and 4). They also had lower *clout* (Tables 2 and 3). This suggests that, overall, they were more authentic in their expression and engaged less in

social posturing (*authenticity* and *clout*). For brevity, all tables show only statistically significant values ($P < .05$) after applying the Benjamini-Hochberg correction, with the mean and CIs rounded to 4 significant figures.

This observation was also reflected visually. The box plots, which show that the overall distributions, in addition to the central measures such as the mean and median, were skewed further left for the at-risk users (Figures 2 and 3). Again, the inverse was observed for *clout* (Figures 4 and 5).

Table 2. Mann-Whitney U test results for expert-annotated users.

Feature	Examples	At-risk, mean (SD)	No-risk, mean (SD)	P value	95% CIs for differences between medians
Clout	N/A ^a	36.81 (16.62)	48.21 (11.48)	.005	-17.83 to -6.590
Authenticity	N/A	64.82 (21.31)	47.35 (20.86)	.005	10.04 to 27.09
First-person singular pronouns	I, my, and mine	7.105 (2.979)	5.419 (2.194)	.04	0.6900 to 2.840
Negation	Not, no, and never	1.391 (0.8524)	0.7924 (0.6987)	.01	0.2250 to 0.9650

^aN/A: not applicable.

Table 3. Mann-Whitney U test results for crowd-annotated users.

Feature	Examples	At-risk, mean (SD)	No-risk, mean (SD)	P value	95% CIs for differences between medians
Clout	N/A ^a	32.00 (15.71)	40.48 (16.42)	<.001	-12.29 to -5.315
Authenticity	N/A	71.66 (19.57)	58.73 (20.18)	<.001	9.985 to 17.75
First-person singular pronouns	I, my, and mine	8.346 (2.902)	6.738 (2.579)	<.001	1.120 to 2.195
Negation	Not, no, and never	1.717 (1.072)	1.284 (1.031)	.001	0.1500 to 0.6000

^aN/A: not applicable.

Figure 2. Box plot for authenticity for at-risk and no-risk users (expert).

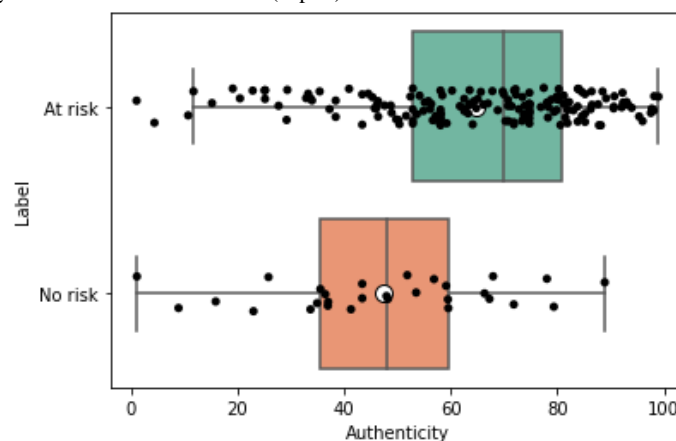


Figure 3. Box plot for authenticity for at-risk and no-risk users (crowd).

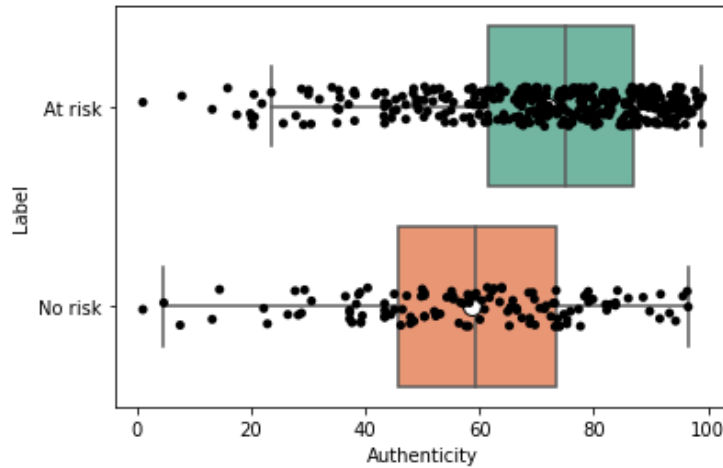


Figure 4. Box plot for clout for at-risk and no-risk users (expert).

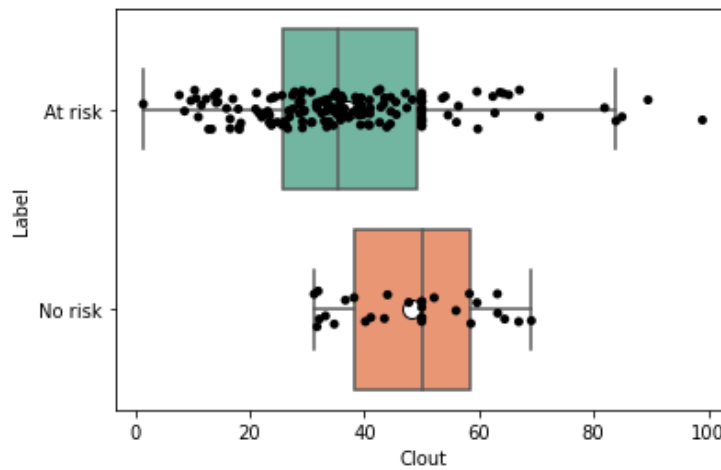
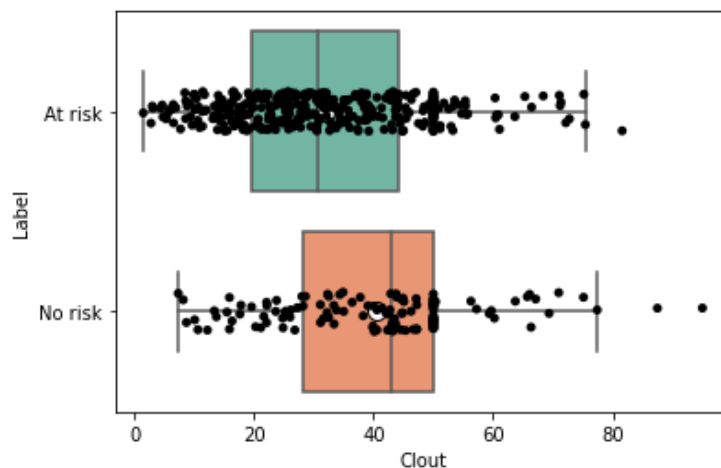


Figure 5. Box plot for clout for at-risk and no-risk users (crowd).



Kruskal-Wallis Test

When comparing the severe-, moderate-, low-, and no-risk groups (Multimedia Appendices 5 and 6), no LIWC or *TextStat* features were significant ($P < .05$) for both the expert- and crowd-annotated data sets after correction. This indicates that although certain linguistic variables are associated with at-risk versus no-risk groups, there are no significant differences within the at-risk groups themselves.

Correlation Analysis

Using the Spearman correlation coefficient (Multimedia Appendices 7-10), we found the following.

For LIWC, various parts of speech (eg, *function words* and *pronouns*; $\rho > 0.74$ and 0.84 [unless otherwise specified, the first ρ is the correlation coefficient on the crowd-annotated data set, whereas the second is for the expert-annotated data set; all

figures have been rounded to 2 significant figures]) were highly correlated with each other, indicating redundancy.

In addition, many parts of speech also had moderate correlations with variables measuring post length, such as syllable count (eg, *comparatives*; $\rho > 0.50$ and 0.63) and word count (eg, *focus on the future*; $\rho > 0.59$ and 0.67). This suggests that they could be proxies of length. Intuitively, this association was understandable, as the longer the post, the more parts of speech it will have.

Some features such as *clout* and *authenticity* appeared to be aggregate features, combining other variables, as shown through moderate positive correlations with other variables (eg, *authenticity* and *function words*; $\rho > 0.47$ and 0.59). This was in line with the LIWC manual [57] and suggested that overall, aggregate features could be an efficient way of condensing information. Visual and statistical evidence provided additional support for this conclusion. When examining the box plots (Figures 2-5), we found that the aggregate measures were generally more discernible than individual categories. Furthermore, the P values tended to be smaller ($P < .01$), and the distance between medians also tended to be greater (Tables 2 and 3).

Table 4. Summary of classification results of various machine learning models^a.

Models	AUC ^b	Accuracy	Precision	Recall	F_1 -score
Gradient boost	0.67	0.62	0.61	0.67	0.62
Random forest	0.66	0.75	0.65	0.66	0.65
Support vector machine	0.68	0.53	0.64	0.68	0.52

^aThe precision, recall, and F_1 -scores are the macroaverage of the different classes.

^bAUC: area under the receiving operator curve.

Permutation Importance

A noticeable overlap was present in the features that had higher permutation importance for the GB and RF models (Table 5), with *authenticity*, *negative emotion*, and *clout* contributing to higher precision and AUC (*authenticity* and *negative emotion* only) for both models. Meanwhile, the SVM yielded different results, having no common significant features with other

Model Performance

Overall, all models showed great promise in identifying suicide risk and achieved a similar performance (Table 3; Multimedia Appendices 11 and 12). Most errors lay in a tendency to overassign to the at-risk category. As type II errors are preferable to their type I counterparts in the medical domain, this demonstrated that LIWC and *TextStat* features are effective for building ML risk assessment models.

The performances of all models were largely comparable, with the AUCs for the GB, RF, and SVM models being 0.67, 0.66, and 0.68, respectively. Furthermore, when looking at performance evaluation outcomes (Table 4; Multimedia Appendices 11 and 12), all models were better at classifying at-risk users, with the RF model having the highest performance (F_1 -score of 0.83) for this class. This was most likely because of the imbalanced nature of the data, with more users being at risk than not because of the selection process. It should be noted that the SVM, in particular, performed worse on the no-risk class, as indicated by its noticeably lower F_1 -score (0.52). This implies that it is less useful in practice.

models. However, as noted earlier, the SVM model had a notably lower performance (F_1 -score) than the other 2 models. The permutation importance only measures the importance of a feature for a given model. Hence, if a model did not perform well, its permutation importance analysis results were not necessarily reliable. Thus, rather than showing that the aforementioned features were not important, this disparity could be an indicator of model quality.

Table 5. Permutation importance results for AUC^a, precision, and recall.

Features	Gradient boost, mean (SD)	Random forest, mean (SD)	Support vector machine, mean (SD)
AUC			
Authenticity	0.071 (0.041)	0.041 (0.027)	N/A ^b
Negative emotion	0.034 (0.024)	0.017 (0.01)	N/A
Clout	0.02 (0.016)	N/A	N/A
Whitespace	N/A	N/A	0.01 (0.005)
Precision			
Authenticity	0.057 (0.026)	0.030 (0.013)	N/A
Clout	0.018 (0.013)	0.035 (0.012)	N/A
Negative emotion	0.016 (0.014)	0.020 (0.011)	N/A
First-person singular pronouns	N/A	0.015 (0.008)	N/A
Quantitative processes	N/A	N/A	0.014 (0.010)
Informality	N/A	N/A	0.011 (0.008)
Recall			
Negative emotion	N/A	0.022 (0.015)	N/A
Positive emotion	N/A	0.021 (0.011)	N/A
Question mark	N/A	0.016 (0.007)	N/A
Affect	N/A	0.013 (0.008)	N/A
Function words	N/A	0.013 (0.008)	N/A
Colon	N/A	N/A	0.011 (0.004)
Ingest	N/A	N/A	0.01 (0.005)

^aAUC: area under the receiving operator curve.

^bN/A: not applicable.

Discussion

Principal Findings and Prior Work

A key finding was that linguistic features were significantly ($P < .05$, 95% CIs) associated with suicide risk on social media. This was achieved using nonparametric statistical analysis. Significant variables included social (*authenticity* and *clout*) and grammatical (*first-person singular pronouns* and *negation*) features (Tables 2 and 3). This confirmed prior studies linking suicide risk and depression to the increased use of first-person pronouns [31,58,59].

In addition to complementing prior work [31,58,59], our contribution provided novelty by examining the directionality and distribution of features at a finer granularity. We found that at-risk users tended to be more authentic and less concerned about social posturing (Tables 2 and 3). Overall, at-risk users had a larger median value than no-risk users for most features. However, there was no real difference between the distributions of the significant variables for low-, moderate-, and severe-risk users.

Another notable finding was the identification of redundant features such as various parts of speech. Although numerous studies have examined the relationship between linguistic features and adverse mental health [58,59], few statistically

examined the correlation between the significant features themselves. Moreover, although there are mathematical methods [17,60] for determining feature importance, these techniques are not widely used in the health sciences. Hence, established methods such as the Spearman correlation coefficient may be easier for clinicians to interpret.

Through correlation analysis, we found moderate positive relationships between readability metrics (eg, *Gunning Fog Index*; $\rho > 0.77$ and 0.76), parts of speech (eg, *comparatives*; $\rho > 0.50$ and 0.63), and post length (eg, *syllable*, *word*, and *sentence count*). This indicates that the underlying feature, length, could potentially be used in favor of its proxies. Moreover, using aggregate variables such as *clout* and *authenticity* may further increase computational efficiency. Not only do they combine more detailed categories, but they may also be better at discerning risk levels because of the increased differences between medians.

Another contribution was the demonstration that linguistic features alone could be used to create effective ML models (GB, RF, and SVMs). After hyperparameter tuning, the models achieved commendable AUCs ranging from 0.66 to 0.68 and F_1 -scores ranging from 0.52 to 0.65. This received at par, if not better, performance than other lexical feature-based models whose AUC and F_1 -scores ranged from 0.51 to 0.75 [61] and from 0.20 to 0.32 [62], respectively. In addition, all models had

a markedly better F_1 -score for the at-risk group (Multimedia Appendices 11 and 12). As failing to identify a person with high suicide risk could lead to loss of life, a more conservative model is advantageous for suicide prevention.

Finally, we used permutation importance to identify the features that contributed the most to each model's decision-making. Through this analysis, we found that *authenticity* and *negative emotion* contributed to higher AUC and precision scores for both the GB and RF models, whereas *clout* contributed to a higher precision for the models. This indicated that such features could potentially be important indicators of suicide risk.

Reproducibility

As we are not the data set owners, we will not be able to provide it upon request. Thus, all applications for data access should be directed at the University of Maryland, following their formal request protocol.

By nature, ML for mental health is a sensitive research area. Hence, the source code for our experiments and the parameters of the classifiers will be made available upon reasonable request, with a justification for the intended use. All code distribution will be under the Massachusetts Institute of Technology license.

Limitations

Our study had 4 primary limitations. First, the observational nature of the study should be noted. Owing to privacy concerns, the University of Maryland Suicidality Dataset does not have ground truth labels, and we were unable to confirm whether users labeled as at risk were in fact experiencing suicidal ideation. In addition, it should be acknowledged that a person experiencing suicidal ideation may not be at risk of suicide, and people on the SuicideWatch forum may be affected by suicide through a family member or friend and not be experiencing suicide risk themselves. However, these confounds are likely to have been mitigated by expert annotation and consensus mechanisms.

Second, another limitation was the granularity of the annotations. Annotations were attached to each user and not to each post. Hence, we did not know which posts were more important and used aggregated features to train the models. Therefore, the performance could have potentially been further improved with finer-grained annotations.

Our third main limitation was the use of only linguistic features to train the models. As demonstrated by prior work, behavioral and relational analyses may further improve automated screening for suicide risk [35,63]. However, having a production-ready model was not the aim of this study. Instead, we aimed to determine whether simpler interpretable models could be used to screen for suicide risk. This was done to ensure that the models were accessible to health care professionals. Hence, *black box* ML methods such as deep learning and nonlexical features were not considered.

Our final limitation was the use of permutation importance to indicate the feature importance. As previously stated, permutation importance indicates only the importance of a feature for a particular model. Hence, it is arguably limited by the effectiveness of the models.

Future Work

This study focused on highlighting the usefulness of linguistic features in constructing ML models. Hence, only lexical features were used. However, prior studies [35,63] indicate that features based on behavioral data and metadata can be used to enhance performance. Therefore, before deploying our model for production, the inclusion of a more varied range of features could be investigated. It would also be interesting to explore deep learning as this would help us evaluate whether latent variables could further increase performance.

The usefulness of our findings in practice and how they relate to suicide assessment, intervention, and prevention could also be examined. This can be done in two ways: (1) exploring the use of ML-based models to support risk assessment on social media sites themselves and (2) investigating the integration of our work into clinical practice.

With regard to existing interventions on social media, in March 2020, Reddit developed *Reddit Care Resources*—an initiative aimed at providing mental health resources to users at risk of suicide or self-harm [64–66]. This method operates in 2 ways. First, if a user searches for certain keywords (eg, “suicide” and “kill myself”), the first result displayed is a post indicating where to find mental health support (Figure 6). Second, users can confidentially report other users who they believe are at risk of suicide or self-harm, which then connects them to trained crisis counselors [64,65].

Although these changes mark an increasing awareness of mental health and suicide risk, these measures could still be improved. For instance, the list of keywords that triggers *Reddit Care Resources* is limited, with searches for “depression,” “self-harm,” or “anorexia” not prompting this intervention (Figure 7).

ML models, such as those used in this study, could help alleviate this problem. For example, Reddit could run such models on searches and posts, prompting *Reddit Care Resources* to pop up if a certain risk threshold is met. This would eliminate the need to constantly expand the mental health–related keyword list, as internet slang and neologisms (eg, “proana” for “pro-anorexia”) can make it difficult to record every word related to mental health.

Examining how our work can be integrated into clinical practice would also be meaningful. Social media can offer an outlet for people to express opinions and thoughts that they may find difficult to express face to face [12]. Hence, analysis of such posts by a health care professional may allow for a deeper understanding of their clients if informed consent is granted. However, a problem is that directly reading such posts may result in an unintentional breach of confidentiality [67]. For instance, if a client shares web-based posts with a health care professional that includes self-harm or abuse, they may be required to report this as part of their duty of care and mandatory reporting obligations [67].

Using a combination of ML and linguistic features (eg, LIWC and *TextStat*), as demonstrated in this work, could help address this problem. Being very time poor, health care professionals do not have time to read through social media posts. Instead,

with consent, automated methods could provide a report that summarizes suicide risk and other clinically relevant information, including the affective (eg, *emotional tone*), cognitive (eg, *discrepancy* and *certainty*), and social aspects (eg, *clout* and *authenticity*) of posts. This preserves client privacy while using ML to extract important clinical information that can potentially enhance client engagement and care. Furthermore, coproduction approaches with mental health experts and people with lived experience of suicide risk would help identify user and system requirements. This, in turn, would facilitate the development of future software apps (eg, desktop and mobile).

A final future development would be to diversify the annotated data sets. The University of Maryland Suicidality Dataset was

unique because of its expert annotation and heightened levels of reliability; however, it has some limitations. For example, the demographics of Reddit tend to skew toward young and male [68-70], which is not representative of the world's population. Hence, gathering a wider and more varied data set would increase the generalizability of our work. Moreover, it may be helpful to further increase the granularity of annotations. There are 2 main reasons for this. First, it would help us understand which text posts contributed the most to an annotator's decision. Second, it would allow us to examine the fluctuation of risk within an individual, as a person identified as at risk may no longer be at risk at another point in time. These additions would likely allow us to achieve more informed results.

Figure 6. Screenshot of Reddit Care Resources.

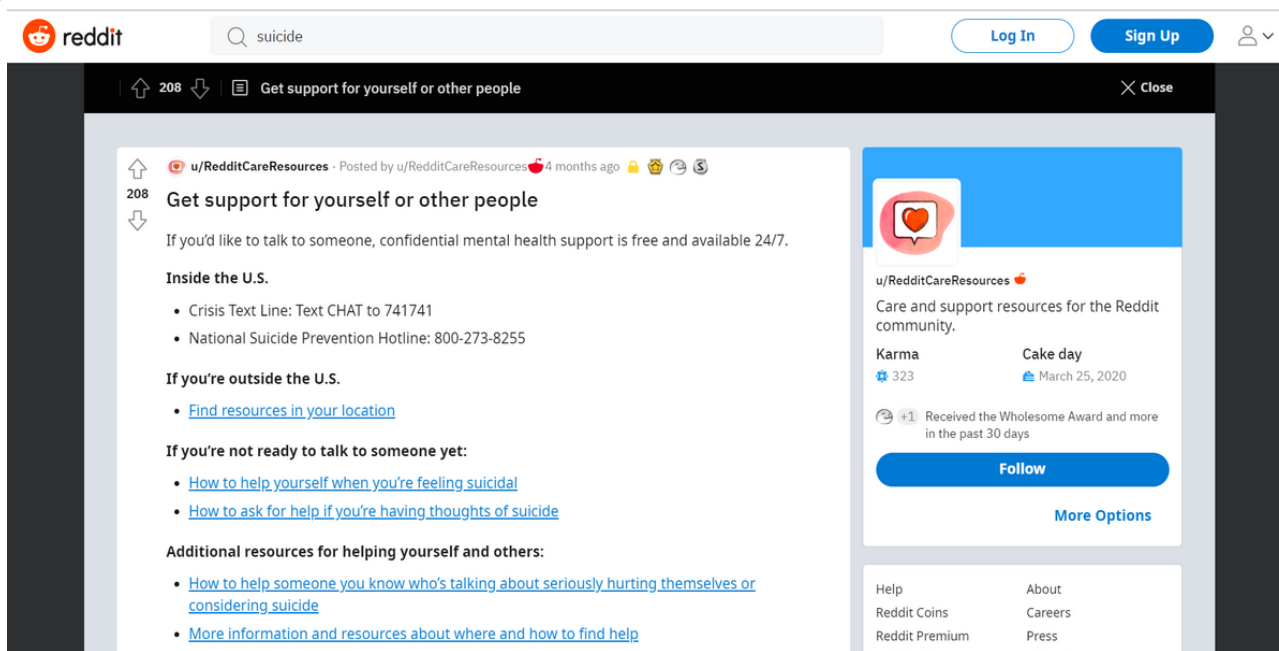
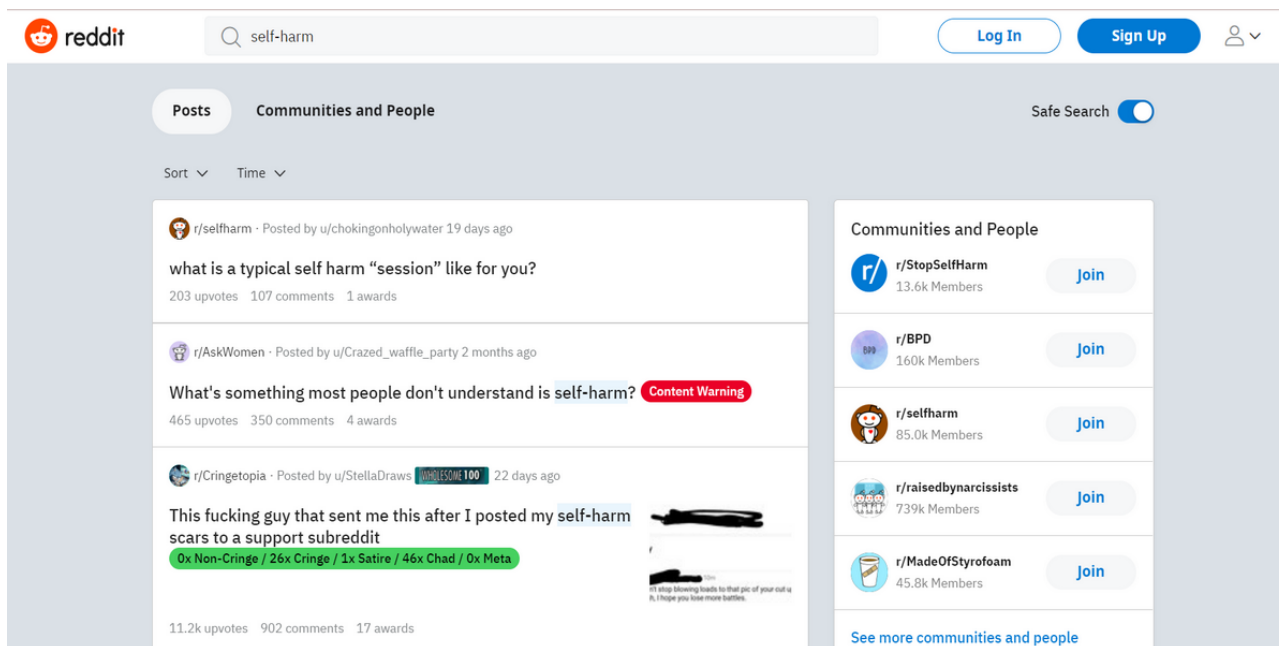


Figure 7. Screenshot of search results for “self-harm”.



Conclusions

In this study, we demonstrated the potency of linguistic features in supporting suicide risk assessment through social media posts. Through statistical and permutation analyses, we were able to determine features significantly related to suicide risk, features

that contributed the most to risk classifications, and redundancy through feature relationships. Finally, the commendable performances of the SVM, GB, and RF models highlight the utility of lexical features alone. This suggests that with future development, these models could be highly useful tools to help enhance clinical care.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Full glossary of Linguistic Inquiry and Word Count features.

[\[DOCX File, 28 KB - formative_v6i8e35563_app1.docx\]](#)

Multimedia Appendix 2

Full glossary of TextStat features.

[\[DOCX File, 20 KB - formative_v6i8e35563_app2.docx\]](#)

Multimedia Appendix 3

Full list of corrected P values for the Mann-Whitney U test (expert).

[\[XLSX File \(Microsoft Excel File\), 12 KB - formative_v6i8e35563_app3.xlsx\]](#)

Multimedia Appendix 4

Full list of corrected P values for Mann-Whitney U test (crowd).

[\[XLSX File \(Microsoft Excel File\), 13 KB - formative_v6i8e35563_app4.xlsx\]](#)

Multimedia Appendix 5

Full list of corrected P values for the Kruskal-Wallis test (expert).

[\[XLSX File \(Microsoft Excel File\), 12 KB - formative_v6i8e35563_app5.xlsx\]](#)

Multimedia Appendix 6

Full list of corrected P values for the Kruskal-Wallis test (crowd).

[\[XLSX File \(Microsoft Excel File\), 13 KB - formative_v6i8e35563_app6.xlsx\]](#)

Multimedia Appendix 7

Spearman correlation coefficients for Linguistic Inquiry and Word Count and TextStat features (expert).

[\[XLSX File \(Microsoft Excel File\), 159 KB - formative_v6i8e35563_app7.xlsx\]](#)

Multimedia Appendix 8

Spearman correlation coefficient–corrected P values for Linguistic Inquiry and Word Count and TextStat features (expert).

[\[XLSX File \(Microsoft Excel File\), 162 KB - formative_v6i8e35563_app8.xlsx\]](#)

Multimedia Appendix 9

Spearman correlation coefficients for Linguistic Inquiry and Word Count and TextStat features (crowd).

[[XLSX File \(Microsoft Excel File\), 159 KB](#) - [formative_v6i8e35563_app9.xlsx](#)]

Multimedia Appendix 10

Spearman correlation coefficients–corrected *P* values for Linguistic Inquiry and Word Count and TextStat features (crowd).

[[XLSX File \(Microsoft Excel File\), 165 KB](#) - [formative_v6i8e35563_app10.xlsx](#)]

Multimedia Appendix 11

Classification matrix for the at-risk class for machine learning models.

[[DOCX File , 16 KB](#) - [formative_v6i8e35563_app11.docx](#)]

Multimedia Appendix 12

Classification matrix for the no-risk class for machine learning models.

[[DOCX File , 16 KB](#) - [formative_v6i8e35563_app12.docx](#)]

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Abbreviations

AUC: area under the receiving operator curve

GB: gradient boost

LIWC: Linguistic Inquiry and Word Count

ML: machine learning

RF: random forest

SVM: support vector machine

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