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Contents

Original Papers

Effectiveness of a Smartphone App With a Wearable Activity Tracker in Preventing the Recurrence of Mood Disorders: Prospective Case-Control Study (e21283)
Chul-Hyun Cho, Taek Lee, Jung-Been Lee, Ju Seo, Hee-Jung Jee, Serhim Son, Hyonggin An, Leen Kim, Heon-Jeong Lee. 3

Digital Cognitive Behavior Therapy Intervention for Depression and Anxiety: Retrospective Study (e21304)
Aarathi Venkatesan, Lily Rahimi, Manpreet Kaur, Christopher Mosunic. 15

Motion-Based Technology for People With Dementia Training at Home: Three-Phase Pilot Study Assessing Feasibility and Efficacy (e19495)
Jindong Petersen, Eva Larsen, Karen la Cour, Cecilie von Bülow, Malene Skouboe, Jeanette Christensen, Frans Waldorff. 28

Implementing Psychological Interventions Through Nonspecialist Providers and Telemedicine in High-Income Countries: Qualitative Study from a Multistakeholder Perspective (e19271)
Daisy Singla, Sasha Lemberg-Pelly, Andrea Lawson, Nika Zahedi, Tyla Thomas-Jacques, Cindy-Lee Dennis. 43

The Public Health Impact and Policy Implications of Online Support Group Use for Mental Health in Singapore: Cross-Sectional Survey (e18114)
Kumarasan Roystonn, Janhavi Vaingankar, Boon Chua, Rajeswari Sambasivam, Saleha Shafie, Anitha Jeyagurunathan, Swapna Verma, Edimansyah Abdin, Siow Chong, Mythily Subramaniam. 57

Dynamic Interactive Social Cognition Training in Virtual Reality (DiSCoVR) for People With a Psychotic Disorder: Single-Group Feasibility and Acceptability Study (e17808)
Saskia Nijman, Wim Veling, Kirstin Greaves-Lord, Maarten Vos, Catharina Zandee, Marije Aan het Rot, Chris Geraets, Gerdina Pijnenborg. . 6 9

Designing a Clinician-Facing Tool for Using Insights From Patients' Social Media Activity: Iterative Co-Design Approach (e16969)
Dong Yoo, Michael Birnbaum, Anna Van Meter, Asra Ali, Elizabeth Arenare, Gregory Abowd, Munmun De Choudhury. 92

COVID-19 and Telepsychiatry: Development of Evidence-Based Guidance for Clinicians (e21108)
Katharine Smith, Edoardo Ostinelli, Orla Macdonald, Andrea Cipriani. 129

Electronic Mental Health as an Option for Egyptian Psychiatry: Cross-Sectional Study (e19591)
Mostafa Kamel, Jean Westenberg, Fiona Choi, Katarina Tabi, Adel Badawy, Hisham Ramy, Hossam Elsawi, Michael Krausz. 148

Barriers and Facilitators for Referrals of Primary Care Patients to Blended Internet-Based Psychotherapy for Depression: Mixed Methods Study of General Practitioners' Views (e18642)
Ingrid Titzler, Matthias Berking, Sandra Schlicker, Heleen Riper, David Ebert. 158

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Personal Perspective

Patient Innovation in Investigating the Effects of Environmental Pollution in Schizophrenia: Case Report of Digital Phenotyping Beyond Apps (e19778)
Aditya Vaidyam, Spencer Roux, John Torous. 87

Review

The Therapeutic Alliance in Digital Mental Health Interventions for Serious Mental Illnesses: Narrative Review (e17204)
Hailey Tremain, Carla McEnery, Kathryn Fletcher, Greg Murray. 110

Letter to the Editor

Comment on "Digital Mental Health and COVID-19: Using Technology Today to Accelerate the Curve on Access and Quality Tomorrow" (e23023)
Nikhil Jain, Mahesh Jayaram. 127

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Original Paper

Effectiveness of a Smartphone App With a Wearable Activity Tracker in Preventing the Recurrence of Mood Disorders: Prospective Case-Control Study

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Abstract

Background: Smartphones and wearable devices can be used to obtain diverse daily log data related to circadian rhythms. For patients with mood disorders, giving feedback via a smartphone app with appropriate behavioral correction guides could play an important therapeutic role in the real world.

Objective: We aimed to evaluate the effectiveness of a smartphone app named Circadian Rhythm for Mood (CRM), which was developed to prevent mood episodes based on a machine learning algorithm that uses passive digital phenotype data of circadian rhythm behaviors obtained with a wearable activity tracker. The feedback intervention for the CRM app consisted of a trend report of mood prediction, H-score feedback with behavioral guidance, and an alert system triggered when trending toward a high-risk state.

Methods: In total, 73 patients with a major mood disorder were recruited and allocated in a nonrandomized fashion into 2 groups: the CRM group (14 patients) and the non-CRM group (59 patients). After the data qualification process, 10 subjects in the CRM group and 33 subjects in the non-CRM group were evaluated over 12 months. Both groups were treated in a similar manner. Patients took their usual medications, wore a wrist-worn activity tracker, and checked their eMoodChart daily. Patients in the CRM group were provided with daily feedback on their mood prediction and health scores based on the algorithm. For the CRM group, warning alerts were given when irregular life patterns were observed. However, these alerts were not given to patients in the non-CRM group. Every 3 months, mood episodes that had occurred in the previous 3 months were assessed based on the completed daily eMoodChart for both groups. The clinical course and prognosis, including mood episodes, were evaluated via face-to-face interviews based on the completed daily eMoodChart. For a 1-year prospective period, the number and duration of mood episodes were compared between the CRM and non-CRM groups using a generalized linear model.

Results: The CRM group had 96.7% fewer total depressive episodes (n/year; exp β=0.033, *P*=.03), 99.5% shorter depressive episodes (total; exp β=0.005, *P*<.001), 96.1% shorter manic or hypomanic episodes (exp β=0.039, *P*<.001), 97.4% fewer total mood episodes (exp β=0.026, *P*=.008), and 98.9% shorter mood episodes (total; exp β=0.011, *P*<.001) than the non-CRM group. Positive changes in health behaviors due to the alerts and in wearable device adherence rates were observed in the CRM group.

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Conclusions: The CRM app with a wearable activity tracker was found to be effective in preventing and reducing the recurrence of mood disorders, improving prognosis, and promoting better health behaviors. Patients appeared to develop a regular habit of using the CRM app.

Trial Registration: ClinicalTrials.gov NCT03088657; https://clinicaltrials.gov/ct2/show/NCT03088657

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KEYWORDS

circadian rhythm; digital therapeutics; mood disorder; recurrence prevention; smartphone app; wearable activity tracker

Introduction

Mood disorders, including major depressive disorder and bipolar disorder, are prevalent throughout a person's life [1,2]. Patients with a mood disorder display a number of clinical manifestations such as mood lability, insomnia or hypersomnia, and reduced quality of life. Recently, there has been growing interest in the management of mood disorders as critical factors directly related to economic and social burden [3-5]. Patients with a mood disorder experience recurrent mood episodes, which are an important factor in determining the clinical prognosis and the chronic course [6,7]. Therefore, effective treatment of mood disorders is essential not only for acute treatment but also for preventing recurrence to enhance prognosis.

With the growth of digital health–related technology, there has been a renewed interest in apps related to mental health [8]. In particular, using daily log data obtained through various technologies called digital phenotypes, it is possible to acquire biometric data such as the amount of daily activity, mood state, sleep, and heart rate [9,10]. Various wearable devices and smartphone apps have already been investigated regarding their clinical applicability in psychiatric fields [11,12]. These new technologies are now being applied to the psychiatric field to determine whether they can play an active interventional role in the prevention, treatment, and prognosis management of psychiatric disorders [13,14]. In recent years, the concept of digital therapeutics has emerged, and attempts have been made to maximize the therapeutic effect by using these therapeutics instead of or in combination with conventional therapy [15]. Digital therapeutics can be considered a more suitable model for psychiatric and chronic diseases because they can help change daily habits or correct cognition and behavior. The advent of appropriate lifestyle-related treatment methods can contribute to better insights and health-related behavior. Until now, only biological and psychotherapeutic treatment have been used within limited clinical boundaries. Therefore, we can expect that in the future, mental health–related digital apps will help to combat these limitations based on real world evidence.

Circadian rhythm is reported to be closely related to clinical manifestations and the pathophysiology of mood disorders [16-19]. The disturbance of the circadian rhythm has been suggested as causing or resulting from the recurrence of a mood episode in patients with a mood disorder [20]. Therefore, measuring the disturbance of the circadian rhythm could reflect or predict the clinical deterioration of the mood disorder. Circadian rhythm can be measured at a biological level based on the expression of circadian genes and hormone secretion, as well as at a behavioral level based on sleep-wake, mealtime, or activity patterns, and the degree or timing of light exposure. With the development of digital technology and apps, smartphones and wearable devices can be used to obtain diverse daily log data related to circadian rhythms at a behavioral level [12,21]. We have reported a machine learning algorithm system using passive digital phenotypes of a wearable activity tracker and smartphone that can predict mood state or mood episodes by collecting daily log data from patients with a mood disorder [22]. For patients with a high risk of recurrence, giving feedback with appropriate behavioral correction guides could play an important therapeutic role in mood disorder management in the real world; this type of continuous feedback is not provided by conventional pharmacotherapy or psychotherapy.

In this study, we performed a 1-year prospective pilot study to investigate the effectiveness of the circadian rhythm of mood (CRM) app combined with a wearable activity tracker in preventing the recurrence of mood disorders. The primary hypothesis of this study is that the CRM app, which provides real-time mood episode risk prediction feedback through machine learning, will help to significantly reduce the recurrence of mood episodes in patients with a mood disorder.

Methods

Subjects and Study Design

The study was conducted between January 2017 and December 2018. The subjects were divided into the CRM and non-CRM groups. All patients met the criteria for major depressive disorder (MDD), bipolar disorder type I (BD I), or bipolar disorder type II (BD II) according to the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition [23]. For the CRM group, 14 patients (12 female, 2 male) diagnosed with a major mood disorder (MDD=1, BD I=11, and BD II=2) were recruited from the Korea University Anam Hospital. For the non-CRM group, 59 patients (30 female, 29 male) diagnosed with a major mood disorder (MDD=19, BD I=17, and BD II=23) were recruited from the Korea University Anam Hospital as a part of the Mood Disorder Cohort Research Consortium (MDCRC) study. The MDCRC study is a multicenter prospective observational cohort study investigating early-onset mood disorders in Korea, and its design and protocol have been reported previously [24]. Subjects with poor compliance were excluded from the analysis. Participants who had a wearable device wear rate (Wearable device wear rate = Total hours of wear/[365×24]) of <60% over the year were excluded. Finally, 43 patients (10 in the CRM group and 33 in the non-CRM group) were included.

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Most of the study procedures related to gathering clinical symptoms and digital phenotypes were conducted in the same way in both groups, except for the daily feedback and warning alert in the CRM group. The recurrence of mood episodes was evaluated through regular follow-up visits based on the daily eMoodChart and confirmation by a psychiatrist (HJL or CHC) in both groups [24]. For the CRM group, information obtained in real time from each participant's wearable device during the study period was analyzed using a circadian rhythm–based machine learning algorithm to predict the subject's current mood condition 3 days later [22].

The study was approved by the Institutional Review Board of Korea University Anam Hospital and conducted in accordance with the Declaration of Helsinki. All participants provided written informed consent before enrollment after receiving a full explanation of the study.

eMoodChart and Wearable Device

All participants in both groups were requested to complete the daily eMoodChart and wear a wearable activity tracker (Fitbit Charge HR [2 or 3], Fitbit Inc) every day. The eMoodChart was a simple, intuitive assessment of their daily mood state (−3 to +3). Detailed information was mentioned in a previous report [24]. Subjects were asked to record their mood at 9 PM daily. If a patient missed a day, a reminder would be sent to their smartphone via SMS text messaging at 9 AM the next morning to remind them to record their previous day's mood by midday. This helped to minimize missing data and encouraged continuous recording.

For smartphones using the Android operating system, the built-in sensor could detect light exposure during the day and night. However, the light sensor data could not be collected for users with an iPhone due to Apple's restrictions. The activity trackers were worn on the wrist continuously and passively collected data related to activity, sleep, and heart rate. The data were then obtained by the researchers from the Fitbit cloud server.

Circadian Rhythm for Mood (CRM) App

The feedback intervention for the CRM group consisted of three main functions: a trend report of mood prediction of the upcoming 3 days with facial icons, H-score feedback with intervention messages, and an alert system triggered if the overall H-scores were heading toward a high-risk state.

Trend Report of Mood Prediction

The purpose of the mood prediction feedback feature was to inform patients that their past behaviors can influence their future mood and to encourage them to change their behavior by showing the impact that these changes had on their mood. When the user turns the app on every day, the facial expression icon (emoticon) intuitively tells users the predicted result of how their mood will change over the next 3 days based on machine learning of real-time–acquired personal digital phenotypes (Multimedia Appendix 1). In the system, we used a mood prediction model evaluated in a previous study [22].

H-score Feedback With Intervention Messages

To provide feedback on changes in circadian rhythm, four types of H-scores were calculated for heart rate, activity, sleep, and light exposure. The following formula was used to calculate the H-score of the heart rate circadian rhythm (CR): CR_h_score = 0.5 N(CR_amplitude) + 0.5 (100 – N[CR_acrophase]). CR_amplitude refers to the amplitude of the circadian rhythm curve obtained when the cosinor method is applied to the heart rate data collected in the previous 48 hours [25,26]. CR_acrophase measures the distance between the midday reference point and the peak point of the currently observed rhythm curve. The function N(x) is a normalization function that converts x into a value between 0 and 100. The CR_h_score value is high when the height of the rhythm curve is getting higher and the rhythm is not misaligned (ie, not delayed or advanced). The following formula was used to calculate the activity rhythm H-score: ACT_h_score = 0.5 (100 – N[steps_during_bedtime]) + 0.5 N(steps_during_daytime). Steps_during_bedtime refers to the number of steps within the time zone bedtime, and steps_during_daytime means the number of steps within the time zone daytime. The following formula was used to calculate the light-exposed H-score: LE_h_score = 0.5 (100 – N[light_exposure_during_bedtime]) + 0.5 N(light_exposure_during_daytime), where light_exposure _during_bedtime and light_exposure_during_daytime refer to the average amount of light exposure at bedtime and during the daytime, respectively. The following formula was used to calculate the sleep H-score: SL_h_score = 0.5 N(sleep_efficiency) + 0.25 (100 – N[sleep_onset_dev]) + 0.25 (100 – N[sleep_offset_dev]). Sleep_efficiency is the ratio of the time spent sleeping without awakening to the total sleep time. Sleep_onset_dev represents the deviation between the ideal going-to-bed time (8 hours before sunrise) and the observed bedtime. Sleep_offset_dev is the deviation between the ideal and observed wake-up times. The weights of the components in each H-score calculation formula were set in a heuristic way.

Based on the four types of H-scores, various feedback such as a risk indicator of the H-score, a trend line of the changes in the H-score, and coaching messages are consequently generated on the CRM app (Multimedia Appendix 1). The risk indicator works according to the spectrum of the average of the four types of H-scores, and a trend line chart uses the average H-score. In the meantime, feedback messages are automatically generated depending on each type of H-score observation and reported on the app screen to help patients change their behavior by reducing bad habits and encouraging good habits toward their desirable H-score management.

Warning Alert for Irregular Life Patterns

If a patient had irregular life patterns, warning alerts were sent in addition to the feedback messages. The warning alerts were delivered to subjects when the average of the four H-scores fell below 50 or the average was below 60 for two consecutive days. Warning alerts were sent to patients via an SMS text message and read "Recently, your life rhythm is irregular." It was hoped that the feedback messages and warning alerts would help prevent recurrences by helping the subject to recognize and modify their behaviors.

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Data Sets From Patients' Smartphones and Wearable Devices

A total of 26,645 (36573) data points were collected from 73 patients (14 in the CRM group and 59 in the non-CRM group) over the 1-year study period. After excluding noncompliant subjects who had a wearable device wear rate of <60%, 15,695 (36543) data points were collected from a total of 43 patients (10 in the CRM group and 33 in the non-CRM group). To observe changes in circadian rhythm in the selected compliant group, representative data of (1) light exposure, (2) activity, (3) sleep, and (4) heart rate were automatically collected through smartphone and Fitbit devices. To capture the factors related to circadian rhythm from digital phenotypes, we extracted a total of 13 basic features, as in our previous study (Multimedia Appendix 2) [22]. Three types of periods (*n* values include 3, 6, and 12 days) and three representative values of the mean, standard deviation, and gradient of the trend line of feature values are extracted as additional features during the *n* days and reflected in the model training. In total, 130 features were used in model construction, including 13 basic features and 117 additionally extended features (13 basic features 3 types of periods 3 representative values for each period). The detailed criteria and methods have been reported previously [22].

Assessments

Comparison of the Recurrence Rate Between the CRM Group and Non-CRM Group

During the 1-year study period, we compared the clinical progress of the two groups. The recurrence of mood episodes was evaluated by a psychiatrist (HJL or CHC). The number and duration of mood episodes were used as indicators, and the differences were compared by separating the depressive and manic/hypomanic episodes. Additionally, the number and duration of the total mood episodes were compared.

Effectiveness of Feedback Intervention of the CRM App on Behavioral Changes

To evaluate the effectiveness of the feedback system of the CRM app with regard to circadian rhythm, two aspects were evaluated. First, after patients received a warning alert, we observed whether this had a positive effect on their circadian rhythm-related features. Therefore, we tried to gauge the effect of the alert by observing what changes occurred in the features before and after the warning alert was received; the changes were observed by comparing the period 3 days before receiving the alert and 3 days after receiving the alert. For a time point *t* of a warning alert occurrence, given that two feature time series, the following equations are used: $X_{before} = (x_{t-3}, x_{t-2}, x_{t-1}, x_t)$ from the period <t-3, t> and $X_{after} = (x_t, x_{t+1}, x_{t+2}, x_{t+3})$ from the period <t, t+3>, the measure *delta of gradient change* (DGC) is calculated using $DGC = g(X_{after}) - g(X_{before})$. Here, g(X) is a function that returns the slope value (gradient) of the trend line obtained through a linear regression analysis for a given time series data *X*. Thus, if the DGC value is positive, the feature *x* tends to increase after the warning alert, and if negative, it means that it tends to decrease.

Second, after patients received feedback (eg, H-score graphs, emotional facial icons, warning alerts), we observed whether there was a positive change in relation to their active use of our proposed system. To quantitatively measure user loyalty in terms of active use, the wearable device wear rate of patients was investigated over time. The wear rate refers to the percentage of time that subjects wore their Fitbit over a month, that is, the wear rate is the total hours of wear divided by 720 hours (3024). Changes in the wear rate during the study period were calculated, and the results were compared between the CRM and non-CRM groups.

Statistical Analyses

The demographic data and disease-related variables at baseline of the two groups were compared using the chi-square test, *t* test, or Fisher exact test, as appropriate. A generalized linear model (GLM) analysis was used to compare the number and duration of the total and individual mood episodes during the study period between the CRM and non-CRM groups. As the two groups were not matched samples, a GLM analysis was performed considering these limitations. In this process, the baseline variables that displayed significant differences were regarded as confounding variables and adjusted for the multivariable GLM. Analyses were performed using SAS 9.4 (SAS Institute Inc).

Kolmogorov-Smirnov and Mann-Whitney *U* tests were used to analyze whether there was a significant difference in the distribution of DGC values between the two groups using the Python SciPy tool. The Kolmogorov-Smirnov test was used to verify that the DGC outcomes from each of the two groups were from different distributions. The Mann-Whitney *U* test was used to show that the median difference in the DGC samples between the two groups was statistically significant.

Results

Participant Demographics and Clinical Information

For the CRM group (n=10), the average age (SD) of the patients, age at the first onset of mood disorder, and age at first psychiatric treatment were 35.30 years (SD 5.33), 16.40 years (SD 5.58), and 22.10 years (SD 9.87), respectively. Furthermore, for the non-CRM group (n=33), the average age of the patients, age at the first onset of mood disorder, and age at first psychiatric treatment was 22.97 years (2.86), 18.00 years (SD 4.81), and 20.42 years (SD 3.95), respectively. The demographic and baseline variables of the two groups are presented in Table 1.

There were statistically significant differences between the two groups in age (*P*<.001), previous psychiatric admission (*P*=.02), previous depressive episodes (*P*=.007), and previous manic episodes (*P*=.005). The following main analyses were conducted by correcting the baseline variables showing significant differences.

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Table 1. Basic demographic and clinical information of the CRM group and non-CRM group.

Demographics and clinical information	Circadian rhythm for mood group (N=10)	Non–circadian rhythm for mood group (N=33)	*P* value
Gender (male), n (%)	2 (20)	15 (45)	.27[a]
Age (years), mean (SD)	35.30 (5.33)	22.97 (2.86)	<.001[b]
Diagnosis, n (%)			.07[c]
Bipolar disorder type I	8 (80)	12 (36)	N/A[d]
Bipolar disorder type II	1 (10)	10 (30)	N/A
Major depressive disorder	1 (10)	11 (33)	N/A
Type of mood episode at the first onset, n (%)			.68[c]
Depressive episode	8 (80)	29 (88)	N/A
Manic episode	2 (20)	3 (9)	N/A
Hypomanic episode	0 (0)	1 (3)	N/A
Age at first onset of mood disorder, mean (SD)	16.40 (5.58)	18.00 (4.81)	.38[e]
Age at the first visit to a psychiatric clinic, mean (SD)	22.10 (9.87)	20.42 (3.95)	.61[e]
Number of previous psychiatric administration, mean (SD)	2.10 (1.60)	0.97 (1.36)	.02[b]
Number of previous depressive episodes, mean (SD)	11.60 (5.42)	6.64 (7.45)	.007[b]
Age at the first onset of depressive episode, mean (SD)	16.13 (6.15)	17.45 (4.76)	.52[e]
Number of previous manic episodes, mean (SD)	3.90 (3.81)	0.82 (1.29)	.005[b]
Age at the first onset of manic episode, mean (SD)	17.50 (3.54)	22.67 (3.79)	.22[e]
Number of previous hypomanic episodes, mean (SD)	10.40 (12.36)	3.45 (6.00)	.06[b]
Age at the first onset of hypomanic episode, mean (SD)	N/A	N/A	N/A

[a]Chi-square test.

[b]Wilcoxon rank-sum test.

[c]Fisher exact test.

[d]N/A: not applicable.

[e]*t* test.

Comparison of the Recurrence of Mood Episodes Between the CRM Group and Non-CRM Group

The univariable GLM analysis showed that the CRM group had 60.7% fewer total depressive episodes (n/year; exp β=0.393, *P*=.03), 48.5% shorter depressive episodes (total; days/year) (exp β=0.515, *P*<.001), 85.7% shorter manic/hypomanic episodes (days/year; exp β=0.143, *P*<.001), 66.4% fewer total mood episodes (exp β=0.336, *P*=.01), and 63% shorter mood episodes (total; exp β=0.370, *P*<.001) than the non-CRM group (Table 2).

The multivariable GLM was applied after adjusting for gender, age, distribution of mood disorders, mood episode type at the first onset, age at the first onset, age of first psychiatric visit, number of previous psychiatric admissions, number of depressive episodes, number of manic episodes, and number of hypomanic episodes. The multivariable GLM analysis showed that the CRM group had 96.7% fewer total depressive episodes (n/year; exp β=0.033, *P*=.03), 99.5% shorter depressive episodes (total; exp β=0.005, *P*<.001), 96.1% shorter manic/hypomanic episodes (exp β=0.039, *P*<.001), 97.4% fewer total mood episodes (exp β=0.026, *P*=.008), and 98.9% shorter mood episodes (total; exp β=0.011, *P*<.001) than the non-CRM group (Table 2).

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Table 2. Comparison of the recurrence of mood episodes between the circadian rhythm for mood group (n=10) and the non–circadian rhythm for mood group (n=33).

Mood episodes	Univariable generalized linear model		Multivariable generalized linear model	
	Exp β (95% CI)	*P* value	Exp β (95% CI)	*P* value
Total depressive episodes (n/year)	0.393 (0.16-0.99)	.048	0.033 (0.00-0.71)	.03
Major depressive episodes (n/year)	0.532 (0.21-1.37)	.191	0.347 (0.00-1.19)	.06
Minor depressive episodes (n/year)	N/A[a]	N/A	N/A	N/A
Brief depressive episodes (n/year)	N/A	N/A	N/A	N/A
Duration of total depressive episodes (days/year)	0.515 (0.45-0.59)	<.001	0.005 (0.00-0.01)	<.001
Total manic/hypomanic episodes (n/year)	0.388 (0.09-1.68)	.21	0.005 (0.00-1.74)	.08
Manic episodes (n/year)	N/A	N/A	N/A	N/A
Hypomanic episodes (n/year)	0.550 (0.12-2.46)	.43	0.005 (0.00-17.22)	.20
Duration of manic/hypomanic episodes (days/year)	0.143 (0.10-0.21)	<.001	0.039 (0.02-0.08)	<.001
Total mood episodes (n/year)	0.336 (0.14-0.78)	.01	0.026 (0.00-0.38)	.008
Duration of total mood episodes (days/year)	0.370 (0.32-0.42)	<.001	0.011 (0.01-0.02)	<.001

[a]N/A: not applicable.

Effectiveness of the Feedback System in Terms of Behavioral Changes

The distribution of the DGC results between the CRM and non-CRM groups can be seen in Figure 1. To compare the results between the two groups, statistical verification was performed for the median DGC values from individuals. Consequently, significant positive behavioral changes after receiving warning alert feedback (assuming 95% CIs, $P<.05$) were CR_amplitude, light_exposure_during_daytime, and steps_during_daytime. In the light_exposure_during_daytime and steps_during_daytime features, an increasing tendency of DGC was observed, meaning that CR_amplitude had increased. Most of the advice provided in the warning alert was about increasing the amount of activity. However, regarding sleep, although mean differences in DGC apparently existed between the two groups, statistical significance was not observed. We found that the efficiency and duration of sleep tended to increase after the warning alert point in both groups (in the non-CRM group, this does not correspond to a real warning alert point). This may be because people naturally replenish their sleep the next day after experiencing trouble sleeping (eg, insomnia experience).

The change in Fitbit wearing rates can be seen in Figure 2. Positive results (ie, maintenance of the wearing rate) were observed in the CRM group but not in the non-CRM group. The trend lines for changes in Fitbit wearing rates were analyzed in two aspects: the moving average (MA) and moving standard deviation (MSD). In the CRM group, the average MA trend line for the wearing rate was almost static over time and increased in the last 60 days. The average MSD trend line remained horizontal and maintained a stably low value without any significant change. This means that the variation in wearing rates was not significant over time in the CRM group. Contrastingly, in the non-CRM group, the average MA trend line shows a downward curve over time, meaning that the Fitbit wearing rate gradually decreased compared to that in the CRM group. Regarding the average MSD trend line, the upward curve shows that the wearing rate in the non-CRM group did not remain stable over time and that the deviation gradually increased.

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Figure 1. Comparison of the distributions of changes in individual features after receiving warning alerts in the CRM and non-CRM groups. The vertical axis refers to the delta of gradient change (DGC). If the median of the box plot (the green horizontal line inside the box) is near zero, this means that there was no significant change in the feature before and after the warning alert. If the median is greater than zero, this means that the feature value tended to increase after the alert. If it is less than zero, this means that the feature value tended to decrease after the alert. For example, if a patient with low activity during the day received a warning alert and the median of the distribution of the DGC value outcome for the feature steps_during_daytime moves in a positive direction, then we can assume that the patient tried to increase their activity. To compare the DGC distributions of the CRM group and non-CRM group for key features related to the H-score, DGCs were calculated based on each of the time points t at which alarms were activated during the experiment. The system logs for the warning alert calculations recorded the past feedback point t of the alert receivers. The actual warning alert was not delivered to the non-CRM group at time t but delivered only to the subjects in the CRM group at time t. In the comparison analysis, patients whose features could not be calculated due to a lack of data were omitted. CRM: Circadian Rhythm for Mood; KST: Kolmogorov-Smirnov test; MWT: Mann-Whitney *U* test.

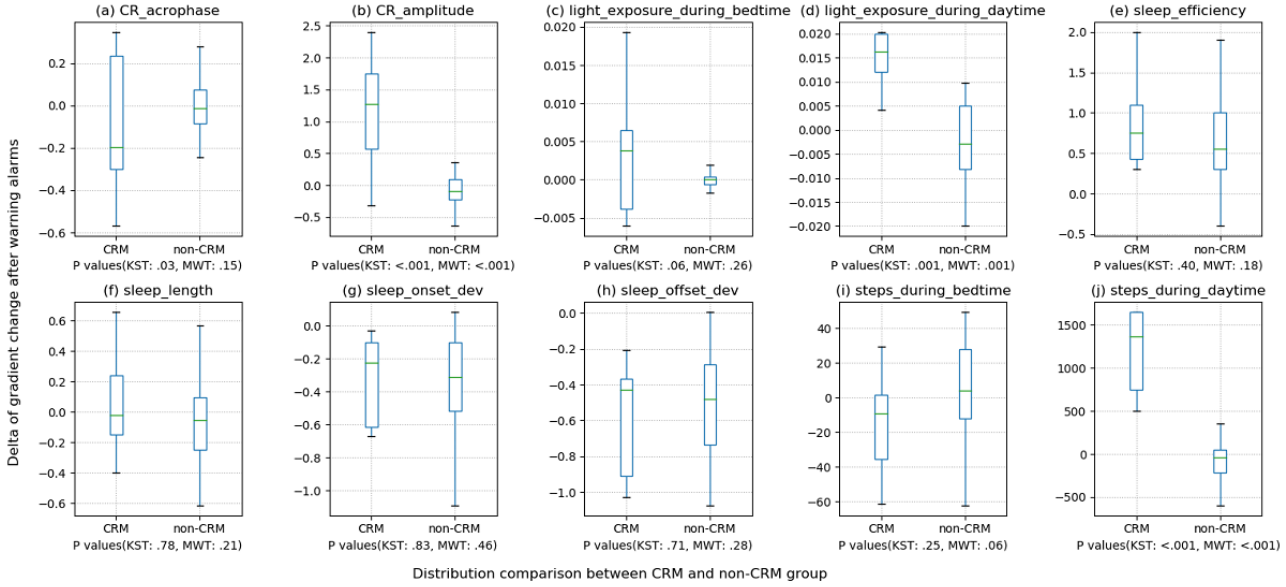
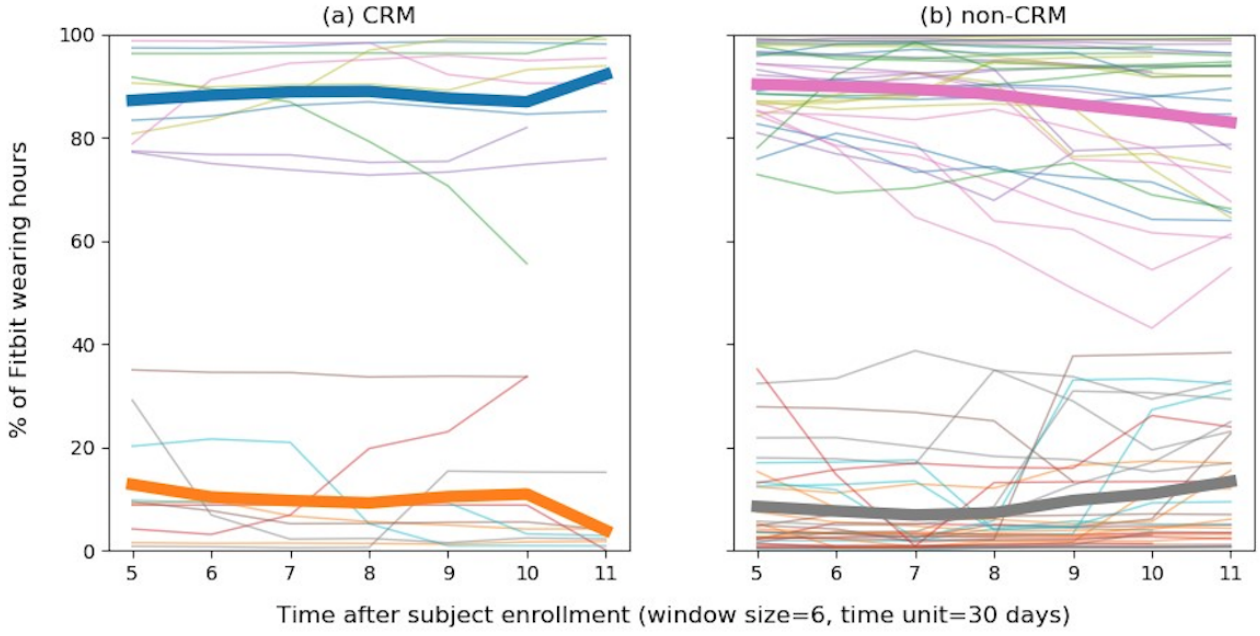


Figure 2. Changes in the Fitbit wearing rate in the CRM and non-CRM groups. A moving average technique was used to report the trend lines by abbreviating the raw time series data (window size=6 days). The time unit on the horizontal axis is 30 days, which means that the number of total wearing hours for 30 days was measured and plotted at each time point. The thin solid lines on the top area are individual trend lines of the change in the Fitbit wearing rate of each patient, and the thick solid line is an average trend line of the individual lines. The lines in the bottom area are the standard deviation trend line (MSD) of the change in the wearing rate. Increasing moving average and decreasing MSD might be positive.



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Discussion

Principal Findings

In this study, we implemented a mood prediction algorithm using a passive digital phenotype in patients with mood disorders previously developed [22] as a CRM feedback system, and conducted a prospective pilot study for 1 year to see if it is effective in preventing the recurrence of mood episodes. We confirmed that giving daily circadian rhythm–based mood prediction feedback by analyzing the life patterns of individual patients with mood disorders significantly lowers the number and duration of mood episodes compared to those in the control group.

As mood disorders are recurrent and progress to a chronic course, reducing the recurrence of mood episodes and improving the prognosis is key to treatment [27,28]. In this regard, it is particularly important to track the real-time psychiatric condition, evaluate the risk of recurrence, and feed it back to help the patient identify the personal characteristics of their mood disorder. Previously, efforts have been made to maintain a stable euthymic state through conventional treatment, including pharmacotherapy [29,30], and there have been reports that nonpharmacological treatments such as cognitive behavioral therapy (CBT) or interpersonal social rhythm therapy can help manage prognosis [31,32]. This study observed the prognosis for 1 year depending on whether the CRM app feedback was applied while maintaining conventional treatment, and a strong and noticeable recurrence prevention effect was observed. The CRM app could be classified as a nonpharmacological treatment, but it appears to be more effective compared to the existing nonpharmacological treatment methods. Considering the study period and the number of samples, the results related to the number of mood episode recurrences should be considered. However, when comparing the periods of depressive, manic/hypomanic, and overall mood episodes, all were significantly shorter than 90% of those in the non-CRM group, which is a favorable result. The markedly shortened period of mood episodes in the CRM group needs to be considered in terms of preventing the recurrence effect of the CRM app and shortening the recovery time after the recurrence of mood episodes. Shortening of the mood episode duration in case of relapse may be affected not only by prevention but also by resilience and speed of recovery. The CRM app provides a guide to mood prediction and life guidance based on circadian rhythms. In addition, it helps patients acquire relevant insights to help them establish regular circadian rhythm–based lifestyle patterns in their daily lives. It could be interpreted that the behavioral change and ongoing use of the CRM app can not only prevent recurrence but also help in rapid recovery after a relapse.

Most of the current conventional treatments have limitations. To overcome the time, space, and cost limitations of conventional treatment methods, the concept of digital therapeutics has recently emerged as a new therapeutic tool [33]. Most digital therapeutics are based on CBT and offer solutions to psychiatric problems in real life [15]. However, it is difficult to provide customized treatment solutions for each patient because the therapist is not leading and individually engaging in therapeutic interventions based on the patient's symptoms and situations through digital therapeutics. Therefore, until now, digital therapeutics with relatively standardized conventional psychotherapy methods such as CBT-I have been actively implemented [34,35]. However, digital therapeutics that provide standardized treatments rather than personalized therapeutic interventions do not provide an agile response to changes in patient symptoms and situations and may result in decreased compliance with increased user fatigue. In particular, in patients with a mood disorder, mood states are influenced by a variety of factors and change so much that standardized therapeutic interventions are difficult, and digital therapy tailored according to symptoms is exceedingly difficult. In this study, since individual mood prediction was applied using passive digital phenotypes of patients with mood disorders, this strategy represents a step forward compared to the digitization of existing standardized therapeutic tools. For the practical clinical application of psychiatric digital therapeutics, it is important to quickly and accurately identify and predict psychiatric conditions (such as mood) using digital phenotypes in real time, and to provide individual therapeutic feedback to patients who are real users.

In the field of psychiatry, the rapid evaluation and diagnosis of psychiatric conditions and prognosis management through timely therapeutic interventions are considered to be particularly important. Furthermore, treatment adherence is an important factor in determining prognosis [36,37]. Therefore, the application of digital technology to psychiatry should be directed toward improving treatment compliance and increasing the associated therapeutic value. In particular, predicting mood or recurrence in patients with a mood disorder would enable faster interventions. Previous studies have predicted mood using variables of multiplex dimensions. Attempts to predict mood or recurrence using traditional markers such as biological markers and brain imaging markers have been made; recently, an analysis using voice, natural language, and variables from wearable devices was undertaken [22,38-42]. In conducting a recurrence prediction study for these mood disorders, (1) predictive performance, (2) practical applicability, and (3) privacy protection should be considered. Prediction performance can increase accuracy if a precise method is applied using as many different layers of data as possible. However, the difficulty of acquiring or analyzing data is exceedingly difficult, and if this is too expensive or takes too long, then its practical applicability is reduced. Therefore, it is important to acquire real-time data at as low a cost as possible to improve predictive performance. Even so, personal variables such as personal health records, voice, location information, and natural language can cause various ethical and legal problems [43,44]. It can be said that this study satisfies the conditions mentioned above because only passive digital phenotypes (such as activity, heart rate, and sleep), which are difficult to identify, were utilized. Thus, our method not only has clinical value but also has practical applicability.

The biggest problem in using digital devices is ensuring that compliance and engagement remain high. In general, as the length of time a wearable device is used increases, the fatigue

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rate increases and the usage rate decreases [45,46]. In this study, the wear rate of the wearable device was evaluated separately between the two groups, and it was confirmed that the wear rate was continuously and stably maintained in the CRM group compared to that in the non-CRM group. This suggests that feedback of useful information to the user (patient) can help to keep the digital device usage rate stable and consistent. Many obstacles must be overcome for the actual clinical application of digital devices and therapeutics. However, there are concerns about technology development, but if the user does not use the developed ones, there is no benefit. In addition, since continuous long-term use is essential for prevention or prognosis management, it is a significant obstacle if the device is only used for a short period of time. To overcome this, there are attempts to provide financial compensation such as incentives or intervention by digital device or treatment managers to maintain compliance [45,47], but there are certain limitations to these tactics in terms of cost-effectiveness. This study shows that the provision of useful information and feedback to users may be vital in maintaining compliance, and it is necessary to develop a technology focused on this. Additionally, it could be speculated that continued compliance in this study may have contributed to the therapeutic effect. However, this is difficult to clarify.

In the H-score calculation, one of challenging issues was to determine an appropriate weight combination. The issue requires further research. In the H-score calculation, if more large-scale patient data can be collected through continuous research in the future, sensitivity analysis will find more appropriate weights mathematically. In this paper, the weight was set to have an equal ratio by recognizing the importance of equality rather than bias among the determinants when calculating H-score. However, there was one exception, and in the case of sleep H-scores, the effect of too little sleep was so great that appropriate weights were set accordingly.

The strengths of this study are as follows. First, the therapeutic effect was studied by implementing a feedback function of a circadian rhythm–based mood prediction algorithm using a digital phenotype verified through previous studies, and a strong recurrence prevention effect was confirmed. Second, although this study is a pilot study, the patients were followed for 1 year, which is sufficient for confirming whether a recurrence occurred. Due to the clinical characteristics of mood disorders, it is exceedingly difficult to observe recurrence. Third, although a sham app was not used, both groups were allowed to use the app and wearable device, thereby minimizing any differences in effect. Fourth, the effects were presented through integrated analysis such as behavior change and compliance as well as recurrence prevention.

Limitations

There are several limitations to this study. First, the case-control sample was not sufficiently matched. Although this is a pilot study to investigate the effectiveness of the CRM app, the case-control groups were not matched samples. We tried to perform statistical analysis by applying the GLM analysis with statistical experts to overcome the sample imbalance. Interestingly, the number of previous psychiatric admissions, number of previous depressive episodes, and number of previous manic episodes were significantly higher in the CRM group in the clinical information analysis. Despite the relatively negative clinical history of the CRM group, it is noteworthy that the pilot study showed a strong positive effect. Second, since this study was not conducted as a randomized controlled trial, allocation to the CRM feedback intervention was nonrandomized. As a result, it is not possible to completely exclude factors such as the influence of the characteristics of patients using the CRM app in the interpretation of the research results. The research team plans to conduct a randomized controlled trial on matched samples to produce reliable research results. Third, the sham app corresponding to the CRM app feedback system was not completely provided to the control group. Fourth, light sensor data could not be collected from iPhone users for technical reasons, so this could not be analyzed.

Conclusions

This study investigated the effectiveness of a CRM app with an activity tracker for recurrence prevention in patients with a major mood disorder. The total mood episodes were fewer and shorter in the CRM group than in the non-CRM group. In the CRM group, positive changes in health behavior due to the warning alerts and maintenance of wearable device adherence rates were observed. The CRM app with a wearable device was found to be effective in preventing and reducing the recurrence of mood disorders, improving prognosis, and promoting better health behavior. Patients appeared to develop a regular habit of using the CRM app. This study is valuable as a preliminary study confirming that the mood prediction machine learning algorithm and feedback system using a circadian rhythm–based digital phenotype are clinically effective and might be used as the basis for the digital treatment of mood disorders. In the future, the CRM app's effectiveness should be verified using a randomized controlled trial with a larger number of patients.

Acknowledgments

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Conflicts of Interest

None declared.

Multimedia Appendix 1

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Screen capture of the CRM app developed and used in the current study. CRM: circadian rhythm for mood.
[DOCX File , 153 KB - mental_v7i8e21283_app1.docx]

Multimedia Appendix 2
The proposed basic features to check circadian rhythm from the automatically measured passive digital log data of patients with mood disorders.
[DOCX File , 18 KB - mental_v7i8e21283_app2.docx]

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Abbreviations

CBT: cognitive behavioral therapy
CRM: circadian rhythm for mood
GLM: generalized linear model
HR: heart rate
MA: moving average
MDCRC: Mood Disorder Cohort Research Consortium
MDD: major depressive disorder
MSD: moving standard deviation

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Original Paper

Digital Cognitive Behavior Therapy Intervention for Depression and Anxiety: Retrospective Study

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Abstract

Background: Digital mental health interventions offer a scalable solution that reduces barriers to seeking care for clinical depression and anxiety.

Objective: We aimed to examine the effectiveness of a 12-week therapist supported, app-based cognitive behavioral therapy program in improving symptoms of depression and anxiety within 9 months.

Methods: A total of 323 participants with mild to moderately severe depression or anxiety were enrolled in a 12-week digital cognitive behavior therapy program. The analysis was restricted to participants who provided at least one follow-up assessment after baseline. As a result, 146 participants (45.2%) were included in the analysis—74 (50.7%) participants completed assessments at 3 months, 31 participants (21.2%) completed assessments at 6 months, and 21 participants (14.4%) completed assessments at 9 months. The program included structured lessons and tools (ie, exercises and practices) as well as one-on-one weekly video counseling sessions with a licensed therapist for 12 weeks and monthly check-in sessions for 1 year. The clinically validated Patient Health Questionnaire (PHQ-8) and Generalized Anxiety Disorder Scale (GAD-7) were used to assess depression and anxiety, respectively. Linear mixed-effects modeling was employed to examine changes in depression and anxiety over time.

Results: We observed a significant positive effect of program time on improvement in depression (β=–0.12, *P*<.001) and anxiety scores (β=–0.10, *P*<.001). At the end of the 12-week intervention, we observed an average reduction of 3.76 points (95% CI –4.76 to –2.76) in PHQ-8 scores. Further reductions in depression were seen at program month 6 (4.75-point reduction, 95% CI –6.61 to –2.88) and program month 9 (6.42-point reduction, 95% CI –8.66 to –6.55, *P*<.001). A similar pattern of improvement emerged for anxiety, with a 3.17-point reduction at the end of the 12-week intervention (95% CI –4.21 to –2.13). These improvements were maintained at program month 6 (4.87-point reduction, 95% CI –6.85 to –2.87) and program month 9 (5.19-point, 95% –6.85 to 4.81). In addition, greater program engagement during the first 12 weeks predicted a greater reduction in depression (β=–0.29, *P*<.001)

Conclusions: The results suggest that digital interventions can support sustained and clinically meaningful improvements in depression and anxiety. Furthermore, it appears that strong initial digital mental health intervention engagement may facilitate this effect. However, the study was limited by postintervention participant attrition as well as the retrospective observational study design.

(JMIR Ment Health 2020;7(8):e21304) doi:10.2196/21304

KEYWORDS

depression; anxiety; CBT; digital mental health intervention; digital therapeutics; cognitive behavioral therapy; therapy; digital health; intervention; mental health

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Introduction

Telemedicine delivered through smartphone-based apps is fast redefining how care is sought and delivered for disease prevention and management. The emergence of digital health technology is particularly relevant for mental health services. With a 12-month prevalence rate of 6.7% and 3.1% for major depressive disorder and generalized anxiety disorder, respectively, in the United States [1], depression and anxiety are the leading causes of disability and lost productivity [2]. Nevertheless, there are barriers unique to mental health that hinder timely access to care. Besides affordability and accessibility issues, stigma surrounding mental illnesses [3], lack of motivation, and low rates of mental health literacy [4] significantly impact willingness to seek treatment and contribute to low engagement with mental health services.

With the rapid development and application of digital technologies such as smartphone apps, telemedicine has emerged as a compelling solution for disease treatment and management. Digital mental health interventions are growing in appeal because they offer scalable solutions and can improve uptake rates among those who are less inclined to seek mental health services. Digital mental health interventions are an effective means of delivering evidence-based psychological treatment to patients who are unable or unlikely to seek in-person treatment with a provider [5]. In addition, digital mental health interventions also appear to improve access, reduce stigma, and ease pressure when compared to face-to-face services [6].

Given the potential benefits of digital mental health interventions, there has been increased research focusing on their effectiveness. In their meta-analytic review, Richards et al [7] observed a significant and clinically meaningful effect of internet-based interventions for the treatment of generalized anxiety disorder when compared to waitlist controls, including those with comorbid depression. Similarly, in a meta-analysis of randomized controlled trials that employed smartphone-based mental health interventions, Firth et al [8] observed a significant moderate treatment effect of internet-based interventions on depressive symptoms when compared to both waitlist and active controls; a similar treatment effect was observed for anxiety [9].

While early evidence is promising, digital mental health interventions are not monolithic in their treatment approach, design, or delivery. They can be game-based, focus primarily on psychoeducation, or incorporate human interactions. Digital mental health interventions can entail one-on-one interactions in real time with a therapist via audio or video conferencing tools and involve both synchronous and asynchronous text messaging.

Interestingly, Firth et al [8] observed that smartphone-only apps were more effective than interventions that included a human or computerized interaction were and hypothesized that smartphone-only apps may be more comprehensive and self-contained in content and experience than interventions that relied on external input are. Li et al [10] observed a similar pattern: a larger effect size for game-based interventions for the treatment of depression that did not include therapist support than for therapist-supported interventions. On the other hand, Spek et al [11] noted the opposite pattern, wherein a stronger effect size was observed for therapist-supported internet-based cognitive behavior therapy interventions for anxiety symptoms. It is important to note here that digital mental health interventions can vary substantially in their therapeutic approach from a focus on mindfulness and psychoeducation to therapist-supported digital cognitive behavior therapy. Indeed, Firth et al [8] did observe cognitive behavior–based interventions were associated with significantly greater reductions in depression compared to those associated with other approaches. Additionally, research suggests that internet-based cognitive behavior therapy programs are roughly equivalent in effectiveness compared to those of face-to-face therapy [12,13].

Digital mental health interventions are not without their drawbacks. Importantly, it is still unclear if all digital psychological treatments are equally effective. For instance, in their review of digital mental health interventions for students, Lattie et al [14] found that web-based interventions were effective in improving depression, anxiety, and psychological well-being. However, they noted participant attrition and program discontinuation across studies, suggesting that sustaining patient engagement remains a continued challenge for digital interventions.

In summary, recent interest and demand for remotely delivered mental health interventions has led to an increase in app-based solutions. Technology-based mental health programs have been shown to be effective in improving access and treating common mental health conditions such as depression. However, given the heterogeneity of digital mental health interventions in terms of treatment approach and modality and continued challenges of attrition, their overall effectiveness remains an open question. Though a fairly robust body of academic research supports the efficacy of digital mental health interventions in the treatment of mild to moderate depression and anxiety, there remain gaps. Specifically, commercially available, app-based mental health programs have received less research scrutiny, particularly, in evaluating medium-term and long-term outcomes. Second, hybrid models that combine a cognitive behavior therapy–based digital intervention with one-on-one remote therapist support have been assessed to a lesser extent.

In this study, we evaluated the Vida Health therapy program, a digital therapeutic intervention for mild to moderate depression and anxiety. Vida Health is a commercially available, app-based digital health program for mental health and cardiometabolic conditions. The program is available direct to consumers, as an employee-based benefit or via select health plans. The Vida Health app offers tailored digital content paired with remote therapy and health coaching with licensed therapists, registered dieticians, certified diabetes educators or health education specialists. Vida Health program offerings include cognitive behavior therapy, mindfulness-based stress management, weight management, and chronic disease (eg, type 2 diabetes) management. Available in all 50 states, the therapy program that is the focus of this study is based on cognitive behavior therapy, a therapeutic approach that has shown the strongest evidence for treating depression and anxiety [15,16]. Cognitive

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behavior therapy stands out as the leading therapeutic modality for depression and anxiety, as it is both shorter in duration, and its positive outcomes last longer, as compared to those of other therapeutic modalities [17]. Our primary objective was to assess the long-term outcomes from a digital mental health intervention incorporating evidence-based psychotherapeutic content along with one-on-one sessions with a remote licensed therapist. Our secondary objective was to examine if intervention engagement was associated with stronger outcomes at the end of the intervention. This study also examined depression and anxiety improvements during the postintervention maintenance phase.

Methods

Design

A retrospective observational study design was employed to evaluate changes in depression and anxiety following Vida Health's app-based cognitive behavior therapy program that included one-on-one therapist-supported counseling. The study was approved by an independent institutional review board (Western institutional review board). The institutional review board waived the informed consent because the study was identified as having minimal risk and the data were fully anonymized before retrospective analysis.

Measures

Depression was assessed using the clinically validated 8-item Patient Health Questionnaire (PHQ-8). Although the PHQ-9 may be more widely used, we utilized the PHQ-8 in this program. The key distinction between the two instruments is the inclusion of the suicidality item in the PHQ-9. In lieu of screening via app, all participants were evaluated for suicidality by a licensed therapist during the initial biopsychosocial assessment and intake. The 7-item Generalized Anxiety Disorder (GAD-7) scale was used to evaluate anxiety. These validated self-reported instruments are commonly used in clinical practice to assess depression and generalized anxiety disorder [18,19]. The PHQ-8 and GAD-7 assessments were automatically administered in the app every 2 weeks for the duration of the study. Although participants were encouraged to complete the assessments on the day of receipt, they had the opportunity to complete the assessments at any time during the 2-week period, after which, the next scheduled assessment became available. Additional assessments could also be sent at any time by the therapist, at their discretion. The semimonthly assessment schedule was selected in order to provide therapists with periodic insight into a participant's progress in the program and assess the possible need for additional care or referral to external resources.

Study Sample and Recruitment

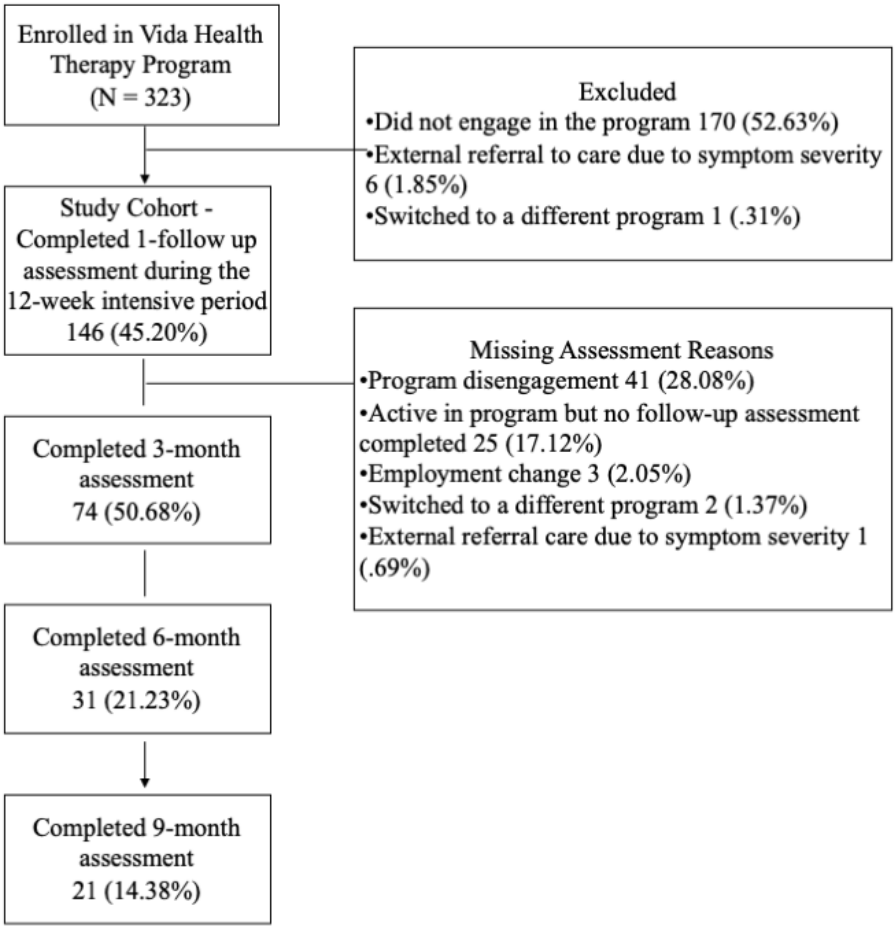
The study included adults (18 years or older) who owned a smartphone or tablet, were fluent in spoken and written English, with mild to moderately severe depression or mild to moderate anxiety. Participants were recruited from companies based in the California Bay Area and in the state of Washington that offered the Vida Health cognitive behavior therapy program as a benefit to employees and spouses. Although Vida Health therapy program patients are currently distributed across the United States, this study focused on participants drawn from organizations where participants had been enrolled in the program for at least 6 months. Between February 2017 and January 2020, 323 participants were recruited through a combination of email announcements, paper flyers, and onsite events at their employers (Figure 1). Participants were directed to download the Vida Health app from the Apple App Store (iOS version) or Google Play Store (Android version) and enroll using an invite code to confirm eligibility.

Prior to enrolling in the Vida Health digital cognitive behavior therapy program, participants completed a brief set of registration questions that included name, contact information, basic demographics (age, gender, height, and weight), and existing health conditions. At program start, participants completed the Patient Health Questionnaire (PHQ-8) and Generalized Anxiety Disorder scale (GAD-7). Study enrollment and participant flow are also presented in Figure 1. Participants with PHQ-8 scores between 5 and 19 or GAD-7 scores between 5 and 14 were included in the study. Participants who scored in severe depression (PHQ-8 score>19) or severe anxiety (GAD-7 score>14) ranges were ineligible for the program. Furthermore, if during the initial intake or any time during the intervention a participant presented with or reported any current or recent active symptoms or conditions that would likely be better supported by an alternative source of care, the therapist explained this to the participant and referred the participant to an alternative care resource or to a Vida Health care navigator for help getting connected to an alternative source of care. Conditions that were the basis for an individual being excluded from program participation included eating disorders, substance use disorders, suicidality, homicidality, acute posttraumatic stress disorders, episodes of mania, or psychosis. Participants with subthreshold or meeting criteria for a psychiatric diagnosis outside of mild to moderate anxiety and or depression were excluded from the study. Participants who were ineligible for the program were referred to a Vida Health care navigator and provided with a list of sources to seek care through in-person clinical services. Vida Health care navigators are licensed mental health professionals who connect ineligible participants to alternative care resources, including in-person treatment through local community counseling centers, private practice providers, employee assistance programs, or referral to an in-network care provider through the participant's health insurance.

Study participants who were eligible were then paired with a licensed therapist based on their state of residence and their preferred times for consultations. Therapists were mental health professionals licensed by their states' respective licensure boards and employed by Vida Health. Therapists were licensed in one or more states. License titles and types, and scope of license-practicing privileges varied by state. Therapists had one or more of the following license types (the list below is not all inclusive): licensed clinical social workers, licensed medical clinical social workers, licensed independent social worker, licensed marriage and family therapists, licensed professional counselors, licensed professional clinical counselors, licensed mental health counselor, licensed clinical psychologists, licensed practicing psychologist, and clinical mental health counselor.

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Figure 1. Schematic of participant flow.



Prior to program intake, all participants received and signed an informed consent to psychotherapy form. Consent to psychotherapy is a standard of care practice at the start of therapy. Its purpose is to inform clients of the expectations of therapy, their rights to confidentiality, and limits to confidentiality (including mandated reporting requirements as stipulated by the therapist's licensing board and state regulations) and supply provider license information. The consent form also included details about the termination process, accessibility through digital text messaging, and video conferencing; the cancellation policy; limitations to teletherapy; and consent to engage in teletherapy. During the first appointment, the therapist conducted a biopsychosocial intake questionnaire that reviewed history of previous treatment or diagnosis, family history of mental health conditions and physical health conditions, current support systems, current medical conditions, current prescribed medications, history of substance use, strengths, current interests, spirituality or religiousness, sleep quality and quantity, appetite, current presenting problem, presenting symptoms, and mental status examination (including assessment of mood, affect, orientation, attire, eye contact, thought process, attention, auditory or visual hallucinations, delusions, and any presenting suicidal or homicidal ideation). After completing the intake, the therapist generated an initial diagnostic impression and determined if a participant was eligible to continue participating in the program. If a participant presented with mild to moderate anxiety or depression, they were eligible to continue the program.

Therapeutic Approach and Intervention

The Vida Health cognitive behavior therapy program is a HIPAA-compliant structured digital program that connects adults living with mild to moderate depression or anxiety with a licensed therapist. Although the core structure, duration, and focus of the digital cognitive behavior therapy program remained the same, certain app-features, improved functionality, and app-enhancements were introduced to the cognitive behavior therapy program between 2017 and 2020, resulting in 3 different program iterations. These program versions were included as a random factor in the final linear mixed methods model, to account for any potential differences in version effectiveness.

As part of the intervention, participants were sent audio-, video-, and text-format lessons, activities and practices based on cognitive behavior therapy by their therapist through the app. Cognitive behavior therapy addresses maladaptive thinking patterns by exploring the relationship between thoughts, emotions, and behavior [20]. The materials sent to the participants through the Vida Health app reviewed core concepts of cognitive behavior therapy including the cognitive model, guided discovery, identifying cognitive distortions, behavioral activation, and techniques for addressing maladaptive thinking [20,21]. Lessons and activities included questions in an effort to support increased awareness of underlying thinking patterns

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and to facilitate the practice of alternative, more adaptive thoughts. Participants could select from multiple choice options, checklists, and free text, as well as review concepts through reading, listening to audio practices, or watching videos (see Figure 2).

The therapist reviewed the completed lessons prior to every weekly consult, and in discussion with the participant, reviewed strategies for applying the concepts and skills that had been covered. The therapist would check-in with the participant about their current mood, set goals for the week, and prepare them for the upcoming lessons and activities as homework for the week ahead. Over the course of the program, the therapist met with the participants on a weekly basis for a duration of 30 minutes over video or phone call. Every week, the therapist generated a personalized treatment plan that reviewed the participant's short-term and long-term goals as well as the habits, actions, and homework they planned to engage in for the week. These treatment plans were reviewed with the participant during the core intervention phase. Toward the end of the intensive phase (at approximately week 10), the therapist sent the participant lessons and tools to help generate a Wellness Recovery Action Plan. The Wellness Recovery Action Plan is a plan that identifies known triggers and coping strategies that the participant has identified to support their management of symptoms [22]. The Wellness Recovery Action Plan is designed to support both maintenance of improved symptoms and functioning as well as prevent relapse.

Figure 2. Vida Health Therapy program screens.



Statistical Analyses

Across all participants, the mean survey completions were 5.75 (SD 3.90) and 5.50 (SD 3.50) for GAD-7 and PHQ-8, respectively. The study design intended to obtain at least one assessment every fortnight. Based on this expectation, we could have received as many 1106 completed PHQ-8 surveys, assuming one survey completion per participant per fortnight; we received 698 PHQ-8 assessments, indicating a survey completion rate of 63.11%. Likewise, out of the 1185 possible GAD-7 survey completions (one per participant per fortnight), we received a total of 744 surveys indicating a completion rate of 62.78%. The temporal resolution of changes in PHQ-8 or GAD-7 scores was far higher for some participants than others. Although the automated assessments were administered every 2 weeks (with additional ones administered by the therapist), a participant could complete the survey at any time during the 2-week period. As a result, a participant could have completed more than one survey within a fortnight. For example, a participant could complete a survey received on week 12, on the day of receipt or 8 days thereafter. The week of survey completion was calculated as the difference in weeks from program start. As a result, on any given program week, only a fraction of participants contributed data, with no consistent cadence. To overcome this data sparsity, curve fitting was applied as a data imputation technique for each participant. All data preparation was performed using the curve_fit function (SciPy library, version 1.5.2 Python, version 3.7.7) [23]. The objective of the analysis was to evaluate changes (from baseline) in depression and anxiety over time for all participants. Data imputation through curve fitting was employed in order to provide participants with equal representation and weighting for all the days from program start to the last program day on which data was available for a participant. Data extrapolation beyond the last day on which a participant had a valid PHQ-8 was not performed due to potential artifacts. As a result, participants did not contribute to the analyses beyond the last day for which they had data. When data was aggregated by program month, participants whose last survey completion occurred during the month, contributed correspondingly fewer points to the estimate. The study cohort included participants who had only one baseline assessment and no follow-up. To assess any baseline differences between program non-starters and program completers, a two-tailed chi-squared analysis was performed.

Care was taken to ensure fidelity of data due to known issues with automated digital data acquisition platforms. Specifically, during onboarding, duplicate entries that could have occurred by participants inadvertently submitting the survey twice were ignored. Furthermore, partially completed assessments were not included in the analysis. For each participant, the timeseries of available PHQ-8 scores was compiled after removing duplicate entries. Three different functional forms were fit to

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this data: linear, quadratic, and sigmoidal (generalized inverse), and the fit that yielded the lowest root mean squared error was chosen as each participant's trajectory. A nonlinear fit was applied only in instances where 6 or more data points were available. Furthermore, for the sigmoidal fit, the magnitude of the coefficients was capped. These two steps were necessary to prevent overfitting. In order to preserve temporal resolution inherent in the data, during curve fitting, predicted scores were calculated for each program day. Predicted scores were then aggregated by program week or month, as applicable, with a month being defined as a 4-week period. The same method was applied for GAD-7 scores.

To determine the effect of program time on changes in depression and anxiety scores, conventional methods such as ordinary least squares can be employed. However, these methods do not account for heterogeneity in the data, specifically, possible differences in the effectiveness across provider and program versions. In this study, participants were drawn from four companies, nested within three cognitive behavior therapy program versions that were nested across 30 providers. Hence, we employed a linear mixed-effects model where company, cognitive behavior therapy program version, and provider were treated as random effects. All analyses were performed using StatsModels (Python) [24]. *P* values<.05 were deemed significant.

Data Availability

The data sets analyzed for this study are available from the corresponding author upon request.

Results

The study included 323 participants enrolled in a digital cognitive behavioral intervention between February 2017 and January 2020 with baseline PHQ-8 scores or GAD-7 scores ≥5. The 9-month study cohort recruitment period ended in October 2019. These analyses were restricted to participants who had at least two valid survey submissions between baseline and program month 9. While the comorbidity of depression with anxiety was prevalent in the majority of participants, there were 7 participants with anxiety but subclinical levels of depression. Therefore, unless otherwise noted, results are reported by condition. Program nonstarters were defined as participants for whom no survey data was available beyond their initial baseline week. Of the 323 participants, 139 participants (43.0%) completed a follow-up PHQ-8 during the 9-month period, and 146 participants (45.2%) completed a GAD-7. There were no significant baseline differences in PHQ-8 between the treatment cohort and program nonstarters (nonstarter: mean 10.08, SD 3.78; treatment cohort: mean 10.48, SD 3.95; *P*=.26). Likewise, no baseline differences in GAD-7 scores were observed between groups (nonstarter: mean 9.19, SD 3.32; treatment cohort: mean 9.52, SD 3.70; *P*=.07). Furthermore, chi-square tests revealed no significant baseline differences between groups in the occurrence of self-reported chronic health conditions such as diabetes, obesity, hypertension, and hyperlipidemia (*P*=.59).

Demographics and baseline characteristics for depression and anxiety are shown in Table 1. While there were more women enrolled in the program than men, there were no significant gender-based differences in depression or anxiety scores during baseline (*P*=.52). For depression, 54.7% (76/139) of the cohort had baseline PHQ-8 scores that corresponded to moderate to severe depression (PHQ-8 score≥10). For anxiety, 41.8% (61/146) of the participants had GAD-7 scores≥10 corresponding to moderate to severe anxiety.

Table 1. Baseline characteristics by condition.

Condition and characteristic	Value
Depression (n=139)	
Baseline PHQ-8 score[a], mean (SD)	10.48 (3.95)
Age (years), mean (SD)	36.42 (9.22)
Gender, n (%)	
Male	42 (30.2)
Female	95 (68.3)
Did not specify	2 (1.4)
Anxiety (n=146)	
Baseline GAD-7 score[b], mean (SD)	9.52 (3.70)
Age (years), mean (SD)	36.10 (9.03)
Gender, n (%)	
Male	41 (28.1)
Female	104 (71.2)
Did not specify	1 (0.7)

[a]PHQ-8: 8-item Patient Health Questionnaire.

[b]GAD-7: 7-item Generalized Anxiety Disorder.

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Depression and Anxiety Outcomes

The available PHQ-8 score assessed at the start of the program served as the intake PHQ-8 and were treated as the baseline. Change from baseline, the outcome variable, was defined as the difference between the baseline and the predicted score derived from curve-fitting to the participant's data. Program time was included as a fixed effect as it was hypothesized that time engaged with cognitive behavior therapy program would predict reduction in depression scores. Baseline PHQ-8 and the composite engagement score were also predictors. As mentioned earlier, the trial period included 3 cognitive behavior therapy program versions. Pairwise comparisons revealed no significant baseline differences in depression or anxiety scores between groups (P=.58). Likewise, there were no company-based baseline differences between groups (P=.91). Company and cognitive behavior therapy program versions were included as the top-level group variables in the model. Providers were included in the model as a nested group and specified as a variance component.

Figure 3 shows the average reduction and standard error in PHQ-8 scores from baseline by program month. We observed clinically significant improvement in depression as a function of program time (β=–0.12, P<.001). A total of 69 PHQ-8 completions at the end of the intensive phase (69/139, 49.6% of participants at month 3), 29 completions at month 6 (29/124, 23.9% of participants at month 6), and 13 completions by month 8 (13/103, 12.6% of participants at month 9) were included in the analyses. Although 77.3% (51/66) and 58.1% (25/43) of participants remained active (ie, therapist contact, lesson completions) in the program at months 6 and 9, respectively, participants did not complete the assessments. There was an average reduction of 3.76 points (95% CI –2.76 to –4.76, P<.001; Hedges g=0.96) by the end of the intensive phase of the program (month 3). Further improvements in depression were seen during the maintenance phase of the intervention, with an average reduction of 4.75 points (95% CI –2.88 to –6.61, P<.001; Hedges g=1.10) at program month 6. By program month 9, we observed a 6.42-point average reduction (95% CI –7.15 to –5.70).

We observed a similar pattern of improvement in anxiety (see Figure 4). There was a significant reduction in anxiety scores with increased program time (β=–0.10, P<.001). A total of 50.7% of participants (74/146) completed the GAD-7 assessment at the end of the intensive phase, 23.5% of participants (31/132) who had been in the program for at least 6 months completed the GAD-7 assessment, and 12.8% of participants (14/109) who had been in the program for at least 9 months completed the GAD-7 assessment; 51.5% of participants (68/132) who had been in the program for 6 months were active in the program. Likewise, 43.1% of participants (47/109) who were in the program for at least 9 months remained active. We observed a 3.17-point reduction in GAD-7 scores by program month 3, the end of the intensive phase of the intervention (95% CI –2.13 to –4.21, P<.001; Hedges g=0.87). Further improvements in anxiety were noted at program month 6 (4.87-point reduction, 95% CI –2.87 to –6.85, P<.001; Hedges g=1.24) and program month 9 (5.19-point reduction, 95% CI –6.85 to 4.81, P<.001).

In the case of both depression and anxiety, participants with higher symptom severity at baseline appeared to show greater postintervention improvement. Higher anxiety scores at baseline predicted greater reduction in GAD-7 scores (β=–0.52, P=.001). A similar trend was observed for depression, but the effect did not reach significance (β=–0.47, P=.08).

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Figure 3. Estimated marginal mean of depression scores by cognitive behavioral therapy program time. PHQ: Patient Health Questionnaire.

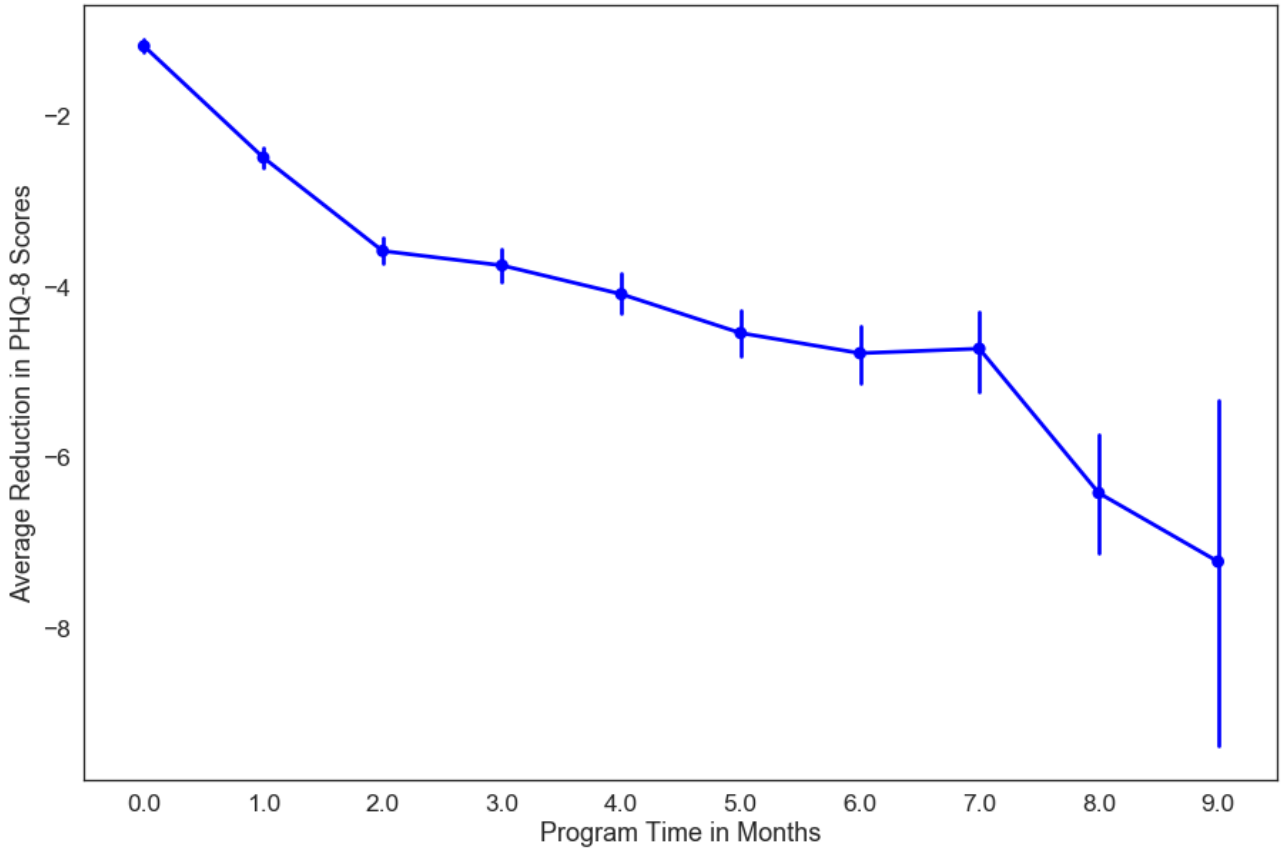
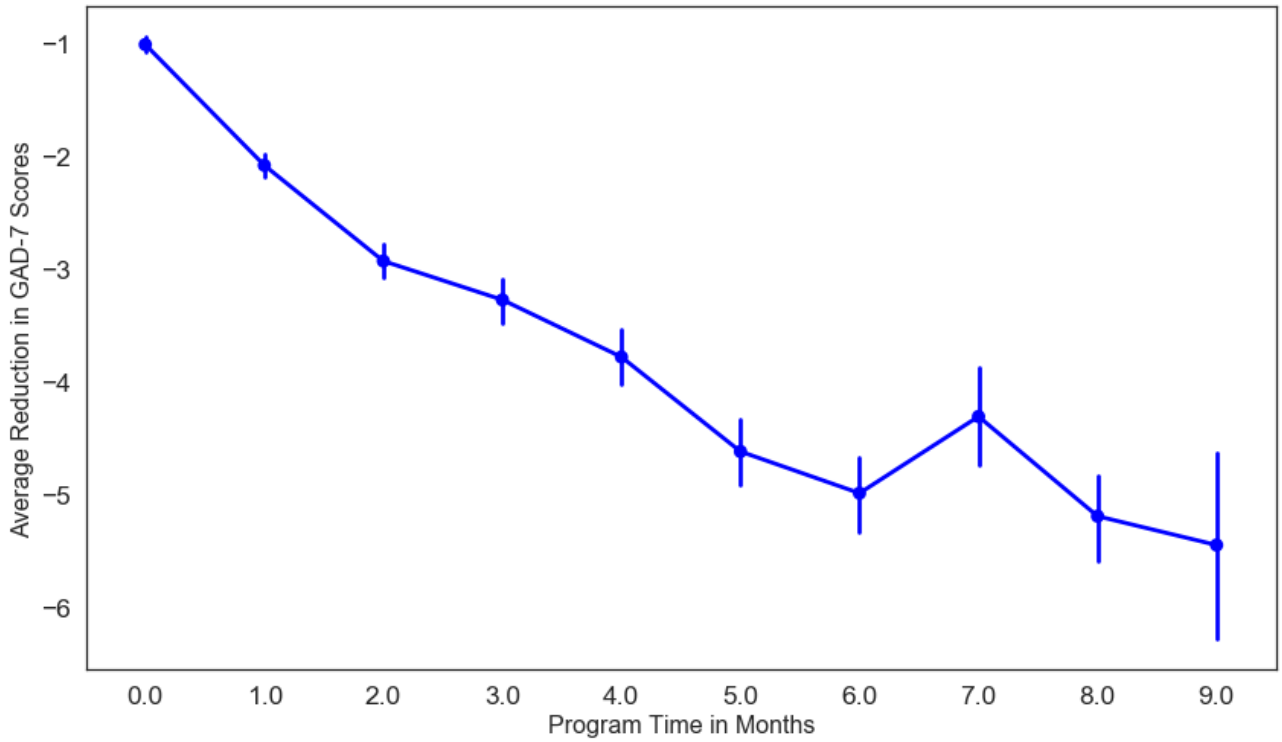


Figure 4. Estimated marginal mean of anxiety scores by cognitive behavioral therapy program time. GAD: Generalized Anxiety Disorder.



Engagement

Summary statistics for program engagement during the intensive phase (first 12 weeks) of the program are shown by condition in Table 2. We measured program engagement along two dimensions: extent of contact with the therapist (ie, consultations and number of messages sent by the participant to the therapist) and interactions with other aspects of the digital health intervention (ie, number of completed assessments and number of completed lessons and activities). As expected, we observed

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a significant positive association between engagement factors (see Table 3). To reduce multicollinearity between factors in the final linear mixed-effects model, each of the engagement variables was first normalized, after which an aggregate engagement score was calculated.

One of the current open questions around digital mental health interventions has been the role of program engagement in facilitating treatment and symptom improvement. We examined if the extent of usage and interaction with the Vida Health cognitive behavior therapy platform was related to mental health outcomes. Indeed, increased program engagement during the intensive phase of the intervention was associated with greater improvement in depression (β=–0.29, *P*=.01) and anxiety (β=–0.29, *P*<.001). Engagement was added in the linear mixed-effects model as a composite factor and was defined a priori, so as to avoid cherry picking factors. In a supplementary analysis, each scaled engagement factor was entered into the model separately. This analysis revealed that therapist consultation, lesson completions, and the number of survey completions were each a significant predictor of PHQ-8 reduction (*P*<.001). However, the number of messages sent to the therapist, while positively associated with the other engagement factors, was not a significant predictor of change in depression and anxiety scores. In other words, activities that did not involve direct interaction with the therapist appear to have also moderated improvement in depression and anxiety. However, as shown in Table 3, we acknowledge that behaviors such as lesson and survey completions may have been facilitated by the therapist, indirectly. Nevertheless, these results suggest a synergistic relationship between app-based features and therapist support.

Table 2. Program engagement during the intensive phase of the program by condition.

Engagement factor	Depression (n=139), mean (SD)	Anxiety (n=146), mean (SD)
Survey Completions	5.54 (3.50)	5.75 (3.90)
Therapist Consultations	4.64 (4.86)	4.90 (5.17)
Messages Sent to Therapist	20.66 (22.71)	22.15 (23.43)
Completed Lessons and Activities	19.57 (17.91)	21.88 (19.63)

Table 3. Pairwise correlation matrix of program engagement factors by condition.

Condition and factor	Survey completion	Therapist consultations	Messages to therapist	Lessons and activities	*P* value
Depression					
Survey completion					.001
r	1	0.32[a]	0.24[a]	0.56[a]	
Therapist consultations					<.001
r	0.32[a]	1	0.63[a]	0.72[a]	
Messages to therapist					.04
r	0.24[a]	0.63[a]	1	0.49[a]	
Lessons and activities					<.001
r	0.56[a]	0.72[a]	0.49[a]	1	
Anxiety					
Survey completion					<.001
r	1	0.34[a]	0.28[a]	0.68[a]	
Therapist consultations					<.001
r	0.34[a]	1	0.63[a]	0.69[a]	
Messages to therapist					.006
r	0.28[a]	0.63[a]	1	0.51[a]	
Lessons and activities					<.001
r	0.68[a]	0.69[a]	0.51[a]	1	

[a]The correlation is significant at a level of .05 (two-tailed).

Overall, the extent of engagement (ie, the number of messages sent and lessons completed per week) declined with program time. However, 77.3% (51/66) of participants who completed an assessment at the end of the intensive phase, remained active

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in the program at month 6 and 58.1% (25/43) were active at program month 9. It was possible that this effect was due to survival bias, in that the program retained participants who were improving. We tested this hypothesis using a logistic regression model to examine if greater reductions in depression at the end of the intensive phase predicted the likelihood of remaining active in the program at month 6. However, changes in depression scores at the end of program month 3 failed to predict the likelihood of remaining active in the program (P=.55).

Discussion

Principal Results

Vida Health's digital cognitive behavior therapy program is an app-based structured intervention that includes one-on-one sessions with a remote licensed therapist. The objective of the study was to assess the effectiveness of Vida Health's digital therapy program in the treatment of mild to moderate depression and anxiety. The analyses revealed significant and clinically meaningful reductions in PHQ-8 and GAD-7 scores relative to baseline, postintervention at 12 weeks, that were then sustained at month 6 of the program. While there is a growing body of evidence that suggests that digital mental health interventions are as efficacious as face-to-face interventions [12], their long-term effectiveness remains an open question. The results of this study suggest that the Vida Health therapy program was associated with improvements in depression and anxiety. Furthermore, the significant association between increased engagement and positive outcomes (depression: P=.01; anxiety: P<.001) suggests that the interaction with the digital platform beyond just therapist contact was a component in the mechanism of action. However, this study lacked a control or comparison group, and instead, employed an observational study design, thereby preventing the drawing of any causal inferences.

Nevertheless, the results of the present study are consistent with findings from previous research. A meta-analysis evaluating the effectiveness of cognitive behavior therapy-based digital mental health intervention for the treatment of anxiety and depression among young adults reported a mean effect size Hedges g=0.72 [25]. Other meta-analytic reviews have observed similarly robust effect sizes for anxiety (Cohen d=1.1) and depression (Cohen d=0.41) [26]. While there is compelling evidence the digital mental health interventions are feasible, acceptable and effective for depression and anxiety disorders specifically [25,27], it remains unclear if all therapeutic approaches are equally effective. Carolan et al [28] observed that a cognitive behavior therapy–based occupational program was no more effective than interventions that utilized other therapeutic approaches; they hypothesized that cognitive behavior therapy–based digital programs are not designed for delivery in occupational settings. Although the Vida Health cognitive behavior therapy program is not delivered in the workplace, the participants in the study were recruited from their place of employment, and the content of the intervention employed a framework mindful of occupational stress. More specifically, behavioral stress reduction techniques suitable to the workplace such as progressive muscle relaxation and mindfulness practices were integrated into cognitive behavior therapy and delivered as homework via the app.

Previous research also suggests that digital mental health interventions that are self-contained may facilitate improved program outcomes compared to those of hybrid interventions that integrate therapist support and app-based content delivery [8,10]. In this study, we observed strong positive associations between contact with the therapist, defined by consultations or in-app messaging, and overall program engagement, by way of utilization and completion of lessons and activities in the app. While the Vida Health cognitive behavior therapy program can be completed without therapist contact and as a standalone app-experience, we observed that therapist support and comprehensive engagement across the platform was associated with improved outcomes. Overall, the results of this study are encouraging and suggest avenues for improving engagement and achieving enduring positive outcomes.

Limitations

This study utilized a nonrandomized observational design. As such, this approach precludes any causal conclusions on the effectiveness of the intervention on the observed mental health outcomes. Self-selection bias and the lack of random assignment increase the likelihood of an overestimation of the effect size and limit generalizability of the findings. Furthermore, it was noted earlier that 54.7% of participants (177/323) completed the initial mental health assessment but failed to engage in the intervention, and as a result, these participants were excluded from all subsequent analyses. Attrition is a crucial study limitation and remains a continuing challenge for digital health interventions, particularly those focused on mental health. Fleming et al [29] have noted that uptake and usage of self-guided digital mental health interventions vary significantly, where program completions ranged from 0.5% to 28.6%. While we did not observe significant baseline differences between program nonstarters and participants who continued with the program, it is possible that participants who chose to continue in the program differed systematically from program nonstarters on factors such as the presence of co-occurring health conditions that were not disclosed during onboarding or patient activation and technology acceptance factors that were not assessed during enrollment, thereby limiting the generalizability of the findings.

The Vida Health cognitive behavior therapy program can be completed without interaction with a therapist; however, the program is designed to be therapist supported. It is possible that participants who failed to engage were seeking a self-guided approach. It is also important to note that patients may disengage from the program as symptoms improve; therefore, lack of engagement or incomplete key outcome measures, may not necessarily imply lack of improvement. Another key limitation to the generalizability of this study is the low completion rate of the assessment during the maintenance phase. While participants were encouraged by their therapist and through in-app messaging to complete the assessments, survey completion was mandatory only at the time of program enrollment and was optional at all future time-points. However, it is possible that the semimonthly assessment for the entire study duration prompted survey fatigue. Baseline score severity

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and changes in depression scores at the end of the intensive phase did not increase the likelihood of assessment completion at program month 6 (P=.45) and 9 (P=.86). It, therefore, seems unlikely that only participants who improved were motivated to complete future assessments. Furthermore, other tools and activities such as tracking moods, anxiety episodes, and mindfulness minutes were also available throughout the program. It is possible that, in some cases, participants used a multitude of these tools instead of the assessment to track progress. App-based activities in Vida Health therapy program included guided lessons and interactive trackers (eg, tracking mindfulness or meditation minutes). Supplementary analyses revealed that lessons pertaining to maladaptive thinking patterns had the highest rates of completion across participants compared to content related to mindfulness or sleep. It is possible that altering or expanding content to include topics with the greatest uptake may be associated with improved program retention. We also noted that lessons were consistently utilized at a greater rate than tools throughout the study duration. In the intensive phase (ie, 12 weeks), participants utilized 2.64 more lessons than tracking tools. During the maintenance phase of the program, participants completed 3.21 more lessons than tracking tools. While beyond the scope of this paper, additional research is warranted to understand if specific patterns of lesson and tool usage are associated with improved retention, and moreover, if specific guided lessons that incorporate interactive tracking tools or videos are associated with greater program engagement.

The Vida Health therapy program offers a structured approach that combines core concepts from cognitive behavior therapy including cognitive model, guided discovery, behavioral activation, and techniques including mindfulness for addressing maladaptive thinking. While an analysis of which of these features may have contributed to program uptake, engagement, and behavioral outcomes was beyond the scope of this study, future research must be undertaken to better understand how these elements influence program effectiveness. Further exploration into how patterns of program engagement alter as symptoms improve or worsen may broaden our understanding of program uptake and retention from that of binary (engaged or not engaged) to multidimensional understanding. In this study, engagement was defined as the combined additive effect of app-based behaviors and the extent of therapist contact. However, dimensionality reduction techniques such as principal component or factor analysis may provide more nuanced insight into patterns of engagement and possible changes with time.

As health care increasingly leverages technology for delivering remote on-demand care and interventions, research on their effectiveness has largely taken a single condition, single outcome approach. However, mental health conditions such as depression and anxiety are often comorbid with other chronic conditions such as obesity and type 2 diabetes. Approximately 40% of adults are living with multiple chronic conditions in the United States [30]. It is estimated that about one in three adults with type 2 diabetes experience clinically significant symptoms of depression [31,32]. We did not examine possible associations between depression or anxiety and other health factors. However, research suggests the co-occurrence of depression and anxiety with other chronic conditions may negatively impact psychological well-being and disease management. While participants in this study were exclusively enrolled in the Vida Health therapy program, the platform supports integrated care wherein a patient may concurrently seek care from a therapist, while also working on the management of a cardiometabolic health condition. Additional research is warranted in understanding the association between improvements in depression and chronic health outcomes.

Conclusions

It is estimated that 7.1% of all Americans have experienced at least one major depressive episode, with increased prevalence among women and the highest prevalence observed among young adults (18-25 years) [33]. Similar high prevalence rates have been observed for anxiety [34]. In this study, adults with mild to moderate depression or anxiety were enrolled in a digital cognitive behavior therapy program with remote one-on-one video sessions with a licensed therapist. The results of this study indicate significant and clinically meaningful improvements in depression and anxiety scores relative to baseline that were observed postintervention at 12 weeks and sustained at program month 6. However, participant attrition, the lack of a control group, and observational design were study limitations, and therefore, qualify the generalizability of these findings. Nevertheless, evidence-based digital cognitive behavior therapy interventions such as the Vida Health therapy program show promise in increasing access and providing effective care for the management of depression and anxiety.

Acknowledgments

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Authors' Contributions

AV, LR, and CM developed the study concept and design. Data acquisition was supervised by AV, MK, and LR. LR and CM oversaw study intervention. AV performed statistical analyses and interpretation of data. Drafting of manuscript was done by AM, LR, MK, and CM

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Conflicts of Interest

AV, LR, MK, and CM are employees of Vida Health and receive compensation by way of salary and equity. CM is the chief clinical officer at Vida Health.

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Abbreviations

GAD-7: Generalized Anxiety Disorder, 7-item
HIPAA: Health Insurance Portability and Accountability Act
PHQ-8: Personal Health Questionnaire, 8-item

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Original Paper

Motion-Based Technology for People With Dementia Training at Home: Three-Phase Pilot Study Assessing Feasibility and Efficacy

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Abstract

Background: Persons with dementia tend to be vulnerable to mobility challenges and hence face a greater risk of fall and subsequent fractures, morbidity, and mortality. Motion-based technologies (MBTs), also called sensor-based technologies or virtual reality, have the potential for assisting physical exercise and training as a part of a disease management and rehabilitation program, but little is known about its' use for people with dementia.

Objective: The purpose of this pilot study was to investigate the feasibility and efficacy of MBT physical training at home for people with dementia.

Methods: A 3-phase pilot study: (1) baseline start-up, (2) 15 weeks of group training at a local care center twice a week, and (3) 12 weeks of group training reduced to once a week, supplemented with individual MBT training twice a week at home. A total of 26 people with dementia from a municipality in Southern Denmark were eligible and agreed to participate in this study. Three withdrew from the study, leaving 23 participants for the final analysis. Feasibility was measured by the percentage of participants who trained with MBT at home, and their completion rate of total scheduled MBT sessions. Efficacy was evaluated by physical function, measured by Sit-to-Stand (STS), Timed-Up-and-Go (TUG), 6-minute Walk Test (6MW), and 10-meter Dual-task Walking Test (10MDW); cognitive function was measured by Mini-Mental State Examination (MMSE) and Neuropsychiatric Inventory-Questionnaire (NPI-Q); and European Quality of Life 5 dimensions questionnaire (EQOL5) was used for measuring quality of life. Descriptive statistics were applied accordingly. Wilcoxon signed-rank and rank-sum tests were applied to explore significant differences within and between the groups.

Results: As much as 12 of 23 participants (52%) used the supplemental MBT training at home. Among them, 6 (50%) completed 75% or more scheduled sessions, 3 completed 25% or less, and 3 completed between 25% and 75% of scheduled sessions. For physical and cognitive function tests, supplementing with MBT training at home showed a tendency of overall stabilization of scores among the group of participants who actively trained with MBT; especially, the 10MDW test even showed a significant improvement from 9.2 to 7.1 seconds (P=.03). We found no positive effect on EQOL5 tests.

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Conclusions: More than half of the study population with dementia used MBT training at home, and among them, half had an overall high adherence to the home training activity. Physical function tended to remain stable or even improved among high-adherence MBT individuals. We conclude that MBT training at home may be feasible for some individuals with dementia. Further research is warranted.

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KEYWORDS

dementia; motion-based technology; virtual reality; telerehabilitation; physical training; physical and mental function

Introduction

Dementia is characterized by cognitive impairments that gradually change the individual's behavior, personality, and physical functioning [1]. As the disease progresses, individuals with dementia experience increasing difficulties with everyday tasks and often require support from caregivers to complete daily activities [2]. Worldwide, approximately 50 million people live with dementia [3], and this number will increase dramatically over the coming decades with the aging population. This will place heavy health and economic burdens on individuals, families, and society at large [1].

Many rehabilitation interventions to improve everyday life for people with dementia and their families have been explored, and many more are under consideration from research to implementation in the future [4]. Among such interventions, a suite of new technologies has gained popularity in recent years as an aid to support elderly care. Some of these technologies, such as electronic health (eHealth) and smart home devices, seem promising and feasible for the elderly both in institutions and at home [5-7], although one may be more effective than another depending on chronic diseases under management [8].

Alongside new technology development, usage of new technologies for assisting physical exercise and training as a part of disease management and rehabilitation has grown in parallel with the decentralization of health care, shifting from skilled facility care to in-home care [9,10]. Among such technologies are motion-based technologies (MBTs), also called sensor-based technologies or virtual reality. This kind of assistive technology has been approved as beneficial for stroke recovery and atraumatic brain injury rehabilitation [11,12].

For dementia, a growing body of research reports on the possibility of improving the lives of people with dementia using MBTs, but most training programs researched thus far have featured games and leisure activities and were conducted in group settings [13]. MBTs for individuals with dementia training at home and focusing on physical and cognitive function through structured exercise have rarely been studied, although many people with early stage dementia are capable of using computers and touchscreen tablets [14]. A single-case feasibility study from Canada testing a 2-week virtual reality training for a patient with dementia reported that an exercise-based virtual reality intervention was tolerated well by the patient; however, the patient's balance and mobility remained unaffected [15].

Persons with dementia tend to be vulnerable to mobility challenges and hence face a greater risk of fall and subsequent fractures, morbidity, and mortality [16]. Physical exercise involving the movement of skeletal muscles has been associated with improvement of balance, functions, and mood among older people, aside from other health improvement benefits [17,18]. Therefore, strengthening body capacity levels through exercise among people with dementia may not only reduce these risks but also has the potential to improve physical and cognitive function as well as overall well-being [19-22], although some benefits of exercise are still debated [23].

The current public policy in Denmark aims to promote living at home for as long as possible, providing the elderly with in-home care and support, including those with dementia [24]. Many individuals with early stage dementia can live independently and tend to do so; approximately 60% of all persons with dementia live in their own home [25]. Effective home-based rehabilitation using MBTs is desirable as compared with center-based rehabilitation, an intervention which has demonstrated efficacy but presents challenges for individuals who require assistance to attend in-person visits [26]. A combination of home- and center-based training could present flexibility for people with dementia and their carers, serving to stabilize physical and cognitive function without losing social contacts.

However, it is unknown how individuals with dementia living at home respond to this type of intervention, or its potential benefits. Prior to implementing and evaluating the effects of MBTs in a larger randomized controlled trial (RCT), it is relevant to understand whether individuals will accept and implement MBTs, as well as the completion rate and preliminary physical and cognitive effect outcomes. We thus conducted this pilot study aiming to test the feasibility and efficacy of MBT training at home for people with dementia.

Methods

MBT Hardware and Software

The MBT used for this project utilized an online administration system developed by Welfare Denmark (Wellfaster), which has been tested in people who were at higher risk of fall in Denmark [27].

The MBT hardware consisted of a touchscreen, a Microsoft Kinect camera, and a modem (Figure 1). The screen was placed in a room with at least 1.5 × 3 m of space to perform the exercises, and with no sharp light, which would disable registration of the participant's movements by the camera.

The MBT training program software consisted of 142 exercises, covering all major muscle groups. The exercise program was integrated with a calendar system, allowing a physiotherapist

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to schedule and select daily training exercises to fit each individual participant's needs.

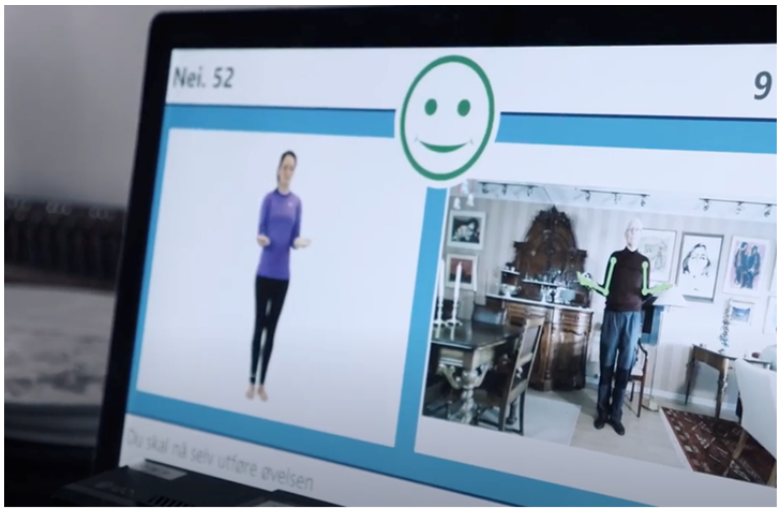
The system, when initiated, guided the participant through various exercises via text, recorded instructions, and animations. The Kinect camera detected the individual's movements and corrected possible errors with onscreen feedback; once the participant successfully completed each exercise, visual feedback in the form of a green smiling icon was displayed onscreen. If the exercise was properly performed, the green smiling icon appears on the screen; if performed incorrectly, then a frowning icon appears (Figure 2). After finishing the daily training session, the participants received visual feedback displaying the percentage of correctly completed exercises.

The training data were transmitted to a physiotherapist in the form of graphic charts including the date of the training performed, percentage of correctly completed exercises, and number of training sessions completed that day. If the participants did not train as agreed or trained but with discrepancies in terms of quality, an email was automatically generated to the responsible physiotherapist to follow-up with necessary measures.

Figure 1. Model layout of the motion-based technology for persons with dementia training at home (Welfare Denmark [Wellfaster]).



Figure 2. Model layout of movement detection and visual feedback with a green smiling icon (Welfare Denmark [Wellfaster]).



Study Participants

The study participants were from Esbjerg, a municipality located in southwestern Denmark with approximately 115,000 inhabitants. The municipality offers rehabilitation to citizens with dementia, comprising physical training and social and psychological support at local care centers free of charge. Support is also offered to relatives caring for individuals with dementia [28].

For this pilot study, participant selection proceeded through 2 steps: (1) once a person was diagnosed with dementia at a memory clinic in Esbjerg in 2016-2017, s/he was asked whether s/he was willing to be contacted by the municipality's Dementia Knowledge Center (DKC); (2) among those who consented to further contact, a nurse from the DKC contacted and used the inclusion criteria to invite potential participants to a start-up meeting at the center.

The nurse at the DKC selected the study participants based on a diagnosis of mild to moderate dementia from the municipality memory clinics. Other inclusion criteria included participants (1) with a Mini-Mental State Examination (MMSE) score ≥18 diagnosed from the memory clinics, (2) over 50 years of age,

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(3) living at home, (4) sufficient fluency in Danish to participate in tests and interviews, and (5) a close relative in daily contact with the participant who also possessed sufficient fluency in Danish to participate.

In addition, we excluded participants who (1) lived at a nursing home, (2) had a diagnosis of other serious physical or psychiatric illness, including severe sight or hearing disabilities that could affect their ability to participate, or (3) were participating in other intervention projects or drug trials.

Pilot Intervention

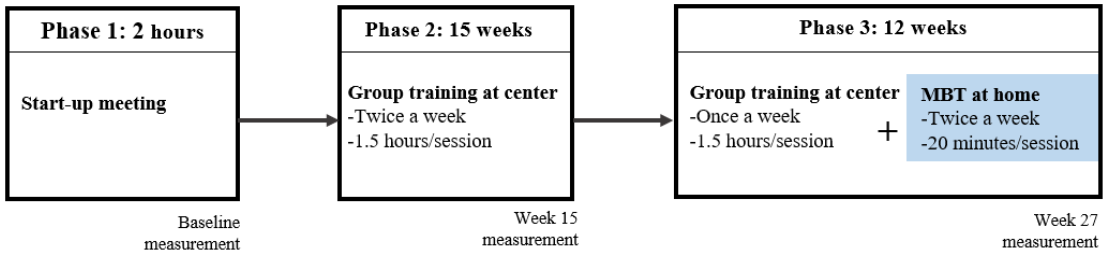
This study intervention had 3 phases, illustrated in Figure 3.

Phase 1, which was conducted in 2016 and 2017, consisted of a 2-hour start-up meeting held at the DKC. During the meeting, a physiotherapist verbally introduced the detailed study plan to the participant and the caregiver. Practical operation of the MBT device, communications from the screen to the participant, and feedback methods were introduced. The individuals who agreed to participate in the study provided their consent for participation (regardless of which training option was self-chosen) and completed the baseline questionnaire survey and further physical and cognitive function measurements. Those who agreed to train supplementing with MBT received a follow-up home visit for MBT device installation, by either a technical support person or the physiotherapist, if the participant had difficulties with unfamiliar persons.

Phase 2 consisted of 15 weeks of group physical training at the local care center in 2016-2017 for all the study participants; physical training took place twice a week for 1.5 hours per session. A physiotherapist from the local care center facilitated group physical trainings, comprising exercises for balance, coordination, strength, and cardio adjusted to participants' strength, flexibility, and endurance. While the individuals completed the physical training session, caregivers were provided with a separate room with free coffee, facilitating an opportunity to meet and talk to other caregivers.

Phase 3 was a 12-week training including the MBT intervention. In this phase, the participants, based on the decisions they made in Phase 1, self-directed to either (1) continue with the group training at the local training center twice a week for 1.5 hours per session, or (2) continue with the group training at the local training center but reduced to once a week for 1.5 hours per session, supplemented with individual MBT training at home twice a week for 20 minutes each session.

Figure 3. Pilot study phases.



Variable Measurements

The study outcomes were feasibility and efficacy. We defined the feasibility as the percentage of the participants who trained with MBT at home, examining their completion rate for the scheduled total 24 sessions over the 12 weeks of the intervention. We defined the efficacy as improvement of participants' physical and cognitive function and quality of life (QoL).

Baseline Demographic Characteristics of Participants and Caregivers

The characteristics of participants at baseline were obtained using semistructured questionnaires administered by a project nurse during the start-up meeting, gathering information on sociodemographics, dementia diagnosis, chronic diseases, and social relations. The baseline characteristics of caregivers were also self-reported in the questionnaire and included sociodemographic information and relationship to the participant.

Physical Function Measurements

To evaluate the effects of physical training, including MBT, we measured participants' physical functions at baseline, at Week 15, and at Week 27 using 4 measurements discussed next, all of which are common physical performance measures for muscular strength, balance, walking ability, and gait speed in older adults, including those with a dementia diagnosis [29-31].

Sit-to-Stand Test

The Sit-to-Stand (STS) test determines a person's functional level by quantifying performance of lower extremity muscles [32]. STS is performed using a chair without armrests, with a seat height of 43 cm; participants are required to stand up from the chair and then sit back. The number of repetitions completed (sit to stand) over 30 seconds was counted. The same chair was used for all participants during all 3 study phases.

Timed-Up-and-Go Test

The Timed-Up-and-Go (TUG) test evaluates dynamic balance and is used to assess persons at risk of falling due to gait problems and balance. It is a reliable and validated test in the elderly population to measure functional ability and clinical changes over time [29]. TUG measures the time in seconds that participants require to rise from a straight-backed chair without using their arms, walk 3 meters, turn around, walk back to the chair, and sit down. The same chair was used in the TUG test for all participants for all 3 study phases.

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6-Minute Walk Test

The 6-minute Walk Test (6MW) was originally developed for patients with heart failure [33], and it is a reliable and validated measure in evaluating walking ability among older people with dementia [30]. The participants were asked to walk for 6 minutes as far as they could, at their usual pace. The distance in meters they walked in 6 minutes was recorded. The participants could stop and/or rest if they felt it necessary.

10-Meter Dual-Task Walking Test

Previous studies have shown that dual-task training improves dual-task performance in people with mild to moderate dementia [34,35]. The 10-meter Dual-Task Walking Test (10MDW) required participants to walk for 10 m at a comfortable, normal pace without assistance or mobility aids (straight walk) and then to walk the same distance back (turn walk/dual task). The participants were asked to wear comfortable footwear to the test. The time to traverse 10 m on the two occasions was also averaged to calculate their gait velocity.

Cognitive Function and Quality of Life Measurements

Mini-Mental State Examination

Even if the participants had fulfilled the MMSE score inclusion criteria, there was a time gap from the date of diagnosis by the local memory clinic to the date of study entrance, and changes in cognitive functions vary among the study participants. We, therefore, again measured their cognitive function by using MMSE at the baseline and at Week 27 (the end of the supplemental MBT), administered by a consultant specialized in dementia. MMSE is a validated and widely used screening tool for assessing cognitive impairment and tracking cognitive changes over time. It briefly measures several domains, including orientation to time and plan, immediate recall, short-term verbal, memory, calculation, language, and construct ability [36]. MMSE has in total 30 points, and in DKC daily practice, a score of 25-30 is considered mild dementia, a score of 18-24 is considered moderate dementia, and any score under 18 is categorized as severe dementia.

Neuropsychiatric Inventory-Questionnaire

We applied the Neuropsychiatric Inventory-Questionnaire (NPI-Q) to assess the presence of the participants' dementia symptom severity and distress [37]. NPI-Q includes 12 categories of behavioral disturbance: delusions, hallucinations, anxiety, depression/dysphoria, agitation/aggression, elation/euphoria, disinhibition, irritability/lability, apathy/indifference, motor disturbance, nighttime behavior problems, and problems with appetite/eating. For this study, we presented a total NPI-Q score as the sum of the total severity score and total distress score [38], which were self-reported by the participant.

Quality of Life

Participants' and their caregivers' QoL at baseline, Week 15, and Week 27 were measured using the Euro Quality of Life 5D questionnaire (EQOL5), which is a short, simple, validated questionnaire for the health-related QoL assessment [39]. It contains 5 three-level dimensions covering morbidity, self-care, usual activities, pain/discomfort, and anxiety/depression. A single summary score ranging from 0 to 100 is given by the participant to indicate his/her health status. The higher the score, the better the participant's QoL.

Statistical Analysis

The proportion of participants who trained with supplemental MBT training at home, the successful completion rate, the correction rate (ie, the percentage of all training sessions completed correctly), and the characteristics of the participants at baseline according to whether they supplemented with MBT training at home were all described statistically. The differences between the two groups were tested using Pearson chi-squared test for the categorical variables, or two-sample *t* tests for the continuous variables.

Physical and cognitive functions and QoL on 3 occasions (Phases 1, 2, and 3) were presented as medians with first and third quartile (25%-75%). Given the relatively small number of study participants and the potential skewing of their functional data distribution, we therefore applied Wilcoxon signed-rank and rank-sum tests to explore the significant differences between 2 occasions (Phase 1 and Phase 2, and Phase 2 and Phase 3), both within and between the groups with and without supplemental MBT training at home.

Subgroup analysis was conducted among the participants according to their MBT training completion status: those who trained more actively (completion of 75% or more sessions as scheduled) and those who trained less actively (completion of 25% or less sessions as scheduled) at home using MBT.

The person who conducted the questionnaire surveys, the person who collected the MBT training data, and the person who analyzed the data were independent and blinded for each other's tasks.

Stata Statistical Software Release 16 (StataCorp) was used for statistical analysis, and *P* values less than .05 were considered statistically significant.

Consent and Ethical Considerations

Individuals with dementia and their relatives were instructed verbally and in writing regarding the project. Those who wished to participate in the study signed a consent statement. This study has been submitted to the University Scientific Ethics Committee and assessed as requiring no need for notification (Journal number 2016-41-4844). The Danish Data Inspectorate approved the project (Journal number 2016-41-4844).

Results

Selection of Participants

A total of 49 potential participants were identified with a diagnosis of dementia from Esbjerg memory clinics within 12 months prior to the study baseline. Among them, 18 were excluded as they did not fulfill the inclusion criteria, which left 31 persons eligible for study participation. Of those 31, 5 declined to participate in the study.

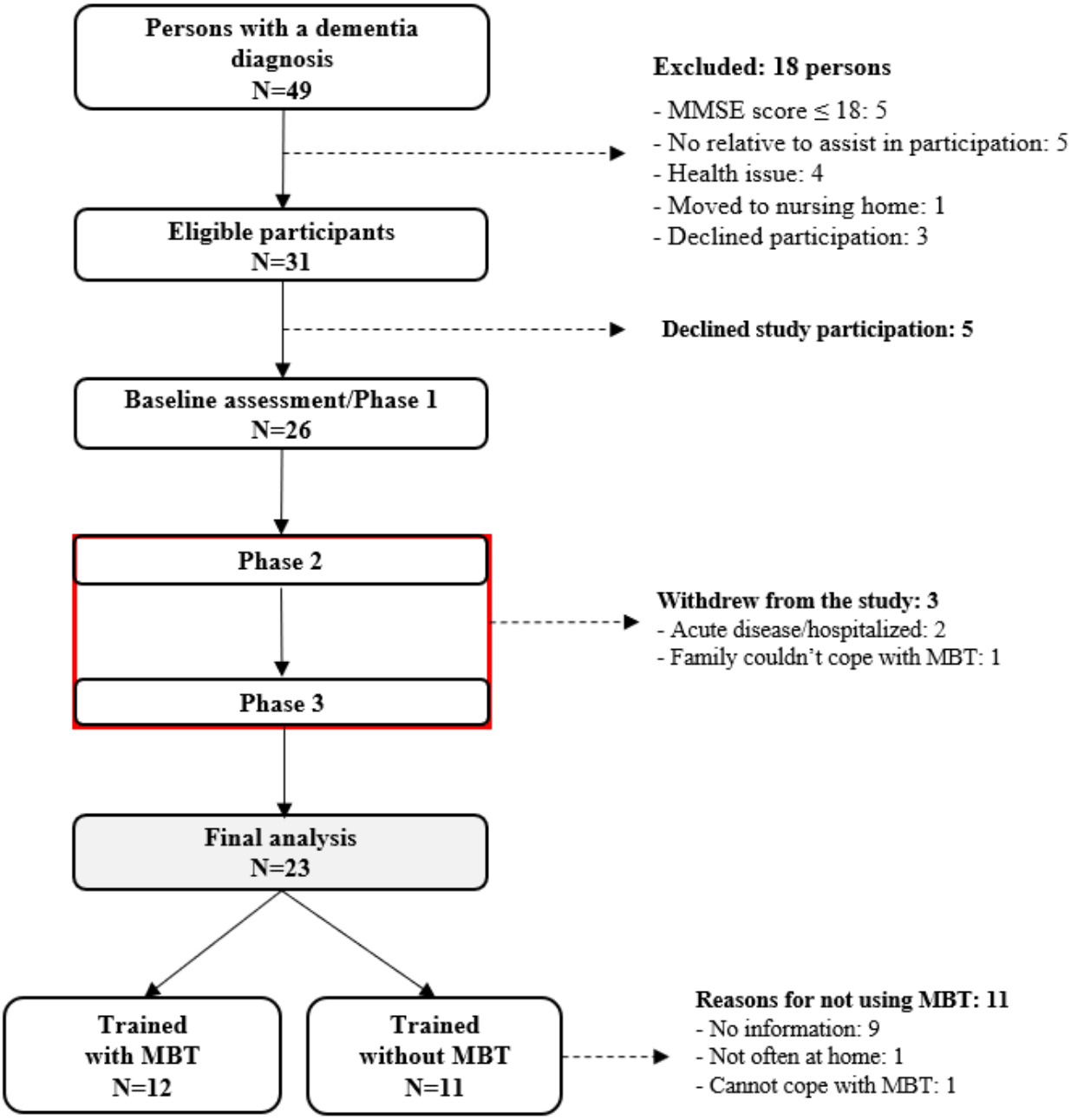
A total of 26 participants were assessed during the start-up meeting (baseline) in 2016-2017. However, 3 persons withdrew from the study due to acute illness/hospitalization (n=2) or

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because the family could not cope with MBT technological difficulties (n=1). This left 23 participants for the final analysis, including 12 who supplemented with MBT training at home and 11 who only completed the center-based group training with no additional supplementation (Figure 4).

There were different reasons as to why the 11 participants chose not to train with MBT at home: not at home very often (n=1), had a hard time coping with MBT technology (n=1), and no information was provided (n=9).

Figure 4. Flowchart of study participation.



Characteristics of the Participants at Baseline

Table 1 presents the characteristics of the 23 participants at baseline in the 2 groups. The mean age of the 12 participants who supplemented their training with at-home MBT was 75.6 years (SD 6.4), and the mean age of those who trained without MBT was 79.1 years (SD 4.4).

Overall, the 2 groups had no significant difference in age, gender, health conditions, physical functioning, socioeconomic status, or caregiver characteristics. However, those who trained with MBT had on average a higher QoL and a slower 10MDW than those who did not train with MBT at baseline (P<.05).

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Table 1. Characteristics of the participants at baseline (n=23) by the status of supplemental at-home MBT[a] training.

Characteristics	Supplemented with MBT at home		
	MBT (n=12)	No MBT (n=11)	*P* value
Participants			
Age, mean (SD)	75.6 (6.4)	79.1 (4.4)	.14
Gender			.06
Male	10	5	
Female	2	6	
Height, cm (SD)	173.6 (7.4)	166.7 (7.2)	.04
Weight, kg (SD)	80.5 (13.4)	71.5 (12.9)	.12
Health conditions			
Dementia type			.18
Alzheimer	5	3	
Vascular dementia	1	4	
Dementia with Lewy body	3	3	
Mild cognitive impairment	0	1	
Unspecified dementia	3	0	
Computed tomography/Magnetic resonance imaging scanning for dementia diagnosis			.29
Yes	12	10	
No	0	1	
Comorbidity			
Diabetes	2	0	.16
Heart disease	4	3	.75
Chronic obstructive pulmonary disease	1	1	.95
Depression	4	3	.75
Cognitive and physical functioning			
MMSE[b] scores			.008
Mild (25-30)	10	5	
Moderate (18-24)	2	0	
No report		6	
Neuropsychiatric Inventory-Questionnaire, mean (SD)	14.3 (8.4)	11.6 (2.5)	.67
European Quality of Life 5 dimensions, mean (SD)	78.5 (20.1)	59.7 (19.1)	.01
Sit-to-Stand in numbers[c], mean (SD)	13 (3.2)	12 (2.7)	.53
Timed-Up-and-Go in seconds, mean (SD)	8.4 (4.2)	7.7 (1.9)	.60
10-meter Dual-Task Walking Test in seconds, mean (SD)	10.5 (2.9)	8.2 (1.8)	.036
6-minute Walk Test in meters, mean (SD)	370.5 (156.8)	383.1 (74.7)	.81
Socioeconomics			
Education			.54
Have education	10	8	
Do not have any education	2	3	
Living alone			.13
Yes	2	5	
No	10	6	

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Characteristics	Supplemented with MBT at home		
	MBT (n=12)	No MBT (n=11)	*P* value
House living status			.51
Own home	10	9	
Elderly community	0	1	
Other	2	1	
Caregivers			
Living together with dementia patient			.13
Yes	10	6	
No	2	5	
Contact with the person with dementia			.09
Daily	11	8	
Several times per week	1	3	
Education			.95
Have some education	11	10	
No education	1	1	
Currently working			.90
Yes	3	3	
No	9	8	
European Quality of Life 5 dimensions, mean (SD)	79.8 (20.1)	70.5 (16.5)	.24

[a]MBT: motion-based technology.

[b]MMSE: Mini-Mental State Examination.

[c]Number of repetitions completed (sit to stand) over 30 seconds.

Feasibility of Using MBT Training at Home

Of the 23 participants, 12 (52%) trained with MBT at home. Among them, 6 (50%) completed (≥75%) all 24 sessions as scheduled, with a correction quality (ie, the percentage of all training sessions completed correctly) ranging from 70% to 94%, 3 completed 25%-75%, and 3 completed less than 25% as scheduled. The successful intervention implementation rate among those who trained with MBT at home was thus 50% (6/12; Table 2).

Table 2. Completed sessions as scheduled (n=24) among 12 participants who trained with supplemental at-home motion-based technology.

Completion as scheduled	Participants, n (%)	Completed sessions, n (correction rate %)[a]
≥75% completion[b]	6 (50)	25 (90), 26 (70), 30 (84), 32 (93), 50 (74), 62 (94)
25%-75% completion	3 (25)	9 (92), 10 (85), 16 (82)
≤25% as completion	3 (25)	1 (57), 2 (42), 3 (58)

[a]The percentage of all training sessions that participants completed correctly.

[b]All participants in this group completed all training sessions as scheduled.

Development of Physical and Cognitive Functions and Quality of Life

Table 3 lists the physical and cognitive function as well as QoL measured at each occasion among the participants who trained with and without MBT at home.

In general, physical function measured using the 10MDW among the participants who trained with MBT showed a tendency of improvement throughout the study, including during the period of MBT implementation from Week 15 (9.1 seconds) to Week 27 (8.0 seconds), whereas other measures for physical function including STS, TUG, and 6MW, showed a tendency to stabilize in both groups.

No significant change was observed in MMSE or NPI-Q throughout the study between the 2 groups. Regarding QoL, the participants showed a decline from Week 15 to Week 27 in both groups during the period of MBT implementation. However, their caregivers showed two tendencies for this period: a declining tendency of QoL score among those who trained with MBT, and an increasing tendency of QoL score among those who trained without.

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A Wilcoxon signed-rank test showed no statistically significant differences between the groups at Week 27 as well as within the group between Week 15 and Week 27 for all measurements (ie, the period when MBT was implemented).

Table 3. Physical and mental function on 3 occasions among the participants who trained with (n=12) and without (n=11) MBT[a] at home.

Functional status	Median (interquartile range Q1-Q3)		
	P1: Baseline	P2: Week 15	P3: Week 27
Physical function			
Sit-to-Stand in numbers[b]			
With MBT	14 (10-16)	14 (12-16)	14 (12-16)
Without MBT	12 (10-14)	12 (11-15)	13 (11-16)
Timed-Up-and-Go in seconds			
With MBT	6.7 (6.7-8.5)	6.7 (5.5-7.9)	6.5 (5.5-7.8)
Without MBT	8.0 (6.1-9.2)	7.1 (5.7-9.1)	7.8 (5.9-8.5)
10-meter Dual-Task Walking Test in seconds			
With MBT	10.0 (9.2-12.2)[c]	9.1 (7.5-9.8)[d]	8.0 (7.1-8.9)
Without MBT	8.6 (7.2-9.5)	8.7 (7.5-9.5)	8.6 (7.2-10.1)
6-minute Walking Test in meters			
With MBT	443 (345-474)	416 (350-472)	418 (334-501)
Without MBT	385 (311-457)	339 (304-468)	360 (334-493)
Cognitive function and quality of life			
MMSE[e] score			
With MBT	26 (24-27)		24 (22-28)
Without MBT	24 (24-26)		24 (23-26)
NPI-Q[f] score			
With MBT	10 (3-17)	7 (2-12)	10 (3-12)
Without MBT	10 (4-11)	13 (5-23)	12 (8-12)
QoL[g] score			
With MBT	80 (72-80)[c]	85 (70-90)	78 (68-80)
Without MBT	60 (50-75)	75 (70-80)[d]	70 (60-80)
Caregivers' QoL score			
With MBT	90 (70-92)	94 (80-100)[d]	83 (67-98)
Without MBT	70 (50-90)	78 (75-83)	90 (70-90)

[a]MBT: motion-based technology.

[b]Number of repetitions completed (sit to stand) over 30 seconds

[c]Significant difference between two groups at baseline (P<.05)

[d]Significant difference within the group between baseline and Week 15 (P<.05)

[e]MMSE: Mini-Mental State Examination.

[f]NPI-Q: Neuropsychiatric Inventory-Questionnaire.

[g]QoL: quality of life.

Subgroup of Participants Who Trained Actively With MBT

A subgroup analysis showed that among those who more actively trained with MBT at home (completion rate ≥75% as scheduled) had a significant improvement of 2.1 seconds in the 10MDW test, from 9.2 at Week 15 to 7.1 seconds at Week 27 (P=.031), as shown in Table 4. The other 3 tests (STS, TUG, and 6MW), however, showed a tendency of stabilization in this period. For the group of participants who trained less actively with MBT (completion rate ≤25% as scheduled), all 4 physical function tests showed a tendency of either no change or a decline from Week 15 to Week 27.

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MMSE and NPI-Q seemed stable among those who more actively trained with MBT. QoL of the participants and their caregivers both had a tendency of decline regardless of whether they trained more or trained less actively with MBT. Again, except 10MDW, all other test measurements were statistically insignificant between or within the group between Week 15 and Week 27.

Table 4. Physical and mental function of participants who more actively (n=6) and less actively (n=3) used MBT[a] at home.

Functional status	Median (interquartile range Q1-Q3)		
	P1: Baseline	P2: Week 15	P3: Week 27
Physical function			
Sit-to-Stand in numbers[b]			
More active	13 (11-14)	14 (12-15)	14 (12-15)
Less active	16 (9-17)	12 (11-20)	11 (10-16)
Timed-Up-and-Go in seconds			
More active	7.1 (6.7-9.6)	6.6 (5.5-8.5)	6.5 (5.4-7.8)
Less active	6.7 (6.6-6.7)	6.4 (5.4-6.9)	6.5 (5.4-7.8)
10-meter Dual-Task Walking Test in seconds			
More active	10.1 (9.7-14.5)	9.2 (7.8-9.7)	7.1 (6.4-7.9)[c]
Less active	10.0 (8.8-10.0)	7.8 (7.2-9.5)	8.5 (8.4-12.2)
6-minute Walking Test in meters			
More active	443 (348-455)	423 (370-480)	424 (345-548)
Less active	345 (345-462)	400 (330-464)	334 (277-465)
Cognitive function and quality of life			
MMSE[d] score			
More active	25 (23-27)		24 (20-25)
Less active	25 (25-26)		22 (22-28)
NPI-Q[e] score			
More active	6 (1-12)	8 (3-11)	6 (5-11)
Less active	15 (2-20)	7 (1-17)	10 (0-24)
QoL[f] score			
More active	80 (76-80)	90 (80-90)	80 (70-100)
Less active	70 (60-75)[g]	70 (60-90)	65 (60-75)
Caregivers' QoL score			
More active	78 (65-90)	86 (74-94)	71 (61-78)
Less active	90 (45-100)	100 (40-100)	95 (60-100)

[a]MBT: motion-based technology.

[b]Number of repetitions completed (sit to stand) over 30 seconds.

[c]Among those who more actively and less actively trained with MBT between Week 15 and Week 27, Wilcoxon signed-rank test *P*=.031.

[d]MMSE: Mini-Mental State Examination.

[e]NPI-Q: Neuropsychiatric Inventory-Questionnaire.

[f]QoL: quality of life.

[g]Among those who more actively and less actively trained with MBT at home at baseline, rank-sum test *P*=.048.

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Discussion

Principal Findings

This pilot study tested whether supplementing with MBT training at home is feasible and can improve physical and cognitive function as well as QoL of people with mild dementia. Among the 23 participants in the final analysis, more than half (12/23, 52%) trained with MBT and among that group, half (6/12, 50%) had an overall high adherence to this home training activity. Supplementing with MBT training at home showed a tendency to stabilize physical and cognitive functioning; physical function even improved in some participants who more actively trained with MBT. However, our results revealed a tendency of declining QoL with MBT implementation, for both the participants and their caregivers, a finding which requires further study.

Studies of physical training using MBT at home (with a similar platform) in people with dementia are sparse, and it is therefore difficult to compare our study with others conducted under similar circumstances. A literature review of 45 studies concludes that people with dementia are able to independently use touchscreen technology for cognitive rehabilitation with featured games or leisure activities [40]. Other researchers report that although people with early stage dementia are largely not confident with new technology devices, half were able to use a tablet computer independently [14]. In our study, we also found half of the participants had high adherence with the use of MBT at home, which shows consistency with the aforementioned studies in a broader sense.

Learning a new technology can be both physically and emotionally challenging for elderly individuals, especially for those with dementia. These challenges can include unfamiliarity with new technology operation, lack of understanding the purpose, fear of mistakes, or forgetfulness about how the technology works, which can affect the participants' adherence to using MBT training at home [41]. Adaptability to new technology is lower among the elderly than among younger populations [42]. For those with cognitive impairment, adaptability can be even lower. Indeed, cognitive impairment of persons with dementia can limit memory, attention, concentration, visuality, execution, and speed, which can affect both performance and the experience of using MBT. Additionally, the introduction to MBT can be critical, influencing the patients and their caregivers' choice or desire to learn to use MBT [41], even if the program, including the MBT, was free of charge and offered by the municipality.

Alongside the intervention, the QoL of the participants and their caregivers, among those who trained with MBT, showed a tendency of decline. This has been interviewed with 4 pilot study participants (2 with dementia and 2 caregivers) which revealed that caregivers enjoyed the center-based training because it presented an opportunity to talk to other caregivers while the group training took place; MBT training at home was viewed as less enjoyable because it was difficult to adapt to the new technology. MBT provides many small exercises for training different body muscles; although an introduction and demonstration of MBT was provided prior to the intervention, elderly persons and especially those with dementia may benefit from a longer learning process to become comfortable with new technology. There is an ongoing study evaluating the participants' experiences of using MBT and their interactions with the physiotherapist during the training process, which may potentially provide valuable information for further refinement of this intervention.

Compared with the group training at the local center, the individual home training environment reduces social contacts, social activity, and social coherence. Social participation is important for well-being and maintenance of cognitive function [43,44]. However, a previous study of people with Alzheimer's dementia living at home showed that fewer than 40% had participated in social activities outside their home more than once a week, and nearly 30% never left their home for social activities [45]. While technological interventions have the potential to improve care, some may also create barriers to social participation, resulting in overall dissatisfaction and other adverse health consequences for both patients and their family caregivers [46].

Family caregivers play an important role in the everyday lives of individuals with dementia. For people with dementia living at home, based on evidence from the United States, approximately 75% of the care for these individuals is provided by family and friends [47]. In this study, we do not know how many participants needed and/or received support/assistance from caregivers, or how much, while training with MBT at home. A study found that people with dementia who lived with their partners tended to rely on them for support when implementing a new electronic assistive device [48]. In this pilot study, it was also often up to relatives whether to activate the MBT during the start-up meeting. Caring for a person with dementia is stressful in daily life. Too much demand for assistance with MBT training at home may have caused distress to the relative/caregiver, thereby reducing their own QoL, and additional stress if they are also unfamiliar with the MBT program's setup and operation.

Teaching and training the caregivers on hands-on skills with the assistive device may increase their ability to facilitate, support, and assist the people with dementia. A randomized controlled trail of 153 community-dwelling individuals with dementia found that home-based exercise training combined with teaching behavior management techniques to caregivers improved physical health and depression, compared with only routine care [49]. In this RCT, caregivers showed their capacity to encourage and supervise exercise participation, thus increasing the patients' physical and social activity and providing a successful integrated home-exercise program model that may apply for further research.

Despite the abovementioned, MBT training at home can provide freedom and flexibility compared with training in groups at a center. People with dementia face barriers to exercise, and researchers and health professionals are actively working together to find effective ways to deliver exercise to people with dementia; it is still unknown whether center- or home-based training is superior [50,51]. As populations age, and more elderly tend to stay at home for as long as possible, a growing

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trend for home-based care demands has arisen, including rehabilitation. As Denmark provides free health care to citizens, evaluation of the efficacy of such interventions should also consider the economic component.

Study Limitations

A relatively small sample size is one of the limitations of this study, especially the subgroups, which may have floor and ceiling effect for the results' reliability [52]. However, given that this is a pilot study to test the feasibility and efficacy of MBT training at home, a small sample size study is a rational design in terms of resource use and financial cost. Based on this pilot study's results, a larger study with improved strategic design will be implemented, preferably as a randomized control trial.

Beyond the sample size limitation, this pilot study also has generalizability weaknesses. Only those with newly diagnosed dementia who were interested in physical exercise training were invited to the start-up meeting. During that meeting, participants were drawn only from among those who were willing to use the MBT training at home and comply with the MBT regimen. Therefore, the participants in our study cannot be viewed as representative of all individuals with dementia who might train with MBT.

Moreover, involvement of users as informants and co-designers is vital for successful rehabilitation interventions and research. A systematic review of 26 publications involving people with dementia in the development of supportive IT applications concluded that involvement in all phases lead to better applications as well as empowering effects on the users [53]. We lacked this aspect in this pilot study; although the MBT platform was intended to be easy to operate, it had never been tested in people with dementia.

Of the 12 participants who trained with MBT at home, we saw 2 polar opposite phenomena: a group of participants who actively trained with a high correction rate (ranging from 70% to 94%), and a group who trained much less with a lower correction rate (ranging from 42% to 58%). For this latter group, we lack full knowledge on their reasons for not completing the scheduled training sessions. Despite difficulties in adapting to new technology, incorrect performance during MBT training may cause emotional distress, leading to dropping out or withdrawing. However, this pilot intervention lacked a comprehensive formal evaluation to identify what factors affected MBT completion rates not limited to adaptation to the new technology, such as physical, emotional, social, and spiritual well-being perspectives.

We implemented MBT twice a week together with group training at a local center once a week. Center-based group training is part of the usual care in Denmark among this population and is continuously offered to older citizens with dementia in Esbjerg, as it has shown positive effects, including social participation. As this MBT self-training at home is a pilot study with uncertainty about its effects, the weekly group training was included to at least maintain the patients' and their caregivers' social contacts. However, such a combination may have influenced the outcomes to some extent. As this pilot study showed positive potential, a further study might involve a large sample RCT designing MBT as one single arm.

Conclusion

More than half of the participants with dementia trained with MBT at home, and among them, half had an overall high adherence to the preset MBT training activity. Physical and cognitive tests showed stable scores throughout the intervention and to some extent even improvements. We conclude that MBT training at home for people with dementia may be feasible for some people with dementia together with center-based training. Further research is warranted to identify the capacities and challenges of MBT implementation and successful completion, preferably targeting both the participants and their family caregivers.

Acknowledgments

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Authors' Contributions

FW initiated the project protocol and implemented the intervention. MS was the project manager. JP conducted the data analysis and drafted the manuscript. EL, KC, CB, and JC provided academic inputs, first for the study's outcome measures, and second for the manuscript. All the authors interpreted the study results, commented, and contributed to the manuscript. All authors approved the manuscript for publishing in this journal.

Conflicts of Interest

None declared.

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Abbreviations

6MW: 6-minute Walk
10MDW: 10-meter Dual-Task Walking
DKC: Dementia Knowledge Center
EQOL5: European Quality of Life 5 dimensions questionnaire
MBT: motion-based technology
MMSE: Mini-Mental State Examination
NPI-Q: Neuropsychiatric Inventory-Questionnaire
QoL: quality of life
RCT: randomized controlled trial
STS: Sit-to-Stand
TUG: Timed-Up-and-Go

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Original Paper

Implementing Psychological Interventions Through Nonspecialist Providers and Telemedicine in High-Income Countries: Qualitative Study from a Multistakeholder Perspective

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Abstract

Background: Task sharing has been used worldwide to improve access to mental health care, where nonspecialist providers—individuals with no formal training in mental health—have been trained to effectively treat perinatal depressive and anxiety symptoms. Little formative research has been conducted to examine relevant barriers and facilitators of nonspecialist providers and the use of telemedicine in treatment service delivery.

Objective: The primary objective of this study was to examine the main barriers and facilitators of nonspecialist provider–delivered psychological treatments for perinatal populations with common mental health disorders, such as depression and anxiety, from a multistakeholder perspective.

Methods: This study took place in Toronto, Canada. In total, 33 in-depth interviews were conducted with multiple stakeholder groups (women with lived experience and their significant others, as well as health and mental health professionals). Qualitative data were quantified to estimate commonly endorsed themes within and across stakeholder groups.

Results: Psychological treatments delivered by nonspecialist providers were considered acceptable by the vast majority of participants (30/33, 90%). Across all stakeholder groups, nurses (20/33, 61%) and midwives (14/33, 42%) were the most commonly endorsed cadre of nonspecialist providers. The majority of stakeholders (32/33, 97%) were amenable to nonspecialist providers delivering psychological treatment via telemedicine (27/33, 82%), although concerns were raised about the ability to establish a therapeutic alliance via telemedicine (16/33, 48%). Empathy was the most desired characteristic of a nonspecialist provider (61%). Patient and patient advocate stakeholders were more likely to emphasize stigma as an important barrier to accessing psychological treatments (7/12, 58%), compared to clinicians (2/9, 22%) and spouses (1/5, 20%). Clinician stakeholders were more likely to emphasize the importance of ensuring nonspecialist providers were trained to deliver psychological treatments (3/9, 33%), compared to other stakeholder groups.

Conclusions: These results can inform the design, implementation, and integration of nonspecialist-delivered interventions via telemedicine for women with perinatal depressive and anxiety symptoms in high-income country contexts.

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KEYWORDS

nonspecialist providers; task sharing; perinatal mental health; perinatal depression; telemedicine; psychological treatments

Introduction

Depression is the leading cause of disability worldwide [1], with an estimated 10% to 15% of women experiencing depression and anxiety during pregnancy or in the year following childbirth [2-4]. Psychological interventions, including cognitive, behavioral, and interpersonal therapies, are effective in targeting common perinatal mental health issues such as depression and anxiety [5,6] and are preferred by women over pharmacological treatment [7,8]. However, as few as 20% of women with perinatal depression receive evidence-based psychological treatments [9]. The poor dissemination of effective psychological treatments is due, in part, to the limited number of available mental health professionals [10].

Task sharing has been used worldwide to improve access to care, where nonspecialist providers—individuals with no formal training in mental health, who include peers, lay counsellors, midwives, and nurses—have been trained to effectively treat perinatal depressive and anxiety symptoms worldwide [11,12]. The term "task sharing" is appropriate in high-income countries (HICs) when few physicians are available and tasks may be shared with other providers with some supervision or referral to physicians [13]. This concept was derived from the paraprofessional model in the United States and United Kingdom, where substantive evidence demonstrated the comparative effectiveness of paraprofessional and professional specialists, highlighting paraprofessionals as potential effective additions to mental health fields [14,15]. In low- and middle-income countries (LMICs), nonspecialist providers are an important human resource because they are widely available, cost-effective, and have regular, frequent contact with mothers [16,17]. Similarly, in HICs, nonspecialist providers have been successfully trained to address perinatal mental health [18-20] but little formative research has been conducted to determine the relevant barriers and facilitators of nonspecialist-delivered mental health interventions in HIC contexts.

Telemedicine, the remote delivery of health care services using telecommunication technology that typically involves an audiovisual interface, has become increasingly common among mental health specialists to increase access to health care treatments among perinatal populations [21]. Within high-income countries, psychological treatments delivered via telemedicine have been used to address perinatal depression and have shown great potential for effectively alleviating symptoms [21]. However, the application of telemedicine or other technological solutions in nonspecialist provider–delivered psychological treatments has been largely unexplored [11], despite its potential scalability and widespread use during the COVID-19 pandemic [22]. Exploring these innovations from a multistakeholder perspective may address relevant barriers and facilitators related to the acceptability and demand of mental health services [23,24]. Examining these processes can ultimately facilitate their successful implementation and uptake [24-26].

The primary objective of this study was to examine relevant barriers and facilitators of nonspecialist provider–delivered psychological treatments for perinatal populations with common mental health disorders such as depression and anxiety from a multistakeholder perspective. This included women with lived experience, their significant others, patient advocates, and health care providers such as nurses, midwives, obstetricians, physicians, psychiatrists, psychologists, and health administrators.

Specifically, we aimed to obtain a multistakeholder perspective on the following central research questions:

1. What are the main barriers to and facilitators for perinatal women accessing psychological treatments?
2. Can nonspecialist providers deliver brief psychological treatments for common perinatal mental health issues? If so, who is the preferred nonspecialist provider for psychological treatments in high-income countries? What are their most preferred characteristics?
3. What are the main barriers to and facilitators of telemedicine-delivered psychological treatments for perinatal women when delivered by nonspecialist providers?
4. What is the role of experts in nonspecialist provider–delivered treatments for perinatal women?
5. How can nonspecialist provider–delivered psychological treatments be optimally integrated and sustained within the larger health care system?

Methods

Setting and Ethics

The study was conducted at Mount Sinai Hospital in Toronto, Canada. Mount Sinai Hospital is home to Canada's most productive obstetric and perinatal mental health teams, with almost 10,000 births per year; it is an academic hospital affiliated with the University of Toronto. Ethical approval was obtained from the Research Ethics Board at Mount Sinai Hospital (18-0235-E).

Participants and Data Collection

Data collection took place between December 2018 and May 2019 through individual, semistructured interviews (see Multimedia Appendix 1 for an example of an interview guide). Key domains included access to psychological treatments during the perinatal period; preferred nonspecialist provider; barriers and facilitators related to nonspecialist providers delivering psychological treatments via telemedicine; the role of experts in nonspecialist-delivered treatments; and integration and sustainability of nonspecialist providers in the broader health care system.

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Participants were recruited through an extensive referral network. Perinatal women were first approached by someone in their clinical care team and asked if they could be contacted by a member of the research team regarding an ongoing study. Partners of women were contacted with consent. To avoid response cohesion between partners and spouses, perinatal women were asked to not share interview questions with spouses and research assistants waited a minimum of 2 weeks to contact spouses. Health care professionals, administrators, and mental health specialists were recruited using convenience sampling of the patient and health professional networks and listservs in Toronto.

All consenting individuals were contacted by independent and trained research staff via phone or email and provided information about the study. If individuals agreed to participate, the research staff requested informed consent. Interviews conducted in person took place at Sinai Health System, via phone, or in a confidential location of the participant's choosing. Two trained interviewers (SL-P and TT-J) conducted and audio-recorded interviews that each lasted 30 to 50 minutes. An index guide was developed to reflect the main barriers and facilitators and these were explored from the perspectives of multiple stakeholders.

Data Analysis

Content analysis [27] and data analysis (ie, coding) were conducted by 2 independent raters. Using κ, there was a process of first independently coding and then discussing cases until moderate (κ=0.61-0.80) to substantial (κ≤0.81) agreement was achieved. Coding was conducted in a stepwise manner to facilitate iterative revision and then finalization of a coding scheme. Specifically, emergent codes were noted to identify themes in the data. A coding index was developed to organize themes and subthemes. Revisions and additions to codes were made throughout the coding process to most accurately capture themes as they materialized. This process informed the creation of a finalized coding scheme.

After coding, a set of 4 charts (one for each stakeholder group) was created. The charting process was used to organize data into apposite themes and subthemes. Quotations were entered into the charts to provide meaningful exemplars of the themes to which they corresponded. Qualitative data was quantified to reveal the most commonly endorsed themes within stakeholder groups, and then triangulated across stakeholder groups to uncover the most frequently reported themes overall. A numeric table portraying themes with the highest frequencies both within and across stakeholder groups was created to assist with the final analysis.

Results

Participant Details

In total, 45 participants were contacted, of which 33 agreed and consented to participate in the study. This included a wide range of stakeholders (see Table 1 for the sampling matrix according to stakeholder group). The majority of interviews (20/33, 60.6%) took place over the telephone as requested by the participant. No consenting participants withdrew from the study.

Coding the qualitative data resulted in a κ value of 0.83, indicating substantial agreements between data analysts [28]. Results were triangulated, both within and across stakeholder groups over 5 broad themes that reflected the 5 questions mentioned above: (1) access to psychological treatments during the perinatal period, (2) barriers and facilitators of nonspecialist providers delivering psychological treatments, (3) barriers and facilitators to nonspecialist provider–delivered treatment via telemedicine, (4) the role of experts in nonspecialist provider–delivered treatment, and (5) integrating and sustaining nonspecialist providers within the broader health care system. Results were then used to determine the most commonly endorsed themes overall, and to ascertain similarities and differences in the perspectives of a diverse range of stakeholders. These themes, alongside stakeholder responses, are described in Table 2 and discussed in detail below.

Table 1. Participants by stakeholder group (N=33).

Stakeholder	Participants, n
Patients and advocates	12
Clinicians and hospital administrators	9
Psychiatrists	2
Psychologists	1
Obstetricians	1
Family physicians	3
Health administrators	2
Nurses and midwives	7
Spouses of patients	5

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Table 2. Key themes related to accessing psychological treatment, accessing nonspecialist provider–delivered treatment, and involving nonspecialist providers in delivering treatment.

Theme	Stakeholder groups				Overall
	Patients and advocates (n=12), n (%)	Clinicians (n=9), n (%)	Potential nonspecialist providers (n=7), n (%)	Spouses (n=5), n (%)	All stakeholders (N=33), n (%)
Access to therapy during the perinatal period					
Barriers					
Cost	7 (58)	6 (67)	4 (57)	2 (40)	19 (57)
Long waitlist times	5 (42)	6 (67)	6 (86)	1 (20)	18 (55)
Stigma or shame	7 (58)	2 (22)	3 (43)	1 (20)	13 (39)
Not enough treatment providers	2 (16)	2 (22)	5 (71)	1 (20)	10 (30)
Facilitators					
Resources on how to find treatment	6 (50)	NE[a]	1 (14)	2 (40)	9 (27)
Provincial health insurance	2 (20)	3 (33)	2 (29)	1 (20)	8 (24)
Access to information about mental health	2 (16)	1 (11)	3 (43)	2 (40)	8 (24)
Training nonspecialists	1 (10)	3 (33)	1 (14)	NE	5 (15)
Nonspecialist provider–delivered psychological treatment					
Could nonspecialist providers deliver brief talk therapies?					
Yes	10 (83)	8 (88)	7 (100)	5 (100)	30 (90)
No	1 (8)	NE	NE	NE	1 (3)
Maybe	1 (8)	1 (11)	NE	NE	2 (6)
Who would make the ideal nonspecialist provider?					
Nurse	9 (75)	5 (55)	5 (71)	1 (20)	20 (61)
Midwife	3 (25)	3 (33)	5 (71)	3 (60)	14 (42)
Most preferred nonspecialist provider characteristics					
Empathetic	5 (50)	7 (77)	5 (71)	3 (60)	20 (61)
Lived experience of mental health issues	7 (58)	NE	3 (43)	4 (80)	14 (42)
Strong communication skills	3 (30)	6 (66)	2 (29)	1 (20)	12 (36)
Good listener	4 (33)	2 (22)	5 (71)	1 (20)	12 (36)
Barriers					
Perceived legitimacy of nonspecialists	2 (16)	2 (22)	4 (57)	1 (20)	9 (27)
Assessment of symptoms	2 (16)	4 (44)	NE	NE	6 (18)
Facilitators					
Excellent training and education	8 (67)	3 (33)	4 (57)	3 (60)	18 (55)
Guidelines for referrals	4 (33)	4 (44)	2 (29)	1 (20)	11 (33)
Scope of treatment is clearly defined	2 (16)	3 (33)	1 (14)	1 (20)	7 (21)
Involving nonspecialist providers in delivering treatment					
Barriers					
Limited time due to primary profession	3 (25)	NE	3 (43)	1 (20)	7 (21)

[a]NE: no endorsement of theme.

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Theme 1: Access to Psychological Treatments During the Perinatal Period

Barriers to Accessing Psychological Treatment

Across all stakeholder groups, the most commonly endorsed barrier to access overall was the cost of therapy (19/33, 57%), with participants noting that psychological treatments are unaffordable and therefore unattainable.

> *Cost…I think that's the biggest one [barrier]. And personally, for myself in the past that's also been like, you know, do I pay rent, or do I prioritize my mental health?* [Patient_003]

> *You know when I sought counsel independently, it was $130 an hour. And um during maternal leave… you're not making any money at all, if you're being paid for maternity leave maybe 60-80 percent of your wages…so the expense is a barrier as to whether or not you even access that treatment.* [Nurse_016]

> *What we also recognize is that once people become aware and are willing to pursue care it is difficult to get timely care...and if you're depressed post-partum you don't want to wait. It's not safe to wait weeks let alone months for care. You want to be seen quickly.* [Psychiatrist_009]

Alongside cost, reported barriers included long waitlist times (18/33, 55%), stigma (13/33, 39%), and too few treatment providers (10/33, 30%). Among specific stakeholder groups, patients and patient advocates were the most likely to report stigma as the most common barrier to accessing psychological treatments (7/12, 58%).

> *I think it's just stigma… after you've had a baby and there's a lot of societal pressure to be really happy…'well don't focus on the negative like you should be so happy you should be so grateful that you have a baby a lot of people can't have babies right?' So, there was- I felt a lot of shame about going through this.* [Patient_017]

> *The stigma attached to it [perinatal anxiety or depression] is a huge barrier.* [Advocate_018]

Facilitators to Accessing Psychological Treatment

Relatedly, and across all stakeholder groups, participants frequently suggested that resources on how to find treatments would be the most common facilitator to improving access (9/33, 27%).

> *I think it would help people if it was very streamlined to be able to access perinatal mental health care. So, if we were able to for example have one number that everybody in the province could call…or you know, one website…so just making it easier for people to know the right place to go.* [Midwife_015]

> *If there was this resource that I hear about just within googling or searching from pregnancy groups…then it would just be a phone call away…or a website away, or a live chat line type of thing then it would be so much easier.* [Patient_022]

In addition, and across all stakeholder groups, access to information about mental health (8/33, 24%) and provincial health insurance (8/33, 24%) were equally endorsed as the second most common facilitators.

> *More education around mental health issues during the perinatal period, so people kind of normalizing it for people that this happens. And yeah I guess education about how to go- like letting family doctors know what to look out for and asking the right questions.* [Nurse_011]

> *We need to look at mental health and mental and emotional well-being the way we begun to look at physical well-being and health… the media is filled with information about better diet, about exercise…so we need to make mental health and mental illness part of the conversation.* [Psychiatrist_009]

Within stakeholder groups, some differences emerged. This was especially apparent among mental health clinicians and health administrators who were the only stakeholder group to commonly endorse training nonspecialist providers as a facilitator of access (3/9, 33%).

> *Use lay therapists…there can be many trained, there are many more of them. The second thing is they [nonspecialist providers] are going to be way less expensive.* [Psychiatrist_006]

Theme 2: Barriers and Facilitators of Nonspecialist Providers Delivering Psychological Treatments

Overview

The vast majority of participants within and across stakeholder groups answered "yes" to the idea of nonspecialist providers delivering brief psychological treatments (30/33, 90%). When asked what would be the most important nonspecialist provider characteristics, the most frequent responses included having empathy (20/33, 61%), having lived experience with depressive and anxiety symptoms (14/33, 42%), having strong communication skills (12/33, 36%), and being a good listener (12/33, 36%). The majority of stakeholders also reported that both nurses (20/33, 61%) and midwives (14/33, 42%) would be the most acceptable nonspecialist providers to deliver psychological treatments because they work in close contact with perinatal women.

> *Nurses are so unique because we do have that bio-psycho-social. We know about growth and development, we know about medications, we know about social support and the different things that you can do to make a difference. And I think that the scope of nursing practice I really think that this is an area that we should be expanding into.* [Nurse_002]

> *Midwives…are there throughout your care the entire time, and they're there I think for six weeks post-delivery just to check-in and make sure he's latching ok, and you're feeling ok. So, I think that that… natural caring role would be an easy thing to progress with because you've already developed a relationship with them.* [Patient_019]

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Perspectives related to the barriers and facilitators of nonspecialist provider–delivered psychological treatments are detailed below and summarized in Table 2.

Barriers to Nonspecialist Provider–Delivered Psychological Treatments

Overall, and among all stakeholder groups, the most common barrier to nonspecialist providers delivering psychological treatments was the perspective that others would not perceive nonspecialist providers as legitimate providers (9/33, 27%). This was followed by difficulty in assessing mental health symptoms (6/33, 18%). However, while at least one individual from all stakeholder groups mentioned that patients may not perceive nonspecialist provider–delivered treatment as being as legitimate as specialist-delivered psychological treatments, only clinician and health administrator stakeholders and a small minority of patients and patient advocates expressed that nonspecialist providers may have trouble assessing symptoms. We should also note that fewer barriers (n=2) than facilitators (n=3) of nonspecialist provider–delivered psychological treatments were mentioned across stakeholder groups.

> *I think another barrier could potentially be even from the client's perspective, right? Like: 'who are you? Why are you the one giving me this service when what I wanted was the psychologist or the PhD right? I don't know what you have to offer me.*' [Nurse_005]
>
> *I think maybe some people might be wondering if these people [nonspecialist providers], maybe they're not the best because they're not medically qualified.* [Patient_023]

In addition, the most commonly reported barrier to involving nonspecialist providers, across stakeholder groups, was that they would have limited time due to other professional responsibilities (7/33, 21%).

> *Maybe not everyone will want to do it. Because that's adding an extra task to them that they might not necessarily want to take on, which you know is understandable as well because they have their plates full.* [Patient_026]
>
> *I think one of the biggest barriers is that many people in our health care system feel like they're working hard and don't have a lot else to give. So, I think there's probably lots of people who might in general be supportive of this but they might feel like they might not necessarily have enough time to do it themselves.* [Midwife_015]

Facilitators of Nonspecialist Provider–Delivered Treatment

The most frequently reported facilitator to nonspecialist provider–delivered psychological treatment was high-quality training and education in mental health (18/33, 55%), followed by guidelines for referring to specialist providers (11/33, 33%). Across most stakeholder groups, training and education was the most commonly reported facilitator; one exception was among mental health clinicians and health administrators who most commonly endorsed guidelines for referring to specialist providers as a facilitator for nonspecialist provider–delivered psychological treatments (4/9, 44%). This stakeholder group was also the only group who emphasized that the scope of treatment for nonspecialist providers should be clearly defined (3/9, 33%).

> *I feel as though it would be valuable to have individuals [nonspecialist providers] in such a role, to be able to at least have those preliminary conversations. And then if they felt that they could not adequately provide that kind of therapy to the person that they're speaking to, to maybe be able to refer them to someone who is more professionally trained.* [Spouse_028]
>
> *There has to be some sort of model where there's a referral possible to people that are more widely trained.* [Physician_004]
>
> *I do think that nonspecialists could be trained to do talk therapy … if it is a very specific treatment that they're doing. I think that where we run into trouble is when nontherapists start to behave as though they are therapists, and they go off script…but I think that certainly for specific interventions it could work very well.* [Physician_027]

Theme 3: Barriers and Facilitators to Nonspecialist Provider–Delivered Treatment via Telemedicine

Common barriers and facilitators related to the theme of nonspecialist provider–delivered psychological treatments via telemedicine are summarized in Table 3 and described below.

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Table 3. Delivering psychological treatments via telemedicine and the role of experts.

Theme	Stakeholder groups				Overall
	Patient and advocates (n=12), n (%)	Clinicians (n=9), n (%)	Potential nonspecialist providers (n=7), n (%)	Spouses (n=5), n (%)	All stakeholders (N=33), n (%)
Telemedicine					
Could nonspecialist providers use telemedicine?					
Yes	10 (83)	8 (88)	6 (86)	2 (40)	26 (79)
No	NE[a]	NE	NE	2 (40)	2 (6)
Maybe	NE	1 (11)	NE	NE	1 (3)
It depends	2 (16)	NE	1 (14)	NE	3 (9)
Barriers					
Difficult to establish therapeutic alliance	6 (50)	5 (55)	2 (29)	3 (60)	16 (48)
Lack of access to technology	2 (17)	4 (44)	3 (41)	1 (20)	10 (30)
Facilitators					
Provide training on telemedicine	1 (8)	2 (22)	3 (43)	NE	6 (18)
Ensure patients are aware of telemedicine	3 (25)	NE	NE	NE	3 (9)
Benefits of telemedicine					
Therapy would feel less daunting	5 (50)	NE	1 (14)	3 (60)	9 (33)
Help decrease issues of access	1 (8)	2 (22)	2 (29)	1 (20)	6 (18)
Role of experts					
Ideal supervisors					
Psychologists	8 (67)	7 (77)	6 (86)	1 (20)	22 (66)
Psychiatrists	6 (50)	5 (55)	6 (86)	NE	17 (51)
Social workers	3 (25)	4 (44)	1 (14)	2 (40)	10 (30)
Facilitators					
Financial compensation	2 (17)	2 (22)	3 (43)	1 (20)	8 (24)
Sincere desire or interest	2 (17)	1 (11)	3 (43)	1 (20)	7 (21)
Regular and scheduled meetings	3 (25)	3 (33)	1 (14)	NE	7 (21)

[a]NE: no endorsement of theme.

Barriers to Telemedicine

The most commonly reported barrier to telemedicine-delivered psychological treatment was the perception of the difficulty in establishing a strong therapeutic alliance remotely (16/33, 48%). Some stakeholders also brought up the issue of patient access to technology as a barrier to telemedicine-delivered psychological treatments (10/33, 30%). There were no barriers mentioned by any stakeholder about this platform being used by nonspecialist providers in particular.

> *I've heard patients say it's difficult to often feel comfortable confiding in somebody that you're just not in the same room with. It doesn't feel like the same personal connection.* [Nurse_011]
>
> *I think it would remove a bit of the personal aspect of it right. Like although it's still a video potentially it's not someone coming to you in person to make you feel like you know there's someone there who cares.* [Patient_021]
>
> *I mean not having access to the internet, not having the ability to pay for a computer or something with…some sort of video device.* [Spouse_029]
>
> *I think that barriers for telemedicine in general are people who don't have access to the technology, you know, lack of internet coverage.* [Physician_010]

Facilitators of Telemedicine

Among all stakeholders, common facilitators were reported around the use of telemedicine to deliver psychological treatments. Stakeholders most frequently commented that training on telemedicine would be an important facilitator (6/33, 18%). Specifically, it was recommended that telemedicine-delivered treatment be addressed within the broader training given to nonspecialist providers. Providing training on telemedicine was reported at the highest frequency

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within stakeholder groups, in addition to ensuring women are aware of telemedicine as a treatment delivery option, which was most commonly endorsed by patients and patient advocates (3/12, 25%).

> *Maybe you need an extra hour of training in your curriculum or a couple of hours to discuss the special challenge [of telemedicine].* [Psychiatrist_006]
>
> *Just maybe advertising it [telemedicine], getting it out there, letting people know that it's available. Cause sometimes when there's really good resources but people don't know about it then no point in that resource right?* [Patient_022]

Perceived Benefits of Telemedicine

Although participants were not asked about the ways in which telemedicine could be beneficial, many perceived benefits were reported. Across all stakeholders, the most commonly reported benefit that emerged was that telemedicine would make psychological therapies more acceptable and feasible and address the many barriers that new mothers encounter (9/33, 33%). This was especially endorsed by patients, patient advocates, and spouses.

> *My wife wasn't comfortable even leaving the house and leaving our child for 7 months. So, the option to be able to video conference, or call and speak to someone is definitely valuable.* [Spouse_028]
>
> *I think that [telemedicine] would help because I think some people are a bit, especially after you just had a baby it's overwhelming to have to leave your house for anything for a while, especially if you're feeling depressed or anxious. So, I do think having access to the resources from home is a really good idea.* [Patient_021]

The second most commonly reported benefit was that telemedicine could decrease issues regarding access to therapy (6/33, 18%).

> *I certainly think both telemedicine and internet-based therapies are the way we have to go in a country like Canada, where just, the population is so dispersed and the providers aren't you know, located where the people need them.* [Physician_010]
>
> *I certainly think it's [telemedicine] helpful for people that live in rural areas, where they can't access therapy as easily.* [Midwife_033]

Theme 4: Role of Experts in Nonspecialist Provider–Delivered Treatment

Across all stakeholder groups, participants reported that the ideal supervisor for nonspecialist providers would be mental health specialists, specifically psychologists (22/33, 66%) and psychiatrists (17/33, 51%). One exception was social workers, who were commonly endorsed by spouses as ideal nonspecialist provider supervisors (2/5, 40%). Overall, stakeholders believed financial compensation to be the greatest incentive to these groups of specialists to provide supervision to nonspecialist providers (8/33, 24%), followed by regular and scheduled meeting times (7/33, 21%), and that supervisors must have a sincere desire or interest in this role (7/33, 21%).

Theme 5: Integrating and Sustaining Nonspecialist Providers Within the Broader Health Care System

Barriers to Integrating Nonspecialist Providers

The most commonly reported barrier to integrating nonspecialist provider–delivered psychological treatment into existing health services was related to competition and concerns raised by mental health specialists (13/33, 39%). The cost involved in implementing nonspecialist provider–delivered treatment was the second most commonly endorsed (8/33, 24%). These results were similar across stakeholder groups (Table 4).

> *Whenever you're putting people in a role where psychologists and physicians have been the only ones allowed to practice a role, it's seen as competition so then they don't want to support the non, sort of official training therapists because they don't want their business taken away.* [Nurse_011]
>
> *It is very hard for human beings to act against their self-interest…even in the caring profession where people care about their patients, people will create all kinds of rationalizations why what they are doing, and they are enjoying, and they are well paid to do should continue and should not be changed.* [Psychiatrist_006]
>
> *It's going to rock the boat a bit I bet…maybe some professionals might not see the benefit in it. They may kind of cringe, like: 'Why are you providing treatment? You're not professionally trained.' You know, there's going to be some backlash I assume and some criticism of nonprofessional providers. So that would kind of be one barrier.* [Patient_026]

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Table 4. Integrating and sustaining nonspecialist providers within the existing health care system.

Theme	Stakeholder groups				Overall
	Patients and advocates (n=12), n (%)	Clinicians (n=9), n (%)	Potential nonspecialist providers (n=7), n (%)	Spouses (n=5), n (%)	All stakeholders (N=33), n (%)
Integrating nonspecialist providers					
Barriers					
Specialist provider resistance and concerns	5 (42)	4 (44)	3 (43)	1 (20)	13 (39)
Cost	3 (25)	3 (33)	1 (14)	1 (20)	8 (24)
Facilitators					
Integrate nonspecialist providers into hospitals or clinics	6 (50)	5 (55)	4 (57)	1 (20)	16 (48)
Educate patients and providers on nonspecialist providers	4 (33)	1 (11)	3 (43)	2 (40)	10 (30)
Triage patients into specialist and nonspecialist streams	2 (17)	4 (44)	2 (29)	NE[a]	8 (24)

[a]NE: no endorsement of theme.

Facilitators to Integrating Nonspecialist Providers

The most commonly suggested facilitator to integrating nonspecialist provider–delivered psychological treatment reflected the location—in particular, the hospital or primary care practice settings that perinatal populations visit, such as obstetrical units (16/33, 48%). The second most commonly endorsed facilitator focused on educating women and providers about the role of nonspecialist providers in implementing psychological treatments (10/33, 30%).

> *If it [nonspecialist provider–delivered treatment] could be implemented within a general practice or obstetrician's office, that person [nonspecialist provider] could become part of the team then that could decrease the cost.* [Nurse_016]

> *I guess working as a team with the medical professionals … would be a good start.* [Patient_023]

One addition to these themes was a suggestion made by many clinician and health administrator stakeholders, who suggested that patients should be triaged into nonspecialist and specialist streams (4/9, 44%).

> *Look at this as one big team …and that having access so that people are triaged with regard to what their needs are, they can be directed appropriately.* [Psychiatrist_009]

Sustaining Nonspecialist Providers

When asked about the best way to sustain nonspecialist providers in their potential roles to deliver psychological treatments, the most commonly reported answer reflected strategies to avoid burnout (6/16, 38%). This included 4/9 clinicians (44%) and 2/7 potential nonspecialist providers (29%). Patients, patient advocates, and spouses were not queried on this topic.

> *I think a lot of a turnover in mental health can be because it is a really hard thing to do… compassion fatigue. So, I think a lot of people end up needing to take breaks when they're providing mental health supports, because it becomes overwhelming for their own mental health.* [Midwife_031]

> *Access to supervision or consultation so that they don't get burnt out or overwhelmed in their role.* [Psychologist_001]

Discussion

Overview

The primary objective of this study was to gather a multistakeholder perspective of the main barriers and facilitators of nonspecialist provider–delivered psychological treatments for perinatal populations with common mental health disorders such as depression and anxiety. We asked a range of stakeholders—including women with lived experiences, their significant others, patient advocates, health care providers, mental health specialists, and health administrators—to comment on accessing psychological treatments, nonspecialist-delivered psychological treatments, the role of experts, the use of telemedicine, and the best way to integrate nonspecialist providers within the broader health care system. In short, and in response to poor access to psychological treatments, we found that psychological treatments delivered by nonspecialist providers were considered both acceptable and feasible by the wide majority of stakeholders, with far more facilitators than barriers mentioned overall. We discuss some additional themes in more detail below.

Access to Psychological Treatments

The most commonly reported barriers to accessing treatments included cost, stigma, long waitlist times, and not enough treatment providers. The most common facilitators to accessing treatments included resources on how to find treatment, access to information on mental health, and health insurance. Many of these barriers and facilitators have been previously studied [29,30] However, despite an emphasis on resources, there is

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evidence that increasing funding for resources does not necessarily translate into access. For example, Thornicroft and colleagues [31] demonstrated that despite spending 20-fold more of their gross domestic product on mental health care, the spending was not commensurate with access to resources. In Canada and the United States, access to minimally adequate care remains at 20% of the population compared to 5% in low- and middle-income countries. Clearly, the solution goes beyond investing more resources in specialist providers. Instead, researchers and policy makers alike have argued it is essential that systematic barriers are addressed to optimize health care systems more generally, while also making efforts to prevent mental illness specifically by addressing known risk and protective factors for poor mental health [32].

Nonspecialist Provider–Delivered Psychological Treatments and the Role of Specialist Providers

In general, the majority of all stakeholder groups reported that nonspecialist providers could indeed be trained to deliver psychological treatments. There is now a rich evidence base, particularly from LMICs, that offers compelling evidence that nonspecialist providers can effectively deliver psychological interventions to manage mood and anxiety disorders among perinatal and general populations [11]. This delivery strategy has the potential to address one of the most significant gaps in mental health care (ie, access to evidence-based psychological treatments). Such approaches are increasingly being advocated for in HICs [33], and it is already a widely accepted approach for mental health care globally (WHO, 2013).

Our findings also suggest that respondents believed that specialist providers could play a unique and important role if nonspecialist providers were trained to deliver psychological treatments. These findings are congruent with a recent review of nonspecialist provider–delivered psychological treatments for common mental disorders [11].The review showed that specialists played the following important roles: assessing psychiatric symptoms, providing referrals and medications, as well as overseeing treatment quality through supervision to ensure that the treatments were implemented with high fidelity (a concern commonly raised by expert clinicians in the current study).

An additional concern raised by a few potential nonspecialist providers and patient stakeholders surrounded whether nonspecialists would be able to fulfil this role on top of their already demanding workloads. These concerns were echoed in a similar study that examined a multistakeholder perspective of nonspecialists delivering PRIME (PRogramme for Implementing Mental health carE) within 5 LMICs [34]. However, there is a dearth of implementation research establishing whether the perception that a nonspecialist role imposes an overly burdensome workload is a real barrier, as opposed to one that is only perceived. Future research could contribute by attempting to clarify this distinction, as well as by exploring facilitators of taking on a nonspecialist provider role alongside other professional duties.

Preferred Type and Characteristics of Nonspecialist Providers

Across a wide variety of stakeholders, the majority reported that nurses and midwives would be the most appropriate nonspecialist providers to be trained to deliver psychological treatments; respondents in the current study commented that these individuals were most likely to interact with women during the perinatal period. These findings complement the overall literature, which shows that nurses followed by midwives were the most common nonspecialist providers to deliver psychological treatments for perinatal populations (Singla et al, unpublished data, 2020). Of 44 randomized controlled trials for perinatal depression or anxiety, the majority (more than 65%) were delivered by nurses and midwives and were found to effectively treat perinatal depressive and anxiety symptoms. Thus, the perception among some stakeholder groups in the current study that nonspecialist providers could not adequately assess symptoms is inaccurate. It is also important to note that these studies were conducted mainly in Australia and the United Kingdom, which include established models of stepped care (defined below).

In addition, our results suggest that respondents valued communication skills, and wanted their nonspecialist providers to demonstrate empathy and be good listeners, as well as have lived experience with depressive and anxiety symptoms; it is worth noting that despite valuing lived experience as a characteristic, peers (women with lived experience) were not commonly endorsed by stakeholders when asked who the ideal nonspecialist provider would be. These findings reflect studies from both HICs and LMICs. In another qualitative study at two separate sites in Pakistan and India, both communication skills and lived experience were ranked the most preferred characteristics, although the preferred nonspecialist provider was different [16]. Similarly, a recent randomized controlled trial in a HIC context showed that trainees with good interpersonal skills had better patient outcomes [35].

Telemedicine and Scalability

Overall, the majority of participants across all stakeholder groups responded that nonspecialist providers could be trained to deliver psychological treatments remotely via telemedicine and noted the important implications of telemedicine in improving access to mental health care. However, more barriers than facilitators were presented and individuals questioned whether any treatment provider, nonspecialists and specialists alike, would be able to establish a strong therapeutic alliance with a patient via a telemedicine platform. In contrast to this opinion, there is growing evidence that psychological treatments are effective when delivered remotely [36] and some evidence suggests that a strong therapeutic alliance can be developed and maintained in telemedicine treatments [37]. This is an especially important consideration given the skepticism expressed by some patient stakeholders regarding the ability to establish a therapeutic alliance through telemedicine; patient beliefs about psychological treatments and providers themselves can impact the patient-provider relationship and treatment effectiveness [38]. Additional research is required to examine whether the therapeutic alliance has been maintained in

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telemedicine-delivered psychological treatments when compared to in-person treatments. This unanswered question complements a recent review that identified the importance of examining the benefits and risks of delivering mental health care through technology instead of face-to-face [39]. In light of the current COVID-19 pandemic, these findings are particularly relevant given the rise of telemedicine in existing health care practice [22].

Furthermore, while remote psychological treatment delivery can be efficacious, there has been minimal exploration of the effectiveness of remote modalities in the context of nonspecialist providers [40]; studies that have explored this have adapted a broader approach than the present study has suggested. For instance, a recent narrative review examined how multiple digital platforms have been leveraged in mental health care to assist nonspecialists with training, diagnosis, treatment guidance, supervision, and the integration of services [41]. Future research is needed to gain an in-depth understanding of nonspecialist provider–delivered treatment via telemedicine, the novel barriers and facilitators that may coincide with this distinct interaction, and whether or not it is effective.

Integrating and Sustaining Nonspecialist Providers

All stakeholder groups indicated that hospitals or relevant specialty care settings, such as obstetrical units, would be the most acceptable and feasible sites within which to integrate nonspecialist providers, while noting advantages, such as the convenience of having all perinatal health services in one setting. However, stakeholders reported that one major barrier to integrating nonspecialist providers could be resistance from mental health specialists. Specifically, participants across all stakeholder groups, including specialist providers such as psychiatrists and psychologists, expressed concerns that specialist clinicians may feel their positions are being threatened or that they would be skeptical of a nonspecialist provider's ability to provide adequate care. Despite these perspectives, the literature is extant and growing in arguing that increasing the number of specialists will not resolve the treatment gap issue [10]. Future research is required to address professional protectionism in settings where nonspecialist providers and specialists can deliver mental health care treatments to address perinatal mood disorders.

Relatedly, clinician and hospital administrator stakeholders suggested a stepped care model. This approach provides initial treatment to patients at the lowest adequate intensity. Patients are continually monitored and then stepped up to a more intensive level of care if clinically necessary. This process of gradual treatment adjustment is repeated until the patient's health status is satisfactory [42]. Stepped care models have been successfully implemented by specialists and nonspecialist providers in a widespread initiative across the United Kingdom, known as Increasing Access for Psychological Treatments [43]. This initiative is a demonstrated stepped model of care with two levels: a low-intensity entry step delivered by nonspecialist providers for the majority of patients with mild to moderate symptoms, and a high-intensity step delivered by specialist providers for the minority of patients who have severe symptoms and do not respond to the first step [43]. This approach has the potential to optimize resources and skill level while maximizing efficiency by reducing wait times [44]. Additional research is required to examine scaling up nonspecialist provider–delivered psychological treatments in community settings during the postpartum period.

Limitations

We note several limitations in our study, including the use of a convenience sample, interviewing only a small sample of spouses, and not including any policy makers. We did not inquire about or account for participants' demographic information, including their age and ethnic backgrounds, despite the potential role that age and other relevant socioeconomic variables may play in perceived barriers and facilitators to digital solutions such as telemedicine. Furthermore, there is evidence that cultural beliefs can play a significant role in the acceptance of psychological treatments, treatment providers, and treatment delivery models [45]. This may be particularly relevant for the current study population, which identified barriers among other groups who may have reduced health and digital literacy; this may affect help-seeking for common mental health issues. Future studies are encouraged to assess relevant socioeconomic variables among a random subset of participants to facilitate an improved understanding of and solutions for vulnerable populations, including racial and ethnic minority, lower socioeconomic status, and linguistically diverse populations.

A strength of the current study is its rigorous and systematic use of qualitative methods to examine practical questions related to nonspecialist provider–delivered psychological treatments via telemedicine for perinatal populations. Although this study was framed for perinatal populations specifically, the findings are relevant to other nonspecialist provider–delivered psychological treatments that target a broader audience. In addition, we examined both barriers and facilitators within and across stakeholder groups. This approach, also referred to as integrative data analysis [46], allows for the pooling of data from numerous sources to examine information from multiple perspectives.

Conclusions

In conclusion, the current study examined the innovations of nonspecialist providers and telemedicine from the perspective of a broad group of stakeholders. Our findings suggest that, despite challenges in accessing psychological treatments, training nonspecialist providers and the use of telemedicine would be largely welcomed and likely used within health care settings. This suggests important implications of acceptability and demand to facilitate future nonspecialist provider–delivered psychological treatments for perinatal and broader populations. In summary, these results can inform the design, implementation, and integration of nonspecialist-delivered interventions via telemedicine for women with perinatal depressive and anxiety symptoms in HIC contexts.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Interview guides.
[DOCX File , 23 KB - mental_v7i8e19271_app1.docx]

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Abbreviations

HICs: high-income countries
LMICs: low- and middle-income countries

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Original Paper

The Public Health Impact and Policy Implications of Online Support Group Use for Mental Health in Singapore: Cross-Sectional Survey

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Abstract

Background: The wide mental health treatment gap continues to pose a global and local public health challenge. Online support groups are on the rise and could be used to complement formal treatment services for mental health.

Objective: This study aimed to examine the prevalence of online support group use and explore factors associated with the use in the general population using data from a national cross-sectional mental health survey in Singapore.

Methods: Singapore residents aged 18 years and above participated in a nationally representative household survey in which the World Health Organization Composite International Diagnostic Interview 3.0 was administered by trained interviewers to examine the use of online support groups for mental health. Multiple logistic regressions were used to analyze the association of online support group use with various sociodemographic and health factors.

Results: A total of 6110 respondents with complete data were included in this study. Overall, 10 individuals per 1000 adults (1%) reported seeking help from online support groups for their mental health problems. Compared to younger adults (those aged 18 to 34 years) and those with university education, individuals aged 50 to 64 years (P<.001; OR 0.1, 95% CI 0.0-0.3) and those with preuniversity qualifications (P=.02; OR 0.1, 95% CI 0.0-0.8) were less likely to use online support groups for mental health, respectively. Participants with a Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) mental disorder were 6.8 times more likely (P<.001; 95% CI 3.0-15.4) to use an online support group; in particular, individuals with major depressive disorder (P<.001; OR 5.4, 95% CI 2.1-13.8) and obsessive compulsive disorder (P=.01; OR 3.5, 95% CI 1.3-9.7) were more likely to use an online support group for their mental health.

Conclusions: Online support groups could be used to complement formal treatment services, especially for mood and anxiety-related disorders. As online support group use for mental health issues may be more prevalent among younger people, early detection and accurate information in online support groups may guide individuals toward seeking professional help for their mental health problems.

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KEYWORDS

online support group; internet; self-help; mental health treatment; mental illness; public health

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Introduction

The internet is increasingly recognized as a valuable self-help resource for individuals. Online support groups in the form of web-based forums, discussion boards, and chat rooms are fast emerging as a popular and accessible means to provide individuals the opportunity to reach out to peers without geographical restrictions, share personal health experiences, and receive emotional support for mental health issues [1]. Disease-specific online mental health groups are especially important because research has shown that people prefer them to other types of support networks or internet features as they provide peer support (support from people going through the same experience) and there is a greater degree of empathy in such mental health forums and chat rooms [2,3]. The increasing use of online and mobile technologies for mental health peer support has been termed "digital peer support"; this is defined by researchers as "live or automated peer support services delivered through technology media such as peer-to-peer networks on social media, peer-delivered interventions supported by smartphone apps, and asynchronous and synchronous technologies" [1]. They also provide other essential elements important for coping, including the following: empowerment, information, advice, a sense of control, and a sense of being able to help others [4,5]. Thus, mental health peer support in online support groups facilitates the sharing of personal experiences, enables information exchange on the day-to-day management of disease, and is a source of advice on resolving some of the most psychologically difficult issues among peers with similar mental health problems and comorbid conditions [6]. Given approximately 450 million people with mental illness worldwide, mental health is deemed a major public concern today [7]. Over one-third of people in most countries experience at least one mental disorder in their lifetime. For example, prevalence estimates suggest 40.9%, 37.5%, and 48.6% of people in the Netherlands, Canada, and United States meet the criteria for a mental disorder at some time in their life, respectively [8]. In Singapore, a city-state in Southeast Asia, 1 in 7 adults are reported to have at least one mood, anxiety, or alcohol use disorder during their lifetime [9]. Researchers estimate that mental health–related online support groups are accessed almost daily, especially in countries with high internet availability [10]. The primary function of such online support groups is to provide a space where mutual support is given and received by anyone affected by mental health issues. People who feel stigmatized about their mental health issues and reluctant to seek professional help in person are more likely to use these online communities privately and anonymously [11]. Many systematic reviews and randomized controlled trials have reported that online support groups have great potential for helping people manage a variety of mental health problems [12,13]. The evidence suggests that the use of these online support groups reduces social isolation, psychological distress, and empowers individuals with knowledge about mental health, treatment options, and symptom management [14-16]. However, national prevalence estimates for online support group use among the general population is limited [17]. Population-based studies and systematic reviews focused on the use of the internet for mental health information, but did not consider the use of online support groups [18-20]. A highly publicized study from the Pew Research Center reported that 510 out of 3001 (17%) internet users in the United States had contacted health-related online support groups [21]. However, this survey accounted for chronic physical conditions, and did not include the use of online support groups for mental health problems. In contrast, a meta-analysis of US population data [22] indicated that 2.7 to 3.3 people per 1000 community-dwelling adults were likely to have visited online mental health support groups or chat rooms, and the figure remained stable despite annual reports of an upward trend in online activities and internet access across the United States [23]. Additionally, while research has shown that the proportion of people in the general population accessing online support groups for mental health may be small, the proportion of people with diagnosed mental disorders accessing mental health support groups and chat rooms online remains relatively high. Researchers report that online support groups are particularly popular among individuals living with a mental disorder worldwide [12,22-25]. Depression support groups and chat rooms have been reported to be one of the most common online support groups sought on the internet [26,27]. In Germany, Diskussionsforum Depression [28] is an established online community for those dealing with specific psychological problems. Other well-known online support groups, such as Care Opinion [29] in the United Kingdom, developed an online community for individuals to share their personal stories including experiences with depression and other mental health problems. People living with bipolar disorder have also reportedly found online chat rooms and web-based social support groups helpful, citing camaraderie, cohesion with their online peers, and feeling empowered to cope with their condition [30]. However, research on the prevalence and use of mental health social support communities in non-Western populations is scant.

Singapore has a resident population of just over 5.6 million people. The literacy rate of Singapore's population is 97.3%. Overall, 84% of the population (4.83 million people) are internet users, and over 4.4 million are active on social media, discussion forums, and various other internet communication tools [31]. Research has consistently shown that Asians prefer to seek help from less formal sources for their mental health problems, which could potentially include support groups and chat rooms online [32-34]. Help-seeking behaviors for mental health problems may also be largely influenced by cultural influences in Asian societies. Stigma may be a deterrent and has been identified as a barrier to service use in Asian societies [35,36]. The use of online support groups for mental health support might be of particular local interest due to its capacity for providing easy access, anonymity, and the potential to overcome perceived stigma in seeking help for mental health issues. In this way, online mental health support communities offer a valuable source of peer advice and may provide the stimulus to seek professional help. Online support groups may have the public health potential to help individuals manage their mental health problems and improve treatment-seeking [37]. Against this background, this study seeks to broadly explore the use of online support groups in Singapore and the factors associated with their use by using population-based and nationally representative data.

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Methods

Survey Population and Subjects

Data for this study were obtained from the Singapore Mental Health Study (SMHS) 2016, a population-based cross-sectional epidemiological survey of noninstitutionalized respondents aged 18 years and above, primarily conducted to establish lifetime and 12-month prevalence of mental disorders, as well as the current use of mental health services. Of the 6126 survey respondents, this study uses data drawn from a subsample of 6110 subjects who responded to a question regarding the use of online support groups for mental health. The study was conducted from 2016 to 2018, and achieved a response rate of 69.5% among eligible adults. The sampling frame was based on a national administrative database of all citizens and permanent residents of Singapore. A probability random sample was selected using a disproportionate stratified sampling design of 16 strata defined with respect to ethnicity (Chinese, Malay, Indian, Others) and age groups (18 to 34, 35 to 49, 50 to 64, and ≥65 years). Older adults (≥65 years) and ethnic minority groups (Malays and Indians) were oversampled to ensure sufficient sample size to improve the reliability of estimates for subgroup analysis.

Procedure

A printed invitation letter was sent to each subject, followed by a household visit to obtain their agreement to participate in the survey. Trained interviewers from a survey research company conducted face-to-face interviews with the respondents who agreed to participate in the study. Respondents were asked to choose their preferred language (questionnaires were available in English, Chinese, and Malay) before the interviewer initiated any study-related procedures. Residents who were living outside of Singapore, institutionalized, or hospitalized at the time of the survey, those who were not contactable due to an incomplete or incorrect address, and those who were unable to complete the interview in one of the specified languages (English, Chinese, or Malay) were excluded from the survey. The SMHS 2016 study methodology has been reported in much greater detail elsewhere [38].

The study was approved by the relevant institutional ethics committee, the National Healthcare Group Domain Specific Review Board. All participants provided written informed consent. For those aged <21 years, written informed consent was also obtained from their parent or legally acceptable representative.

Measures

World Health Organization Composite International Diagnostic Interview

A standardized computer-assisted version of the Composite International Diagnostic Interview version 3.0 (CIDI 3.0) [39] was the primary diagnostic instrument used in this study. The CIDI 3.0 has established psychometric properties and has been used widely in psychiatric epidemiological studies. The Services module within the CIDI 3.0 instrument broadly assesses help-seeking sources used for mental health, which included the following question to establish the prevalence of online support group use: “Did you ever use an internet support group or chat room to get help for problems with your emotions or nerves?”

For each mental disorder, a screening section was administered to all respondents. All participants answering positively to a specific screening question were then referred to the respective diagnostic section of the questionnaire. Given practical survey limitations of time and burden on the participant, only selected modules from the CIDI were included based on input from a stakeholder board. This board included representatives from various stakeholders (Ministry of Health, voluntary organizations working with mentally ill clients, clinicians, sociologists, and representatives from the major ethnic groups in Singapore) who advised the study team on the modules considered locally relevant [38]. The disorders were selected based on the main consideration of what would be of relevance to the country and its policy makers and service providers in the wake of the National Mental Health Blueprint and Policy in Singapore. This study was guided by a review of published literature and national reports. Through these processes, the following mental disorders were assessed based on the diagnostic criteria of the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) [40] and analyzed for this study: major depressive disorder (MDD), dysthymia, and bipolar disorder (mood disorders); generalized anxiety disorder (GAD) and obsessive compulsive disorder (OCD; anxiety disorders); alcohol abuse and alcohol dependence (alcohol use disorders). The CIDI 3.0 interviews lasted approximately 1.5 to 2 hours.

Chronic Physical Conditions

A range of chronic physical conditions were reported by participants on the modified version of the CIDI chronic conditions checklist. The physical conditions included on the checklist were based on their prevalence in Singapore as per local statistics. Participants were asked if they had been clinically diagnosed with the following list of health conditions: hypertension, hyperlipidemia, diabetes, asthma, arthritis or rheumatism, back problems (of disc or spine), migraine headaches, stroke or major paralysis; heart disease including heart attack, coronary heart disease, angina, or congestive heart failure; chronic inflamed bowel problems (eg, stomach ulcer, enteritis, or colitis), neurological disorders (epilepsy, convulsions, and Parkinson disease), thyroid diseases, kidney failure, chronic lung diseases (chronic bronchitis or emphysema), and cancer.

Sociodemographic Information

Sociodemographic data collected from participants included age, gender, ethnicity, income, education, marital status, and employment status.

Statistical Analysis

To ensure that findings would be nationally representative, sample estimates were weighted to account for oversampling and nonresponse, and were poststratified for age group and ethnic distributions between the study sample and the Singapore resident population in 2014. Descriptive statistics were

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performed to describe the sociodemographic profile of the study population. Binary logistic regressions were performed where the outcome variable (use of online support groups) was treated as binary (Yes=1, No=0) and the mental health predictors were similarly treated as binary variables (Yes=1, No=0), where the values (1 or 0) indicated the presence or absence of the condition based on the DSM-IV criteria for the disorder. Multiple logistic regressions were then used to investigate the associations between the outcome (use of online support groups) and each sociodemographic and health condition as an independent variable, controlling for the presence of all other sociodemographic differences in gender, age, ethnicity, marital status, education, employment, and income. The estimates obtained from the analyses were adjusted odds ratios (OR) and statistical significance was established at $P<.05$. All statistical analyses were carried out using SAS software (version 9.3; SAS Institute) [41].

Results

Study Sample Characteristics

The sociodemographic and clinical characteristics of the sample (n=6110) are presented in Multimedia Appendix 1. Weighted analysis of the population sample showed an estimated 10 individuals per 1000 adults (1%, 53/6110) had sought help from an online support group for their mental health problems.

Of the 53 respondents who used online support groups, weighted estimates show that 56.9% (n=29) were female, 76.1% (n=17) were of Chinese ethnicity, 79.4% (n=40) were never married, 70.6% (n=36) were employed, and 82.2% (n=45) were aged 18 to 34 years. In total, 58.2% (n=25) of the online support group users were represented by those with mental illness (Multimedia Appendix 2).

Sociodemographic and Clinical Correlates of Online Support Group Participation

Table 1 presents the results of the logistic regression analysis performed to examine the sociodemographic and clinical correlates of participation in online support groups. Compared to participants aged 18 to 34 years, individuals aged 50 to 64 years ($P<.001$; OR 0.1, 95% CI 0.0-0.3) were less likely to use online support groups for mental health. Compared to participants with a university education, those with preuniversity or junior college education ($P=.02$; OR 0.1, 95% CI 0.0-0.8) were also less likely to use an online support group for mental health. Compared to those without a mental disorder, the odds of use of an online support group was 6.8 times ($P<.001$; 95% CI 3.0-15.4) higher for participants with a mental disorder in this sample.

In Table 2, the associations between types of mental disorders and online support group participation in the sample indicate that individuals with MDD ($P<.001$; OR 5.4, 95% CI 2.1-13.8) or OCD ($P=.01$; OR 3.5, 95% CI 1.3-9.7) are more likely to use online support groups for mental health support.

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Table 1. Sociodemographic and clinical correlates of online support group users.

Parameters	OR[a]	95% CI	*P* value
Age group (years)			
18-34	Reference	N/A[b]	N/A
35-49	0.5	0.1-1.7	.25
50-64	0.1	0.0-0.3	<.001
≥65[c]	—[d]	—	—
Gender			
Female	Reference	N/A	N/A
Male	0.5	0.2-1.2	.11
Ethnicity			
Chinese	Reference	N/A	N/A
Malay	0.9	0.4-2.1	.80
Indian	0.8	0.4-1.8	.56
Other	1.1	0.4-3.5	.83
Marital status			
Married	Reference	N/A	N/A
Never married	2.6	0.9-7.7	.09
Divorced or separated	0.6	0.1-3.8	.62
Widowed[c]	—	—	—
Education			
University	Reference	N/A	N/A
Primary and below[c]	—	—	—
Secondary	0.4	0.1-1.9	.26
Preuniversity/junior college	0.1	0.0-0.8	.02
Vocational institute/Institute of Technical Education	0.7	0.2-2.5	.56
Diploma	0.7	0.2-2.2	.57
Employment			
Employed	Reference	N/A	N/A
Economically inactive[e]	1.2	0.4-3.2	.74
Unemployed	2.0	0.6-6.9	.28
Monthly household income (SGD $)[f]			
<2000	Reference	N/A	N/A
2000-3999	1.5	0.4-6.0	.60
4000-5999	1.3	0.3-5.0	.73
6000-9999	0.6	0.1-2.5	.44
≥10,000	0.9	0.2-5.0	.91
Any mental disorder[g]			
No	Reference	N/A	N/A
Yes	6.8	3.0-15.4	<.001

[a]The odds ratio was derived using multiple logistic regressions after controlling for sociodemographic variables.

[b]N/A: not applicable.

[c]Due to a lower number of cases, the regression coefficient was not estimated.

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[d]Not available.

[e]This group includes homemakers, students, and retirees/pensioners.

[f]SGD: Singapore Dollar.

[g]The participant has at least one of the mental disorders assessed by the Composite International Diagnostic Interview.

Table 2. Association of mental disorders and online support group use in the population.

Mental disorder	OR[a]	95% CI	*P* value
Major depressive disorder	5.4	2.1-13.8	<.001
Dysthymia	0.4	0.0-4.8	.46
Bipolar disorder	2.7	0.5-13.9	.23
Generalized anxiety disorder	3.6	0.9-14.1	.06
Obsessive compulsive disorder	3.5	1.3-9.7	.01
Alcohol abuse	2.7	0.1-12.5	.13
Alcohol dependence	0.9	0.0-0.1	.92

[a]The odds ratio was derived using multiple logistic regressions after controlling for sociodemographic variables.

Sociodemographic and Clinical Correlates of the Psychiatric Population

Multimedia Appendix 3 presents the percentage of online support group users among those with a DSM-IV mental disorder in the population. Among 839 respondents with a mental disorder, 25 (4.3%) of them used an online support group for mental health support.

Table 3 shows that men (*P*=.02; OR 0.3, 95% CI 0.1-0.8), those of Malay ethnicity (*P*=.03; OR 0.2, 95% CI 0.0-0.8), and those aged 50 to 64 years (*P*=.01; OR 0.02, 95% CI 0.0-0.4), were significantly less likely to use online support groups while those who were unemployed (*P*=.02; OR 6.2, 95% CI 1.3-28.2) and living with a comorbid chronic condition (*P*=.04; OR 3.4, 95% CI 1.1-10.7), were more likely to use an online support group for mental health support.

Additionally, Table 4 reveals that after controlling for significant sociodemographic correlates, persons with MDD and OCD were more likely to use an online support group among participants diagnosed with a lifetime mental disorder. The odds of online support group use for participants with MDD and OCD were 4.3 times (*P*<.001; 95% CI 2.1-13.8), and 4.1 times (*P*=.002; 95% CI 1.3-9.7) higher compared to those living with other mental disorders, respectively.

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Table 3. Sociodemographic and clinical correlates of online support group use among those with any mental disorder.

Demographics	OR[a]	95% CI	*P* value
Age group (years)			
18-34	Reference	N/A[b]	N/A
35-49	0.5	0.1-3.6	.53
50-64	0.02	0.0-0.4	.01
≥65[c]	—[d]	—	—
Gender			
Female	Reference	N/A	N/A
Male	0.3	0.1-0.8	.02
Ethnicity			
Chinese	Reference	N/A	N/A
Malay	0.2	0.0-0.8	.03
Indian	0.4	0.1-1.4	.17
Other	0.8	0.2-4.3	.81
Marital status			
Married	Reference	N/A	N/A
Never married	4.4	0.7-28.0	.11
Divorced or separated	1.1	0.1-11.6	.95
Widowed[c]	—	—	—
Education			
University	Reference	N/A	N/A
Primary and below[c]	—	—	—
Secondary	0.7	0.1-5.5	.74
Preuniversity/junior college	—	—	—
Vocational institute/Institute of Technical Education	0.9	0.1-5.7	.88
Diploma	0.5	0.1-3.2	.48
Employment			
Employed	Reference	N/A	N/A
Economically inactive[e]	1.4	0.4-5.1	.62
Unemployed	6.2	1.3-28.2	.02
Monthly household income (SGD $)[f]			
<2000	Reference	N/A	N/A
2000-3999	0.7	0.1-4.1	.70
4000-5999	1.2	0.2-6.3	.85
6000-9999	0.5	0.1-3.5	.47
≥10,000	0.8	0.1-8.3	.82
Any chronic condition[g]			
No	Reference	N/A	N/A
Yes	3.4	1.1-10.7	.04

[a]The odds ratio was derived using multiple logistic regressions after controlling for significant sociodemographic correlates.

[b]N/A: not applicable.

[c]Due to a lower number of cases, the regression coefficient was not estimated.

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[d]Not available.

[e]This group includes homemakers, students, and retirees/pensioners.

[f]SGD: Singapore dollar.

[g]The participant has at least one of the chronic conditions on the checklist assessed by the Composite International Diagnostic Interview.

Table 4. Association of online support group use and type of mental disorder in the psychiatric population.

Mental disorder	OR[a]	95% CI	*P* value
Major depressive disorder	4.3	2.1-13.8	<.001
Dysthymia	0.3	0.0-4.8	.32
Bipolar disorder	4.0	0.5-13.9	.06
Generalized anxiety disorder	3.0	0.9-14.1	.16
Obsessive compulsive disorder	4.1	1.3-9.7	.002
Alcohol abuse	1.7	0.1-12.5	.33
Alcohol dependence	0.6	0.0-0.1	.68

[a]The odds ratio was derived using multiple logistic regressions after controlling for significant sociodemographic correlates.

Discussion

Principal Findings

This study analyzed data from a national cross-sectional mental health survey to examine the prevalence of online support group participation (ie, internet support groups or chat rooms) for mental health, and the sociodemographic and health status factors associated with those who were more likely to engage in these activities. Of the 6110 survey participants, an estimated 10 individuals per 1000 adults (1%) had sought help from an online support group for their mental health problems, and individuals who were aged 18 to 34 years or who had a university education were more likely to use online support groups for mental health. Additionally, this study found that a substantial proportion (58.2%) of those using an online support group had met the criteria for a DSM-IV mental disorder. Among those with mental disorders, individuals with MDD and OCD had the highest rates of online support group participation.

Comparison With Previous Studies

Comparable to other developed countries, more than 80% of the population in Singapore is internet savvy [31]. However, only a small proportion of the sample used an online support group such as an internet support group or chat room to seek help for their mental health issues. In this context, we refer to seeking out peer support in online self-help forums and chat rooms to deal with their mental health problems. Help-seeking in online support groups for mental health support appears to be an infrequent activity in this sample, even though there are many web-based mental health peer support communities and chat rooms in Singapore (eg, web-CHAT [42]). Our estimates are consistent with those reported among general populations elsewhere in the developed world [22,43]. For instance, a meta-analytic survey of household residents in the United States acknowledged that only 0.3% (3 individuals per 1000 adults) had visited support groups or chat rooms for mental health support online [22].

In earlier research, younger individuals and those with tertiary educational qualifications [44,45] were found to seek help for mental health problems on the internet via chats and social groups. Our results mirror previous reports in that those who were younger (versus those aged 50 to 64 years) and university-educated (versus those with preuniversity qualifications) emerge as sociodemographic groups who are more likely to seek help from online support groups for mental health support. Therefore, targeted interventions in these groups, with an emphasis on raising awareness about accessible youth-friendly professional care services offline (as well as online), may lead to more effective prevention and treatment efforts [46].

Additionally, this study found that a substantial proportion (58.2%) of those using an online support group had a diagnosable DSM-IV mental disorder. Griffiths and colleagues [47] previously identified depression support groups on the internet as the most commonly used online support group; this study similarly found that individuals with depression had the highest rates of online support group participation. Online support group participation was also high for individuals with OCD, which holds important implications for psychiatric care providers. Online support groups in the form of internet support groups and chat rooms may offer a valuable source of information and social support for those with mental health problems, particularly mood and anxiety problems. Recent evidence suggests that the wide treatment-seeking gap for mental health continues to pose a local public health challenge [48]. Hence, online support groups could guide individuals to seek professional help for their mental health problems; in addition, they could complement the formal treatment services that patients may receive. Furthermore, health care professionals can explore the impact of online support groups on the individual and provide appropriate support and guidance where needed. Mental health support initiatives can take these findings into consideration when programs are developed and implemented so as to effectively deliver the intended message and services to the targeted audience.

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Strengths and Limitations

A key strength of this study is that it fills an important gap in the extant literature and is among the first to report extensively on nationally representative population data in Singapore. To the best of our knowledge, this study is the first to examine the prevalence and correlates of online support group use for mental health support among the general public in a non-Western society. However, the findings of this study must be considered in view of its limitations. Despite the use of a relatively large population-based survey for analysis, the sample size of those who had used an online support group was rather small. The low rate of online support group participation reported may have been a result of the survey methodology. In this study, participants were asked about their use of internet support groups or chat rooms; however, people may have accessed web forums, mailing lists, or e-blogs to provide or receive online social support or to share mental health experiences. Hence, individuals may not have identified this variety of web communication applications as characteristic of an "internet support group or chat room." Therefore, the true prevalence of online support group use may have been underestimated. In addition, there are new and emerging online peer groups on social networking sites (eg, Twitter, Facebook), which allow users to exchange information or seek emotional support from peers with similar health issues [49]. The impact of such social networking sites may have been missed in this study. Additionally, it is not known if the use of online support groups results in improved clinical outcomes, which is beyond the scope of this study. Nonetheless, this study established an important starting point. Further research is necessary to investigate the reach of online mental health support communities, potential barriers to local participation in such communities, and the impact of this participation on clinical outcomes. Furthermore, specific questions regarding the types of online social support tools (eg, blogs, message boards, mailing lists, social media sites) sought out by internet users today must be incorporated into survey methodology to gain a deeper understanding of user behavior.

Technology is constantly advancing and the use of technology is changing quickly. Health care delivery systems are beginning to integrate the use of electronic Health (eHealth) and internet tools. In the United Kingdom, United States, Europe, Australia, and New Zealand, mental health services such as online support groups are currently being integrated into the health care delivery system [50]. Online support groups are readily accessible online and internet applications are relatively low-cost. It is increasingly likely that individuals with mental health problems may turn to technology for help [51]. Internet-based support communities have great potential to manage mental health at significantly reduced costs to the health care system. Hence, it is vital that we continue to explore whether and how online support groups can be effectively used in the local health care delivery system for mental health services.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Sample characteristics of study participants and the use of online support groups across sociodemographic groups.
[DOCX File , 51 KB - mental_v7i8e18114_app1.docx]

Multimedia Appendix 2
Clinical characteristics of study participants and the use of online support groups.
[DOCX File , 20 KB - mental_v7i8e18114_app2.docx]

Multimedia Appendix 3
Online support group utilization among those with a DSM-IV mental disorder.
[DOCX File , 22 KB - mental_v7i8e18114_app3.docx]

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Abbreviations

CIDI 3.0: Composite International Diagnostic Interview version 3.0
DSM-IV: Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition
GAD: generalized anxiety disorder
MDD: major depressive disorder
OCD: obsessive compulsive disorder
SMHS: Singapore Mental Health Study

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Original Paper

Dynamic Interactive Social Cognition Training in Virtual Reality (DiSCoVR) for People With a Psychotic Disorder: Single-Group Feasibility and Acceptability Study

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Abstract

Background: People with a psychotic disorder commonly experience problems in social cognition and functioning. Social cognition training (SCT) improves social cognition, but may inadequately simulate real-life social interactions. Virtual reality (VR) provides a realistic, interactive, customizable, and controllable training environment, which could facilitate the application of skills in daily life.

Objective: We developed a 16-session immersive VR SCT (Dynamic Interactive Social Cognition Training in Virtual Reality [DiSCoVR]) and conducted a single-group feasibility pilot study.

Methods: A total of 22 people with a psychotic disorder and reported problems in social cognition participated. Feasibility and acceptability were assessed using a survey for participants and therapists, and by examining relevant parameters (eg, dropouts). We analyzed preliminary treatment effects on social cognition, neurocognition, and psychiatric symptoms.

Results: A total of 17 participants completed the study. Participants enjoyed DiSCoVR (mean 7.25, SD 2.05; range 3-10), thought it was useful for daily social activities (mean 7.00, SD 2.05; range 3-10), and enjoyed the combination of VR and a therapist (mean 7.85, SD 2.11; range 3-10). The most frequently mentioned strength of DiSCoVR was the opportunity to practice with personalized social situations (14/20, 70%). A significant improvement of emotion perception was observed (Ekman 60 Faces; t_{16}=–4.79, P<.001, d=–0.67), but no significant change was found in other measures of social cognition, neurocognition, psychiatric symptoms, or self-esteem.

Conclusions: DiSCoVR was feasible and acceptable to participants and therapists, and may improve emotion perception.

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KEYWORDS

social cognition; virtual reality; psychotic disorder; cognitive remediation therapy; emotion perception; theory of mind; social cognition training

Introduction

People with a psychotic disorder commonly experience problems with social functioning, that is, impairments in the ability to interact successfully with the social environment and to adequately fulfil a societal role (eg, work, personal relationships) [1]. These are often related to problems in the cognitive processes used in understanding and thinking about interactions with other people, known as social cognition [2,3].

The most commonly identified domains of social cognition are emotion perception (ie, the identification and processing of emotional cues), social perception and social knowledge (understanding social cues, rules, and context), theory of mind (ToM; identifying and understanding others' mental states and separating these from one's own perspective), and attribution style (inferences about the causes and intentions underlying events and others' behavior) [4]. A meta-analysis found moderate to large deficits in people with schizophrenia in emotion perception, social perception, and ToM, but not in attribution style [2].

Social cognition has become an important treatment target for improvement of social functioning; a multitude of behavioral approaches to improve social cognition and social functioning has emerged in recent years [5]. Three meta-analyses have found moderate to large effects of social cognition training (SCT) interventions on social cognition [6-8]. Broad-based or comprehensive forms of SCT (eg, Social Cognition and Interaction Training [9]) appear to be the most effective overall [8]. Improvements in social functioning were found in 2 meta-analyses [6,8], though only for broad-based SCT in the latter meta-analysis [8].

However, there are some concerns about SCT [5]. First, while positive effects on lower-order social cognitive domains are robust, findings regarding higher-order domains are more heterogeneous, and depend on the type of task used [5]. Second, findings regarding the generalization of social cognitive gains, as measured by social cognition tasks, to daily life social functioning are mixed; many studies do not find a significant effect [5]. Third, the durability of treatment effects has not yet been established; of the available studies, some find sustained improvements at follow-up, whereas others do not [5,8]. Thus, while SCT has a demonstrated effect on social cognition, particularly lower-order domains, these improvements do not always enduringly carry over to higher-order social cognitive domains and social functioning.

One possible explanation for these mixed findings could be that the generalization of training material to social functioning requires better opportunities to apply training techniques in real-life social situations. From studies on cognitive remediation, we know that combining treatment with a meaningful context to practice newly learned behavior is vital for improvement of social functioning [10]. However, the techniques and stimuli that are typically used in SCT, such as group discussions, videos, and pictures, lack the complexity and dynamic interaction that are present in real-life social situations [5,11]. Although it is theoretically possible to accompany patients and practice in real-life social situations, doing so is generally not feasible in clinical practice. Furthermore, real-life situations cannot be controlled for training purposes.

These shortcomings of SCT could be addressed by administering interventions using virtual reality (VR). VR involves wearing a headset that projects continuously rendered 3D images [12]. With VR, highly immersive, dynamic, and interactive social environments can be created, providing a high degree of ecological validity for assessment as well as treatment [13]. Furthermore, VR is controllable, facilitating structured SCT in realistic social situations, and allows for scenarios to be personalized, repeated, and varied. Therapists can observe participants unobtrusively and provide real-time feedback. In addition, VR has practical benefits, because a wide scope of social situations can be simulated without leaving the treatment setting. Finally, barriers to practice may be smaller with VR than in real life, as users know that their actions have no real-world consequences, and that the VR can be stopped at any time.

VR has been found to be an effective tool in treatment of psychotic disorders, for example, for treating paranoid ideation [14] and auditory verbal hallucinations [15]. A recent pilot study (n=19) of SCT using virtual environments in people with first-episode psychosis reported that SCT in a virtual world was acceptable and feasible, and found improvements in emotion recognition and anxiety. However, no significant change was observed in other domains of social cognition and social functioning [16]. Besides, a case series (n=2) of VR SCT in people with psychotic disorder reported improvements in social cognition and social functioning [17].

Furthermore, 2 trials studied the effect of VR social skills training (SST) on participants with a psychotic disorder: Park and colleagues [18] demonstrated enhanced improvement of assertiveness and conversational skills of a VR SST compared with conventional SST, and a pilot study [19] showed improvements in social anxiety, social functioning, and emotion perception after VR SST. Finally, promising results of VR SCT have been reported in other clinical populations, particularly in those with autism spectrum disorder [20,21]. Together, these encouraging preliminary findings support the viability and utility of VR SCT.

We have developed a VR SCT called "Dynamic Interactive Social Cognition Training in Virtual Reality" (DiSCoVR). In this pilot study, our aims were twofold:

- To determine whether providing VR SCT is feasible and acceptable to participants and therapists, evaluated in terms of commonly used criteria for feasibility (ie, acceptability, user satisfaction, demand, perceived usefulness,

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implementation potential, practicality, and perceived ease of use [22-24]).
- To explore the effect of DiSCoVR on social cognition, neurocognition, and psychiatric symptoms, by examining participants' baseline and posttreatment scores.

Methods

Design and Participants

This pilot study had a pretest posttest design with a single treatment group. All participants continued to receive their treatment as usual alongside their participation in the study. People with a psychotic disorder were recruited from 3 mental health treatment centers in the Netherlands (University Medical Center Groningen, GGZ Drenthe, and GGZ Delfland). Potential participants were referred to the study by their treating clinician. To help clinicians determine which patients might be eligible, screening questions were provided: (1) *Does this person struggle to recognize what goes on in another person's mind?*, (2) *Are there observable deficits in their assessment of social situations?*, (3) *Does this person have problems understanding what other people mean?*, and (4) *Do these problems lead to social dysfunction?* Promotional flyers and posters were also distributed. Participants received a compensation of €15 (US $17) for each completed assessment (up to €30 [US $34] if they completed the study), and reimbursement of any travel costs incurred for the assessments.

Inclusion criteria were (1) a diagnosis of a psychotic disorder as determined by a structured diagnostic instrument (eg, Mini-International Neuropsychiatric Interview [M.I.N.I.] [25]) in the past 3 years, or as verified by a structured clinical interview (M.I.N.I. Plus) at baseline; (2) problems in social cognition as indicated by the treating clinician; and (3) an age between 18 and 65 years. Exclusion criteria were (1) an estimated IQ below 70; (2) substance dependence; (3) a diagnosis of a neurological disorder, such as epilepsy or dementia; and (4) inadequate Dutch language proficiency.

Intervention

DiSCoVR consisted of sixteen 45-60-minute individual treatment sessions, which took place two times a week. The intervention was provided on-site by therapists with (at minimum) a clinical psychology master's degree. A treatment protocol was used; all therapists were trained in its use. The protocol included background information, examples of goals and strategies, software manuals, exercises (eg, standard situations to practice in role play and their relation to social cognition), and detailed instructions on how to carry out sessions. Therapists received supervision at least once for each client and could consult the research team as needed for additional supervision and technical support.

Social cognition was trained by practicing with social material in immersive virtual environments (Figure 1) and by learning to apply strategies in these environments (eg, verbalizing facial characteristics, or verifying with others whether a social assessment is correct). Participants formulated concrete personal goals that could be achieved with improvement of social cognition. At the end of each session, participants reflected on how they could use new knowledge and skills to achieve their goals. In (optional, although strongly encouraged) homework assignments throughout the intervention, participants were encouraged to apply strategies in daily life. The intervention was structured to start with lower-order social cognition, and complexity was increased in each module.

Module 1 (Sessions 1-5) targeted emotion perception, practiced using a VR facial emotion recognition task. Participants explored a shopping street with avatars (virtual characters) who showed an emotion upon approach. Participants then selected the emotion they thought the avatar expressed in a multiple-choice menu. Immediate visual feedback on the correctness of their answer (green or red screen) was given. If an answer was incorrect, the same emotion was shown again with greater intensity. Several characteristics of the avatars and environment (eg, intensity of emotions, allotted time for answers) could be altered. Seven standard practice levels were created in which all available parameters increased in difficulty, but therapists could customize these parameters to create tailored levels. Participants learned strategies to recognize emotions (eg, verbalizing salient features) and practiced them both in VR and in their (real-life) home environment.

Module 2 (Sessions 6-9) targeted social perception and ToM. By practicing with interactive social scenarios, participants learned to understand the social context, hints, social missteps and ambiguity, perception of body language, and tone of voice. Participants observed social interactions between avatars in a café and supermarket, containing misunderstandings, hints, true and false beliefs, and social missteps. They answered multiple-choice and open-ended questions within the VR environment about the emotions, thoughts, and intentions of the avatars. Outside of the VR environment, participants continued to practice strategies (eg, remembering your thoughts/emotions in a similar situation) and tried to assess behavior, thoughts, and emotions of themselves and others in (real-life) daily social situations.

Module 3 (Sessions 10-16) targeted application of higher-order social cognition in social interactions, practiced using interactive role-play exercises. Participants interacted with an avatar, whose appearance, voice, and emotions were controlled by the therapist. Participants practiced with situations that were difficult for them or that fit their goals. Therapists could also use standard (nonpersonalized) role-play exercises from the protocol, containing sarcasm, hinting, misunderstandings, and social missteps. Participants learned a social cognitive problem-solving technique in which they first considered the behavior, thoughts, and emotions of themselves and the other person, then formulated (and role-played) different possible reactions, and finally executed the reaction they preferred. Participants were encouraged to also apply this technique in their daily lives.

The virtual environments (a shopping street, a supermarket, and a bar) were shown using an Oculus Rift VR-headset (Consumer Version 1). The software was developed by CleVR BV. The VR software was controlled by the therapist, using one monitor to observe the participant's field of vision, and another monitor to control the virtual environment with the user interface.

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Participants used a Microsoft Xbox game controller to move around and to indicate answers in multiple-choice-menus.

Figure 1. (A) Module 1 (Translation: "Which emotion? Disgust, Neutral, Anger, Happiness"). (B) Module 2 (Translation: "What does Daniel really mean?"). (C) Module 3, participants' point of view, (D) Module 3, therapist interface. (E) Set-up with authors WV and CNWG, who both consented to publication of this image. Images A-D are used with permission from CleVR BV.



Measures

Diagnostic Measures

The following measures were administered at baseline for diagnostic purposes.

Mini International Neuropsychiatric Interview Plus

A semistructured interview—M.I.N.I. Plus [25]—was used to verify the diagnosis of psychotic disorder, if a diagnosis of psychosis had not been determined by a (semi)structured clinical interview (eg, Structured Clinical Interview for DSM, Schedules

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for Clinical Assessment in Neuropsychiatry, M.I.N.I.) in the past 3 years. This was the case for 17 of our 22 participants (77%).

National Adult Reading Test

National Adult Reading Test [26] (Dutch version, Nederlandse Leestest voor Volwassenen, [27]) is a proxy measure of premorbid intelligence. Participants recite a list of 50 increasingly uncommon words. Correct pronunciations yield 2 points.

Feasibility and Acceptability

Feasibility and acceptability of DiSCoVR were assessed in participants by a questionnaire consisting of 2 parts: statements about the intervention (eg, "I enjoyed the training") that were rated on 10-point Likert scales, and open-ended interview questions (eg, "What were strengths of the intervention?"). The complete questionnaire can be found in Tables 2 and 3. We also recorded dropout rate and number of sessions completed as well as the time taken to complete DiSCoVR.

In addition, therapists completed an open-ended questionnaire about their satisfaction with the treatment protocol and materials (Table 4). Protocol fidelity was assessed with a self-report form and checklist after each treatment session, on which therapists could indicate any particularities, whether they deviated from the protocol, and why.

Social Cognition

Ekman 60 Faces Test

Ekman 60 Faces Test [28] is a 60-item computerized picture task, measuring emotion perception. Participants are asked to identify 6 basic emotions (happy, surprised, anxious, disgusted, sad, and angry). The total score (ie, the number of correctly identified stimuli) across all emotions was analyzed.

Bell–Lysaker Emotion Recognition Test

Bell–Lysaker Emotion Recognition Test (BLERT [29], Dutch version unpublished) is a video task measuring emotion perception, consisting of 35 sentences, in which actors portray an emotionally ambiguous sentence neutrally or with 1 of 6 basic emotions. Participants identify the portrayed emotion. Total scores were analyzed.

The Awareness of Social Inference Task

The Awareness of Social Inference Task (TASIT [30]; Dutch version [31]) is a video task containing social vignettes, and consists of 3 parts: I-III. TASIT-I assesses emotion perception, distinguishing between neutral and 6 basic emotions. TASIT-II and -III measure social perception and ToM, and have questions about the intentions, message, thoughts, and feelings of the people in the video. TASIT-II consists of clips with genuine utterings or sarcasm; TASIT-III contains clips of lies or sarcasm. Parallel versions were used; the version order was A-B for all participants. For analysis, we used the total score for each part of TASIT.

Empathic Accuracy Task

Empathic Accuracy Task (EAT [32]; Dutch version [33]) is a computerized video task measuring empathy, with clips of people speaking about emotionally charged autobiographical events with either a positive or a negative valence. Conforming to previous studies [34,35], a shortened version (4 videos; 2 positive and 2 negative) was used. Parallel versions were administered, using counterbalanced randomization. Participants used a rating dial to indicate continuously how speakers were feeling while speaking (very negative to very positive). Empathic accuracy scores were generated for each video clip by correlating participants' affect ratings with original speakers' own affect ratings. These correlations (–1 to +1) underwent a Fisher *z* transformation prior to data analysis. For each participant, the mean Fisher *z* transformed EAT scores across video clips were used in the data analyses.

Faux Pas

Faux Pas [36] is a measure of ToM. Ten stories are read to the participant, 5 of which contain a faux pas. Participants are asked whether a faux pas occurred, who committed it, why it was a faux pas, and why it happened. A story comprehension and empathy question are also asked after each story. Parallel versions were used, but the order was not counterbalanced or randomized. The total score was used for analysis.

Neurocognition

Rapid Visual Processing

Rapid Visual Processing (RVP; [37]) is a measure of sustained visual attention. A white box with alternating numbers (0-9, 100 digits per minute) is shown on a computer screen. Participants press a button if 1 of the 3 target sequences occur. Outcome variables of the RVP are response latency in milliseconds, sensitivity, and probability of hit (0-1).

Trail Making Test

The Trail Making Test (TMT; [38]) assesses processing speed and executive function. Numbers (TMT-A) or numbers and letters (TMT-B) are shown in circles, scattered across a sheet of paper. Participants connect the numbers (and letters) in consecutive order (eg, 1-2-3 or 1-A-2-B). The completion time in seconds for each subtest was used for analysis.

Symptom Measures

Green Paranoid Thought Scale

The Green Paranoid Thought Scale (GPTS; [39]) is a 32-item self-report questionnaire measuring paranoid thoughts on 2 dimensions (social reference and social persecution), using a 5-point Likert scale. We analyzed the total score for both subscales separately.

Social Interaction Anxiety Scale

The Social Interaction Anxiety Scale (SIAS; [40]) is a 20-item self-report questionnaire investigating verbal and nonverbal social anxiety, using a Likert scale: 0 (not at all) to 4 (completely). The total score was analyzed.

Beck Depression Inventory

Beck Depression Inventory (BDI; [41]) is a 21-item self-report questionnaire on symptoms of depression. Each item of the BDI uses statements fitting an increasing severity of depressive symptoms. We used the total BDI score for analysis.

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Self-Esteem Rating Scale

The Self-Esteem Rating Scale (SERS; [42]) is a 20-item self-report questionnaire on (explicit) self-esteem. The SERS uses statements that are rated on a 1 (disagree totally) to 7 (agree totally) Likert scale. The total score was used for analysis.

Positive and Negative Syndrome Scale

The Positive and Negative Syndrome Scale (PANSS; [43]) is a semistructured interview investigating symptoms of psychosis. The positive (7 items) and negative (7 items) subscales were administered. Total subscale scores were used for analysis.

Procedure

After referral from a clinician or self-enrollment, interested patients were contacted and screened by the research team. Participants provided written informed consent during a face-to-face meeting, after which the baseline assessment (approximately 3 hours) took place. An overview of the measures, including their order and length, is included in Multimedia Appendix 1. Measurements were performed by trained assessors. After the baseline measurement, participants were enrolled in DiSCoVR. Upon finishing the training, a (face-to-face) posttreatment assessment (approximately 2.5 hours) took place. Participants who dropped out were asked to participate in the evaluation survey.

This study was approved by the Medical Ethical Committee of the University Medical Center Groningen (ABR: NL55477.042.16, METC: 2016/050), as well as by the ethics boards of the other participating centers (ie, the Committee for Research and Health Care Innovation, GGZ Drenthe, the Committee for Scientific Research, and GGZ Delfland). All participants gave written informed consent in accordance with the Declaration of Helsinki.

Analysis

We assessed 3 types of feasibility and acceptability data: (1) relevant quantitative parameters, such as dropout rates, time to recruit, intervention completion time, protocol adherence, and occurrence of issues (eg, technical problems) in sessions; (2) the participant survey; and (3) the therapist survey.

For quantitative data, descriptive statistics were examined. For qualitative items, similar answers or categories were grouped together and absolute and relative frequencies were evaluated. That is, because questions were open ended, we grouped comparable answers and counted how frequently they occurred. For example, for the question “Did the training meet your treatment needs?”, the answers “I’ve learned what I’d wanted to learn” and “After setting goals, I could work on them very well” were grouped as “Yes,” whereas “I did not fully succeed in developing better empathy, but I was able to practice,” and “On some points, but not others” were grouped as “Partly”.

To compare baseline and posttreatment scores, paired *t* tests were used, unless difference scores (T_1–T_0) were not normally distributed. This was the case for the BLERT, GPTS-A, PANSS Positive, and TMT-B. Thus, Wilcoxon tests were carried out for these measures. Pairwise complete-case analysis was used in case of missing data. To account for the multitude of measures, we adopted an α of .01 as a threshold of significance.

Results

Feasibility and Acceptability

Participants

Demographic and clinical characteristics of the sample are presented in Table 1. Participants were recruited between January and August 2017; 17 of the 22 participants (77%) completed the study. Reasons for dropout (n=5) were having too much going on (n=2), finding the intensity too high (n=1), not feeling a connection with the therapist (n=1), and (self-reported) negative symptoms and social anxiety (n=1). Noncompleters dropped out at Sessions 2 (n=1), 4 (n=1), 7 (n=2), and 10 (n=1). Three of the five participants who dropped out participated in the evaluation survey.

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Table 1. Demographic and clinical characteristics of the sample (N=22).

Variables	Value
Demographic	
Age (years)	35.95 (11.68)
Gender	
Male, n (%)	16 (73)
Female, n (%)	6 (27)
Education level	
None or primary, n (%)	1 (5)
Vocational, n (%)	12 (55)
Secondary, n (%)	8 (36)
Higher, n (%)	1 (5)
National Adult Reading Test score, mean (SD)	78.64 (7.70)
Paid employment	
Employed, n (%)	4 (18)
Unemployed, n (%)	18 (82)
Hours worked per week, mean (SD)	1.14 (3.12)
Work history (years), mean (SD)	6.52 (9.91)
Day activities/volunteering	
Engages in day activities/volunteering, n (%)	12 (55)
Hours spent on day activities/volunteering, mean (SD)	5.7 (8.02)
Substance use	
Alcohol (glasses per week), mean (SD)	3.55 (5.55)
Nicotine (cigarettes per week), mean (SD)	63.45 (90.12)
Marijuana/Cannabis (joints per week), mean (SD)	0.50 (1.67)
Hard drugs (eg, ecstasy, speed, cocaine) in standard units per week, mean (SD)	0.10 (0.44)
Clinical	
Diagnosis	
Schizophrenia, n (%)	17 (77)
Schizoaffective disorder, n (%)	2 (9)
Psychotic disorder, not otherwise specified, n (%)	3 (14)
Hospitalization status	
Never hospitalized, n (%)	3 (14)
Currently hospitalized, n (%)	3 (14)
Previously hospitalized, n (%)	16 (73)
Number of (past) psychotic episodes, mean (SD)	2.31 (1.8)
Illness duration, mean (SD)	13.22 (11.70)
Medication	
Typical antipsychotics, n (%)	0 (0)
Atypical antipsychotics, n (%)	13 (59)
Combination typical/atypical, n (%)	1 (5)
Antidepressants, n (%)	1 (5)
Mood stabilizers, n (%)	1 (5)
Benzodiazepines, n (%)	1 (5)

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Variables	Value
Not using medication, n (%)	2 (9)
Unknown/declined to answer, n (%)	5 (23)
Family history of psychiatric illness	
Yes, n (%)	12 (55)
No, n (%)	10 (45)

The results of the survey are presented in Tables 2 and 3. In the quantitative survey, participants gave positive ratings to their enjoyment of DiSCoVR (mean 7.25, SD 2.05; range 3-10), to the amount they learned (mean 6.65, SD 1.81; range 3-10), and usefulness for daily social activities (mean 7.00, SD 2.05; range 3-10). Participants positively evaluated the combination of a therapist and VR (mean 7.85, SD 2.11; range 3-10) and the appropriateness of the difficulty level (mean 7.20, SD 1.91; range 3-10). Participants gave relatively low ratings to the realism of the appearance of the avatars (mean 5.45, SD 2.18; range 2-10) but ratings for their facial expressions (mean 6.65, SD 2.06; range 3-10) and voices (mean 6.95, SD 2.35; range 3-10) were higher.

In the open-ended questions of the qualitative survey (N=20), participants most commonly (n=14, 70%) mentioned the opportunity to practice with social situations in VR as a strength of the intervention. Other common subjective strengths of DiSCoVR were the personalization of the intervention (ie, targeting specific personal goals and situations; n=5, 25%) and (role of) the therapist (n=5, 25%), the emotion recognition module (n=3, 15%), and realism of emotions and role-play exercises (n=3, 15%). For a majority of people (n=13, 65%), the intervention fit their treatment needs. The most commonly reported subjective effect of DiSCoVR was improved social skills (n=7, 35%), followed by improved emotion recognition (n=6, 30%) and increased assertiveness and confidence (n=5, 25%).

The aspect of DiSCoVR most commonly named as a weakness was technical issues (n=7, 35%), particularly problems with sound regulation in the interaction module, as well as limitations of the content (eg, the inability to practice group conversations) and the graphical quality. Some participants criticized the realism of the intervention (n=4, 20%), particularly the avatars' movements and facial expressions. A few participants (n=4, 20%) indicated that the treatment only partly fit their needs; reasons given were that they felt their social cognition had improved, but not as much as they had wanted (n=1); that the latter part of the training was useful, but not the emotion perception module (n=1); that it was relevant and they had learned useful strategies, but that the intervention could be more focused and that they needed to keep reminding themselves to use them (n=1); and that there was insufficient opportunity to practice "small talk" (n=1). Overall, 3/20 (15%) participants stated that the intervention did not fit their needs: one participant felt it was too focused on (others') behavior; one indicated that recognizing emotions in conversations was still difficult; and one thought the role-play exercises were insufficiently realistic.

Finally, while a majority indicated that they were satisfied with the number (n=10, 50%), intensity (n=5, 25%), and duration (n=13, 65%) of sessions, those who were employed or had a long commute found the intensity too high (n=1, 5%) or somewhat high (n=4, 20%).

Table 2. Quantitative evaluation of VR intervention by participants (N=20).

Question	Mean (SD)	Median	Range	IQR (Q1-Q3)
I liked the VR training (1-10)	7.25 (2.05)	7	3-10	3 (6-9)
I have learned a lot from the VR training (1-10)	6.65 (1.81)	7	3-10	2 (6-8)
I thought the training was useful for daily social contact (1-10)	7.00 (2.05)	7.5	3-10	1.75 (6.25-8)
I thought the virtual characters looked realistic (1-10)	5.45 (2.18)	5.5	2-10	3 (4-7)
I thought the virtual characters' voices sounded realistic (1-10)	6.95 (2.35)	7	2-10	3.5 (5.25-8.75)
I thought the virtual characters' facial expressions looked realistic (1-10)	6.65 (2.06)	6.5	3-10	3.75 (5-8.75)
I enjoyed the combination of a therapist and VR (1-10)	7.85 (2.11)	8.5	3-10	3.5 (6.25-9.75)
The difficulty level of the training was exactly right (1-10)	7.20 (1.91)	7.5	3-10	2.75 (6-8.75)

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Table 3. Qualitative evaluation of the VR intervention by participants (N=20).

Question and answers	n (%)[a]
Were you satisfied with the number, intensity, and duration of sessions?	
Number	
Satisfied	10 (50)
Too many	3 (15)
Too few	1 (5)
Intensity	
Acceptable	5 (25)
Somewhat high	4 (20)
Too high	1 (5)
Duration	
Satisfied	13 (65)
Too long	3 (15)
Too short	1 (5)
What were strengths of the intervention?	
Practice with social situations/interaction module	14 (70)
Tailoring of intervention to personal situation	5 (25)
(Role of) therapist	5 (25)
Emotion recognition module	3 (15)
Realism	3 (15)
Techniques and materials	3 (15)
Other (ie, structure, second module, assessment)	3 (15)
What were weaknesses of the intervention?	
Technical/sound issues	7 (35)
Realism (appearance, movement)	4 (20)
First module (too long/unnecessary)	3 (15)
Techniques/materials	3 (15)
Other (ie, dizziness, assessment duration, therapist, cognitive load, tailoring, too much emphasis on others, difficulty of homework)	6 (30)
None	4 (20)
What have you learned?	
Social skills (talking to others, how to react)	7 (35)
Recognize emotions	6 (30)
Being assertive/confident	5 (25)
Paying attention/showing interest	4 (20)
Think positively/consider alternative explanations	3 (15)
Knowing what is appropriate/being less abrasive	2 (10)
Other (ie, revisiting things, less anxiety)	3 (15)
Nothing	1 (5)
Did the intervention meet your treatment needs?	
Yes	13 (65)
No	3 (15)
Partly	4 (20)

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Question and answers	n (%)[a]
What did you think of the conversations of (Module 2) and with (Module 3) the avatars?	
Good/realistic/opportunity for learning	11 (55)
Okay, needs some improvement	6 (30)
Fake/unrealistic	1 (5)
Funny/takes getting used to	3 (15)
Not applicable	1 (5)

[a]n (%) refers to the number and percentage of participants who provided a certain answer. Because participants could provide multiple answers to a single question (eg, "I learned social skills and assertiveness"), and some participants did not answer all questions completely (eg, "The number of sessions was fine," but said nothing about the intensity/duration), n (%) may not add to 20 (100).

Therapists

The results of the evaluation of DiSCoVR by therapists are presented in Table 4. Therapists noted the role-play exercises and the opportunity to practice with social situations in VR as the main strength of DiSCoVR (4/6, 67%), considering these to be the most important and effective component of the intervention (5/6, 83%), followed by reflection on social situations (3/6, 50%). Other commonly named strengths were the treatment protocol (3/6, 50%) and the structure of the intervention (2/6, 33%). The majority of therapists considered the VR software to be adequate (4/6, 67%) or good (2/6, 33%), stating that it was easy and intuitive to work with (4/6, 67%), and praising its technical support (2/6, 33%).

The therapists mainly criticized the lack of technical reliability and limited capabilities of the software (5/6, 83%). Half of them recommended improving existing functionality, particularly the sound and graphical quality, and half of them recommended adding new features (eg, environments or scenarios). Regarding the relevance of scenarios for daily life, 2/6 (33%) therapists were satisfied, 3/6 (50%) felt they were relevant but could be improved, and 1/6 (17%) was dissatisfied and noted that they felt unnatural.

Therapists reported deviating from the protocol in 18.2% (55/303) of the total number of sessions that were carried out. In addition, technical issues were reported in 14.9% (45/303) of the sessions. Other issues (eg, a participant being late) occurred in 11.6% (35/303) of sessions. A total of 3/303 sessions (0.99%) were terminated early. It took a mean of 12.4 weeks (SD 5.2; range 8-22; median 11) for participants to complete the intervention. The reports indicated that participants spent a mean of 342 minutes practicing in VR across the 16 sessions (SD 28.8; range 227-451; median 362), which is equivalent to a mean of 17.9 minutes per session (SD 6.06; range 5.0-28.2; median 17.9). The mean duration of a session was 55.4 minutes (SD 7.2; range 34-67; median 57).

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Table 4. Evaluation of the VR intervention by therapists (N=6).

Question and answers	n (%)[a]
Was the degree of interaction of the VR SCT adequate?	
More than adequate	2 (33)
Adequate	1 (17)
Somewhat inadequate	2 (33)
Are the used scenarios relevant for daily life?	
Yes	2 (33)
Yes, but needs improvement	3 (50)
No, somewhat unnatural	1 (17)
Do you consider the difficulty level to be adequate?	
Yes	2 (33)
Adequate	1 (17)
Needs to be more difficult	1 (17)
Needs to be less difficult	1 (17)
Depends on therapist	1 (17)
What were strengths of the intervention?	
Interactive role-play exercises (Module 3)	4 (67)
Use of VR/Practice with social situations	3 (50)
(Ease of use of) Protocol	3 (50)
Structure of intervention	2 (33)
Techniques/materials	1 (17)
Enjoyable	1 (17)
Which components were effective or important?	
Role-play exercises (Module 3)	5 (83)
Evaluation/reflection	3 (50)
Practicing	1 (17)
All components	1 (17)
What were weaknesses or annoyances?	
Technical issues/shortcomings	5 (83)
Lack of reference to participants' worksheets	2 (33)
Homework instructions inadequate	1 (17)
Goal setting difficult	1 (17)
Module 1 too long	1 (17)
Scenarios too long	1 (17)
Thoughts–behavior–feelings technique too difficult	1 (17)
What did you think of the VR program?	
Good	2 (33)
Adequate, but needs some improvement	4 (67)
Easy/intuitive interface, easy to work with	4 (67)
Good technical support	2 (33)
Not sufficiently advanced graphically	1 (17)
What did you think of the number and duration of the sessions?	
Fine	4 (67)

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Question and answers	n (%)[a]
Fine, but should be structured differently	1 (17)
Needs more sessions	1 (17)
Needs longer sessions	1 (17)

[a]n (%) refers to the number and percentage of therapists who provided a certain answer. Because they could provide multiple answers to a single question and some therapists did not answer all questions completely, n (%) may not add to 6 (100).

Effects of DiSCoVR (Baseline Versus Posttreatment)

Baseline and posttreatment means, standard deviations, test statistics, and effect sizes are presented in Table 5. Analyses were conducted with 17 participants (unless indicated otherwise). At =.01, only the emotion perception, as measured by the Ekman 60 Faces Test, improved significantly after DiSCoVR (t_{16}=–4.79, P<.001, mean difference 4.18). No significant improvement was observed on the other measures of emotion perception, any of the ToM measures, in neurocognition, or in levels of psychiatric symptoms.

For emotion perception, a moderate, effect size (d=–0.67) was found for the Ekman 60 Faces Test, but for the other measures, effect sizes were negligible (BLERT: d=0.03) and small (TASIT-I: d=–0.15). For social perception and ToM, we found negligible to small effects on all outcome measures (ranging between d=–0.15 and d=0.25). Negligible effects were found for information processing (TMT-A and B; d=0.11 and d=0.08), but small to moderate effects were found for sensitivity and probability of hit of the RVP (d=–0.47 for both). Small improvements were also observed for most symptom domains, with effect sizes ranging between d=0.16 and d=0.34. A small effect size was also found for self-esteem (d=–0.25).

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Table 5. Means, standard deviations, and test statistics (baseline and posttreatment).

Measure	Baseline, mean (SD) N=22	Posttreatment, mean (SD) N=17[a]	*t* or W	*P*	Cohen *d* (95% CI)
Emotion Perception					
Ekman 60 Faces	46.86 (5.95)	51.06 (6.72)	–4.79	<.001[b]	–0.67 (–0.97 to –0.35)
BLERT[a]	22.18 (5.61)	22.12 (7.97)	38.50[c]	.38	0.03 (–0.41 to 0.48)
TASIT, Part 1	11.77 (1.77)	12.24 (1.25)	–0.57	.58	–0.15 (–0.71 to 0.40)
Social perception and Theory of mind					
TASIT, Part 2	26.59 (4.52)	26.71 (3.94)	0.55	.59	0.15 (–0.39 to 0.69)
TASIT, Part 3	22.86 (3.73)	23.76 (4.21)	–0.59	.56	–0.16 (–0.70 to 0.38)
Faux Pas Test	39.14 (7.62)	37.88 (6.87)	0.89	.39	0.17 (–0.22 to 0.56)
EAT[a]	1.12 (0.54)	1.24 (0.33)	0.45	.66	0.25 (–0.51 to 0.81)
Neurocognition					
TMT A	39.59 (14.76)	36.41 (16.70)	0.79	.44	0.11 (–0.17 to 0.29)
TMT B	77.64 (25.13)	78.59 (43.96)	83.5[c]	.42	0.08 (–0.59 to 0.43)
RVP sensitivity (A′)	0.89 (0.05)	0.91 (0.04)	–2.10	.05	–0.47 (–0.95 to 0.01)
RVP mean latency	460.54 (121.43)	473.99 (135.37)	0.271	.79	0.03 (–0.26 to 0.34)
RVP probability of hit	0.56 (0.20)	0.64 (0.17)	–2.21	.04	–0.47 (–0.93 to –0.01)
Symptoms					
Depression (BDI)[a]	14.05 (9.93)	12.50 (7.09)	1.65	.12	0.31 (–0.08 to 0.91)
Paranoia: social reference (GPTS)	34.09 (14.72)	27.88 (10.40)	84.0[c]	.17	0.34 (–0.18 to 0.87)
Paranoia: social persecution (GPTS)	29.77 (14.92)	25.82 (15.10)	1.15	.27	0.16 (–0.23 to 0.55)
Positive symptoms (PANSS)	15.45 (4.27)	13.18 (3.28)	43.5[c]	.72	0.21 (–0.28 to 0.70)
Negative symptoms (PANSS)	14.55 (3.80)	14.94 (4.59)	0.675	.51	0.17 (–0.34 to 0.67)
Social anxiety (SIAS)[a]	41.82 (14.74)	34.13 (13.19)	1.59	.13	0.27 (–0.17 to 0.72)
Self-esteem (SERS)	84.18 (21.08)	90.41 (17.62)	–1.79	.09	–0.25 (–0.67 to 0.17)

[a]Because of missing data, BLERT T_1, n=16; EAT T_1, n=14, BDI T_1, n=15; SIAS T_1, n=15.

[b]Significant at α=.01.

[c]Wilcoxon tests were carried out for the BLERT, GPTS-A, PANSS Positive, and TMT-B.

Discussion

Principal Findings

The main goal of this study was to evaluate the feasibility and acceptability of DiSCoVR, and to identify aspects in need of improvement [22]. We found that participants and therapists were generally satisfied with the intervention. The interactive role-play exercises were most commonly named as a strength of the intervention, as well as the opportunity to practice with social situations and the combination of VR and a therapist. Both therapists and participants provided useful feedback for further development, particularly regarding technical issues. A secondary goal was to obtain an estimate of treatment effect sizes on various outcome domains. We found a significant improvement in emotion perception. However, no significant change was observed on the other measures, and most effect sizes were negligible to small.

As stated in the "Introduction" section, commonly used criteria to evaluate feasibility and acceptance are acceptability, implementation potential, practicality, and limited-efficacy testing [22]. Additional areas of interest regarding the feasibility of technological interventions are provided by the Technology Acceptance Model, which emphasizes perceived ease of use, perceived usefulness, and user attitudes toward the technology [23]. Finally, the Systems Usability Scale [24] was likewise developed to evaluate technological innovations, and enquire about effectiveness, efficiency, and user satisfaction. In the following, we will focus on these criteria to evaluate the feasibility and acceptability of DiSCoVR.

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Acceptability, User Attitudes, and Satisfaction

Participants gave positive ratings to the enjoyability of the intervention, its usefulness for daily social interactions, the combination of VR and a therapist, and the appropriateness of the difficulty level. The most important strength of the intervention, as indicated by both participants and therapists, was the opportunity to practice with interactive social situations resembling daily life. As such, we succeeded in our goal of creating a method to facilitate practice in realistic social situations. However, the use of new technology to accomplish this also has an important disadvantage, in the form of technical issues (particularly problems with sound settings) and limited capability of the software (eg, lack of sophisticated animations and group role-play features). Technical capability and reliability were the most important point of criticism from participants as well as therapists. While these technical limitations were troublesome, it is possible to address them in future iterations of the software.

Notably, some participants considered the emotion recognition module to be particularly useful, but an equal number considered it to be unnecessary. Given the considerable variation in baseline social cognitive ability, it is likely that some participants were relatively unimpaired in emotion perception. For them, the first module may have been unnecessary. Therefore, (VR) SCTs may need to take a modular approach, that is, emphasize different domains for different people, based on their needs.

Demand and Perceived Usefulness

We found that we could recruit participants relatively quickly, and most of them completed the intervention. DiSCoVR met treatment needs for the majority of participants, but not for everyone, mainly because people did not learn (all) the things they had wanted to learn, or because their subjective progress fell short of expectations. From this, we can learn that DiSCoVR does meet a demand, but it remains important that therapists and participants communicate clearly and regularly on social goals and their feasibility.

Implementation Potential, Practicality, and Perceived Ease of Use

The intervention could generally be delivered as intended, with therapists reporting protocol deviations (55/303, 18.2% of sessions) and technical issues (45/303, 14.9% of sessions) relatively rarely. Therapists also indicated that the software and treatment protocol were intuitive and easy to use, and praised the quality and availability of technical support. However, the average time taken to complete the intervention was approximately 50% longer than intended, possibly reflecting that twice-weekly sessions were impractical. Nonetheless, the majority of participants was satisfied with the intensity of DiSCoVR, and the frequency and number of sessions match similar VR studies [14,44] and previous SCT studies [45-47]. Moreover, research suggests that for cognitive training, higher treatment intensity may produce better outcomes [48].

Limited-Efficacy Testing and (Perceived) Effectiveness

Common subjective effects of the intervention were enhanced social skills, improved emotion recognition, and increased confidence and assertiveness. While demonstrating efficacy was not the goal of this study, we observed a significant improvement in emotion perception (specifically in the Ekman 60 Faces Test), but we did not see a statistically significant or clinically relevant improvement in higher-order social cognitive domains. Thus, despite our reasoning that the use of VR would facilitate generalization to higher-order social processes, we observed neither a statistically significant nor a clinically relevant change in any of the measures of ToM.

Although this study was small and uncontrolled, our findings appear to be consistent with previous studies indicating that lower-order processes such as emotion perception can be improved more effectively than higher-order processes [5]. Perhaps this is because, more so than identification of emotions in static pictures, ToM requires synthesis of multiple processes and sources of information [49], such as identifying and remembering relevant contextual details and processing of emotional cues (eg, verbal, auditive, facial, body language).

Our second module may have involved too much emphasis on emotion perception and too little on higher-order reflective processes. While little is known about what it takes to improve ToM [50], a recent meta-analysis [8] suggested that SCTs encompassing multiple domains of social cognition may be more effective than targeted interventions. Therefore, going forward, a greater emphasis on integration of higher-order social cognitive processes and application in social situations may be necessary.

Adjustments as a Result of the Pilot Study

To address concerns about the interaction module (Module 3), the graphical quality, character animations, and sound control settings of the software were updated. Given the lack of an effect on ToM, we have also updated the second VR module. We changed the multiple-choice questions into open-ended questions to incite in-depth reflection on avatars' behavior, thoughts, and feelings. That is, instead of asking only how an avatar is feeling (from a 4-choice menu), we now also ask *why*, what they are thinking, and how this relates to their behavior. This way, we hope to stimulate integrative reflection on social situations and engagement of higher-order social cognition.

We also adjusted the treatment protocol, to stimulate practical application of social cognition in daily life, and to better align the intervention with participants' treatment needs. First, we placed a stronger emphasis on the use and practice of strategies throughout the intervention: therapists were more explicitly instructed to select a strategy with participants before each VR session, and to encourage its application in homework exercises. Second, we simplified the way goals are set, reflected upon, and evaluated, allowing goals to not only exclusively target social cognition (eg, recognizing social cues better), but also social functioning (eg, making friends). This way, we aim to enhance the relevance and generalization of training content, to ensure treatment needs are met. Lastly, we have added a monthly supervision group where therapists can receive input and advice from the research team and one another.

Limitations

As an uncontrolled pilot study, the results of this study lack statistical power and methodological rigor to draw conclusions

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concerning the efficacy of DiSCoVR. Moreover, parallel versions were unavailable (Ekman 60 Faces, BLERT, TMT, all questionnaires) or were not administered in a randomized order (TASIT, Faux Pas). We therefore cannot exclude the possibility of learning, repetition, and order effects. For example, administering TASIT-A before B has been shown to result in significantly higher scores on TASIT-A [31] than if B is administered before A. This could potentially obfuscate treatment effects, as in this study TASIT-A was administered first. In addition, our recruitment method required potential participants to have sufficient ability for reflection to recognize a need for social-cognitive treatment. Therefore, we may have failed to recruit people with more severe (social) cognitive deficits, limiting the generalizability of our findings. Finally, we did not use a standardized measure to assess feasibility and acceptability, such as the System Usability Scale [24] or the Simulator Sickness Questionnaire [51] because we were interested in elements specific to our intervention. Thus, while our custom survey was informative for further development, it cannot be directly compared with previous research.

Conclusions

We set out to develop a new type of SCT, building upon existing interventions by using VR as a tool. Taking into account the criteria described above [22-24], we can conclude that VR SCT is feasible and acceptable for both patients and therapists, and captures the interactive nature of social situations. This pilot study therefore demonstrates that a larger-scale clinical trial using these research and treatment protocols is feasible and acceptable. However, this study also demonstrated that there is room for improvement, particularly regarding the content and reliability of the VR software and hardware. Based on these results, we have adjusted DiSCoVR. Our next step will be to test this adjusted version in a randomized controlled trial [52], comparing it with an active control condition (VR relaxation).

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Order and length of measures.
[DOCX File , 16 KB - mental_v7i8e17808_app1.docx]

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Abbreviations

BDI: Beck Depression Inventory
BLERT: Bell–Lysaker Emotion Recognition Test
DiSCoVR: Dynamic Interactive Social Cognition Training in Virtual Reality
EAT: Empathic Accuracy Task
GPTS: Green Paranoid Thought Scale
M.I.N.I. Plus: Mini International Neuropsychiatric Interview Plus
PANSS: Positive and Negative Syndrome Scale
RVP: Rapid Visual Processing
SCT: Social Cognition Training
SERS: Self-Esteem Rating Scale
SIAS: Social Interaction Anxiety Scale
TASIT: The Awareness of Social Inference Test
TMT: Trail Making Test
VR: virtual reality

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Personal Perspective

Patient Innovation in Investigating the Effects of Environmental Pollution in Schizophrenia: Case Report of Digital Phenotyping Beyond Apps

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Abstract

This patient perspective highlights the role of patients in the innovation and codesign of digital mental health technology. Though digital mental health apps have evolved and become highly functional, many still act as data collection silos without adequate support for patients to understand and investigate potentially meaningful inferences in their own data. Few digital health platforms respect the patient's agency and curiosity, allowing the individual to wear the hat of researcher and data scientist and share their experiences and insight with their clinicians. This case is cowritten with an individual with lived experiences of schizophrenia who has decided to openly share their name and experiences to share with others the methods and results of their curiosity and encourage and inspire others to follow their curiosity as well.

(JMIR Ment Health 2020;7(8):e19778) doi:10.2196/19778

KEYWORDS

digital mental health; mHealth; apps; serious mental illness; schizophrenia; psychiatry; digital phenotyping

Introduction

Digital health software, including apps, are designed to serve people and help improve clinical outcomes. Although apps have become more functional and able to capture both surveys and sensor information (ie, digital phenotyping [1]), technical limitations in smartphone software and hardware limit potential data capture. Highlighting the potential of health software beyond smartphones (apps), this case report demonstrates the potential for such software to transition between different devices and hardware toward better serving people. Building off a prior case report where an individual started with an app to track symptoms but found a tally counter more useful [2], here we discuss a case where an app was used at first, followed by a transition to a novel device that proved to be a more comprehensive solution.

Brief Case

Spencer Roux (henceforth referred to as SR) is a male in his thirties who was diagnosed with schizophrenia in 2013. His symptoms are currently well managed with exercise, lifestyle interventions, and medications. Seeking to constantly improve his condition and curious about the impact of various environmental aspects on his mental health, SR sought to quantify such environmental aspects. SR also considered tracking noise level, temperature, and ambient lighting, the latter serving as a proxy for sunlight.

Mental health concerns related to environmental variations, including global warming, climate change, and pollution are rising while pollution itself is a known trigger for brain inflammation [3-5], which may be related to the onset and exacerbation of numerous illnesses. The strongest available evidence is for the relationship between pollution and depression [6] but emerging evidence indicates that ambient pollution could

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be associated with hospitalization in illnesses such as schizophrenia [7,8]. However, tracking environmental conditions such as pollution is not possible today through the use of common smartphone apps, as no major smartphone devices support indoor precision air quality sensors. Although it is possible to purchase such sensors individually, there is no off-the-shelf indoor precision air quality sensor that also tracks mental health available on the market today.

Though he had no prior knowledge of this literature, SR wanted to assess the relationship between air quality and the number of auditory hallucinations he experienced day-to-day. As his symptoms are well controlled, he believed this was a practical time to learn more about environmental factors that may be related to his symptoms. Previously, SR used a tally counter device to identify a relationship between his auditory hallucination count and the number of times he responded to his hallucinations [2], and here sought to capture new data. As with the tally counter, he wanted to track his symptoms in a manner that was inconspicuous and easy to engage with.

The Nordic Thingy prototyping platform (Figure 1; Nordic Semiconductor) was temporarily provided to SR at no cost as it would be suitable for his needs and is compatible with the LAMP platform, which enables visualization and statistical inference. The LAMP platform has been used in prior clinical cases for similar purposes [9], using only sensors available on commercial smartphone devices. The Nordic Thingy prototyping platform has numerous sensors not available in a smartphone that are able to achieve a high fidelity of measurement recording. The device was preloaded with a long-term evolution (LTE) data plan. The sensors include the following: LTE, Bluetooth, Wi-Fi, near-field communication (NFC), button, temperature, humidity, air quality, air pressure, ambient color, ambient light, high-g accelerometer, low-power accelerometer, global position system (GPS), digital microphone, radio frequency (RF) antenna, barometer, altitude, 9-axis motion tracker. It also has a multicolor light emitting diode (LED) and digital buzzer (a low-quality speaker) for responding to the user if necessary.

Figure 1. The size of a Nordic Thingy shown in comparison to a smartphone device. The primary input method is the surface containing the Nordic Semiconductors logo, which acts as a pressure-insensitive button pad.



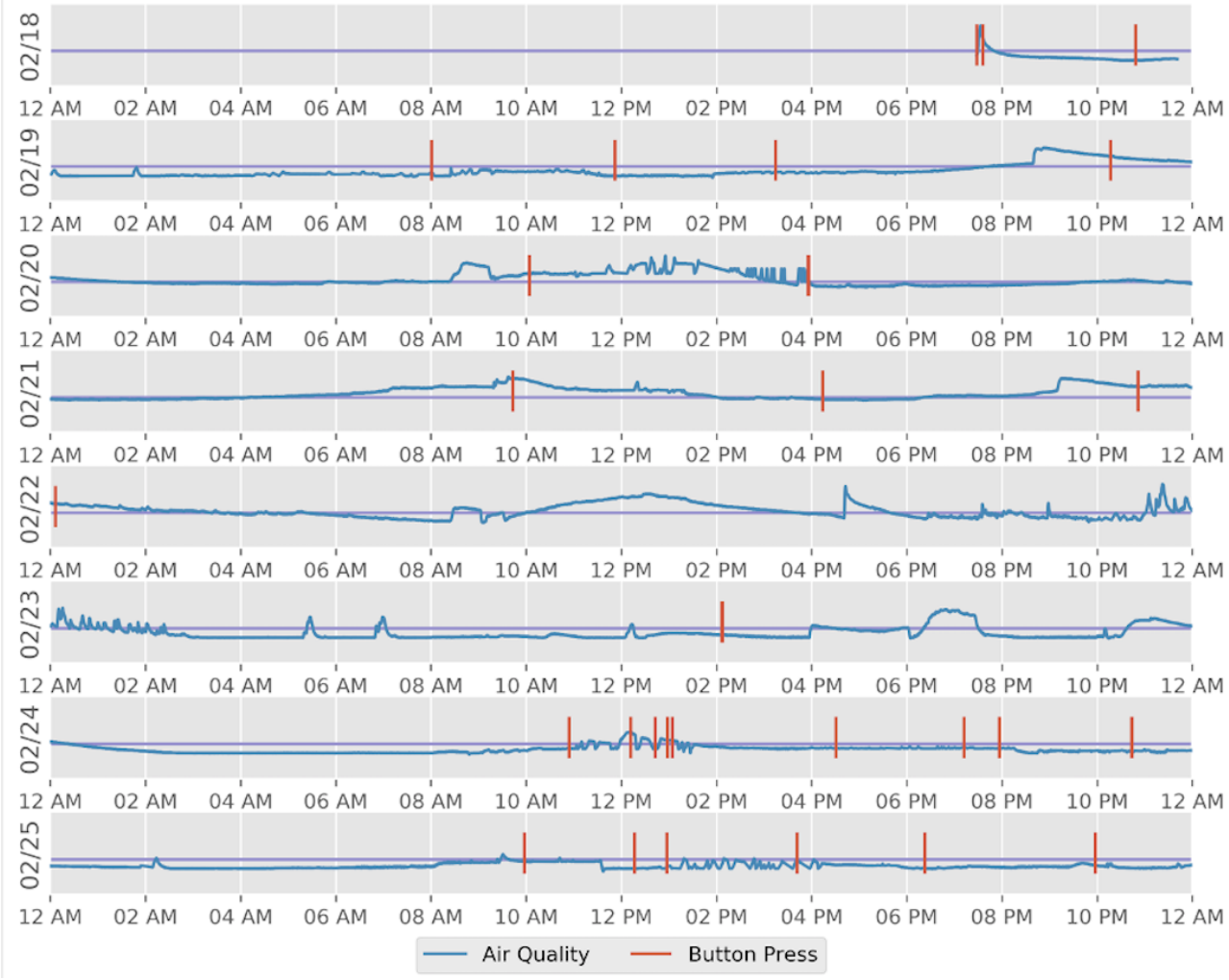
Due to its literal “black box” nature, it was not distracting to use, and was convenient and easy to manage. Noting its primary purpose as a prototyping system, it was purchased from a Nordic Semiconductors distributor for US $120. As the Nordic Thingy can capture data but does not offer data management, integration, or visualization, the LAMP platform was then installed to enable digital mental health–related functionality [10,11]. The Nordic Thingy was charged roughly alongside SR's smartphone and captured or measured the environment of SR's home throughout the day, for most of which SR was present. The button press was used to record auditory hallucinations, similar to the tally counter SR had used previously.

SR independently collected over 200,000 data points via the Nordic Thingy in the span of seven days, producing about 65 MB of uncompressed data. The humidity, temperature, air pressure, and air quality data appeared as sensor data in the LAMP platform, and the button presses appeared as active data in the form of responses to a survey with a single yes or no question. With the assistance of the LAMP programming interfaces, the data were plotted and are shown in Figure 2.

Though his findings showed no significant relationship between indoor air quality and auditory hallucinations (McNemar chi-squared test with continuity correction = 3179.4, df=1, P<.001), SR was able to devise a hypothesis, perform an experiment, analyze the data, and produce a tangible outcome within the span of 1 week. The installation of the LAMP platform on a non–smartphone device proved useful in yielding high-quality data suitable for actionable digital phenotyping as well as data visualization.

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Figure 2. SR's experimental data. The red lines indicate a button press, the blue line indicates indoor air quality, and the purple line indicates the threshold for indoor air quality >100; higher values indicate poorer air quality.



Brief Discussion

As a single case report, SR's example highlights the potential for innovation in and codesign of digital mental health technology by those with lived experiences of serious mental illness. As technology and sensors evolve, it is possible to collect novel data streams like pollution on a highly personalized scale. Understanding the role of digital mental health technology beyond just apps and ensuring it is flexible enough to move between devices and contexts ensures that both patients and clinicians can take full advantage of these advances in technology. The design and evolution of digital mental health tools and platforms will likely rapidly evolve toward devices similar to the one used in this case report, and must involve individuals such as SR, whose lived experiences offer insight into both the problems and solutions encountered when building and using such systems.

As novel sensors like those used in this case report continue to add new accessible data, it is also critical for the field to understand their clinical uses, personal meaning, and therapeutic targets. Although it is easy to use such data in machine learning algorithms or artificial intelligence systems, starting with patient-centric clinical use cases can minimize bias, increase utility, and accelerate clinical translation. From an experimental methods standpoint, it is also important to consider privacy, safety, and ethics when developing individual study protocols, ensuring that all parties involved obtain recorded consent and respect the wishes of other parties. Furthermore, as seen in this case example, there was actually no need for advanced analytical methods beyond simple visualization and a statistical test, highlighting how the right data used in the right clinical case can itself be definitive.

As SR's case yet again shows, a smartphone app may not always be the solution. Although smartphones and wearables are considered highly accessible and usable devices that are practically always within reach, the potential of other digital hardware should not be ignored. The software can be the same, as demonstrated by the use of the LAMP platform on a non–smartphone device. Focusing less on the device and more on how the software serves unique clinical purposes offers a useful reminder toward focusing on fluid and interoperable technology that is not tied to any one platform or device. SR's case shows the merits of using non–smartphone devices for their specialized sensors and unobtrusive behavior.

Through a unique experimental journey, SR's case presents a clear message to other curious and innovative individuals with lived experiences, as well as creators and implementors of digital mental health technologies. Clinicians may also choose to

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actively take part or passively encourage innovation, lending clinical context and insight in either case. Through creativity, innovation, and in small part the accessibility and actionability of data, individuals given the right tools can understand and impact their own mental health.

Conflicts of Interest

JT reports unrelated research support for Otuska. The remaining authors declare no conflicts of interest.

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Abbreviations

GPS: global positioning system
LED: light emitting diode
LTE: long-term evolution
NFC: near-field communication
RF: radio frequency

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Original Paper

Designing a Clinician-Facing Tool for Using Insights From Patients' Social Media Activity: Iterative Co-Design Approach

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Abstract

Background: Recent research has emphasized the need for accessing information about patients to augment mental health patients' verbal reports in clinical settings. Although it has not been introduced in clinical settings, computational linguistic analysis on social media has proved it can infer mental health attributes, implying a potential use as collateral information at the point of care. To realize this potential and make social media insights actionable to clinical decision making, the gaps between computational linguistic analysis on social media and the current work practices of mental health clinicians must be bridged.

Objective: This study aimed to identify information derived from patients' social media data that can benefit clinicians and to develop a set of design implications, via a series of low-fidelity (lo-fi) prototypes, on how to deliver the information at the point of care.

Methods: A team of clinical researchers and human-computer interaction (HCI) researchers conducted a long-term co-design activity for over 6 months. The needs-affordances analysis framework was used to refine the clinicians' potential needs, which can be supported by patients' social media data. On the basis of those identified needs, the HCI researchers iteratively created 3 different lo-fi prototypes. The prototypes were shared with both groups of researchers via a videoconferencing software for discussion and feedback. During the remote meetings, potential clinical utility, potential use of the different prototypes in a treatment setting, and areas of improvement were discussed.

Results: Our first prototype was a card-type interface that supported treatment goal tracking. Each card included attribute levels: depression, anxiety, social activities, alcohol, and drug use. This version confirmed what types of information are helpful but revealed the need for a glanceable dashboard that highlights the trends of these information. As a result, we then developed the second prototype, an interface that shows the clinical state and trend. We found that focusing more on the changes since the last visit without visual representation can be more compatible with clinicians' work practices. In addition, the second phase of needs-affordances analysis identified 3 categories of information relevant to patients with schizophrenia: symptoms related to psychosis, symptoms related to mood and anxiety, and social functioning. Finally, we developed the third prototype, a clinical summary dashboard that showed changes from the last visit in plain texts and contrasting colors.

Conclusions: This exploratory co-design research confirmed that mental health attributes inferred from patients' social media data can be useful for clinicians, although it also revealed a gap between computational social media analyses and clinicians' expectations and conceptualizations of patients' mental health states. In summary, the iterative co-design process crystallized design directions for the future interface, including how we can organize and provide symptom-related information in a way that minimizes the clinicians' workloads.

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KEYWORDS

social media; psychotic disorders; information technology

Introduction

Background

Psychotic disorders, such as schizophrenia and schizoaffective disorder, constitute a serious menace to personal health [1]. Symptoms characterizing these conditions emerge during critical years of adolescence; interfere with the establishment of healthy social, educational, and vocational foundations; and are associated with devastating individual and familial loss [2]. However, there are no known cures for these conditions [3]. Once developed, they often become chronic and must be managed [4]. Subjective patient experiences in the form of clinical interviews, questionnaires, patient self-reports, and family observations have played a central role in the management of these conditions for over a century [5]. These approaches require that behavioral, emotional, or cognitive symptoms are recalled from a patient's memory, a method prone to retrospective recall bias [6,7]. Patients also frequently withhold information from their clinicians because of stigma, guilt or shame, failure to remember relevant events, or to meet impression management goals [8]. In fact, the psychopathology of serious mental illnesses may affect the very mental, emotional, and social judgments on which patients' self-reported responses are based [9]. Therefore, there is a need to access more objective information about patients to augment patients' verbal reports in clinical settings.

In recent years, patient-generated data, machine learning, and digital health technologies have been recognized to offer unprecedented opportunities to help consumers, clinicians, researchers, and other stakeholders measure, manage, and improve mental health [10-12]. In particular, digital records of people's activities on social media, such as Facebook and Twitter, have been shown to enable the development of machine learning algorithms that can assess and even predict risk to a variety of mental health challenges [10], such as major depression [13], postpartum depression [14], posttraumatic stress [15,16], and schizophrenia [17]. Research has also demonstrated that a variety of symptomatic expressions and outcomes of clinical interest (eg, depression risk or suicidal ideation) may be gleaned from such data [18,19]. Although social media platforms may negatively affect users' behaviors (eg, being confined to echo chambers [20], exposure to misinformation [21], and increased social comparison [22]), they constitute voluntarily shared and recorded data that include the feelings, opinions, and daily experiences of their users. Therefore, with social media, it is possible to unobtrusively and longitudinally gather insights about people's social interactions, affect, and cognitive styles—signals characteristic of one's mental health state and thus critical to management and treatment of mental illnesses but which may be challenging to assess via psychometric or self-reported means because of concerns of impression management and retrospective recall bias [10].

Although researchers have argued that social media analysis can be used to support real-world mental health care settings, interventions, and clinical diagnosis and assessment [23,24], actual opportunities concerning such technology in the clinical setting have not been explored. As a way to bridge this gap, through this research, our ultimate goal is to develop a clinician-facing tool that can provide mental health insights derived from patients' social media at the point of care. This future tool will collect patients' social media data under their informed consent and analyze the collected data to distill clinically meaningful insights. The analyzed data will be shown in a way that can support mental health clinicians' work practices without adding intellectual burden or information overload.

Objectives

To achieve the aforementioned design goal, there are many challenges we need to overcome: we must understand the current work practices of mental health clinicians; we need to explore clinicians' potential needs, barriers, and concerns regarding the concept of this future interface; and, most importantly, we need to introduce the concept of delivering mental health insights from patients' social media to clinicians—a practice that currently does not exist. Therefore, as a first step toward conceptualizing this future technology, drawing on approaches in the human-computer interaction (HCI) field, we aimed to create a series of low-fidelity (lo-fi) prototypes informed by the clinicians' opinions and needs regarding these insights gleaned from social media. These include whether social media analysis can be useful in the context of their clinical practices, what kinds of insights from patients' social media data may be useful, and how these insights can be presented so as to be seamlessly integrated into their workflows in the future.

We, as an interdisciplinary research team, co-designed the lo-fi prototypes. Co-design, which is widely used in the design research community, can be defined as a dialog between end users and designers [25]. We extended the concept of co-design as a long-term discussion between end users and designers. The 4 clinical researchers in this team were the potential end users of the prototype. At the same time, they were also domain experts who could represent end users. The rest of the HCI researchers served as designers and builders of future tools that can support clinicians.

Over the 6 months of co-design activities, we adopted the needs-affordances analysis framework to support the iterative process. Needs-affordances analysis is a method to refine concrete design directions based on both what the users want to have (needs) and what the technology/platform can provide (affordances) [26].

We first discuss the concept of co-design and needs-affordances analysis as the method of this project. Then, we present the 3 different lo-fi prototypes that are the results of our co-design activities. Finally, we discuss the lessons learned from this

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project and future plans for building clinician-facing mental health technologies that are powered by patients' social media data.

Methods

Iterative Co-Design Process

Our research explores the building of technologies to support clinicians in mental health treatment, specifically focusing on schizophrenia, as a case example. Schizophrenia is a chronic and severe mental disorder characterized by abnormal social behaviors and distorted perceptions of reality [2]. Clinical observations indicate that it is among the most challenging mental illnesses to manage, primarily because of its high likelihood of relapse. Most patients experience multiple relapses during the course of the illness [27]. Management of the illness, therefore, involves preventing the occurrence of a relapse as well as symptomatic exacerbation [28]. Previous research has demonstrated that we can computationally extract behavioral and linguistic patterns from social media posts of patients with schizophrenia [17,29]. These approaches help us to predict mental health states and clinical outcomes, such as relapse episodes in schizophrenia [30], or to identify a clinically valid diagnosis of the illness [31]. Given the rich evidence that social media can be helpful for understanding patients with schizophrenia, we deemed focusing on the context of schizophrenia, which allows us to examine whether such information may be used at the point of care through a technological interface.

These empirical evidences are further supported by recent research that has revealed patients' interest in and willingness to use their social media data to improve their treatment outcomes. Padrez et al [24] found that as many as 70.4% (1008/1432) of patients who reported using social media and were willing to participate in research also agreed to share these data and have them linked to their medical records for health research. Similarly, Rieger et al [32] reported that in a survey of 238 mental health patients, of those who had a social media account and were receiving therapy, 74.4% (99/133) indicated that they would be willing to share their social media posts with their therapists, if their therapists were concerned about how they were doing, including 53% (50/94) who were willing to share both public and private posts. Specific to psychotic disorders and most relevant to our context, based on semistructured interviews with 112 psychotic disorder patients, in a work by Birnbaum et al [33], 80.7% (88/109) of patients were open to sharing their social media data with clinical researchers to explore how it can potentially inform their treatment. Drawing on these findings, and because clinical researchers have advocated that it is important to first focus on issues related to the accuracy, interpretability, meaning, and actionability of these data such as social media [34], in this paper, we focus on co-design exercises with clinicians. Our rationale is further bolstered by Baier's [35] observation, "Without judicious consideration, social media use by [clinicians] can lead to inadvertent self-disclosures to [patients] that risk damaging the therapeutic alliance, interfering with therapeutic processes, and placing both the [patient] and clinician at risk".

As mentioned earlier, this paper focuses particularly on the process of building a series of lo-fi prototypes toward the aforementioned goal. In its basic form, a prototype is an expression of design intent. Prototyping allows designers to present their designs and see them in action. In the context of digital technologies such as our case, a prototype is a simulation of the final interaction between the user (the clinician) and the interface (communicating insights from patients' social media activities). lo-fi prototyping is a quick and easy way to translate high-level design concepts into tangible and testable artifacts. The first and most important role of lo-fi prototypes is to check and test functionality rather than the visual appearance of the product.

To develop our lo-fi prototypes, an interdisciplinary research team collaborated for 6 months to envision future technologies through an iterative co-design process (Table 1 provides the details of the team members). The team members spoke for roughly an hour via video conference calling every 2 weeks because the team was geographically distributed. In earlier meetings, we discussed experts' user needs and the potential affordances of our future technology. Experts included clinicians working at a large health care system in the northeast of the United States. After we (HCI researchers at a large public university in the southeast of the United States) developed design sketches based on those discussions, we exchanged our ideas and thoughts while reviewing our sketches via the video conferencing app. During the discussion, one of the researchers wrote the points discussed and shared the notes with other researchers. The written notes mainly informed our design decisions during the iterative process, and the decisions were reflected during the subsequent meetings. This research was approved by the institutional review boards of the relevant institutions.

Table 1. Details of the backgrounds of the team members.

Types of researchers	Number of researchers	Job role	Types of work	Research experience, years
HCI[a] researchers	3	1 PhD student, 2 Computer Science professors	Research in social media analytics, health sensing, and design	5-32
Clinical researchers	4	1 psychiatrist, 1 clinical psychologist, and 2 clinical research coordinators	Mental health care delivery to patients and clinical and intervention research	6-10

[a]HCI: human-computer interaction.

More elaborately, we adopted an iterative strategy, in which we created a design sketch led by the HCI researcher on the team, obtained feedback on it from the clinician collaborators, and then adjusted it accordingly to create a modified or new sketch.

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Over time, the clinicians felt insights from social media could work as *collateral information* [36,37], which could complement existing ways of gathering information from patients and thereby overcome some of their limitations. Collateral information, which is information obtained from sources such as family members, primary providers, and friends, in mental health is important because it may supply objective, finer-grained data; can facilitate time-sensitive monitoring of symptoms; and can provide an ability to detect subtle but burgeoning changes in a patient's condition, eventually improving clinical assessments.

Furthermore, we postulated Facebook as our target social media platform for discussions surrounding the co-design process. This is because Facebook is widely adopted among young adults [38], and previous research has established that it is the most widely used social media site among the target patient population [23]. Moreover, in contrast to other social media platforms, Facebook provides higher identity and social affordances and has a rich set of social interaction capabilities [39], which allows the possibility to glean a variety of potentially relevant mental health insights.

The abovementioned iterative process of our co-design activities was open ended because of the exploratory nature of our study; however, we used the following questions as starting points when we evaluated our sketches:

- Do the visualizations support the clinicians' needs that are identified by a needs-affordances analysis?
- Are the visualizations easy to understand?
- Will the visualizations be compatible with clinicians' work practices?
- What are the more/less important categories?
- What are the other categories that can be helpful for clinicians?
- What are the areas of improvement?

On the basis of the feedback from these questions, we decided the direction of the next iterations. The details of the 3 iterations are described in *Results* section.

Needs-Affordances Analysis

Affordance refers to the features of an object in the physical environment that may cause interactions between the object and an agent [26]. In other words, affordances basically represent the opportunities for action that an object offers. Moreno and D'Angelo [39] proposed an affordances framework to design platform-sensitive social media–based health interventions. They also presented empirical evidence supporting why the consideration of platform affordances can support future health intervention designs. We follow this line of thought: we use this framework to choose our target social media platform, Facebook, and then, we consider the affordances of Facebook to create our lo-fi prototypes for eventual tools that can be used to augment clinical care and treatment settings.

Antonenko et al [26] used the concept of affordances to enable researchers to design/evaluate new technologies that can support user needs. They proposed a needs-affordances analysis as a framework developed within the field of education research to design and evaluate new education technologies. It helped them to define user needs, identify a potentially appropriate technology, and align technological affordances with the specific needs of target users. Technological affordances are the possibilities of interactions a new technology can offer to potential users, which can be similar to the affordances of interventions in Moreno and D'Angelo's framework.

In this study, we apply a needs-affordances analysis to the process of creating lo-fi prototypes. It plays 2 vital roles in the process. First, it provides a systematic structure to the discussion between HCI researchers and clinical researchers. This highlights the need for clinical researchers to define user needs to crystallize a future interface while providing opportunities for HCI researchers to explain what kinds of needs can be supported by social media data analysis. Second, although this analytical framework does not provide a detailed guideline for design decisions, its ability to reveal the alignment of needs and affordances provides a hint of what the prototypes should be.

The combination of iterative co-design and needs-affordances analysis gave us 3 prototypes: (1) a card-type interface for treatment goal tracking, (2) a clinical state and trend visualization interface, and (3) a clinical summary dashboard.

Results

A Card-Type Interface for Treatment Goal Tracking

On the basis of consensus in the early discussions that social media can be a source of collateral information, our first lo-fi prototype generation process began by exploring the needs of our possible user group: mental health clinicians. Clinical researchers, grounded in clinical theory and practice, made a list of common treatment goals [40] they care about in the real-world clinical setting (Table 2). We compiled a list of the different kinds of information and computational insights that can help to assess whether a patient is close to, progressing toward, or digressing from their treatment goals. Next, we discussed the affordances of our chosen social media platform (Facebook) that can be relevant to meeting these treatment goals. For example, social and emotional affordances, which are related to the opportunities to communicate with others and express their emotions on social media, can be relevant to assess whether the patients are increasing or decreasing their social interactions and/or sharing emotional vulnerability with their friends. On the basis of the affordances of Facebook, we then discussed the affordances of the first version of the future interface. In connection to the aforementioned example, this step translated to discussing how information gleaned from patients' Facebook data can be supported by Facebook's affordances such as tagging, messaging, and *friending*. The frequency of tagging others in a post, the volume of private messages patients exchanged with others, and the number of newly added Facebook friends could be indicative of social interaction in a patient's life, a critical dimension of most patients' treatment goals and illness management.

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Table 2. The first needs-affordances analysis.

Needs (treatment goals)	Affordances	
	Social media (Facebook)	Sketch (prototype)
Reduce the risk for relapse (comply with medication and attend all appointments)	N/A[a]	N/A
Establish social network (increase social interaction and share emotional vulnerability with a new friend)	Social and emotional	Inferring the level of social interactions using Facebook data
Improve existing relationships (apologize for past transgressions and ask for support)	Social and emotional	Inferring the level of social interactions using Facebook data
Reduce/eliminate alcohol and/or drug use (do not buy alcohol, limit consumption to one drink per day, and avoid situations where drugs are present)	Identity	Inferring alcohol-/drug-related behaviors using Facebook data
Get 7 hours of sleep (improve sleep hygiene)	Functional	Inferring sleep hygiene
Eliminate depressed mood (reduce negative cognitions and increase positive activities)	Identity, social, and emotional	Inferring the level of depressed mood
Reduce impairing anxiety (approach feared situations)	Identity, social, and emotional	Inferring the level of anxiety

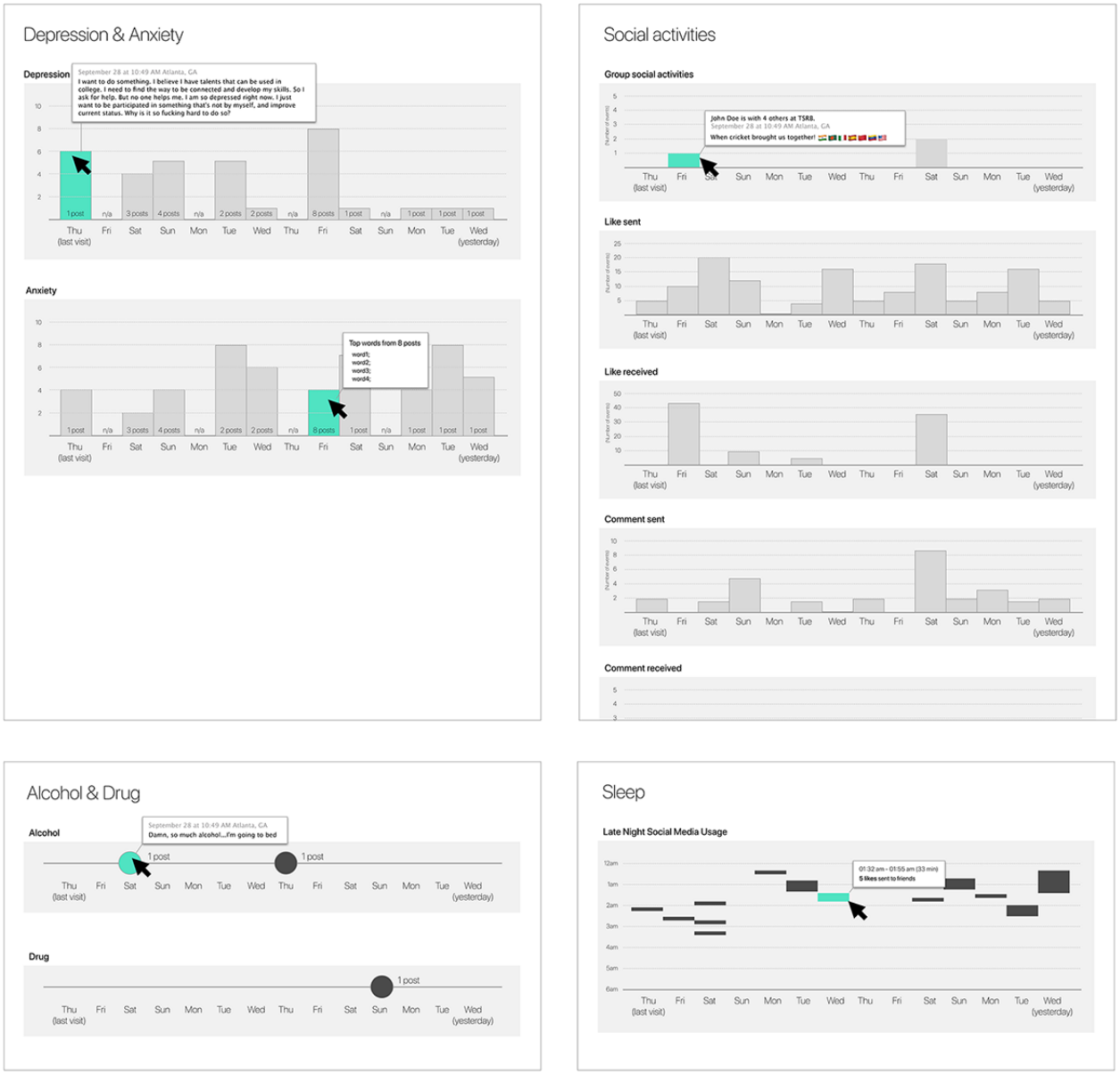
[a]N/A: not applicable.

In addition to the needs identified earlier, we referred to previous work that visualized patient-generated data for clinicians [41-43]. Previous studies used a dashboard design including a card-type interface where one card represents one type of data/information and users can modify the order and types of cards on the dashboard. We also adopted their design directions because a card-type interface provides flexibility, so researchers can iteratively add and change different types of information. Similar to the previous work, our first sketch (Figure 1) is a card-type visualization, where each card includes the level of the attribute, such as depression, anxiety, social activities, alcohol and drug use, and sleep—all dimensions identified by the clinicians to be important components of tracking common treatment goals in schizophrenia. For depression and anxiety, we envisioned a scale for each symptom that a machine learning approach could automatically infer from the posts (eg, based on the algorithm developed in a study by Saha et al [44]). If a clinician intended to read the actual posts for a specific day, they could hover their mouse over the bar and read the posts on the pop-up layer. For social activities, the page was mainly based on the social affordances of Facebook, such as likes, check-ins, and comments. For the alcohol and drug card, we assumed our interface to identify alcohol- and drug-related posts and present them as a circle on the timeline. For sleep, because social media may not be the best proxy for measuring sleep patterns, we chose to present social media activities after midnight, which may imply some level of sleep hygiene—previous work by De Choudhury et al [13], for instance, found that the degree of night-time social media activity, operationalized as an *insomnia index*, was positively correlated with increased depression risk.

Taken together, clinical collaborators were able to see some value in this form of visualization while pointing out areas of improvement; they pointed out that clinicians may not have time to review all the different cards during an ongoing session with a patient. Furthermore, they noted that they are likely to be most interested in learning about trends around when and how specific mental health attributes showed a change for the patient in question. They also clarified that social media activities related to the quality of life measurement can be interesting to them [15]; hence, a goal of this second prototype was to explore how to present such information derived from the social media data of patients.

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Figure 1. The first prototype: a card-type interface for treatment goal tracking.



A Clinical State and Trend Visualization Interface

Incorporating feedback from clinical collaborators, we developed the second version of our sketch. This interface is a desktop app that clinicians can access using their personal machines during appointments. The interface consists of 3 different components: the first area is the left menu, which presents information about the patient and clinicians as well as a tree menu of different pages (*Mood*, *Cognition*, *Social Functioning*, and *Language*); the second area is the main content of the page, an overview dashboard as default; and the third area shows long-term trends of all relevant attributes at the bottom.

To arrive at the different components of this interface, in addition to needs-affordances analysis, the widely studied stress-vulnerability model [45] of schizophrenia informed the process of selecting and organizing the additional pages of mood, cognition, social functioning, and language. The model assumes that individuals have an intrinsic level of psychosocial vulnerability, which, in turn, can decide the level of impact realized from different, external, and stressful events. When their vulnerability is high enough and the stressor is strong enough, they will experience transient intermediate states that can be characterized by processing capacity overload, autonomic hyperarousal, and impaired processing of social stimuli. Transient intermediate states can negatively impact a person's social environment, which can result in repetitive experiences of these states. If this harmful cycle continues until the transient intermediate states surpass an individual's threshold, it can cause the development of schizophrenic symptoms. Therefore, determining vulnerability is important in assessing and treating people who are suffering from schizophrenia. Previous work has identified various attributes as markers of psychosocial vulnerability: mood, cognition, linguistic style, social functioning, semantic disorganization, syntactic disorientation, and others [46,47], corresponding to each of which we created a page in our second prototype.

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In addition, recall that a necessity identified during the discussion of the first prototype centered on clinicians' desire to learn about patients' quality of life attributes. Typically, clinicians track such attributes via unstructured conversations with their patients during visits, and it can range over a variety of topics, such as information about their romantic life, work, family, socialization activities, and so on. Inclusion of the *Mood*, *Cognition*, *Social Functioning*, and *Language* pages in this prototype can thus enable tracking such trends over short and long periods in patients' Facebook data.

We now describe the different components in detail below.

The overview page, in particular, shows a default view; as shown in Figure 2, the interface uses simple visualization techniques (eg, dot, bar, and line charts) to provide insights that can support common treatment goals, such as learning about trends and monitoring changes related to depression, anxiety, social functioning, drug and alcohol use, and sleep hygiene, since the patient's last clinical visit.

Figure 2. The second prototype: a clinical state and trend visualization interface – "Overview" dashboard.



Moving on the specific pages in this interface, first, Figure 3 shows the *Mood* category, which provides detailed information about mood and affective states that can augment depression and anxiety information shown in the summary page. Following psychology literature, we provided the level of the 2 different facets of mood—valence (the extent of positivity or negativity of mood) and arousal (the intensity of mood) [48]—and the level of 11 different affective states, such as joviality and fatigue, which have been reliably inferred from computational analyses of social media data in previous work [49]. Owing to the complexity of the nature of mood and affective states, we created simple line graphs for each dimension of those categories.

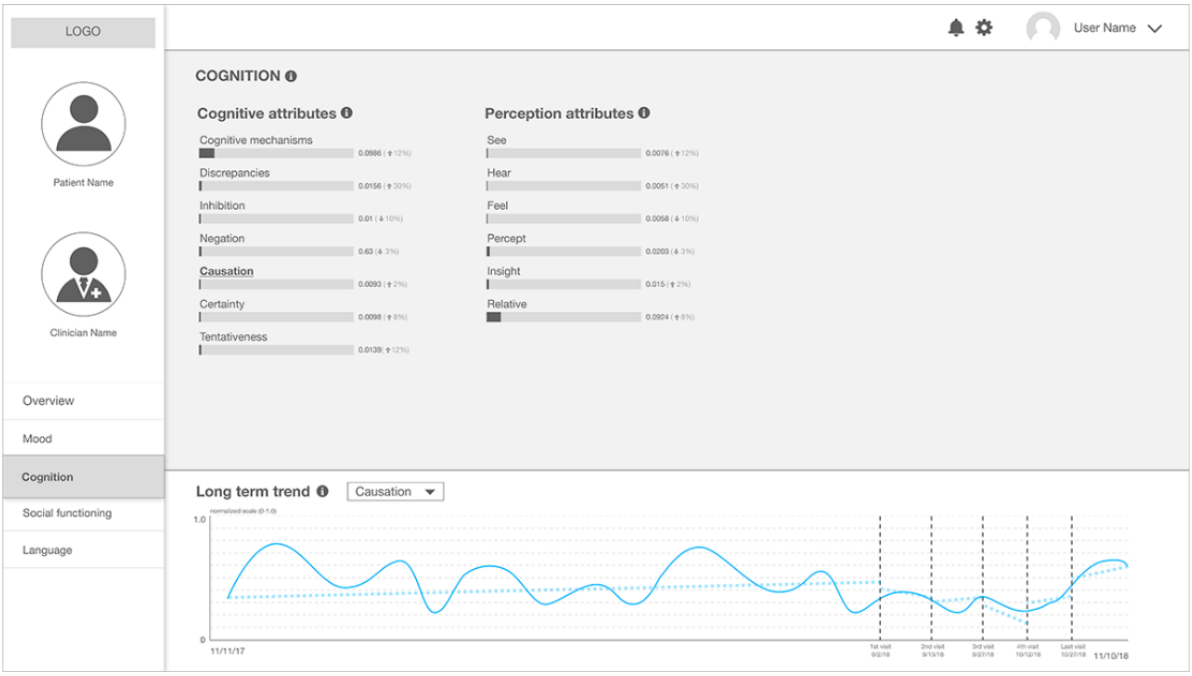
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Figure 3. The second prototype: a clinical state and trend visualization interface – "Mood".



Another category that originated from the stress-vulnerability model, *Cognition*, is important in understanding schizophrenia because the model defines stress as the perceived discrepancies between an individual and the environment surrounding the individual [45]. The additional page (Figure 4) provides scores related to the cognitive processes based on the well-validated computerized text analysis tool, Linguistic Inquiry and Word Count (LIWC) [17,50]. The validity of LIWC was initially approved by the level of agreement between human judges and LIWC's objective word counting [51], and many studies using social media posts show that LIWC can be applicable to understanding mental health attributes [15,17,52].

Figure 4. The second prototype: a clinical state and trend visualization interface – "Cognition".



Next, *Social Functioning* provides 6 different levels of social media activities that can function as features of a hypothetical machine learning algorithm that can calculate the overall social function score (Figure 5). We selected interpersonal relationships that are accessible on Facebook (number of posts and number of friends) as well as work- and school-related posts because the clinician researchers highlighted the importance of being able to return to their daily activities. Social media activities include the number of posts they have written, the interactions with other Facebook users, work- or school-related posts, and their number of friends.

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Figure 5. The second prototype: a clinical state and trend visualization interface – "Social Functioning".



Among the different *Language*-related pages, the linguistic style page (Figure 6) includes some categories from LIWC. The scores for a specific category (eg, 0.08 for first-person singular pronouns) are calculated from the aggregated texts they have posted on Facebook since their last clinical visit; this implies the fraction of words in those texts that are first-person singular pronouns. Previous work has shown that people who self-disclose themselves as patients with schizophrenia show different patterns in pronoun use [17]. The bottom of the page, the long-term trend window, shows temporal changes of a selected category of linguistic style (shown for preposition use) since the patient created their Facebook account.

Figure 6. The second prototype: a clinical state and trend visualization interface – "Linguistic Style".



Another *Language* page in this prototype, entitled *semantic disorganization* (Figure 7), shows the result of topic modeling applied to patients' Facebook data. Topic models are algorithms for discovering the latent themes that pervade a large, and otherwise unstructured, collection of documents [53]. We used a visualization technique to use topic models as a navigator that enables users to explore the hidden structure that the algorithm reveals [53]. In Figure 7, the themes identified by the algorithm are listed. As the themes are grouped in a quantitative way, the label of the theme is a group of prevalent words in the theme rather than an intuitive, interpretable title. We envision that human annotation of the label of the theme can provide more meaningful/interpretable information, as has been leveraged in previous work [17]. When users click a theme on the list, the words in the theme and the actual posts in the theme are shown on the right side of the page.

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Figure 7. The second sketch: a clinical state and trend visualization interface – "Semantic Disorganization".

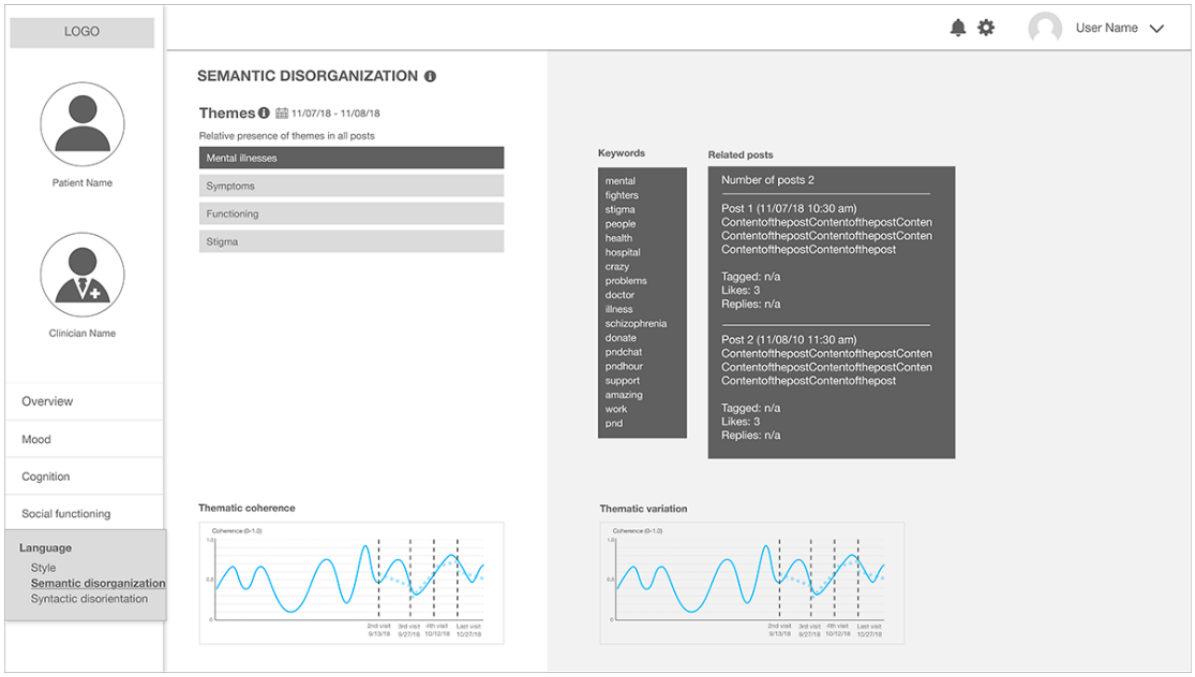
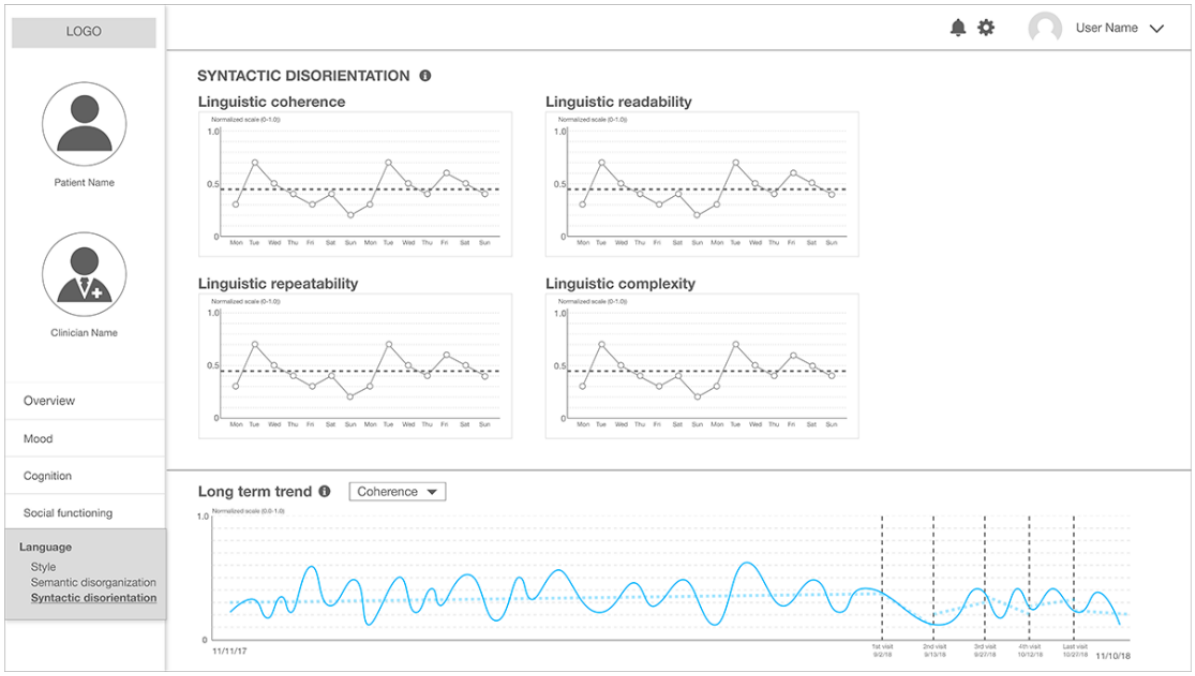


Figure 8 presents the final page within the *Language* category, entitled *syntactic disorientation*, which contains information about linguistic coherence, readability, repeatability, and complexity. We have added this information because of empirical evidence from the literature. Previous work that used natural language analysis models of linguistic change proved that social media users, who self-disclosed themselves as patients with schizophrenia, showed higher repeatability and complexity while, at the same time, lowering coherence and readability when compared with a control group [17]. We selected a simple line graph to maintain the coherence of the visual elements throughout the sketches.

Figure 8. The second prototype: a clinical state and trend visualization interface – "Syntactic Disorientation".



Owing to the elaborate nature of this prototype, clinical researchers provided several rounds of feedback, spanning multiple weeks. Broadly speaking, they appreciated the richness of the information conceptualized to be presented at the interface, which spanned both common treatment goal markers as well as other potentially useful information that can be gleaned from patients' social media data, which, in turn, could be relevant to gather an understanding of a patient's quality of life. At the same time, they were skeptical about maintaining the linguistic style page because they felt that our potential users may not have the time to review these highly elaborate different bar charts; may not be familiar with specific language analytic tools such as LIWC, despite being commonplace in the research literature; and may lack knowledge of how the different

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linguistic analyses were performed. Consequently, they may not be able to interpret the line graphs in a clinically meaningful way. However, clinical researchers have found some value in the linguistic style page; for example, they believed that the temporal reference category, such as past tense, present tense, and future tense, can be meaningful because it is related to understanding the future orientation of patient's thoughts; future orientation can often indicate an improvement in mental health state [54].

Furthermore, the detailed navigation of patient postings that topic models provide intrigued clinical researchers; the topic model allowed clinical researchers to start thinking about psychosis-related symptoms. Although we did not discuss psychosis-related vulnerability attributes in the first needs-affordances analysis (Table 2), the clinical researchers realized that this information can help lead to a better understanding of their patients. Therefore, we decided to discuss more deeply how we can cover psychosis-related symptoms of schizophrenia in our next iterations of the prototype. We believe this is one of the positive results of the iterative co-design of prototypes; conceptualizing what we need from new technology is difficult even using needs-affordances analysis because domain experts have to ideate several different possible needs while dealing with an unfamiliar and complicated concept for a new, futuristic technology. As a result, the sketches provide a chance to both reflect on potential needs and consider missing needs. In our case, the second prototype focused on mood- and social functioning–related information, but the resulting sketch that highlighted the potential usefulness of the information related to psychosis was missing. Therefore, we decided to conduct a second needs-affordances analysis focusing on the symptoms of schizophrenia patients, which led us to develop a new sketch.

A Clinical Summary Dashboard

As noted earlier, because we discovered the value of psychosis-related symptoms after reviewing the second version of the sketches, before iterating over and creating the next sketch, we conducted a second needs-affordances analysis (Table 3). During this needs-affordances analysis, the clinical researchers first provided a list of symptoms of interest that are considered expert needs, and then, HCI researchers identified the affordances of platforms and the future interfaces that can correspond with the symptoms. For instance, for symptoms associated with psychosis, the clinical researchers have made a list of symptoms, such as delusions, preoccupations, and hallucinations. We assumed that these symptoms could be inferred from linguistic characteristics and interaction patterns in their Facebook use because of the identity and cognitive affordances of Facebook, as shown in previous computational work on social media and schizophrenia [17].

This second needs-affordances analysis produced 3 groups of expert user needs—symptoms associated with psychosis [46], symptoms associated with mood/anxiety subject to the comorbidities of schizophrenia [55], and social functioning [56]. The first group, symptoms associated with psychosis, was the most deviant part from the previous prototype. The latter 2 groups were similar to treatment goals, such as eliminating depressed mood and improving existing relationships, but as a positive outcome of this iterative process, we were able to make a more detailed list of information needs of mental health clinicians that were represented by the clinical researchers in our team.

From the same needs-affordances analysis, we also learned that clinicians may wish to have an extremely simple summary of social media analysis. Clinical researchers suggested just letting them know whether the severity of symptoms has changed since the last visit using plain text, rather than visuals such as bar graphs. The purpose of the plain text summary is to provide both concise information and opportunities to further explore details when they think the change is interesting, from the perspective of a particular patient meeting their desired treatment goal(s).

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Table 3. The second needs-affordances analysis.

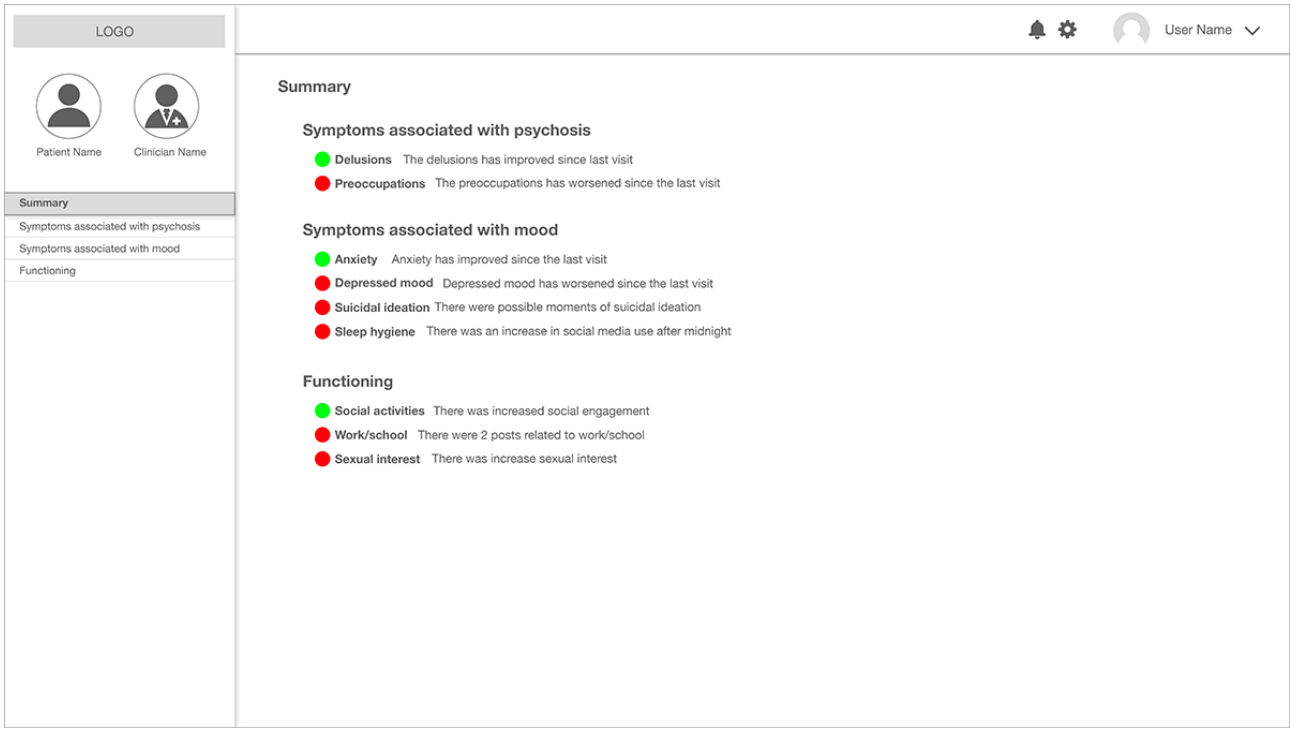
Needs	Affordances	
	Social media	Future interface
Symptoms associated with psychosis		
Delusions	Identity and cognitive	Measuring the severity of delusion
Preoccupations	Identity and cognitive	Measuring the severity of preoccupations
Hallucinations	Identity and cognitive	Measuring the severity of hallucinations
Paranoia	Identity and cognitive	Measuring the severity of paranoia
Thought disorganization	Identity and cognitive	Measuring the level of thought disorganization
Shifting or fast thoughts	Identity and cognitive	Detecting extreme/abnormal thought shifting
Health concerns	Identity and cognitive	Detecting extreme/abnormal health concerns
Awareness	Identity and cognitive	Inferring levels of awareness of their illnesses/symptoms
Changes in concentration	Identity and cognitive	Detecting extreme/abnormal changes in concentration
Symptoms associated with mood/anxiety		
Anxiety/worries	Emotional	Measuring levels of anxiety
Low mood/high mood/mood swings	Emotional	Inferring mood
Feelings of guilt/shame	Emotional	Measuring affective states (guilty)
Suicidal/homicidal thoughts	Emotional	Detecting suicidal thoughts
Grandiosity	Emotional	Detecting exaggerated self-confidence
Irritability/hostility/aggression	Emotional	Measuring affective states (hostility)
Decreased energy/increased energy	Emotional	Measuring affective states (fatigue and attentiveness)
Sleep changes	Emotional	N/A[a]
Feelings about the future	Emotional	N/A
Hopelessness/hopeful/worthlessness	Emotional	N/A
Appetite changes	Emotional	N/A
Social functioning		
Engaging in/initiating pleasurable activities	Emotional and social	Counting the number of “interested in” events
Engaging in social activities/avoiding people/socially isolated	Emotional and social	Counting the number of “check in” posts
Motivation for school/work/volunteering	Emotional and social	N/A
Strength of social ties	Emotional and social	Number of interactions (messages, likes, taggings, reply, and posts)
Role function (going to work/school/volunteering)	Emotional and social	Detecting posts related to work/school
Sexual interest/dating	Emotional and social	Counting words related to sexual interest

[a]N/A: not applicable.

Figure 9 shows the first page of this summative dashboard. Symptoms from the second needs-affordance analysis that have changed since the last visit are shown using colored circles and plain text. The green circles indicate the symptoms that have improved since the last visit, and the red circles indicate the deterioration of a symptom. The plain text tells which symptoms have changed, and if applicable, what the changes were (eg, there were 2 posts related to work/school for the work/school category in the illustration of Figure 9). We assumed that symptoms that have changed since the last few visits can be interesting starting points for clinicians; if they want to look at the details, they can click and see bar charts that are similar to those in Figure 2.

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Figure 9. The final (third) version of our prototype: A clinical summary dashboard.



Discussion

Lessons Learned

The iterative nature of our co-design process enabled us to expand the potential use of the prototype. Clinical researchers' immediate responses to the first sketches were ambivalent: they were positive about being able to gather more fine-grained collateral information about their patients, which may help them overcome the weaknesses of current self-report–based information gathering processes. At the same time, they were concerned about whether the potential information could overload their work practices, as social media–derived information could be seen as another layer of noise. After they reviewed the revised sketches that were more well aligned with their needs and concise enough to be used in a limited amount of time, they started to consider other details. For example, they were highly interested in social functioning–related information in general.

Clinical researchers also envisioned potential alternative uses of the tool that can support their work practices. In earlier meetings, the clinical researchers suggested that future tools could be more beneficial for therapists than psychiatrists because therapists usually have longer interactions with patients that can be aided by the proposed technology. However, after they saw the second prototype—the clinical state and trend visualization interface (Figure 2)—they were of the opinion that they may be able to use the dashboard to facilitate conversations between the treatment team—a combination of psychiatrists, psychologists, therapists, and social workers—which meets periodically in smaller, more cutting-edge, care-centric mental health clinics.

In addition, our co-design activities essentially revealed an *information abstraction gap*, that is, a gap between the *computational abstraction of patients' Facebook data* and the *clinical abstraction of patients' states*. We introduced computational approaches within our designs because clinicians expressed the busy nature of their job, and patient social media data, although perceived to be valuable, can be gigantic. Computational approaches allow converting raw social media data into a more consumable unit of information (ie, from *the total number of posts* to *the number of depression-indicative posts*). These types of abstracted information derived from computational approaches were successful when the information was intuitive and compatible with clinical concepts. One of the most successful cases was the measures in the overview page in the second prototype (Figure 2). However, at the same time, aside from this potential, clinical researchers were skeptical in other measures that are based on either machine learning algorithms (eg, the performance metrics of the algorithms) or psycholinguistic analysis (eg, LIWC scores) because interpreting these measures is not a part of the current clinical culture; some measures may not be clinically meaningful or align with how a clinician assesses a patient's mental health state, whereas others may not support their current workflows.

Therefore, our co-design focused on bridging the gaps between *what the computational approaches can provide* and *what clinicians can actually use at the point of care*. The 2 needs-affordances analyses crystalized the latter part—how they abstract the diverse types of patient information into clinical categories. The second analysis yielded the 3 categories that summarized clinicians' mental models of how they navigate patients' information to make a clinical decision. The second and third prototypes explored how computational approaches can be matched to the clinicians' mental models. The simplified visual representation in the third prototype reconciled the vast amount of data with the clinicians' needs for immediate, actionable insights from new technology.

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Although we were able to result in a meaningful bridge between the gaps, there are still interesting aspects to explore; most importantly, the flow of patient-clinician consultations varied based on the types of clinicians, patients, and treatment strategies. In addition, information abstraction gaps can exist between stakeholders, such as clinicians, patients, the managers of hospitals, family members, and other caregivers. We need to explore, in future work, how computational abstraction can support/hamper communications between the stakeholders. Finally, the information abstraction gap is a sociotechnical phenomenon that is situated in cultures, policies, and laws surrounding the computational artifact and the users of the artifact. Therefore, future research should take into account institutional and cultural support to make new technologies implementable and sustainable.

Comparison With Previous Work

The concept of the use of mental health insights from social media is relatively novel. Fisher et al [57] provided case reports where clinicians had begun to incorporate patients' electronic communications, such as social media in their care. For instance, these authors reported that one clinical team reviewed an outpatient's Facebook feed because the patient was vulnerable to self-harm and violent behavior. In the face of these isolated incidents, to understand systematically how social media data may augment treatment for mental health conditions, Hobbs et al [58] surveyed 115 outpatient psychotherapy clinicians associated with McLean Hospital in Belmont, Massachusetts. They found that 61.7% (71/115) of clinicians reported viewing at least one patient's social or electronic media as part of psychotherapy, and 92% (65/71) of those endorsed being able to provide more effective treatment using this information.

However, despite revealing these potentials, design opportunities for social media at the point of care have not yet been explored. Our work is based on evidence in recent literature that explored the use of digital phenotyping data [59-61]. For example, Luo et al [60] identified dietitians' needs for patient information regarding food, reflection, symptoms, activity, and physical state. Similar to this work and others, our co-design approach also identified clinicians' needs for more objective patient information and contextualized the use of social media for this purpose. Our findings regarding clinicians' needs for symptoms and social functioning in patients with schizophrenia, in fact, resonate with similar observations in previous research. Specifically, we suggest that patient information can be grouped as symptoms related to psychosis, symptoms related to mood/anxiety, and social functioning. Furthermore, to address the cognitive overload of clinicians that has been identified in previous work [62], our co-design approach resulted in a clinical summary view that provides changes in an extremely simple form.

Limitations and Future Research

Even though we were able to learn valuable lessons from the co-design approach, we acknowledge that there are certain limitations in this work. First, we note that the computational approaches that are considered in our prototype are in the early stages of research and require more rigorous and clinical validation before being deployed in clinical settings. Second, the user needs we considered are the potential user needs that are inferred by a small number of clinical researchers. It is possible that their projections of user needs may not fully represent our target groups' opinions. We believe this limitation can be overcome with subsequent studies to gather user needs with a representative group of participants. It should be noted that we have not evaluated our prototype with potential users as a form of user study that can yield diverse design implications and guidelines. As mentioned earlier, this is the very first stage of a long-term project where we envisioned a future tool as an interdisciplinary working group, and we considered using a long-term co-design activity for the first step. We believe this first step has informed our team to proceed to the next stage of our research, including building a medium-fidelity prototype and a user study using the functioning prototype.

In addition to the abovementioned points, we also acknowledge that patient perspectives and ethical considerations are massive issues surrounding the concept of using patient-generated data, such as with our proposed technology. That said, as a formative step, we wanted to ensure that clinicians perceived the technology in question to have clinical value before involving patients directly. We know that patients' autonomy and agency are critical in designing a technology that uses sensitive information from vulnerable populations. Future endeavors will augment these insights by including patients in an iterative design process to explore their perspectives, especially their autonomy and agency.

As a next step, we intend to conduct a qualitative evaluation study using our prototype, where we will introduce the concept of the future interface to a diverse set of clinicians. At the same time, we will seek their opinions about adopting this future technology, potential barriers to using this concept, and other concerns. We believe our prototypes can be useful for exploring these opinions because we co-designed these prototypes with domain experts who can represent our potential user group. This was the result of a relatively long-term discussion between HCI researchers and domain experts, which enabled them to educate each other on their own expertise, ideate future directions, and discuss remaining concerns. It might not be possible to have this deep discussion during traditional user study sessions, such as one-time, one-hour long interviews. We believe our future participants in the user study sessions using our prototypes can provide rich responses to questions regarding the adoption of this concept because our prototypes can be well aligned with their potential needs and work practices. Specifically, we are interested in questions related to usability (whether they can understand and use the prototype without problems), compatibility (whether the tools can be used in their work practices without frictions), and perceived clinical usefulness (whether they foresee the clinical value of using the prototype). We hope this co-design process and future qualitative study using the prototypes can lead us to develop a usable and useful clinician-facing tool in the future that can be used efficaciously at the point of care.

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Acknowledgments

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Conflicts of Interest

None declared.

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Abbreviations

HCI: human-computer interaction
LIWC: Linguistic Inquiry and Word Count
lo-fi: low-fidelity

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Review

The Therapeutic Alliance in Digital Mental Health Interventions for Serious Mental Illnesses: Narrative Review

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Abstract

Background: Digital mental health interventions offer unique advantages, and research indicates that these interventions are effective for a range of mental health concerns. Although these interventions are less established for individuals with serious mental illnesses, they demonstrate significant promise. A central consideration in traditional face-to-face therapies is the therapeutic alliance, whereas the nature of a digital therapeutic alliance and its relationship with outcomes requires further attention, particularly for individuals with serious mental illnesses.

Objective: This narrative review aims to encourage further consideration and critical evaluation of the therapeutic alliance in digital mental health, specifically for individuals with serious mental illnesses.

Methods: A narrative review was conducted by combining 3 main areas of the literature: the first examining the evidence for digital mental health interventions for serious mental illnesses, the second illuminating the nature and role of the therapeutic alliance in digital interventions, and the third surrounding practical considerations to enhance a digital therapeutic alliance.

Results: Results indicated that a therapeutic alliance can be cultivated in digital interventions for those with serious mental illnesses, but that it may have unique, yet-to-be-confirmed characteristics in digital contexts. In addition, a therapeutic alliance appears to be less directly associated with outcomes in digital interventions than with those in face-to-face therapies. One possibility is that the digital therapeutic alliance is associated with increased engagement and adherence to digital interventions, through which it appears to influence outcomes. A number of design and implementation considerations may enhance the digital therapeutic alliance, including human support and technological features.

Conclusions: More research is required to further understand the nature and specific role of a therapeutic alliance in digital interventions for serious mental illnesses, particularly in informing their design. This review revealed several key research priorities to advance the therapeutic alliance in digital interventions.

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KEYWORDS

mental health; mHealth; eHealth; telehealth; psychosis; bipolar disorder; mobile phone

Introduction

A therapeutic alliance is considered fundamental to the success of face-to-face psychological therapies but is an underrecognized consideration in digital mental health [1]. Given that digital mental health research and implementation is rapidly expanding, further exploration of the nature and role of a therapeutic alliance in this context is essential. The driving aim of this narrative review was to encourage further consideration and critical evaluation of a therapeutic alliance in digital mental health, particularly for serious mental illnesses. This review begins with a discussion of the current status of the literature

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regarding digital interventions and, specifically, those for serious mental illnesses. The following section highlights the relevance of a digital therapeutic alliance and the differences in the traditional conceptualization of therapeutic alliance. Next, the review focuses on conceptual issues surrounding a digital therapeutic alliance in the presence and absence of human support. Finally, practical considerations for enhancing digital therapeutic alliance are explored.

Methods

To achieve the aims of this review, three areas of literature were integrated. The first was literature examining the potential of digital mental health interventions for serious mental illnesses, the second was literature illuminating the role of the therapeutic alliance in digital interventions, and the third providing practical considerations with the potential to enhance the digital therapeutic alliance. Digital mental health interventions can be defined as "interventions that provide information, support and therapy (emotional, decisional, behavioural and neurocognitive) for physical and/or mental health problems via a technological or digital platform" [2]. This paper will refer to mental health interventions with (supported) or without (unsupported) human support, accessed via mobile health or electronic health platforms. Given that the focus of this review was not contexts where a human delivers the majority of the intervention, including using digital means to deliver traditional face-to-face therapy sessions via the web or combinations of face-to-face and digital interventions (blended therapy), these were excluded where identified. The focus of this review was intervention studies with participants with a psychotic spectrum or bipolar disorder (BD) or any author-defined *serious mental illness*; however, where minimal data about serious mental illnesses are available, the broader mental health literature will be drawn upon.

Results

Potential Benefits of Digital Interventions

There are several obvious benefits of digital interventions to enhance mental health, such as overcoming logistical barriers and reducing therapeutic costs [3-5]. Indeed, some studies have suggested that these offer benefits not attainable through traditional therapy, such as the extension of the therapeutic hour, accessibility when and where users desire, and the provision of anonymity [4,6]. For these reasons, research into digital interventions is a burgeoning area, with many programs developed and evaluated in recent years.

Specific Benefits of Digital Interventions for Serious Mental Illnesses

Perceived stigma, lack of insight, and lack of trust in available face-to-face treatments have been cited as key reasons for individuals with serious mental illnesses not seeking support for mental health concerns [7,8]. In addition, the symptoms and sequelae of BD and psychotic disorders, such as positive and negative symptoms, cognitive difficulties, general psychopathology, and poor social adjustment, are key predictors of poor adherence and engagement in face-to-face therapy [9-12]. Digital interventions offer the potential to address some of these specific barriers, for example, by increasing accessibility and a sense of autonomy and enabling self-pacing and reviewing of therapeutic content. Additional advantages include the provision of real-time and longitudinal patient data, potentially leading to a more accurate diagnosis and treatment decisions, moment-to-moment monitoring, and timely interventions [13]. Furthermore, digital interventions may be uniquely positioned to target the multilevel risk factors associated with poor physical health and mortality in serious mental illnesses [14]. Indeed, personal preference may mean that self-guided interventions are ideal for some [15].

Use of Digital Interventions

An additional layer of stigma that individuals with serious mental illnesses may experience is the assumption that they *cannot* or *do not* use digital devices for their mental health. A digital divide exists in mental health, wherein individuals experiencing serious mental illnesses are excluded from receiving support through digital means because of a lack of access, skills, or confidence [16]. However, evidence suggests that this exclusion is declining [17], particularly within psychotic disorders and BD [18,19]. However, developing digital interventions for individuals experiencing serious mental illnesses can introduce additional challenges because of illness-related factors, such as cognitive impairments or mistrust, thus requiring specific design considerations [12,16].

Effectiveness of Digital Interventions

Overall, digital interventions for improving mental health have demonstrated significant promise. For example, 3 meta-analyses demonstrated that supported digital interventions for a range of mental health concerns were comparable in efficacy (moderate effect sizes) with face-to-face psychological interventions [20-22]. Currently, the greatest support exists for the effectiveness of digital interventions for depression and anxiety disorders, whereas data for other clinical disorders are fragmented at this stage. For example, a recent narrative review of digital interventions reported large effect sizes for participants with major depressive disorder, anxiety disorders, obsessive-compulsive disorder, and posttraumatic stress disorder and small effect sizes for eating disorders or problematic alcohol use [23].

Effectiveness of Digital Interventions for Serious Mental Illnesses

The findings of 6 recent systematic reviews of digital interventions for serious mental illnesses demonstrate that these are feasible and acceptable, with preliminary indications that these may be effective for symptoms and cognitive and social outcomes [24-29]. However, in each review, insufficient data were available to draw firm conclusions. Specifically, in a systematic review including individuals with psychosis, results provided preliminary evidence that these may have benefits for positive psychotic symptoms and depression, hospital admissions, medication adherence, socialization, and social connectedness [30]. For example, the recent Actissist proof-of-concept trial, in a small sample of individuals with early psychosis, demonstrated feasibility and acceptability

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through high use and adherence as well as symptom improvements in favor of the intervention group [31]. The handful of digital interventions for BD evaluated to date have produced inconsistent results. A systematic review of these studies showed that while these appear to be feasible and acceptable intervention options, inconsistent evidence was found for their effectiveness for symptoms or recovery outcomes such as quality of life [32]. The current Canadian Network for Mood and Anxiety Treatments and International Society for Bipolar Disorders treatment guidelines conclude that, to date, there is insufficient evidence to support the use of digital interventions as adjunctive therapies for BD [33]. However, multiple trials are underway, which will advance this literature [34-38].

Therapeutic Alliance

The original conceptualization of the therapeutic alliance by Bordin [39] included 3 components: (1) the bond between the client and therapist, (2) agreement on the tasks directed toward improvement, and (3) agreement on therapeutic goals. This pantheoretical conceptualization has been widely adopted; however, there are various understandings of the therapeutic alliance. For example, Rogers [40] described the ideal qualities of a therapeutic relationship as acceptance, empathic understanding, and congruence, arguing that it is via these facilitative conditions that growth is achieved in therapy. An additional conceptualization, which forms the basis of the widely used Agnew Relationship Measure (ARM), comprises bond, partnership, confidence, openness, and client initiative [41].

Therapeutic Alliance and Outcomes in Face-to-Face Therapy

A number of meta-analyses point to a modest but reliable relationship between the quality of therapeutic alliance and outcomes of face-to-face therapy, with effect sizes typically in the moderate range [42-44]. Some research also supports the notion of a causal relationship between therapeutic alliance and outcomes in serious mental illnesses, for example, increasing the number of sessions attended was only beneficial in the presence of a strong therapeutic alliance for individuals experiencing psychosis [45]. Two systematic reviews focusing on psychosis found some evidence that the therapeutic alliance was related to reductions in psychotic symptoms, hospitalizations, and self-esteem outcomes [46] as well as functioning and treatment adherence [47]. Similarly, in BD, therapeutic alliance have been linked with decreased stigma, more positive attitudes toward medication, and, less conclusively, a reduction in symptoms [48].

Conceptualizing the Therapeutic Alliance in Digital Interventions

Given that the therapeutic relationship is a necessary (and some argue, sufficient) component of change in traditional face-to-face psychotherapies, a significant reservation toward digital interventions is the loss or, at a minimum, the modification of the therapeutic relationship. Some commenters have started to consider whether and, if so, how the therapeutic alliance plays a role in digital interventions [49]. Indeed, the James Lind Alliance identification of key priorities in advancing digital interventions included concerns relating to the therapeutic alliance in the top 10 issues raised [50]. The definition by Bordin has been transplanted to web-based environments, most commonly, digital interventions with human support components. However, it cannot be presumed that traditional conceptualizations of therapeutic alliance transfer to digital environments nor that different digital environments foster therapeutic alliance in equivalent ways.

The dimensions of the therapeutic alliance may differ in digital environments. A systematic review identified additional themes of *availability*, indicating how freely and conveniently accessible the digital intervention is, and *interactivity*, indicating the degree to which personalization and feedback based on user input is provided and to which the user feels in control [51]. These themes support the possibility of a perceived bidirectional relationship between a user and a digital system, in which automated aspects of the experience could emulate a reciprocal, trusted relationship. A qualitative analysis mirrored the importance of these domains within the therapeutic alliance for participants. For example, one participant identified that automated personalization helped them understood and conversely, another user would have perceived a *relationship* if the site responded intelligently [51]. Furthermore, following an examination of a supported digital intervention for carers, users perceived automated feedback, designed to emulate human communication, as supportive and helpful [52]. More work is needed to explore therapeutic alliance features and domains within digital contexts. Nonetheless, these investigations shed some light on the nature of the alliance in digital contexts, providing a *provisional characterization* of factors relevant to the alliance in digital contexts.

In parallel, the measurement of the therapeutic alliance requires specific consideration for digital environments. Simply replacing *therapist* with *program* or *app* in existing measures may fail to account for the complexity of the therapeutic alliance in digital interventions and parcel out the relative contributions of human-human and human-technology relationships. Researchers are beginning to acknowledge this; for example, WAI-Tech, a digital adaptation of the frequently used alliance instrument, the Working Alliance Inventory (WAI), includes reworded items in the *bond* subscale, omitting the human element [53]. Another adaptation applies to supported contexts, anchoring the task and goals subscales to the intervention and the bond subscale to the therapist [54]. Similarly, Berry et al [55] adapted the ARM for digital contexts by consulting end users and mental health professionals. In addition, the recently developed Enlight measure was specifically designed to assess the features of digital interventions, including those related to therapeutic alliance [56]. These measures require further validation but represent a starting point for capturing the unique qualities of the digital therapeutic alliance.

Therapeutic Alliance Ratings in Digital Interventions

Several recent reviews have demonstrated that client ratings of the therapeutic alliance in various digital interventions are of similar magnitude to those found in face-to-face therapies [42,57-59], including a small number of samples with serious mental illnesses [42]. Cavanagh et al [60] suggest that *common factors* cultivated within the face-to-face therapeutic alliance,

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such as hope, empowerment, credibility, expectancy, perspective, and emotional processing, might be achieved within digital interventions through a combination of human support components and the intervention itself, a triadic alliance.

Role of Human Supporters in Digital Interventions

Digital interventions vary with regard to their level of professional support, including no support (entirely self-managed interventions); minimal administrative or technical support; and tailored, regular support from a professional [61]. The frequency and type of support also ranges, but most frequently involve regular asynchronous message contact, typically with a professional, aimed at supporting participants' engagement and progress through the program's components [22]. Similarly, the content and model of support vary, and this may be an additional factor that impacts effectiveness and engagement [62].

A key issue when conceptualizing the therapeutic alliance in the digital context is whether this is dependent upon a relationship with a human supporter, and therefore whether a therapeutic alliance can be cultivated within wholly *unsupported* digital environments. In general, ratings of the therapeutic alliance are lower in unsupported interventions. For example, as shown in Multimedia Appendix 1 [53,63-78], 2 recent digital interventions for depression demonstrated positive ratings of the therapeutic alliance, which were lower than those in face-to-face versions [64,65]. On the other hand, qualitative interview participants largely rejected the idea of a relationship with the digital intervention, despite indications in their responses that they were experiencing alliance-like processes [51].

Digital interventions appear to be more effective when support is offered. The findings of multiple meta-analytic and systematic reviews suggest that digital interventions with support tend to have greater effect sizes than those without human support [21,79-83] for outcomes, including depression and anxiety symptoms, and general well-being. Several meta-analyses have shown that human support moderates the effectiveness of digital interventions [80,84]. Following a systematic review of factors influencing the successful implementation of digital interventions for those with serious mental illnesses, a key recommendation was the inclusion of human support elements [12].

In addition, supported digital interventions have comparably smaller attrition rates and greater engagement, as demonstrated in systematic reviews [23,85]. For example, a study evaluating predictors of adherence to digital interventions for individuals experiencing psychosis reported that support was associated with greater adherence [86]. Similarly, a recent study compared a digital intervention with and without support for individuals with a history of psychosis, finding that those receiving support engaged significantly more with the site, across a range of engagement parameters [87]. Furthermore, the inclusion of peer coaching within a digital intervention for BD significantly enhanced engagement and adherence [88].

However, it should be noted that some studies involving direct comparisons of supported and unsupported interventions have failed to demonstrate significant differences in effectiveness and/or adherence [89-91], with authors questioning whether a degree of human support is inherent under randomized controlled trial (RCT) conditions, while cautioning against interpreting these findings as evidence that support is not necessary. For example, Berger et al [92] found no differences in the effectiveness of a digital intervention for social anxiety across a range of clinical outcomes between unsupported, minimally supported, and flexibly (on-demand) supported programs; however, participants had access to peer support in this program, potentially providing relational benefits. More direct comparisons are required to draw definitive conclusions.

What Kind of Support and How Often?

Although it is evident that support is beneficial within digital interventions, little research has been conducted on the optimal form of support. A small group of studies have attempted to identify whether comparable benefits are attained with more versus less intensive (and, therefore, cost- and resource-effective) support. Klein et al [93] compared low (once weekly) and high (thrice weekly) frequency email support within a CBT digital intervention for panic disorder. Comparable symptom improvement, perceptions of a therapeutic alliance, and attrition were reported between conditions, suggesting that increased frequency of contact was neither a moderator of these outcomes nor essential to engagement. A recent review of digital interventions for psychosis similarly found that there was a little difference in adherence between interventions with low-, high-, or very high–frequency contact with supports [86].

Conversely, Palmqvist et al [82] reported a positive correlation between the amount of therapist contact in minutes and the effect sizes reported in 15 (supported and unsupported) digital interventions. A more recent systematic review of physical and mental health interventions with and without support reported that a higher frequency of support predicted better adherence [94]. One explanation for these contrasting findings is that the latter studies included unsupported interventions in their analyses, potentially skewing results, that is, these differences may reflect differences between no support versus support, rather than frequency. More research is required to unravel these contradictory findings and identify optimal levels of support and to examine these associations within serious mental illnesses.

Other potential influences on the impact of human support are the type of support or supporter. However, data to date do not support this conclusion. Lindner et al [95] found no differences in effectiveness between telephone and email support in a small trial. Baumeister et al [81] found no evidence that the qualifications of supporters influenced the outcomes in their systematic review. Similarly, the level of training did not impact the effectiveness of a digital intervention for depression [96]. Furthermore, a meta-analysis by Gellatly et al [84] failed to demonstrate any impact of the number of sessions, level of training, the content of the guidance, or mode of contact on therapeutic outcomes.

Potential Mechanisms

Support within digital interventions may be important for several reasons. For example, individuals with BD identified that

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managing procrastination and motivation issues were likely to be the primary benefits of support within a digital intervention [97]. Participants in an unsupported CBT digital intervention for depression echoed this, expressing the desire for support to assist with discipline and motivation [98]. Similarly, a meta-analysis of digital interventions for depression and anxiety disorders found that clients reporting lower motivation were less likely to benefit from interventions without support [61]. Furthermore, 2 qualitative analyses following digital interventions (for generalized anxiety disorder and depression) revealed that personalized support led to improved motivation to engage while fulfilling the needs for relatedness [99,100]. Therefore, a vital function of support within digital interventions may enhance motivation and a sense of relatedness.

Association of Therapeutic Alliance to Outcomes in Digital Interventions, With and Without Support

Although it has been established that the therapeutic alliance can be experienced in digital interventions, links to outcomes are less clear than in face-to-face therapies.

Supported Digital Interventions

A handful of studies on supported digital interventions have reported that ratings of therapeutic alliance are related to treatment outcomes. The first was a small secondary analysis from an RCT targeting anxiety disorders [67]. Ratings on a modified version of the WAI correlated with outcomes, specifically the degree of improvement in well-being and symptoms. In addition, Herbst et al [68] found that WAI ratings were associated with symptom reduction in a supported digital intervention for obsessive compulsive disorder (OCD). Following another OCD digital intervention in a larger sample, a therapeutic alliance was the best predictor of response to the intervention [69]. A systematic review aiming to examine whether a therapeutic alliance is associated with mental health outcomes found an association only within these 3 studies [58]. Two further studies demonstrated that, following small trials of a supported digital intervention for posttraumatic stress disorder (PTSD), ratings on the WAI were associated with reductions in PTSD symptoms [72,74].

Conversely, multiple studies have failed to find associations between the therapeutic alliance and treatment outcomes in supported digital interventions. For example, Andersson et al [70] found that high ratings on the WAI in 3 supported digital interventions did not correlate with change scores across outcome measures for depression, generalized anxiety disorder, and social anxiety disorder. Furthermore, Hadjistavropoulos et al [71] reported that ratings were unrelated to outcomes of supported digital interventions for either depression or generalized anxiety disorder. Similarly, Preschl et al [73] found that high WAI ratings, equivalent to the face-to-face comparison group, were not associated with treatment outcomes following a supported digital intervention for depression. Some quality issues should be noted here, specifically that these analyses were mostly secondary analyses with small samples and no controls, and, therefore, these findings require validation. In addition, studies have measured the alliance at different times (midtreatment [69,70], postintervention [68,73], or both [67,71,72]), whereas prior face-to-face research has indicated that the timing of alliance measurement influences its relationship with outcomes [101]. These inconsistencies may partly explain the discrepancies in the findings.

Unsupported Digital Interventions

In a small, open trial of an unsupported digital intervention, modified ARM ratings were lower than in face-to-face CBT and showed no associations with depression outcomes [65]. In another study, ratings on the WAI-Tech for a digital intervention were similar to those on the WAI in a face-to-face (treatment as usual) group but were not associated with the outcome: cocaine abstinence [53]. A further study found that ratings on the ARM were not correlated with outcomes for those with depression and anxiety, following an unsupported digital intervention [63]. As mentioned above, these are small studies, including an open trial [65] and secondary analyses [53,63], and the alliance was heterogeneously assessed, raising questions about reliability.

Taken together, there appears to be conflicting evidence that the therapeutic alliance links with outcomes in supported digital interventions, and no evidence of such an association is found in unsupported digital interventions. It appears that although the therapeutic relationship is robust to the reduced contact and distance in digital interventions, it may be less intimately tied to outcomes than in traditional therapies. Importantly, for this review, minimal data were available regarding these relationships for serious mental illnesses.

Association of Therapeutic Alliance With Engagement and Adherence in Digital Interventions, With and Without Support

Although evidence relating to a direct relationship between ratings of therapeutic alliance and treatment outcomes is inconclusive for digital interventions, one possibility is that the therapeutic alliance is associated with increased engagement and adherence, in turn, influencing outcomes [102]. It should be noted that engagement and adherence are often used interchangeably or poorly defined, limiting conclusions. In this review, engagement will refer to measures of the amount, frequency, or depth of program usage, whereas adherence will refer to whether participants met an a priori metric of intended usage or *dose*; however, we are limited to the information presented. For example, a real-world analysis of a range of apps and sites available to the public, with varying support, demonstrated that ratings of the therapeutic alliance (measured using the Enlight measure) were associated with increased user engagement [76].

Alliances and Engagement in Supported Interventions

Considering adherence, a study by Hargreaves et al [77] demonstrated that WAI ratings were the most significant predictor of adherence to a supported digital intervention for individuals experiencing psychosis. In another supported intervention, those that completed the intervention provided higher alliance ratings (in a sample with PTSD) [74]. A further study found a relationship between alliance ratings and engagement with intervention features in adolescents [78].

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Alliances and Engagement in Unsupported Interventions

Clarke et al [63] did not find a direct relationship between therapeutic alliance (assessed with the ARM) and outcomes, while a significant association was discovered between the alliance and level of engagement with the unsupported digital intervention. In a further supported intervention, the WAI-Tech goal and bond subscales were positively correlated with the number of modules completed [53].

As can be seen, across the few studies that considered the possibility of a relationship between the alliance and engagement in digital interventions, all have reported an association. However, conclusions are complicated by the small number of studies and the range of conceptualizations of engagement and/or adherence therein.

Association of Engagement and Adherence to Outcomes in Digital Interventions

The above findings are especially compelling given that adherence and engagement are themselves associated with improved outcomes in digital interventions. For example, a meta-analysis demonstrated that adherence to both the intervention and the study was associated with a range of behavioral and health outcomes in digital interventions [103]. Furthermore, a systematic review showed that a broad range of *adherence* measures (many of which align with our definition of *engagement*) was associated with physical and psychological outcomes in digital interventions [104]. Associations with adherence have been demonstrated for a range of outcomes, including depression [105,106] and anxiety [107,108].

Engagement with digital interventions has also been linked to outcomes. Across outcomes such as depression and anxiety [109-111], greater changes in symptoms have been associated with better engagement with the site. Similarly, in a program for preventing eating disorders, the duration and extent of program use predicted some outcomes [112].

These findings suggest that a therapeutic alliance is associated with increased engagement with and adherence to digital interventions, in turn, influencing outcomes. However, this explanation represents one possible interpretation of these limited data and requires direct examination. Given to the inconsistencies within this literature [113], more work is needed to identify the engagement and adherence metrics with the most importance. In addition, no identified studies investigating links between outcomes, adherence, and engagement included samples with serious mental illnesses.

Conceptualizing the Therapeutic Alliance in Unsupported Digital Interventions

Although it appears that human support is beneficial for therapeutic alliance, in many cases, human support is not practical or desirable. Some users, including those with serious mental illnesses, report a preference for unsupported interventions, with benefits such as the reduced potential for judgment and increased honesty [25,51]. How the definition by Bordin [39] on therapeutic alliance can apply to unsupported interventions is not yet clear, but it has been suggested that therapeutic goals and therapeutic task components (or analogs thereof) may be cultivated within interactions between users and the intervention, while the *bond* element may be either entirely absent or modified [114]. For example, while equivalent ratings on the remaining alliance subscales were reported, the bond subscale of the WAI was significantly lower in a digital intervention for cocaine dependence than in a face-to-face group [53].

In the absence of human support, it may be more important to ensure that unsupported digital interventions incorporate automated features that resemble a bidirectional therapeutic relationship, such as the communication of empathy, responsiveness, and supporting the user's motivation. Barazzone et al [115] examined the content of 3 widely used CBT programs to investigate the extent to which they incorporated key features for the establishment, development, and maintenance of a therapeutic alliance between the user and the program. They concluded that the programs exhibited substantial evidence of therapeutic alliance features, such as empathy and acceptance, and the negotiation of goals, providing feedback and building confidence in the program's effectiveness, and rupture prevention and repair by encouraging users to return to the program after a break. Similarly, Holter et al [116] describe their attempts to cultivate a therapeutic alliance in a smoking cessation digital intervention, simulating a therapeutic alliance by allowing users to negotiate goals and using a conversational agent to implement *human* strategies such as empathy, interactivity (via *remembering* previous communications and tailoring), and humor. These authors did not assess the therapeutic alliance, its relationship with program features, or outcomes. However, Bickmore et al [66] evaluated the impact of introducing a relational agent that simulated alliance-promoting behaviors such as social dialogue, empathetic feedback, process comments, humor, and nonverbal communication, alongside a fitness digital intervention. The bond subscale was rated significantly higher within the group that had contact with the agent, whereas the overall WAI scores did not differ significantly.

Furthermore, additional *provisional characteristics* of the digital therapeutic alliance, availability, and interactivity, are not grounded in human support [51] and speak to the unique strengths of digital interventions. Technology is ideally positioned to be accessible when and wherever users require it, and a number of technological features can be optimized to cultivate interactivity, that is, a bidirectional relationship might be effectively emulated between a user and a digital intervention, with automated features. In addition, people may form attachments to smartphones, similar to an alliance [117,118], although users appear hesitant to call this a *relationship* [51]. Although human presence may be an important predictor of the therapeutic alliance in digital interventions, the *experience* of human presence may not require direct human contact. For example, the object-relations theory explains how devices may act as proxies for relationships with caregivers (the humans behind the intervention [119]).

Examining which technological features are best positioned to foster the therapeutic alliance in both supported and unsupported digital interventions is therefore an important next step, and we propose that exploring the additional provisional characteristics

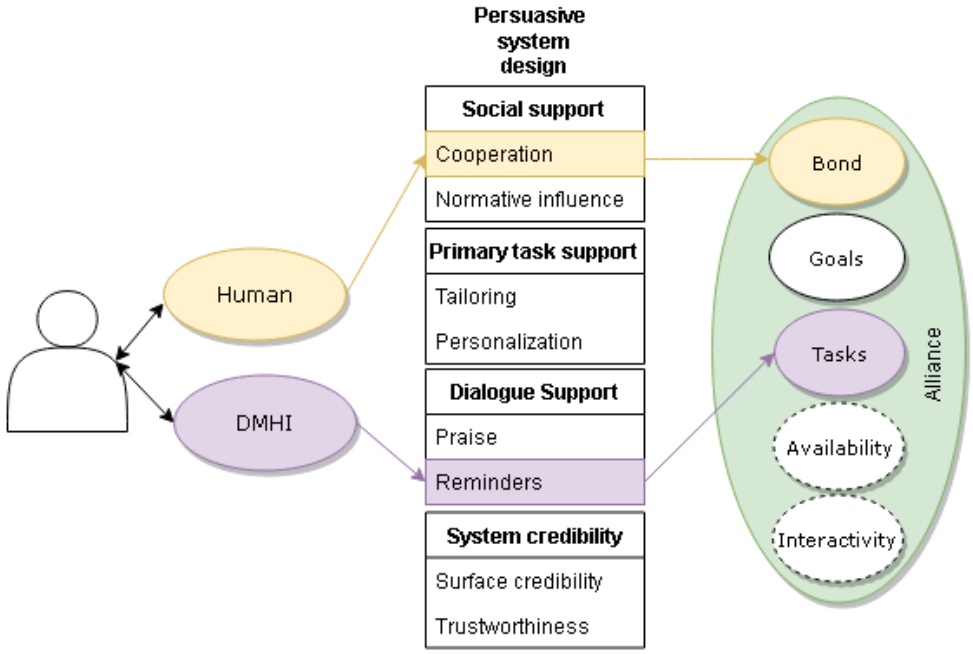
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of availability and interactivity may represent a significant advancement.

Persuasive Systems Design: Potential for Digital Therapeutic Alliance

Particular consideration of the features of the intervention and their ability to promote behavior change [120] may provide direction for enhancing the therapeutic alliance. Persuasive systems design (PSD) is a broad term used to describe the technological features of a digital intervention specifically intended to motivate behavior or attitudinal change [94,121]. The study findings indicate that incorporating PSD features within interventions can be effective in motivating individuals toward specific goals across physical health [122,123], mental health [124,125], exercise [126,127], and educational [128] domains. The implementation of PSD with the specific intention of promoting the digital therapeutic alliance has not been examined to date; however, a number of PSD features [121] are likely to promote the development of a therapeutic alliance between users and digital platforms. This section provides an overview of the PSD factors that are likely to be relevant to the fostering of a therapeutic alliance in the digital space and comments on the potential role of human supporters, where applicable. Figure 1 presents an example of how aspects of the digital intervention itself and interaction with human supporters may promote specific, provisional components of the digital therapeutic alliance.

Figure 1. Representation of how specific persuasive systems design features could link to specific domains within the digital therapeutic alliance. DMHI: digital mental health intervention.



Tailoring and Personalization as Primary Task Supports

Tailoring systems and *personalizing* messages to users are important components of system design [121]. An example of tailoring is to suggest specific content based on what is known about users' preferences or background, whereas personalization might reflect the person's name or information about their medications, functioning, or previous responses [121].

Empirical research findings have indicated that when intervention content is matched with users' psychosocial and behavioral characteristics, it is perceived as personally relevant, which enhances engagement [129] in line with the elaboration likelihood model [130]. Conversely, a 2016 review [85] indicated that the most commonly cited reason for low adherence within the digital intervention was a perception of impersonal or irrelevant content.

Therefore, tailoring and personalization may help foster a digital therapeutic alliance via congruency between the users' personal needs and goals and interactions with the intervention. In addition, tailoring and personalization speak directly to the provisional digital therapeutic alliance's characteristic of *interactivity*. For example, tailoring the intervention to a person's stage of recovery in face-to-face therapy and not assuming *motivation* to change is predictive of a strong therapeutic alliance and outcomes [131]. In this vein, it has been argued that individually tailored content or responses within digital interventions enhance the sense of relationship with the platform, whether supported or unsupported [55]. Research findings provide some support for this claim, with qualitative accounts indicating that when users perceived an app as not tailored to their individual needs (eg, generic), the development of a relationship was hindered [55]. This is an important consideration when developing digital interventions for individuals with serious mental illnesses, where concerted efforts to build trust that the treatment will address the clients' own unique goals may provide a buffer against feelings of mistrust or coercion [132].

Dialogue Support

Dialogue support is a PSD strategy that supports user-digital interactions deemed by users to be interpersonal or social interactions [121]. Specific examples of dialogue support in digital interventions include offering positive feedback (praise),

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reflecting users' goals and tasks (reminders), linking users with peers via forums (social role), or providing recommendations for appropriate content (suggestions) [94,121]. Sustained engagement with a digital intervention is likely when the intervention offers ongoing interaction that is relevant, motivating, and tailored to users' needs [113]. Review findings have demonstrated that adherence to digital interventions, in general, is contingent on the extent to which dialogue support elements are utilized [94]. Similarly, a recent review showed that a greater number of dialogue support elements was associated with beneficial outcomes [125].

Research findings also demonstrate that the quality of the therapeutic alliance is contingent on the perceived quality of the interaction and, therefore, implementing responsive dialogue support features within digital interventions should be a consideration in fostering a digital therapeutic alliance [133]. Improved dialogue between users and digital interventions could not only assist users to achieve their goals and foster a sense of interactivity but also enhance self-efficacy [121]. This is an important consideration for individuals with serious mental illnesses because research findings indicate that individuals who perceive greater control over their lives (ie, internal locus of control and greater self-efficacy) are more positive about the therapeutic alliance [134]. Furthermore, although it has not been studied in the context of digital interventions, an internal locus of control is associated with increased treatment motivation, compliance and treatment adherence, and better treatment outcomes in individuals with serious mental illnesses [135].

Credibility Support

System credibility or *credibility support* refers to how digital interventions incorporate technological features that convince the user that the system is credible [94,121]. Examples of how credibility support can be used in digital interventions include providing evidence-based content, expert moderation (eg, clinician support), and explicit, credible third-party endorsements [136]. Credibility support is associated with perceived authority, expertise, and trustworthiness among users of digital interventions, and findings show that its deliberate implementation is also associated with engagement [137].

Implementing credibility support features to increase users' perceptions of expertise and trustworthiness is likely to help strengthen therapeutic alliance. For example, the bond between therapists and clients in face-to-face settings is contingent on the client's confidence in the therapist's competence [138]. Scant literature has examined this phenomenon within a digital context; however, Mackie et al [139] examined the effectiveness of a mobile-based intervention to treat harmful substance use in veterans presenting with self-harm and found that trust was associated with the quality of the digital therapeutic alliance, whereas damaged trust can lead to disengagement. This is a particularly important clinical consideration for individuals with serious mental illnesses who are often difficult to engage in ongoing treatment and have high dropout rates [132].

Social Support

Persuasive design strategies in the *social support* category refer to technological strategies that motivate users by leveraging social influence (eg, cooperation, social facilitation, and social comparison) [121]. Theoretically, individuals will be more motivated to perform a target behavior if they can use a system to observe (eg, social facilitation) or compare themselves (eg, social comparison) with others performing the behavior and if they are provided with a means to cooperate or connect [94,121]. An example of how digital interventions can include technological features to facilitate social support include incorporating newsfeeds and/or social forums. There is some support to suggest that the inclusion of social networking facilities in digital interventions for individuals with serious mental illnesses can assist in fostering a sense of social connectedness [35,140,141], a sense of cooperation (shared goals), and increased accountability toward treatment [137].

Developing digital interventions that utilize social support technological features may also help foster a digital therapeutic alliance. For example, study findings relating to face-to-face therapy have shown an association between clients' levels of perceived social support and their ratings of the therapeutic alliance [142]. Research findings demonstrate that individuals with serious mental illnesses report benefits from interacting with peers on the web, including greater feelings of group belonging and social connectedness [143]. In addition, as discussed previously, individuals with serious mental illnesses who may be uncomfortable with or avoidant of conventional social contact may perceive digital interactions as less threatening [144]. Therefore, the facilitation of social support should be a design feature of digital interventions for individuals with serious mental illnesses.

Discussion

Implications

There are a number of implications of these findings for the development and evaluation of digital interventions, specifically for designing interventions for individuals with serious mental illnesses. Specifically, there have been very few investigations into the role of specific design features in cultivating digital alliances. For example, if *interactivity* is confirmed as an important feature of the digital alliance, some specific design principles (such as tailoring and personalization strategies) are ideally positioned to promote users' perceptions of interactivity. Furthermore, the unique nature of the alliance in digital contexts is likely to interact specifically with serious mental illnesses. For example, individuals who may be uncomfortable with or encounter barriers to interacting within traditional therapeutic encounters may be differentially receptive to forming relationships in digital contexts (even those without human support), and as noted, some individuals prefer accessing digital interventions over traditional forms of support.

Limitations

The main limitations of this review were that no systematic search methods or formal bias and quality assessment methods were used, as the aim was a broad integration of relevant literature to identify key gaps for future research. Accordingly, there is a significant risk of selection bias. Therefore, the included studies cannot be presumed to represent the available literature, and firm conclusions are not warranted on these bases.

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In addition, in many included studies, the analyses that were included were secondary analyses (Multimedia Appendix 1), and many were underpowered because of sample size, inflating type I and type II error risk. There may also be some conceptual issues impacting the results. For example, issues unique to the experiences of individuals with serious mental illnesses and their potential interactions with the relationships of interest should be considered. For example, social withdrawal, mistrust, or paranoia could interact with engagement and independently with an alliance.

Future Directions

More research is required to further understand the specific role of the therapeutic alliance in digital interventions for serious mental illnesses, particularly in informing their design. Specifically, based on the findings of this review, systematic reviews could examine the role of the therapeutic alliance in both engagement and outcomes of digital interventions. Furthermore, a great deal of research has provided data about the role of human support, largely indicating that it is beneficial (but not essential). However, further inquiry is needed to identify the optimal form, intensity, and role that should be taken and to examine nuances such as interactions with different presentations or populations, including those with serious mental illnesses. Separate to this, ways of maximizing therapeutic alliance that are independent of human support require further investigation, and new technologies present multiple promising avenues. The potential for PSD features to enhance the digital therapeutic alliance requires further investigation. Digital phenotyping and machine learning approaches, integrating physiological and behavioral signals to tailor interventions with the aim of enhancing outcomes, demonstrate promise, and for serious mental illnesses, the research in this area is growing [13,145-147]. However, the specific role of such technologies in cultivating digital therapeutic alliance remains to be unknown. Virtual reality (VR) is another area of growth in mental health; however, limitations to date inhibit the potential for exploring its impact on the therapeutic alliance, including that most VR settings require face-to-face contact with a human, and these technologies currently offer the minimal ability for interpersonal interactions within virtual environments [148]. Research on the role of a therapeutic alliance in VR is limited, with preliminary studies showing that therapeutic alliance can be cultivated with these technologies [149]. An additional line of research requiring further attention is concerned with the way digital interventions might be integrated with or enhance care models, such as stepped care, blended models, and virtual clinics, each with specific implications upon a therapeutic alliance [150].

Conclusions

Digital mental health interventions continue to garner significant research attention, demonstrating effectiveness for a range of mental health outcomes and holding significant promise for those with serious mental illnesses. Although a long tradition of research has demonstrated that the therapeutic alliance is central to outcomes in face-to-face therapy, less emphasis has been placed on the therapeutic alliance in digital contexts. Overall, it appears that a therapeutic alliance can be cultivated in digital interventions, but it may have unique, yet to be confirmed, features in these contexts. With further investigation, it may emerge that the nature of the alliance is so divergent as to reflect a unique construct; however, at this juncture, we believe it is reasonable to consider relationships cultivated in digital context analogs of traditional, bidirectional therapeutic alliance, and hence, this term is used throughout this work. In addition, it appears likely that the therapeutic alliance is less directly linked with outcomes in digital interventions than in face-to-face therapies. Rather, it may be that the therapeutic alliance is associated with increased engagement with and adherence to digital interventions, which, in turn, leads to improved outcomes. Human support is an effective method of enhancing both engagement and therapeutic alliance; however, this is not always feasible or desirable. Alternatively, alongside or in lieu of human support, technological features may be capable of cultivating therapeutic alliance, especially when these are automated to emulate relational characteristics, but more research is needed to explore which features are most closely aligned with the improved therapeutic alliance and, ultimately, improved outcomes. Accordingly, several research priorities have been identified to advance this understanding.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Intervention characteristics and reported links between alliance, engagement, and outcomes.
[PDF File (Adobe PDF File), 210 KB - mental_v7i8e17204_app1.pdf]

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Abbreviations

ARM: Agnew Relationship Measure
BD: bipolar disorder
OCD: obsessive compulsive disorder
PSD: persuasive systems design

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PTSD: posttraumatic stress disorder
RCT: randomized controlled trial
VR: virtual reality
WAI: Working Alliance Inventory

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Letter to the Editor

Comment on "Digital Mental Health and COVID-19: Using Technology Today to Accelerate the Curve on Access and Quality Tomorrow"

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KEYWORDS

telepsychiatry; COVID-19; Australia

The article titled, “Digital Mental Health and COVID-19: Using Technology Today to Accelerate the Curve on Access and Quality Tomorrow” [1] was an interesting read. The coronavirus disease (COVID-19) pandemic has catalyzed the use of telepsychiatry and broken down barriers, giving way to a “can do” approach. The editorial rightly discusses accelerating the use of information technology in psychiatry. This is a good time to collect global experiences on this subject; we discuss telepsychiatry use in metropolitan Melbourne, Australia.

Although telepsychiatry has always been available, there was a notable reluctance to embrace it despite support from accrediting bodies. The Royal Australian and New Zealand College of Psychiatrists, for example, endorsed its implementation in situations where in-person consults are not feasible. Like most public mental health services in Australia, our service also transitioned to telepsychiatry quickly during the COVID-19 pandemic to provide safe consulting services. We collated some of our experiences by conducting a rapid survey, which was sent out to 40 professionals, and received 14 responses. In total, 70% of the respondents reported that teleconsults had increased significantly during this time. A further 70% noted that there were fewer missed appointments, and the workflow was generally more efficient following the transition to telepsychiatry; 79% were satisfied with the care they were able to provide.

A few challenges were also encountered during this transition. Difficulties using new technology were experienced by 70% of the respondents. A plethora of platforms, such as Zoom, Doxy, CoViu, etc, are available in Australia, each with its own benefits and shortcomings. There was a lack of consensus about which platform to use and guidelines changed frequently, which required learning and relearning when switching between platforms; this created difficulty for some staff and patients alike. Another challenge experienced by the team was maintaining therapeutic alliance (eg, effective communication of empathy and use of nonverbal gestures during a teleconsult). The lack of data available for video consults for some disadvantaged patients was also noted. Training around the effective use of information technology could be helpful, and the survey revealed that only 1 out of 14 respondents had sought such training.

Suitability of patients for teleconsults is a key issue to consider. Often, patients with anxiety and mood spectrum disorders were easier to engage compared to patients with psychosis or drug use. There are advantages of using video over telephone since someone who is distressed (eg, crying) or hypomanic cannot be easily identified through the latter.

Another challenge was the absence of a seamless delivery method to ensure electronic prescription dispatch to the pharmacy. Faxing or emailing prescriptions not only increased

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workload but was also unreliable. We hope that adding the Australian experience of using telepsychiatry during the COVID-19 pandemic will help in planning better telepsychiatry services in the future—a future where the integration of key clinical functions can occur within telehealth platforms that enable the delivery of accessible, seamless, and safe care.

Conflicts of Interest

None declared.

Reference

1. Torous J, Jän Myrick K, Rauseo-Ricupero N, Firth J. Digital Mental Health and COVID-19: Using Technology Today to Accelerate the Curve on Access and Quality Tomorrow. JMIR Ment Health 2020 Mar 26;7(3):e18848 [FREE Full text] [doi: 10.2196/18848] [Medline: 32213476]

Abbreviations

COVID-19: coronavirus disease

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Original Paper

COVID-19 and Telepsychiatry: Development of Evidence-Based Guidance for Clinicians

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Abstract

Background: The coronavirus disease (COVID-19) presents unique challenges in health care, including mental health care provision. Telepsychiatry can provide an alternative to face-to-face assessment and can also be used creatively with other technologies to enhance care, but clinicians and patients may feel underconfident about embracing this new way of working.

Objective: The aim of this paper is to produce an open-access, easy-to-consult, and reliable source of information and guidance about telepsychiatry and COVID-19 using an evidence-based approach.

Methods: We systematically searched existing English language guidelines and websites for information on telepsychiatry in the context of COVID-19 up to and including May 2020. We used broad search criteria and included pre–COVID-19 guidelines and other digital mental health topics where relevant. We summarized the data we extracted as answers to specific clinical questions.

Results: Findings from this study are presented as both a short practical checklist for clinicians and detailed textboxes with a full summary of all the guidelines. The summary textboxes are also available on an open-access webpage, which is regularly updated. These findings reflected the strong evidence base for the use of telepsychiatry and included guidelines for many of the common concerns expressed by clinicians about practical implementation, technology, information governance, and safety. Guidelines across countries differ significantly, with UK guidelines more conservative and focused on practical implementation and US guidelines more expansive and detailed. Guidelines on possible combinations with other digital technologies such as apps (eg, from the US Food and Drug Administration, the National Health Service Apps Library, and the National Institute for Health and Care Excellence) are less detailed. Several key areas were not represented. Although some special populations such as child and adolescent, and older adult, and cultural issues are specifically included, important populations such as learning disabilities, psychosis, personality disorder, and eating disorders, which may present particular challenges for telepsychiatry, are not. In addition, the initial consultation and follow-up sessions are not clearly distinguished. Finally, a hybrid model of care (combining telepsychiatry with other technologies and in-person care) is not explicitly covered by the existing guidelines.

Conclusions: We produced a comprehensive synthesis of guidance answering a wide range of clinical questions in telepsychiatry. This meets the urgent need for practical information for both clinicians and health care organizations who are rapidly adapting to the pandemic and implementing remote consultation. It reflects variations across countries and can be used as a basis for organizational change in the short- and long-term. Providing easily accessible guidance is a first step but will need cultural change to implement as clinicians start to view telepsychiatry not just as a replacement but as a parallel and complementary form of delivering therapy with its own advantages and benefits as well as restrictions. A combination or hybrid approach can be the most successful approach in the new world of mental health post–COVID-19, and guidance will need to expand to encompass the use of telepsychiatry in conjunction with other in-person and digital technologies, and its use across all psychiatric disorders, not just those who are the first to access and engage with remote treatment.

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KEYWORDS

digital mental health; telepsychiatry; evidence-based guidance; systematic review; mental health; COVID-19

Introduction

The coronavirus disease (COVID-19) and the measures taken to limit its spread present unique challenges in all aspects of our everyday life. It is a rapidly progressing disease, evolving from its first description in December 2019 to a global pandemic with consequences worldwide [1]. In the absence of a new and effective vaccine, social distancing, isolation, and quarantine are the most effective interventions used across many countries to slow the spread of transmission [2].

These interventions have provided significant challenges for mental health care systems who (as part of wider health care) have been forced to reappraise ways of working in a rapid time frame, to change to telepsychiatry where possible and to provide adequate information technology systems for mental health care staff to provide remote care. This has happened in a time frame that in many countries, including the United Kingdom, would have been considered impossible only a few months ago [3]. In addition, the need for mental health support is likely to increase. Although COVID-19 is primarily a respiratory disease, data from the long-term neuropsychiatric sequelae of other severe coronavirus infections such as severe acute respiratory syndrome (SARS) and Middle East respiratory syndrome (MERS), and preliminary data for COVID-19 suggest not only significant rates of delirium in the acute stage but also depression, anxiety, fatigue, posttraumatic stress disorder (PTSD), and rarer neuropsychiatric syndromes in the longer term [4]. These longer-term mental health symptoms combined with the stresses of quarantine and self-isolation [5] are likely to increase demand for assessment and support from mental health services.

Despite evidence that e-therapy is equivalent to face-to-face therapy in terms of therapeutic alliance [6], there remains a concern from clinicians that telepsychiatry, in general, may not be as effective as “in-person” mental health care. In addition, clinicians are concerned that telepsychiatry cannot replace the team assessment and multidisciplinary approach that are at the center of modern mental health care provision [7]. It is also often assumed that patients may be reluctant or unable to engage with the technology involved. Mental health care provision, especially in the United Kingdom, has previously reflected this view [8], and although telepsychiatry has been introduced in the United Kingdom in some more remote areas [9], this has been, to at least some extent, out of necessity rather than preference.

In fact, the evidence, especially from the United States [10] shows the opposite. Telemedicine and telepsychiatry are well-established fields and are preferable in many areas such as for patients on the autistic spectrum and those with anxiety symptoms [11]. It can add value, for example, in bringing together subspecialty expertise in an easier and quicker way than in-person assessment, and in completing home and nursing home assessments more rapidly and efficiently. There is strong evidence of effectiveness and acceptability across different settings and many disciplines of psychiatry including older adult, child, and adolescent psychiatry, and across different cultures [11].

COVID-19 and its associated restrictions have prompted both clinicians and patients to reconsider telepsychiatry as a viable and valuable option. However, with change comes uncertainty and many clinicians in mental health feel unprepared for the new ways of working [12]. Areas of uncertainty such as issues of information governance, consent and confidentiality, accuracy of diagnosis, and modifications to any physical examination that may be appropriate are frequent questions in implementing digital technologies in the era of COVID-19 [8].

To integrate telepsychiatry successfully into the post–COVID-19 plan for clinical practice in psychiatry, clinicians, patients, and health care organizations need access to reliable and pragmatic clinical guidance and evidence [13]. In this rapidly evolving situation, with daily updates from specialties, countries, and world organizations, the amount of information available for the busy clinician can be overwhelming. We aim to meet this need by providing focused, evidence-based guidance on the use of digital technologies and telepsychiatry.

Methods

A team of researchers with multidisciplinary backgrounds (including mental health clinicians, researchers, methodologists, and a pharmacist) from the Oxford Precision Psychiatry Lab [14] systematically searched English language websites from the United Kingdom, the United States, Australia, New Zealand, Canada, and Singapore for guidelines on telepsychiatry and telemedicine relevant to mental health and applicable in the context of the current COVID-19 pandemic and afterwards. We decided to focus on English language guidelines in the initial search both to meet the rapid time scale for focused guidance requested by our local clinicians and to include non-UK sites to ensure the synthesis of guidelines is relevant across other countries [13]. Two researchers (KS and EO) searched independently across the following sources in English, without age limits: Public Health England, Royal College of Psychiatrists, Royal College of Nursing, The National Association of Intensive Care and Low Secure Units, Royal College of Physicians, Healthcare Improvement Scotland, South London and Maudsley National Health Service (NHS) Trust, the National Institute for Health and Care Excellence, NHS Wales, General Medical Council, NHSX, Nursing and Midwifery Council (NMC), Centers for Disease Control and Prevention (CDC), US Department of Labor, American Psychiatric Association, Massachusetts General Hospital Department of Psychiatry, Federation of State Medical Boards (FSMB), Centers for Medicare and Medicaid Services (CMS), World Health Organization, Inter Agency Standing Committee, the United Nations International Children's Emergency Fund, World Psychiatric Association, Singapore Ministry of Health, Singapore Psychiatric Association, Singapore Medical Association, Health Canada, Canadian Psychiatric Association, Australian Government Department of Health, and the Royal

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Australian and New Zealand College of Psychiatrists. References to other sources from each website were also searched. Our search focused on guidelines for telepsychiatry in the context of COVID-19 up to and including May 2020. However, we decided to use a broad approach to the search to include both pre–COVID-19 guidelines where appropriate and guidelines for relevant digital technologies such as digital platforms for monitoring symptoms and the use of apps. A search on Google was also completed using keywords relevant to COVID-19 (eg, COVID-19, coronavirus, SARS-CoV-2 [severe acute respiratory syndrome coronavirus 2]), digital mental health (eg, digital mental health, telepsychiatry, digital psychiatry), and guidelines (eg, guideline, guidance, recommendation). Queries or disagreements were resolved by team discussion, and the team collaborated with an expert in the field to keep the guidance global, focused, and comprehensive.

The final synthesis of guidelines on telepsychiatry (including other relevant digital technologies) is presented here and is also available in an open-access webpage [15] in three different formats: (1) a webpage with embedded hyperlinks for online viewing, (2) a downloadable PDF for saving or printing, and (3) a detailed Word (Microsoft Corporation) document with sources and all information. Feedback and corrections from readers of the webpage are actively invited. Questions and answers are grouped together for ease of use. The sources are searched on a regular basis, and the tables on the webpage are updated accordingly.

Results

We synthesized the guidelines and produced both a short practical checklist (Textbox 1) for clinicians to consider before, during, and after the consultation, and detailed textboxes (Textboxes 2-8) with a full summary of all the guidelines. Different guidelines use different terms (for example, telemedicine, telepsychiatry, videoconferencing, and telephone consultation). In our textboxes we have used the original terms from each guideline, and a glossary of definitions is included at the beginning of Textbox 2. Textboxes 2-8 cover general guidance (for all ages) with specific-labelled sections for children and adolescents, and older adults. The most up to date and detailed versions of the textboxes are available online [15].

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Textbox 1. Checklist of things to consider before, during, and after the telepsychiatry consultation (detailed guidance for each point is contained in the numbered sections of the other textboxes).

Before the consultation

- *Consult relevant national guidance for your country* (*section 2a*, in Textbox 3)
- *Consider information governance issues* and the *information technology* (*IT*) *system* that you and your patient will be using (*section 2b*, in Textbox 3)
- *Prepare the patient*: ensure the patient has relevant information before the consultation (*section 3a*, in Textbox 4)
- *Prepare yourself*:
  - Be familiar with the IT system you will use (*section 3b*, in Textbox 4)
  - Ensure your environment is set up appropriately (*section 3b*, in Textbox 4)

During the consultation

- Starting the consultation: *use a written checklist* such as the one shown below, derived from the American Psychiatric Association's Telepsychiatry Toolkit [16] (*section 4a*, in Textbox 5):
  - *Name of clinician and patient* (eg, "Hello, I am Dr AB. Am I speaking to Mrs CD? Is there anyone else in the room you want me to be aware of?")
  - *Location of the patient* (eg, "Can you let me know where you are right now? It is important for me to know this before each session.")
  - *Immediate contact information for clinician and patient* (eg, "If we get cut off for any reason, how else can I reach you? If there is an emergency, you can also reach me at...")
  - *Expectations about contact between sessions* (eg, "Although we are connecting in real time here and now, I want to review how we will communicate outside of these video visits. [Insert plan and note you cannot respond in real time outside of these visits.]")
  - *Emergency management plan between sessions* (eg, "Should an emergency happen between visits, the plan that we have made is for you to [insert plan].")
- Alternative checklists are available at [17,18]
- During the consultation focus on: (*section 4b*, in Textbox 5)
  - *Communication* (include nonverbal communication, slow down your speech, allow pauses, look at the camera)
  - *Contingencies/backup plan* in case of difficulties (IT or clinical issues), with contact details confirmed
  - *Confidentiality* (confirm you are talking to the correct person and they are expecting a mental health assessment, who else is in each room, manage your own environment)
  - *Consent* (discuss the possible limitations of remote contact and security of the IT platform)
  - *Confidence* (in using technology, give a clear plan if IT fails and clear plan at the end for the next steps)
- *Physical examination* is possible but *may need to be adapted* (*section 4c*, in Textbox 5).
- Consider *combining with other digital technologies* (eg, apps, websites for information, platforms for recording data such as mood symptoms; *section 4d*, in Textbox 5)
- Consider *safety and emergency plans* (*section 4e*, in Textbox 5)

After the consultation

- *Document appropriately*, just as you would for face-to-face contact with additional details relevant to telepsychiatry (*section 5a*, in Textbox 6)
- *Are the any special considerations?* (eg, older adults, child/adolescent, cultural issues, assessments by more than one member of the team; *section 6a-d*, in Textbox 7).
- *Are there any training issues to consider?* (*section 7a*, in Textbox 8)

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Textbox 2. Background to telepsychiatry and what we know already (section 1).

1a. Definitions of terms relevant to telepsychiatry

- *Telehealth* is the delivery of health care from a distance using technologies such as telephone, email, computer, interactive video, digital imaging, and health care monitoring devices. It is a broad term that covers many different types of health care including not only clinical but also nonclinical medical services such as education, research, and administrative functions.
- *Telemedicine* is a subset of telehealth. It includes many medical subspecialties (eg, telepediatrics, telepsychiatry, teleradiology, and telecardiology). It describes the use of technology to provide clinical medical services when the health care provider and patient are separated by a geographic distance.
- *Telepsychiatry* is a subspecialty of telemedicine and includes psychiatric assessments or follow-up interviews conducted using telephone calls, and audio and video digital platforms (videoconferencing, video consultation).

1b. Is telepsychiatry a new skill and what do we know about it?

- Videoconferencing in psychiatry began during the 1950s. By the 2000s, it was accepted as effective but slightly different from in-person care, and research in outcome studies provided a platform for *practice guidelines* (eg, the American Telemedicine Association in the United States). It has been applied successfully to *many cultures and international settings*. Telepsychiatry is equivalent to in-person care in *diagnostic accuracy, treatment effectiveness, and patient satisfaction. Patient privacy and confidentiality issues parallel in-person care*. It uses *specialty expertise* effectively, facilitating patient-centered and integrated care.

1c. What is the evidence supporting telepsychiatry?

- Good outcomes depend on *high-quality clinicians, organizations* (including leadership, clinical, technical, and administrative teamwork), and *technology*.
- The evidence base is substantial, and outcomes have been measured as follows [19]:
  - *Feasibility* rating: outstanding (based on satisfaction and usability)
  - *Validity* rating: outstanding
  - *Reliability* rating: outstanding
  - *Satisfaction* rating: outstanding among patients, psychiatrists, and other professionals
  - *Cost and cost-effectiveness* rating: similar to in-person or better
  - *Clinical measures*:
    - Interviewing, assessment, cognitive testing, and others: outstanding
    - Disorders include depression, anxiety, psychosis, substance misuse, cognitive/attentional/behavioral (assistance for those with learning disabilities or dementia), personality/behavioral, and many others: outstanding
    - Settings well-studied include outpatient, primary care/medical: outstanding. Settings less well-studied include accident and emergency departments (A and E), prisons, in-patient units, and schools: similar to in-person care.

1d. Are there any settings where telepsychiatry might be better than in-person care?

- For *children and adolescents on the autistic spectrum, and adults with disabling anxiety it may be preferable*.
- A growing body of evidence suggests that telepsychiatry may have *significant added value in A and E***,** where it can improve liaison with outpatient mental health services and reduce transportation costs, in-patient and A and E use, and overall hospital costs. It can also improve care *within primary care settings and specialty care clinics, prisons, and nursing homes*.
- Previous work (before the coronavirus disease [COVID-19] pandemic) has described effective strategies for using telemedicine in *disasters and public health emergencies*.
- COVID-19 specific preliminary advice: consider using telemedicine as a strategy for *health care surge control using "forward triage"* to sort patients before they arrive at the hospital and reduce the number who need to be seen in person. *Respiratory symptoms* (as an indicator of early COVID-19) can be evaluated by telemedicine along with detailed *travel and exposure histories*. *Automated screening algorithms* can be built in with local epidemiological information to standardize screening. For example, more than 50 US health systems already have such programs, which could be adopted for use during the current pandemic.

1e. What treatment modalities can I use in telepsychiatry?

- Telepsychiatric interventions have demonstrated clinical utility with a variety of treatment modalities *including group, individual, and family therapies*. Evidence-based psychological treatments have yielded positive outcomes (eg, *cognitive behavioral therapy*, *interpersonal therapy*, *exposure therapy*, *psychodynamic psychotherapy*, and *dialectical behavioral treatment*), and *evidence-based pharmacological interventions* can be prescribed electronically after telepsychiatric assessments.

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Textbox 3. Guidelines and information governance on telemedicine and telepsychiatry (section 2).

2a. Are there guidelines I should be aware of?

- *UK guidance*
  - *Royal College of Psychiatrists (RCPsych; coronavirus disease [COVID-19] guideline)*:
    - Remote consultations should be *encouraged where safe and appropriate*.
    - Ideally, an *adjunct* to, rather than substitute for, face-to-face consultation
    - For *initial consultations*, this may be even more challenging but should go ahead where possible.
    - Show *sensitivity* to the patient's comfort level with technology
    - Do not disadvantage *those with lack of digital literacy or no access to digital platforms*
    - *Use of telephone consultations may be sufficient* for lower risk conversations or to ensure engagement with those who lack digital technology or skills.
  - *RCPsych, private and independent practice special interest group of the RCPsych (PIPSIG), incorporating General Medical Council (GMC) guidance (pre–COVID-19 guideline)*:
    - The *standards expected of doctors* by the GMC also apply to digital consultation settings.
    - Consideration should be given to *any potential limitations*: GMC guidance is that a doctor must be able to undertake an adequate assessment, establish dialogue, and obtain consent including consent to the remote consultation process.
    - Consider the *security of the system used* (see section 2b)
    - *Legal issues*:
      - Consider the *limitations* of telepsychiatry
      - The GMC *does not permit disclaimers* regarding the quality of a consultation.
      - You *may not be indemnified* for patients who are not in the United Kingdom.
    - *General areas to consider:*
      - Remote video consultation *may not be suitable for everyone*.
      - *When telepsychiatry would be used* (eg, should the first consultation be face-to-face)
      - How will you assess *suitability of the client* for telepsychiatric consultation?
      - How will you assess *suitability of the equipment*?
      - How often suitability would be *reassessed*
      - Consider *patient safety*: discuss and agree on supplying the contact information of a family or community member if needed
      - Whether you are *indemnified*
      - *Confidentiality issues*
      - The *right of the patient to withdraw* at any time
      - The taking and storage of *clinical notes and correspondence*
  - *General Medical Council (GMC) (pre-COVID-19 guideline):*
    - Consent and continuity of care are key issues to remember when you are advising or prescribing treatment for a patient via remote consultation.
    - *Consent*
      - *Explicit consent should be sought*: include the *right to withdraw* at any time; if the consultation is *recorded, consent is essential* and a GMC requirement; give patients *information about all the options* available to them; tailor the information you give and check that they have understood it. If you are not sure, consider whether it is safe to provide treatment and whether you have valid consent. You must ensure you can *assess a patient's capacity*. If a patient lacks capacity to make a decision, consider whether remote consultation is appropriate.
    - *Continuity of care*
      - Ask the patient for *consent to get information and a history from their general practitioner* and to send details of any treatment plan. If the patient refuses, explore their reasons and explain the potential impact of their decision on their continuing care. If the patient continues to refuse, consider whether it is safe to provide treatment and make a record of your decision.

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- *If you are providing services remotely, remember to*:
  - Follow GMC guidance on consent and good practice in prescribing, work within your competence, check that you have adequate indemnity cover, discuss with your responsible officer at appraisal.
- *Face-to-face treatment* may be preferable when there are complex needs or higher risk, you do not have access to the patient's medical records, you do not have a safe system in place to prescribe, you need to complete a physical examination, you cannot give the patient all the information, or you are unsure about the patient's capacity.

- *National Institute for Health and Care Excellence (COVID-19 guideline)*:
  - Minimize face-to-face contact by offering telephone/video consultations, reducing nonessential face-to-face follow-up, and using electronic prescriptions and different methods to deliver medicines to patients.
- *National Health Service (NHS) England (COVID-19 guideline):*
  - *Clinical teams should discuss with patients and families/carers in advance* about suitability and willingness to engage via technology.
  - Providers *may consider stratifying patients* where there is the highest risk of losing contact and agreeing how contact will be retained.
  - Where patients and carers live at a significant distance or are in isolation, *it may be appropriate to offer access to "virtual (ward) rounds"* (where a number of clinicians together consult remotely with a patient).
- *UK guidance on remote prescribing:*
  - *Follow GMC guidance* on prescribing (outlined above)
  - *Follow UK legislation* on prescribing [20]
  - *Follow local guidance* for remote prescribing (see [21] for an example)
  - *Additional prescription requirements* may be required
  - Consider other *licensing restrictions*

- *US guidance*
  - *Federation of State Medical Boards (pre–COVID-19 guidelines*):
    - 49 state boards (plus the medical boards of the District of Columbia, Puerto Rico, and the Virgin Islands) require physicians engaged in telemedicine to be *licensed in the state in which the patient is located*.
    - 12 state boards *issue a special purpose license, telemedicine license/certificate, or license to practice medicine across state lines* to allow telemedicine. 6 state boards *require physicians to register if they wish to practice across state lines.*
    - Payment arrangements vary across states for telemedicine.
    - [22] summarizes US legislation related to telemedicine in different states.
  - *Centers for Medicare and Medicaid Services* recently broadened access to Medicare telehealth services in the context of COVID-19 on a *temporary and emergency basis.* Medicare can now pay for visits via telehealth across the country, including in patient's homes, provided by doctors, nurses, clinical psychologists, and social workers. Prior to this, Medicare could only pay for telehealth on a limited basis (eg, in a designated rural area).
  - *American Psychiatric Association (Telepsychiatry)* does not give specific guidance but provides a practical "toolkit" of advice for general methods in telepsychiatry (not COVID-19 specific; sections are also referenced in relevant sections of this paper).
  - *Centers for Disease Control and Prevention (COVID-19 guideline*):
    - Explore alternatives to face-to-face triage and visits.
    - For example, use *available advice lines, patient portals, and online self-assessment tools*; identify staff to *telephone patients*; develop protocols so that staff can triage quickly; and have *algorithms to identify which patients can be managed by telephone* and which will need to be assessed in person.
    - Those with *respiratory symptoms must call before they leave home*, so staff can be prepared when they arrive.
  - American College of Physicians has produced an online course (open-access without certificate) on the use of telemedicine in general.
- *Singapore guidance*
  - *Singapore Medical Association (COVID-19 guideline*):
    - Assess the patient's profile for *suitability*
    - Explain the *limitations* of telemedicine before consent

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- Recognize the *challenges and limitations*
- Verify *patient identity* before proceeding and include in clinical documentation
- Take a *thorough and comprehensive history*
- Be confident that physical examination of the patient is unlikely to add critical information
- Be aware of the *clinical "red flags,"* which would trigger the need for urgent in-person consultation, such as increased acute risk to self or others
- *Clinical documentation* should be maintained at the same standard as an in-person consult.

2b. What information governance issues should I consider?

- *NHSX* has published *pragmatic guidance* on information governance since the outbreak of the COVID-19 pandemic, encouraging the use of videoconferencing to carry out consultations with patients and service users. The guidance states that it is acceptable to use tools such as Skype, WhatsApp, and Facetime as well as commercial products designed specifically for this purpose. The *consent of the patient is implied* by engaging in the consultation and clinicians should *safeguard personal/confidential patient information*.
- *Public Health England* strongly advise the use of remote access of NHS and essential services for anyone *over 70, with an underlying health condition, or who is pregnant* during the COVID-19 pandemic.
- RCPsych and PIPSIG suggest also considering:
  - Check that the *application is suitable* for a confidential psychiatric interview
  - Use a *secure system*
  - Have a *dedicated clinical account*
  - Make sure both parties have the *necessary technology*
  - Make sure both parties have the *skill to use the system*
  - Ask if an *advocate or carer* is present
  - Take *contact details* early in the proceedings
  - Agree who will contact whom in the event of a lost connection
  - Consider the *environment* beyond your video camera
  - Is there *anyone else* in the room with the clinician who cannot be seen? If so, introduce them and explain.
  - Does the *patient have anyone else* present in the room? Ask them to introduce themselves and move in front of the camera.
  - Consider the *volume* of loudspeakers and suggest that the patient does the same
  - Consider the use of *headphones*
  - Ask your *local information technology* (*IT*) *training/support team* for help (refer to [23])
  - Use a broadband internet connection of *at least 5 MB* upload/download
  - Choose a software solution that is compliant with your *local and national guidance*
  - Use a *secure, trusted platform*
  - Make sure your audio and video transmission is *encrypted* (follow local and national guidance)
  - Make sure your device uses *security features* such as passphrases and two-factor authentication
  - Use the latest *security patches and updates*; IT staff should approve of and manage your device.

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Textbox 4. Tasks before the consultation (section 3).

3a. What should the patient know before the consultation?

- Ensure the patient has *access to the technology* they require, including internet access, as well as the *skills to use it*. (If an administrator is setting up the call this could be something they can check or test as a trial run in advance.)
- Consider any problems with *accessibility*
- Do they have a *carer* who can facilitate the video consultation?
- Consider skills on a *case-by-case basis*

3b. What should I do to prepare in advance?

- Specific guidance is available through your *internal website or information technology training team*
- *Familiarize* yourself with the video consultation platform available
- *Test* the use of the platform and its features with a *colleague*
- *Make a note* of the features you might want to use and have a *summary sheet*
- *Restart* your computer every day
- *Close* any unnecessary programs and applications
- *Install recommended updates* from sources you trust
- Locate the volume control and *adjust the volume* or mute/unmute your speakers
- Use a *wired network connection* instead of Wi-Fi
- Sit a *comfortable distance* from the camera so your patient can see and hear you clearly
- Sit without windows or bright lights behind you
- Place your device on a *table or desk* facing you
- Keep *background noise* to a minimum

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Textbox 5. During the consultation (Section 4).

4a. How should I start the consultation?

- At the beginning of a video session with a patient, verify and document essential information and use a *checklist* (see Textbox 1).

4b. What should I try to do throughout the consultation?

- *Communication*:
  - Allow *nonverbal communication*: include your head, neck, upper body, and arms in the video screen
  - *Slow* your rate of speech and *pause longer* between sentences
  - Use *clear language*
  - *Look at the camera*, not at the patient's eyes
  - Use any *features* such as a shared "white board" function you are familiar with
  - *Lighting and background* are important—plain, darker static/uncluttered background with light directly on your face may help.
  - Take *more time* over the introduction and *signpost* what is going to happen next.
  - Adjust your *position* before you start
  - *Avoid* looking away
  - *Give ample time* for a patient to hear your question and to reply
- *Contingencies*:
  - Have a clear understanding of what to do when the consultation is not going well
  - Have a *backup plan* for managing any technical difficulties and provide this via email
  - Check that you have the right mobile *telephone number* and agree who will contact whom in the event of a lost connection
  - Brief the patient that if you do not feel able to complete an adequate assessment you will discuss what steps to take next
  - Ideally have this process *mapped out in front of you* until you are familiar with it
  - *Practice the "script"* that you might want to use for managing contingencies
  - Make sure the technology is *charged or plugged* in and have a backup device available
- *Confidentiality*
  - If the patient is new to you, verify *they are the right person* and that they are expecting to review *their mental health*
  - Check *who is in the room* with the patient
  - If the patient is in *a public place*, consider with them whether it is appropriate to continue
  - *Manage your own environment* and avoid sensitive, personal details in the background
  - *Blur the background behind you* if possible (or use a standard, preset background) to hide personal details and present a professional appearance
  - Use a *dedicated clinical account*
- *Consent*
  - Be clear about the *limitations* of the assessment or review and ask whether they have any concerns
  - Ensure that you are clear about the security of the platform you are using, that it is fit for the purpose and be able to discuss this
  - Discuss with the patient about recording the session, agree what might be useful and only for private use
- *Confidence*
  - Be confident in *using the technology* and have a *clear plan* of what to do if something goes wrong
  - Say if it is not possible to do a good enough review and develop a clear plan of what to do next

4c. How do I manage examinations that require physical interactions?

- Although physical examination may be restricted, a significant amount of information can be obtained remotely**.** For example, a good representation of a neurological exam can be obtained [24]. Some aspects may also require a family or staff member to help.

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4d. How can I integrate telepsychiatry with other digital technologies?

- Examples include health information websites, connecting with others through chat rooms or social media, using mental health mobile apps, email, or other technologies
- In general, *assess patients' use of other technologies*: what they use, how often, and why they prefer certain types. How does it influence their life or affect their understanding of their presenting problem? How does it affect the therapeutic relationship? Are they aware of safety issues?
- Key considerations about *website health information, texting (SMS), and email*:
  - Health information on the internet for the public *is rarely regulated*.
  - Seek out information from organizations/institutions/businesses that have some *oversight/expertise*
  - Remember to *verify* the identification of the person on the other end of the receiving technology
  - Be cautious about *privacy/confidentiality* issues when using new digital communications that are not secure
  - Regulate requests for other *contact between visits* and use email/text only for patients who maintain in-person follow-up
- *Social media and professionalism*:
  - Be mindful of *privacy, professional image, confidentiality, and expectations*
  - Follow professional recommendations about *professionalism and social media*
  - *Consider pros/cons of gathering information about patients via search engines and social media*
  - For blogs, microblogs, and comments: *"pause before posting"* to consider the impact
  - *Separate* personal and professional life
- Apps (for mental health and general well-being) *and other digital technologies*:
  - Mobile health apps have many potential advantages. They are easily *accessible*, have increasing *precision and therapeutic potential, and offer unique insights into physical and cognitive behavior*. However, they are developed and shared at a fast rate, so it is hard to assess *clinical efficacy, safety, and security*, and depends on the user so may not be as effective in clinical settings as in research**.**
- *Regulatory bodies for apps and digital technologies:*
  - *The US Food and Drug Administration regulates mobile medical apps* [25] but prioritizes monitoring and approval of mobile apps that directly control medical devices or function as these, which excludes most mental health–related resources from evaluation. A pilot in 2019 to "pre-certify" digital health developers who have already shown credibility/excellence in software design speeds up the process but may introduce bias. They are now piloting a program that accredits developers and software companies, not the technology itself.
  - The *National Health Service* (*NHS*) *Apps Library* [26] contains recommended digital health tools but does not regulate development or enforce data security standards and offers advice (rather than regulation) only.
  - The *NHS also collaborated with National Institute of Health and Care Excellence* (*NICE*) to establish credentials for digital health tools or *"Digital Health Technologies"* [27]. NICE assesses the evidence base as well as its financial footprint.
- Evaluation websites
  - Often show a lack of concordance between ratings of the same apps, use qualitative measures, and are quickly out of date
  - The *American Psychiatric Association app evaluation framework* [28] suggests that patients and clinicians ask questions across four areas, in order of descending importance: safety and privacy, evidence, ease of use, and interoperability [29]. This could also be supplemented with a self-certification checklist completed by developers or volunteers as a public, interactive approach.

4e. What about safety and emergency considerations?

- When evaluating patient safety, assess the level of *agitation*, the potential for *harm to self or others*, as well as any *safety hazards*. Be familiar with *where* the patient is located, including any *immediate staff* who will be available for emergency procedures, and ways to obtain *collateral information*. Technology can be used to manipulate the image and sound quality of the video to assess agitation or patient safety (see also section 6b in Textbox 7, for further guidance).

Textbox 6. What should I do after the consultation (section 5)?

5a. What do I need to document during and after the assessment?

- Clinical documentation as usual, with the addition of the *time, date, remote site location, time spent with the patient, the location and personnel*, as well as the *full clinical history, mental state examination, diagnosis, and treatment plan that you would normally document*

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Textbox 7. What about subspecialties and special situations (section 6)?

6a. Are there any special considerations for older adults?

- *Positive outcomes have been described for* satisfaction, validity/reliability, and clinical outcomes, and *satisfaction has been superior* for patients, families, carers, and providers. There has been effective use in the treatment of *depression, anxiety, dementia/cognitive impairment, and associated behavioral problems*.
- Clinicians need to make a few key changes: it is helpful to have *previsit accounting* of general events and the patient's attitude, comments, complaints, sources of information, and clinician observations, and the clinical examination *may require staff or family assistance* (see section 4c in Textbox 5).
- The benefits are that *family and carers are appreciative of services, assessment, and cognitive intervention, and outcome results are similar to in-person care*. In addition, the clinician is part of an *interdisciplinary team* who can all be easily and efficiently connected through telemedicine and deliver specialty expertise for *nursing home and home outreach.*

6b. What about child and adolescent patient consultations?

- *Evidence base:*
  - Telepsychiatry services have been successfully used with diverse populations *across diagnoses (eg, depression/attention-deficit/hyperactivity disorder/tics/obsessive compulsive disorder/autism/psychosis) and settings (including urban/rural, community/school/home/inpatient/forensic [juvenile justice])*. Multiple studies have shown its *feasibility*. Referrers, psychiatrists, and families report *high satisfaction* with telepsychiatry services. The ability to establish a *therapeutic rapport* with youth and families through telepsychiatry is well established.
- *Practical suggestions in telepsychiatry with young people*
  - *Comment on real features* in the patient's room so they know you can see and hear them.
  - *Greet patients*: How are you? Can you see and hear me OK?
  - *Replace the handshake* (eg, with a wave or fist bump)
  - *Use nonverbal communication*: facial expression, gestures, eye contact, tone of voice
  - *Ask about physical comfort*: privacy, temperature, lighting
  - *Adjust your voice*: slower and clearer, with longer pauses after questions to avoid talking over each other.
  - *Nod and smile frequently*
  - *Maintain eye contact* (look at the camera)
  - *Direct the family arrangement* at the beginning so all remain visible throughout the consultation and make sure the lighting is adequate
  - Use the *zoom and wide function* if needed
  - Position yourself so your *eyes appear one-third of the way down from the top of the screen*
  - Arrange the patient's picture on your screen *as close as possible to your camera* (to allow for "relative eye contact")
  - *Keep both cameras still*
  - *Ensure adequate lighting*
- *Safety*
  - Establish at each site what the *infrastructure and emergency management protocols* are in place, which can be adapted
  - Ensure that the *contact information* for parent(s)/caregiver(s) are up to date and available
  - In *hospital and community settings* these will be well established, but in *nontraditional settings* (eg, shelters for families and children), these will need to be developed and established before starting.
  - Emergency management is a *team effort*: *identify on-site staff* who can help by physically intervening during the emergency. Community resources must be identified to incorporate into *emergency management protocols and the patient's care plan*.
  - Safety and mobilization procedures at a patient site should be both *accessible to staff for review and an integral part of their training*.
  - *Manipulate the technology* to maximize video and audio quality to assess signs of agitation, substance use, and medication side effects.
  - If technology falters, have *a preplanned backup emergency management plan* (eg, calling a named coordinator at site to enter room and ensure safety)
- *Training*
  - Official guidelines for training competencies have not yet been established.
  - *Primary skill areas* (see section 7a in Textbox 8) all have special applications for children and adolescents.
  - Clinicians need to learn to *increase nonverbal communication by approximately 15-20%* for effective use on screen.

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- Be *collaborative* with all staff at patient site across disciplines to integrate into the team remotely
- Be sensitive to *cultural and community issues*
- *Help staff* to be comfortable with telepsychiatry
- *Be flexible in your role* in the child's system of care and vary your role depending on the resources available at the patient site
- *Understand legal/policy/regulation guidelines*

- *Developing a therapeutic space and establishing rapport*
  - *Clinician's room*:
    - *Minimize detail* (to facilitate the camera's focus and not distract the patient)
    - *Do a room tour* to show privacy and welcome patient and family
    - *Show the therapist from waist up* (like a news broadcaster) to include all nonverbal communication
    - Include in frame *any tools or gadgets you intend to use*
  - *Patient's room*:
    - *Large enough* for patient plus family plus any caregivers/staff attending
    - *Large enough* to assess patient's physique, motor skills, behavior, mental status examination, gross motor and fine motor skills, affect, and rapport
    - For one participant, they should sit *2-4 feet* away from the camera. For each additional participant, *another 2 feet back* from the camera will keep all participants in the screen's framing.
    - Camera needs to be *far enough* away that young children are always in shot, even if they move to play on the floor
    - Consider the *selection of toys*: useful as a distraction but avoid noisy toys and those with lots of pieces; ideal is a small table with paper and crayons
    - In general, *control use of electronics* by patients during the interview but be flexible (eg, for teens)
    - Use *creative ways to establish rapport* (eg, comment on the child's toys/clothing/room features to show you can really see them, check they are happy with the room layout, ask them to check their own image on the screen)
    - Two-thirds of the meaning of a consultation comes from *nonverbal communication.* It is often not what is said, but how it is said, that matters most to our patients.
    - Be creative with *seating arrangements*: children can sit next to or between their parents, on their lap, or in front on a chair or on the floor.
    - If *a hyperactive or autistic child* cannot remain in the camera frame, keep the parent(s) in and call the child back to the camera when they need to answer a question.
    - If a child *refuses to sit* within the camera frame and behavior management strategies do not work, consider seating them further from the camera but in the frame, or allowing more privacy for part or all of the session.

- *School-based telepsychiatry*
  - There are *many advantages*: reduced travel time for psychiatrists, reduced parents' work leave, reduced child absence from school, increased attendance at psychiatry appointments, facilitates a team-based approach with earlier interventions and better compliance. However, the following should be considered: finding a *private/secure space, understanding and respecting school staff, policies and structures, knowledge of existing school support and learning support, continuity outside school* (evenings, holidays, etc). Ideally, clinicians should use a *hybrid approach* with some in-person meetings at the beginning. Clinicians should identify which staff will support with practical arrangements and in the meetings if needed.

- *Forensic (juvenile justice) settings*
  - Can be *challenging*: some young people are reluctant to speak with psychiatric and other mental health staff, particularly if sessions interfere with their participation in recreational activities or there are concerns about staff being present and confidentiality.
  - Telepsychiatrists must *define their role* in the youth's system of care and treatment (ie, to clarify a forensic vs direct care role).
  - *On-site therapists* (but not correctional staff) typically participate in sessions to aid the psychiatrist in obtaining pertinent patient information and to facilitate clinical care.
  - *Background information and reports* may be available in advance, and these should be used proactively in the interview.
  - Telepsychiatrists should be familiar with regulations regarding *consent to pharmacological treatment of minors in forensic settings*.
  - Telepsychiatrists may ask staff to provide a *"virtual tour"* of the facility with a mobile device to ensure privacy, security, management of mental health records, and other concerns.

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- *Cultural issues*
  - See section 6c; note that *family structure* may differ in different cultures; take care to use *professional interpreters*, not family members
- *Behavior management*
  - Evidence-based behavior management training can be offered via telepsychiatry in clinic and home settings.
  - Psychiatrists can both model and coach parents on the concepts of behavior management in real time.
  - In clinic, staff can clarify subtleties in the child's behavior that may not be evident through videoconferencing.
  - Treatment can be offered in naturalistic settings such as the home, potentially providing more ecologically valid assessments and interventions.
  - Develop a *safety and crisis plan* (including contact lists of trusted family/friends, local general practitioner, and emergency services) at the beginning in case the child's behavior becomes unmanageable or unsafe during a session

6c. How should we consider cultural issues?

- Be *knowledgeable about the culture(s) and environments* in which care is provided
- Be aware that cultural differences can be highlighted by the patient and provider locations
- Assess how a patient's cultural background influences their *comfort and use of technology*
- Consider how best to *adapt* their communication style and clinical processes

6d. How do we manage a patient interaction when more than one member of the team is present on the call?

- It is important to incorporate each member in the process. Each member of the team at both sites should *introduce* themselves with their name, title, and role and make sure that the patient understands the nature of the encounter. After interviewing and examining the patient, the clinician should *check in with each team member* for their input and to *clarify the diagnostic impression and feasibility of a treatment plan*.

Textbox 8. Training and service needs (section 7).

7a. How can I prepare to be a good telepsychiatrist?

- *Useful previous experience* includes settings with communication skills and adjustments for the setting, audience, and objectives of the event (eg, public speaking, acting, coaching, and media experience)
- *General considerations*
  - *Practice and self-observe* (for example, by recording a practice interview with a colleague)
  - Focus on *patient-centered, respectful, active listening, expressing empathy, cultural sensitivity, use of nonverbal behavior and replace physical contact with welcoming statements*
  - In team assessments, remember *introductions, engaging others* to get involved, and *giving directions or ground rules* to provide *structure*
  - Use elements of *good public speaking*
  - *Plan* and manage the session, be *organized*, consider an *opening script* for new assessments
- Clinical considerations
  - Maintain the *standard of care and quality* of service
  - Document *informed consent*
  - *Engage* the patient and put them at ease
  - *Previsit preparation* is helpful
  - *Allocate enough time*: video interviewing takes longer and requires more concentration
  - *The setting/room*: both ends private/secure, announce anyone who is unseen to the patient, check lighting, and check equipment
  - Check in with the client at the *end of the session*
  - *Minimize interruptions* and reduce the amount of information dispensed
  - *Dress appropriately* and *project your voice and other gestures about 15% greater* than in-person
  - *Adjust to age* (eg, toys and table for kids; support person for older adults)
  - *Adapt your clinical examination* where needed
  - *Encourage family members* to attend if possible and the patient agrees

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We used a synthesis of the guidelines to answer specific questions generated by clinicians on telepsychiatry and related digital technologies using the following sources: *American Psychiatric Association (APA), CDC, CMS, FSMB, General Medical Council (GMC), Massachusetts General Hospital Department of Psychiatry, NHS Wales, NHSX (a joint team from the Department of Health and Social Care and NHS England and NHS Improvement), the National Institute for Health and Care Excellence (NICE), NMC, Public Health England, Royal College of Psychiatrists*, and *Singapore Psychiatric Association.*

The full list of the sources searched, specific sources used, and further detail with webpage links on each point are contained in Multimedia Appendix 1.

Discussion

In this paper we have summarized the available evidence base for guidelines in telepsychiatry across a wide variety of treatment modalities and populations. Telepsychiatric treatment has not previously been implemented on the scale and speed demanded by the current COVID-19 crisis. This is, at least in part, because mental health clinicians feel a lack of detailed knowledge and experience in telepsychiatry, and often express concerns about establishing rapport and therapeutic alliance [12], and key areas such as assessing risk and safeguarding [7]. Developing skills in telepsychiatry, including competence in creating a so-called "webside manner" [30] requires knowledge, training, and experience. Building confidence and knowledge is the first important step and requires easy access to a reliable source of existing information, such as that summarized in our synthesis of guidance.

Training clinicians is the next key area, both in the practical use of remote consultations and in the use of digital interventions, treatments, and mobile apps. Frameworks for training exist [31,32] but have not been widely implemented in practice. However, teaching experience such as with psychiatry residents has been positive, and there are already many successful examples of teaching telemedicine [10]. Training takes time, so it does not offer an immediate solution to the current crisis, but it will build capacity for increased access to care for the mental health sequelae of the current crisis and help to prepare for the next.

Training for clinicians is only one part of the story. It is also important to ensure that all patients have access to telepsychiatry. Many people may be prevented from accessing digital health, either because of a lack of skill or competence, or because of a lack of suitable access to reliable internet connections, smartphones, or similar platforms [10]. These reasons affect particularly the most vulnerable in society; issues such as age, language, cultural background, and homelessness can all contribute. Training programs for patients [33] have been effective in increasing patients' confidence and competence, but practical access to relevant technology is a wider societal issue. Clinicians also need to be aware that telepsychiatry is a tool for consultation, which needs to be adapted flexibly and creatively to each patient's needs, preferences, and circumstances. As the guidelines in section 2a of Textbox 3 outline, a pragmatic approach needs to be taken, particularly during the constraints of the COVID-19 pandemic; for example, telephone consultations may be used to facilitate engagement with those who lack access to digital technology or the skills or confidence to use video platforms. Alternatively, a hybrid or blended approach (as discussed later) may be the best option for some patients after weighing the potential risks and benefits for an individual, even during the COVID-19–related constraints imposed on in-person contact. Careful preparation in advance, as outlined in section 3a of Textbox 4, can also help to ensure that time spent during the consultation is as comfortable and effective for the patient as possible. Part of this preparation should also be to remind patients that their usual rights (for example, for a second opinion, to make a complaint, or decline a treatment) are the same whether the meeting is in person or delivered remotely.

As well as clinicians and patients, organizations providing services in mental health care also need to implement changes to reflect the acceptance of telepsychiatry as a valid and beneficial treatment option. In the short-term response to the crisis, there have been examples of organizational changes such as the lifting of state and federal regulation in the United States that had previously been barriers [3]. Longer term, it is unclear whether these changes will return to pre–COVID-19 rules or not. To ensure that these changes continue, clinicians and organizations need to campaign proactively for long-term change [3]. Central to this will be widespread dissemination of evidence-based guidance to clinicians who can then gain the confidence and competence needed to implement telepsychiatry and to extend its use beyond the short-term crisis. Research on the implementation of telepsychiatry will also need to assess outcomes and their cost-effectiveness, to support long-term change to systems of payment and insurance [12].

One route to demonstrating the clinical efficacy and cost-effectiveness of telepsychiatry, particularly as a longer-term strategy, will be to assess its use not only as a replacement for face-to-face care but also as a possibility for an enhanced level of care. It offers options for patients to personalize their treatment in choosing how they want to see their psychiatrist. In the aftermath of COVID-19, many patients may choose to continue with remote consultation because of its advantages such as privacy (reducing stigma) and convenience. For a small minority, particularly those with psychosis or persecutory beliefs, remote psychiatry may seem less trustworthy than in-person care. Post–COVID-19, patients will be able to individualize their care, balancing the pros and cons for their own treatment, with many opting for a hybrid model across different remote and in-person settings. Clinicians will need to balance the strengths, limitations, and adjustments needed for each approach and feel competent in using all media [34].

Telepsychiatry also offers options for easily combining with other digital technologies. These include platforms for monitoring symptoms such as mood monitoring systems [35] or combining care with apps [34]. Smartphone apps offer advantages in accessibility, insights into physical and cognitive behavior, and a range of resources designed to aid health. However, there are challenges to be addressed; clinicians and patients need to assess these digital resources for efficacy, safety,

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and security so that only high quality and clinically effective apps are offered to patients [36]. Although there are app comparison sites (for example, [37]), the volume of work in appraising apps is ever increasing, so sites often show a lack of concordance between ratings of the same app, may use qualitative measures, and are quickly out of date. For example, the initial version of the NHS Apps Library [26] was withdrawn after criticism of a lack of consistency in evidence of effectiveness, privacy, and confidentiality. The library was relaunched but now offers advice rather than regulation. The APA app evaluation framework [29] suggests that users (patients and clinicians) ask questions across the areas of safety and privacy, evidence, ease of use, and interoperability, supplemented if possible with a self-certification checklist completed by developers or volunteers on a frequent basis. Ideally, this would mean that a patient could filter categories for app choices that meet their requirements across the areas assessed. Apps are twice as effective when used with a clinician [38], so their combination with telepsychiatry presents exciting opportunities. Similarly, the addition of apps to provide lifestyle interventions [10] is particularly relevant during the current restrictions and will be an important opportunity both during the acute crisis of COVID-19 and afterwards.

Some potential limitations of our work should be acknowledged. The original search was restricted to English language sources, but international collaborators are producing translations (for example, in French, Turkish, and Chinese) and adaptations for local use before dissemination. Any summary of guidance needs to reflect the global perspective, as implementation and advice on telemedicine and telepsychiatry vary. Balancing guidelines across countries is a key area of concern when producing a summary of evidence. UK guidelines on telepsychiatry (for example, those from the Royal College of Psychiatrists and GMC) are generally more cautious and emphasize possible constraints, whereas US views are more expansive, with stronger emphasis on the evidence base and the potential benefits of combining with apps and other technologies. Although valuable COVID-19 specific mental health treatment guidance is starting to be generated (for example, in the UK, COVID-19–specific guidance in how to remotely deliver the NICE recommended cognitive therapies for PTSD, social anxiety disorder, and panic disorder [39]), the vast majority of guidance and evidence on use of telepsychiatry is based on the pre–COVID-19 era. Although there is some preliminary data on the use of telepsychiatry in other disasters [40], the COVID-19 crisis is different to previous pandemics. Thus, this synthesis of guidance contains a combination of pre–COVID-19 guidelines mixed with recent crisis guidelines. Although the COVID-19 guidelines are more pragmatic and perhaps more relevant, this combination does produce inconsistencies (for example, on whether consent to telepsychiatry meetings is implicit or needs to be explicit).

Most of the guidelines focus on practical implementation in general adult psychiatry (with some specific guidelines for younger and older patients). Although this is helpful, if telepsychiatry is to be integrated into routine care in the longer term, then guidance also needs to focus on those areas and patient populations who may be more difficult to engage, for example, those with learning disabilities, psychotic symptoms including persecutory beliefs, personality disorders, and eating disorders. In addition, the guidelines do not clearly differentiate between initial assessment and follow-up. Although the general principles may be the same, the focus of these different encounters may vary, and these are not clearly defined. The existing guidelines do not specifically include the concept of hybrid or blended care, which is the route most likely to be effective in the longer term. This involves the combination of telepsychiatry with not only in-person care but also other digital technologies. Frameworks for telepsychiatry alone are well established and are more preliminary for digital technologies, and there is no clear guidance on the combination of all. Hybrid care will be key in the way forward post–COVID-19 to allow clinicians and their patients to choose the individual combination of care that offers the most advantages. To do this, mental health clinicians need to become adept at managing hybrid clinician-patient relationships and have a detailed understanding of the advantages and limitations of all the tools they use to care for patients [34].

The acute COVID-19 pandemic and its aftermath present new challenges. Although the benefits of implementing telepsychiatry are clear, this can only be fully realized if clinicians see this as an opportunity for not only a short-term solution to a crisis but also a cultural shift and opportunity to integrate the benefits of telepsychiatry into a model of blended care in the future. The acute crisis can be an opportunity to develop and implement digital mental health in a collaborative environment between patients, carers, and clinicians. This is an important moment where mental health professionals and health care providers can embrace telepsychiatry and introduce new and innovative strategies to make long-lasting improvements in the access to and quality of mental health care provision.

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Conflicts of Interest

AC has received research and consultancy fees from the Italian Network for Paediatric Trials, the Cariplo Foundation, and Angelini Pharma outside the submitted work. KS, OM, and EO have nothing to declare.

Multimedia Appendix 1
Supplementary material.
[DOCX File , 22 KB - mental_v7i8e21108_app1.docx]

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Abbreviations

APA: American Psyciatric Association
CDC: Centers for Disease Control and Prevention
CMS: Centers for Medicare and Medicaid Services
COVID-19: coronavirus disease
FSMB: Federation of State Medical Boards
GMC: General Medical Council
NHS: National Health Service
NICE: National Institute of Health and Care Excellence
NIHR: National Institute for Health Research
NMC: Nursing and Midwifery Council
PTSD: posttraumatic stress disorder
SARS-CoV-2: severe acute respiratory syndrome coronavirus 2

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Original Paper

Electronic Mental Health as an Option for Egyptian Psychiatry: Cross-Sectional Study

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Abstract

Background: Egypt is a country of nearly 100 million citizens, and there are less than 1000 registered psychiatrists. The mental health care system is under resourced and nearly inaccessible for the majority of the population. In addition, youth under the age of 25 years represent 50% of Egyptian citizens; however, there are no specific services addressing their unique needs. How can the needs of the largest population in the Middle East be effectively addressed? Is a web-based framework an option for Egyptian psychiatrists to serve the population?

Objective: The aims of this study were to better understand the opinions of psychiatrists on the current state of mental health care services in Egypt and their current knowledge on electronic mental health (EMH); assess the attitudes of Egyptian psychiatrists toward web-based interventions and telemedicine for mental health; and identify perceived advantages and barriers of EMH development in Egypt.

Methods: A cross-sectional survey was conducted online among 640 Egyptian psychiatrists. It included a total of 36 items within a set of 16 questions asking about EMH literacy, integrating EMH into the mental health care system, and the perceived priorities and barriers of EMH. The sampling was supported by Tanta University, a large academic institution close to Cairo. Statistical analysis was performed using SPSS 25 (IBM Corp). Descriptive statistics, the chi-square test, the independent sample *t* test, and analysis of variance were applied.

Results: A total of 188 participants responded (response rate of 29.4%), of which 54.2% (102/188) were female and 54.3% (102/188) were between 30 and 45 years old. Less than half of the participants thought that the current health care system was efficient for adults (69/155, 44.4%), and even less thought it was efficient for youth (44/155, 28.3%). Almost all participants agreed that EMH would be beneficial for patient care (147/155, 94.8%) and that integrating EMH into the current health care system would be a good idea (118/155, 76.2%). The highest rated utility of web-based solutions was documentation, followed by psychoeducation and communication with professionals. The main advantages were to improve access to care in rural areas of the country and its convenience.

Conclusions: There is scarcity of mental health resources in Egypt. Egyptian psychiatrists are interested in EMH and believe web-based platforms can become part of the solution for the Egyptian mental health care system.

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KEYWORDS

psychiatry; e-mental health; Arab countries; mental health care; psychiatrists; health care providers

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Introduction

Arab countries generally have a higher burden of mental health disorders, as measured by the disability-adjusted life years, relative to the rest of the world [1,2]. In fact, of all the countries within the Eastern Mediterranean Region, Egypt is the only country to have a burden of mental illness equivalent to the global level [3]. The General Health Questionnaire administered to over 25,000 individuals in Egypt estimated a prevalence of 24.9% for psychiatric comorbidity, and these mainly included mood (depressive), anxiety, and substance use disorders [4]. Importantly, people with mental illness in Egypt and other Arab countries tend to somaticize their psychological symptoms and often seek traditional healers for most types of mental and physical health problems owing to societal acceptance, affordability, and accessibility [5,6]. Stigmatizing attitudes toward people with mental illness contributes to a reluctance to seek psychiatric care, and similarly, expensive and inaccessible psychiatric care deters individuals from the mental health system, which is characterized by a relevant shortage of human resources [5,7]. According to the Egyptian governmental mental health system assessment in 2018, there were 705 registered psychiatrists, 117 psychologists, and 224 social workers serving a population of nearly 100 million citizens [8]. In contrast, the World Health Organization recommends that the total number of psychiatrists, psychologists, and social workers in Egypt be about 5600, 24,000, and 1600, respectively [9]. Additionally, there is not only a relevant shortage of human resources, but also an unequal distribution of these resources throughout the country, with a much higher density of psychiatrists and nurses in or around Cairo compared with the rest of the country [9]. The lack of sufficient mental health staff and their unequal distribution between rural and urban areas play important roles in the under-developed mental health system of Egypt. To increase accessibility and provide higher effectiveness with the limited available resources, the mental health care system needs a new approach.

Electronic mental health (EMH) could be a strategy for improving psychiatric mental health care in Egypt. EMH is defined as mental health services and information delivered or enhanced through the internet and related technologies, and it is an expanding field with some core components as follows: psychoeducation, lifestyle mentoring, prevention, and treatment [10-12]. These technologies can help provide quality care to individuals by improving awareness, early assessment, and targeted intervention, as well as help reduce the expenditure of the health care system [13,14]. Similarly, the use of EMH through web-based psychological interventions has been shown to be effective, especially for depression and anxiety [15]. Moreover, computerized cognitive behavioral therapy and face-to-face cognitive behavioral therapy have been found to be equally beneficial to patients [16,17]. Finally, EMH allows for immediate crisis intervention, recovery, and peer support, and can be particularly useful at targeting youth [18]. Therefore, with these clear advantages, EMH would be able to help transform the Egyptian mental health care system and compensate for the low amount of human resources. However, its feasibility and implementation depend on its acceptance by specialists and other professionals in the system.

At present, individual health care apps are available in Egypt; however, there is no public implementation of EMH in health care. Available mobile apps are typically administrative in nature and help facilitate health care services, such as booking appointments with doctors and delivering medication from the pharmacy [19]. There are minimal resources that offer video conferencing with medical professionals, and those that are available have a fee-for-service model [20]. Given the increasing availability of smartphones and the increasing use of the internet, increasing EMH capacity is feasible within the Egyptian context. For instance, internet penetration has reached almost 50% of the population, with an estimated 49.23 million internet users in 2018 [21]. Egypt is a leader in technology and media for the Arab world, and EMH implementation is realistic and attainable [22]. However, support from health care providers is essential for widespread adoption of EMH tools.

Assessing the willingness and motivation of care providers to accept web-based mental health programs is an important initial step for the paradigm shift toward EMH. To answer this question, a survey was distributed and completed by Egyptian psychiatrists in order to assess their view of the current health care system, their readiness for EMH, and the perceived advantages, barriers, and priorities of EMH in Egypt. The core components of EMH assessed in the survey included screening, psychoeducation, prevention, assessment, skills training, treatment program, follow-up, peer support, communication with professionals, documentation, and informed decision-making. We aimed to better understand the opinions of psychiatrists on the current state of health care services in Egypt, their knowledge of eHealth, a topic which is not currently in the curriculum of any medical school, and their perception of how EMH could be used to improve the current system of care. Results from this survey would help conceptualize an effective, attractive, and appropriate web-based service in order to encourage a paradigm shift toward EMH within the Egyptian health care system. This survey is the first to examine the attitudes of care providers toward web-based interventions and EMH in Egypt.

Methods

Survey Design

The survey was developed by mental health researchers from the University of British Columbia and Tanta University, based on pre-existing questionnaires, expert opinions, and pilot testing by members of the research team. The preliminary survey was subsequently used in a workshop with 50 psychiatrists at Tanta University during a conference in March 2019 for feedback and criticism from the target population. Based on their responses, some questions were modified in order to improve the overall quality of the questionnaire and increase the legibility and coherency of the tool. The study received approval from the Tanta University Ethics Board (31674/07/17).

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Recruitment

We contacted 640 psychiatrists who were on the mailing list of the Egyptian Psychiatric Association and the Tanta University Psychiatric Department. Survey response was also encouraged during the annual psychiatric conference hosted by Tanta University in collaboration with the Egyptian Psychiatric Association. Given the number of registered psychiatrists in Egypt (less than 800 in 2018), the mailing list coverage was extensive and reached almost all registered psychiatrists within the country [8]. They were provided with an online link that directed them to the questionnaire hosted on Qualtrics Surveys [23]. Participants did not receive any reimbursement for their participation, which was entirely voluntary and anonymous. Information regarding the study purpose, research team, data collection, and confidentiality were included in the electronic consent form, which participants needed to provide before proceeding to the questions.

Survey

The survey consisted of 36 items organized within 16 questions (Multimedia Appendix 1). Depending on participants' previous answers, they may be asked less than 16 questions owing to skip logic. The survey was in English, as medical education in Egypt is delivered in English [24]. The internal consistency of the survey was measured by Cronbach α, which showed acceptable reliability (α=.81). The survey took between 10 and 15 minutes and consisted of both quantitative and qualitative questions organized into five broad domains as follows: (1) demographics; (2) EMH literacy and frequency of technology use; (3) efficiency of the current system of care for youth; (4) readiness to integrate EMH into the health care system; and (5) perceived priorities and barriers of EMH in Egypt. Only three questions out of 19 were open-ended, which allowed participants to elaborate on the possible drawbacks and priorities of EMH and their personal preferences for EMH in Egypt. All other questions were closed-ended and were presented as 5-point Likert scales or multiple-choice questions.

Data Collection

The survey was available online on March 28, 2019, and kept active for 3 months. In order to avoid duplication, participants who had completed the survey were unable to submit responses again. Responses were collected electronically by Qualtrics Surveys and stored in a password-protected account. The data were stored and managed according to the data protection guidelines of the University of British Columbia. Throughout the study, the privacy of the participants was respected, and all data gathered were strictly confidential and completely anonymous.

Data Analysis

Chi-square and one-way analysis of variance tests were performed for inferential analyses using a significance level of .05. Descriptive and inferential statistical analyses were performed using SPSS 25 (IBM Corp). The results from the web-based survey have been reported according to the Checklist for Reporting Results of Internet E-Surveys (CHERRIES) [25].

Results

Sample

The web-based survey was sent to 640 psychiatrists in Egypt, and of these, a total of 188 completed the survey (29.4% response rate, 90% completion rate). Given that there are less than 800 registered psychiatrists in Egypt, this sample represents nearly 25% of all registered psychiatrists in Egypt. More than half (102/188, 54.3%) of the participants were between 30 and 45 years old, while 27.7% (52/188) of the participants were over 45 years old and 18.0% (34/188) were under 30 years old. The sample was quite evenly split between females and males (54.3% [102/188] of the participants were female and 45.7% [86/188] were male).

Technology and EMH

Of the 158 participants who responded about technology use, most said they used technology either "once daily" or "several times a day" in their everyday life (125/158, 79.3%) and at work (85/158, 53%) (Table 1). Younger participants used technology in their daily lives and at work significantly more than older participants (P<.001 and P=.02 respectively).

Of the 155 participants who responded about the efficiency of the current system and integration of EMH, only 69 (44.4%) perceived the system of care for mental health as either "extremely efficient" or "somewhat efficient" and only 44 (28.3%) reported it to be efficient for youth (Table 2). No statistical differences were found with regard to age or gender. Over half (81/155, 52.2%) of the participants said that they had current understanding and knowledge about EMH, and almost all (147/155, 94.8%) of the participants agreed that it would be beneficial for patient care. The vast majority (118/155, 76.2%) of the participants either "strongly agreed" or "somewhat agreed" with the idea of integrating EMH into the health care system (Table 2). With regard to technology use, the majority (138/155, 89.0%) of the participants agreed that the internet would be a good addition to face-to-face therapy for psychoeducation and psychosocial interventions. Additionally, 69.7% (108/155) of the participants said that they would integrate web-based mental health resources with conventional therapy if some trustworthy national internet platform for mental health and substance is present. Finally, almost all (145/155, 93.5%) of the participants said that web-based mental health resources would be useful in delivering mental health care to youth, specifically owing to their use of technology and familiarity with it.

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Table 1. Technology use (N=158).

Characteristic	Value, n (%)	Age (years), mean (SD)
Use of technology in everyday life		
Not at all	2 (1.2%)	70.0 (0.0)
Rarely	6 (3.7%)	44.0 (21.6)
Several times a week	25 (15.8%)	50.9 (9.2)
Once daily	35 (22.1%)	43.2 (9.3)
Several times a day	90 (57.2%)	37.5 (8.8)
Use of technology at work		
Not at all	9 (5.7%)	47.3 (18.5)
Rarely	10 (6.3%)	49 (16.9)
Several times a week	54 (34.2%)	42.4 (11.3)
Once daily	35 (22.2%)	43.9 (8.6)
Several times a day	50 (31.6%)	36.7 (8.1)

Table 2. Efficiency of the current system and integration of electronic mental health (N=155).

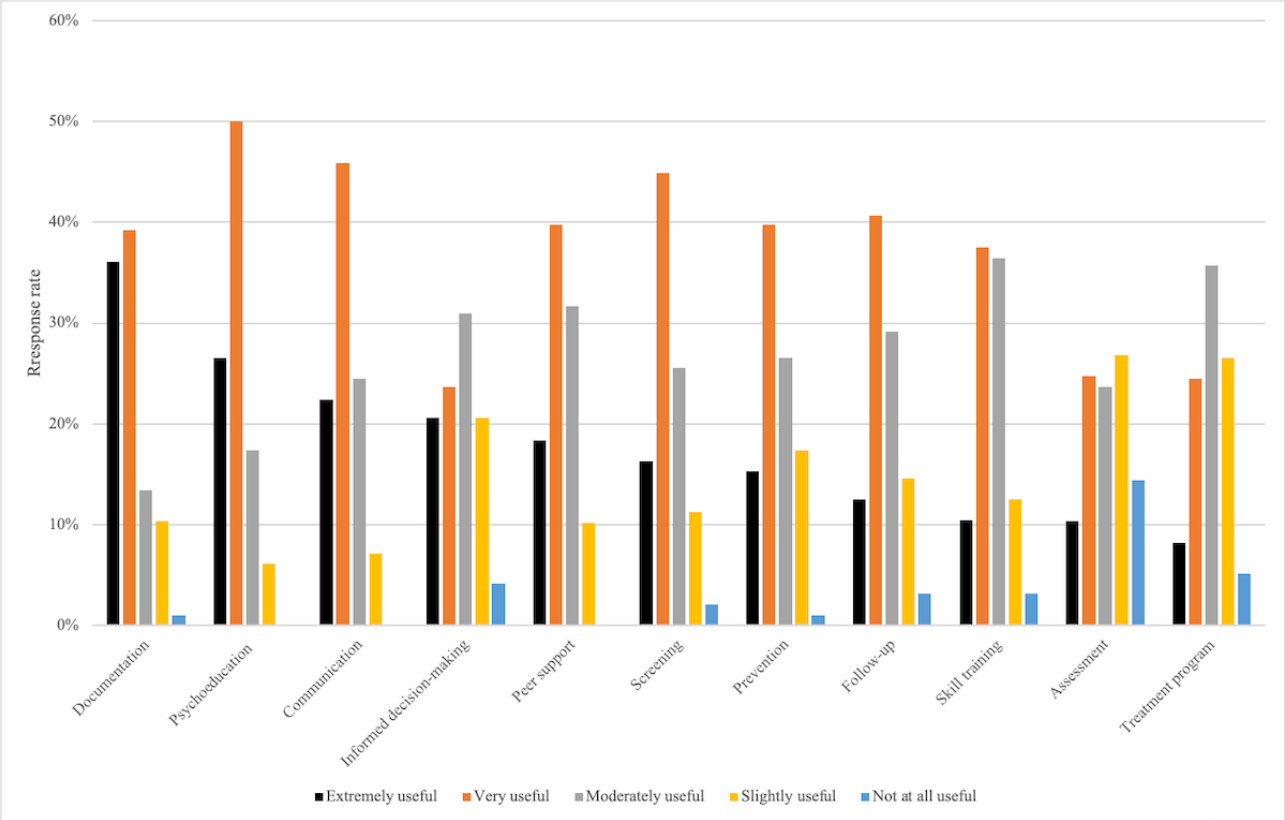
Characteristic	Value, n (%)
Efficiency of the mental health care system	
Extremely inefficient	17 (10.9%)
Somewhat inefficient	41 (26.5%)
Neither inefficient nor efficient	28 (18.2%)
Somewhat efficient	63 (40.6%)
Extremely efficient	6 (3.8%)
Efficiency of the system of care for youth	
Extremely inefficient	35 (22.6%)
Somewhat inefficient	50 (32.3%)
Neither inefficient nor efficient	26 (16.8%)
Somewhat efficient	39 (25.1%)
Extremely efficient	5 (3.2%)
Integration of EMH[a] in the mental health care system	
Strongly disagree	1 (0.6%)
Somewhat disagree	18 (11.6%)
Neither agree nor disagree	18 (11.6%)
Somewhat agree	79 (51.0%)
Strongly agree	39 (25.2%)

[a]EMH: electronic mental health.

The perceived areas of health care that could benefit the most from EMH are shown in Figure 1. Out of the 150 participants who answered these questions, EMH was thought to be extremely useful for documentation (55/150, 36.7%), psychoeducation (40/150, 26.7%), and communication (34/150, 22.7%).

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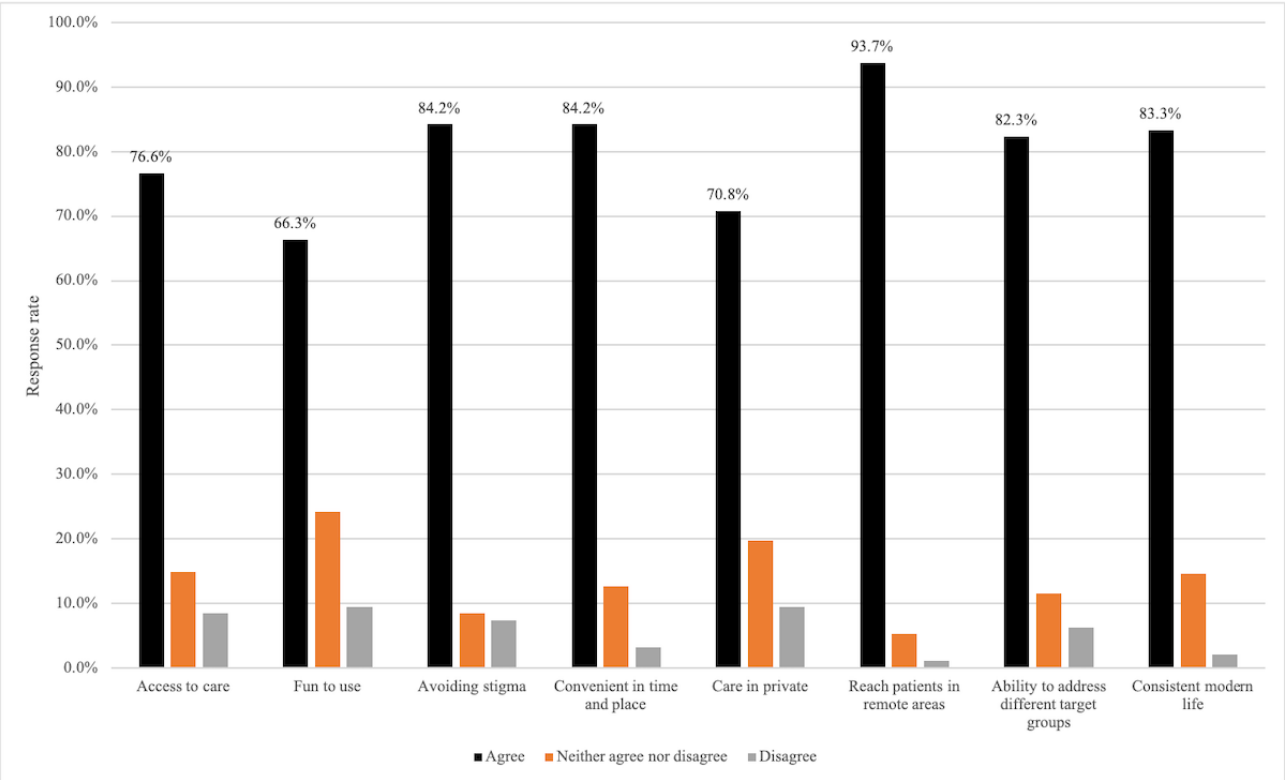
Figure 1. Perceived importance of certain applications of web-based mental health resources.



Advantages and Drawbacks

The perceived advantages of web-based mental health resources are illustrated in Figure 2. The most prevalent advantage of EMH reported by those who answered these questions (N=145) was the ability to reach patients in remote areas, with 93.8% (136/145) of the participants strongly or somewhat strongly agreeing. The ability for EMH to help avoid stigma (122/145, 84.1%) and be consistent in time and place (122/145, 84.1%) were highly valued strengths as well.

Figure 2. Perceived importance of certain advantages of web-based mental health resources.



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The drawbacks of using web-based mental health resources were collected with open response forms and grouped together (97 participants answered this question). The possibility that personal data would be acquired by hacking the system was an important drawback, as mentioned by 27.8% (27/97) of the participants. Similarly, 20.6% (20/97) of the participants thought that the internet did not offer good information in Arabic, and 17.5% (17/97) believed that the high level of illiteracy in Egypt would hinder the implementation and use of EMH. Difficulty connecting to the internet (14/97, 14.4%) and technological problems (20/97, 20.6%) were also mentioned as drawbacks to EMH. Finally, many (16/97, 16.5%) participants believed that web-based mental health resources would negatively affect the rapport between patients and caregivers.

Priorities

The participants were also asked in an open question to list what domain of mental health should be prioritized by web-based resources (113 participants answered this question). The majority of the participants thought that EMH should be geared toward helping mental health in youth (70/113, 61.9%) and children (32/113, 28.3%). Other domains that were reported as benefitting from EMH included substance use (23/113, 20.4%), geriatric mental health (23/113, 20.4%), suicide management (17/113, 15.0%), and personality disorders (14/113, 12.4%).

Discussion

Principal Findings

In our study, we explored the perspectives of Egyptian psychiatrists with regard to the state of health care services in Egypt and their interest in web-based mental health technologies. Our findings showed that the minority of participants believed that the current health care system was efficient and that almost all participants believed EMH to be a promising solution.

The findings suggest that psychiatrists in Egypt do not believe the current mental health care system in Egypt is properly equipped to meet the demand. Their perspectives are not unfounded, as several studies have also demonstrated the lack of accessible mental health resources [8]. The lack of government funding toward mental health and the high rate of physician emigration are factors that explain the deficiencies observed within the Egyptian health care system. In 2014, in Egypt, less than 1% of the total health care budget was allocated to mental health services, and about 60% of mental health services were being paid out of pocket [26]. Additionally, it is estimated that 110,000 of the 220,000 registered physicians have emigrated outside of Egypt [27]. In these situations, individuals are more likely to seek informal resources that are more accessible, such as traditional healers, religious consultants, and family members, rather than formal resources [1].

A great deal of interest for web-based solutions was expressed by the psychiatrists in our study, as almost all respondents said that these solutions would be beneficial for patient care. This was demonstrated by a trial launched in 2015 within Arabic countries called Shezlong, which allowed qualified therapists to provide web-based psychotherapy anonymously, and over 14,000 individuals sought treatment through online classrooms and video conference sessions only a year after its launch, half of which were from Egypt [28]. This staggering demand for mental health resources in Egypt is intersecting with the growth of web-based interventions in psychiatry and psychotherapy globally [29]. Medical experts have recognized that web-based interventions could lower the accessibility threshold and provide useful psychoeducation for patients [30].

Most respondents also reported they would integrate web-based solutions with their conventional therapy if a reliable internet platform is present. This is in line with previous findings that have discouraged technology as a replacement for traditional therapy, but it has been considered a new way of supporting mental health treatment [31]. Similarly, reliable eHealth solutions have been implemented in the national health systems of countries, such as Norway, Sweden, and Australia, which can provide Egypt with a blueprint [29,32]. Though resistance to change has been a major obstacle to the development of telemedicine and eHealth in Egypt, the coronavirus disease has demonstrated the utility of virtual care, which has been called into action as an emergency response to the crisis [33,34]. The Ministry of Health has designated a special hotline to provide psychological support to Egyptians isolated at home in response to the pandemic [14,35]. The adaptation to the crisis and the positive attitudes reported by the psychiatrists in our survey are promising for the implementation of web-based approaches for therapeutic interventions in Egypt.

In relation to the advantages of EMH as reported by the psychiatrists in our sample, the ability of EMH to reduce the physical and societal barriers to care was the most prevalent response. Similar advantages have been reported in the literature, including the potential for greater coverage, particularly for individuals in remote areas, and the capability to anonymously access services in order to avoid stigmatization and negative public perceptions surrounding mental illness and treatment [7,36,37]. Conversely, our findings revealed that psychiatrists believed privacy, confidentiality, and security to be the most important barriers to the implementation of EMH, similar to other studies [30,38]. Similarly, the lack of reliable content in Arabic has been shown to be a common barrier to effective web-based interventions in Middle Eastern countries and is reflected by our findings [36,39]. Cultural incompatibility in the form of differing gender-related norms, public awareness, and stigma of mental disorders, as well as language and presentation of distress are important factors to consider before using Western-developed interventions in the Middle East. It has been reported that the popularity of traditional healers in Egypt is in part a result of the comprehensive and holistic approach they offer by encompassing the patient's spiritual beliefs, cosmology, and world view [40]. Though psychiatric services bring tremendous value to the improvement and treatment of mental illnesses, they sometimes fail to provide care within the patient's broader cultural framework [6].

Implications

From the psychiatrists who were surveyed in this study, our findings demonstrate that online technology seems to be an interesting and promising avenue for mental health care, not as

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a standalone program but as an adjunct to traditional psychotherapy. However, the implications of integrating EMH into the broader health care system will reveal challenges that will need to be addressed when necessary. In effect, at the 9th Annual Canadian E-Mental Health Conference, emphasis was placed on trust and transparency in the development of digital mental health technologies and on equity, inclusion, and access in the implementation of EMH services [41]. In developing and emerging countries, integrating new technologies, acquiring sustainable funding, and coordinating the diverse stakeholders are seen as the biggest challenges to the reorganization of the system of care [42]. However, the lack of mental health resources in Arab countries has created a surge of innovative approaches to increase access. In Lebanon, EMH has been included in the national mental health strategy. In parallel, the World Health Organization has produced a web-based intervention called "Step-by-Step" to treat symptoms of depression, which is currently being tested in Lebanon with cultural and contextual adaptations [36]. Similarly, in Saudi Arabia, a 10-year national eHealth program was launched in 2011 with the aim of developing clinical automation, telecommunication infrastructure, and a nationwide eHealth record system [43]. In Egypt, the use of online consultations in specific fields, such as dermatology and psychiatry, is starting to develop [28,44]. This is promising for the health care systems of all Arab countries, and integrating EMH seems feasible, especially given the internet penetration and mobile ownership. Egypt is among the countries with the highest proportion of mobile phone users, with around 94% of the population subscribed to a mobile phone network, and the number of Egyptian internet users reached 50 million in 2019 [21]. Health-related internet searches are also increasing (from 29.7% in 2012 to 32.4% in 2013) [45]. Despite these findings, the content of physical and mental health websites can sometimes be incomplete or inadequate [46]. A reliable online public platform for Egyptians would be beneficial for increasing mental health literacy through pertinent and up-to-date information [47].

Limitations

The study sample (188 participants) represents over 20% of all registered psychiatrists in Egypt (around 800). Though the response rate was low for the study (28%), the findings provide valuable insights into the opinions of one in every five psychiatrists within the entire country. Similarly, although these findings are not generalizable to psychiatrists in other Arab countries or to other mental health care professionals in Egypt, the study calls for further research to look into the acceptability and use of EMH within other developing and emerging countries. Despite our findings, the participants' responses were self-reported and could not be verified. Similarly, a web-based questionnaire by nature produces sampling bias, as we are not able to collect data from those who do not use the internet or check their emails regularly. Given the internet penetration in Egypt, this appears to be a relatively minor limitation, but one nonetheless. Within the survey itself, the validity was never tested. However, ambiguous terms, such as EMH and technology, were defined for the participants. The questionnaire was also developed through substantial pilot testing within our target population, and any misleading terminology was replaced. Finally, not many questions about the participants' background were included, mainly because this survey was intended to be brief. If the survey had included more items, the response rate might have been even lower.

Conclusions

Modern technology presents an opportunity to transform mobile phones into devices that can provide more cost-effective and accessible mental health care wherever and whenever it is needed. We found that Egyptian psychiatrists believed that the current mental health care system is not meeting the demand and that utilizing EMH as an adjunct to the traditional system of care would be of great interest to them. As a solution to the limited mental health resources currently available, a reliable web-based platform could take advantage of the high internet penetration and mobile ownership to increase the accessibility of psychiatric interventions throughout the country. Future research should assess the perspectives of other mental health care professionals toward web-based platforms, as well as the steps required to facilitate the development and integration of EMH within the current system of care. Finally, assessing the mental health care needs of the population, and especially those of the youth, will ensure that web-based interventions are patient-centered and effective.

Acknowledgments

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Survey assessing the perspectives of Egyptian psychiatrists toward electronic mental health.
[PDF File (Adobe PDF File), 151 KB - mental_v7i8e19591_app1.pdf]

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Abbreviations

CHERRIES: Checklist for Reporting Results of Internet E-Surveys
EMH: electronic mental health

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Original Paper

Barriers and Facilitators for Referrals of Primary Care Patients to Blended Internet-Based Psychotherapy for Depression: Mixed Methods Study of General Practitioners' Views

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Abstract

Background: Major depressive disorder (MDD) is highly prevalent and often managed by general practitioners (GPs). GPs mostly prescribe medication and show low referral rates to psychotherapy. Many patients remain untreated. Blended psychotherapy (bPT) combines internet-based interventions with face-to-face psychotherapy and could increase treatment access and availability. Effectively implementing bPT in routine care requires an understanding of professional users' perspectives and behavior.

Objective: This study aims to identify barriers and facilitators perceived by GPs in referring patients to bPT. Explanations for variations in referral rates were examined.

Methods: Semistructured interviews were conducted with 12 of 110 GPs participating in a German randomized controlled trial (RCT) to investigate barriers to and facilitators for referrals to bPT for MDD (10 web-based modules, app-based assessments, and 6 face-to-face sessions). The interview guide was based on the theoretical domains framework. The interviews were audio recorded and transcribed verbatim, and the qualitative content was analyzed by 2 independent coders (intercoder agreement, k=0.71). A follow-up survey with 12 interviewed GPs enabled the validation of emergent themes. The differences in the barriers and facilitators identified between groups with different characteristics (eg, GPs with high or low referral rates) were described. Correlations between referrals and characteristics, self-rated competences, and experiences managing depression of the RCT-GPs (n=76) were conducted.

Results: GPs referred few patients to bPT, although varied in their referral rates, and interviewees referred more than twice as many patients as RCT-GPs (interview-GPs: mean 6.34, SD 9.42; RCT-GPs: mean 2.65, SD 3.92). A negative correlation was found between GPs' referrals and their self-rated pharmacotherapeutic competence, $r(73)=-0.31$, $P<.001$. The qualitative findings revealed a total of 19 barriers (B) and 29 facilitators (F), at the levels of GP (B=4 and F=11), patient (B=11 and F=9), GP practice (B=1 and F=3), and sociopolitical circumstances (B=3 and F=6). Key barriers stated by all interviewed GPs included "little knowledge about internet-based interventions" and "patients' lack of familiarity with technology/internet/media" (number of statements, each k=22). Key facilitators were "perceived patient suitability, e.g. well-educated, young" (k=22) and "no conflict with GP's role" (k=16). The follow-up survey showed a very high agreement rate of at least 75% for 71% (34/48) of the identified themes. Descriptive findings indicated differences between GPs with low and high referral rates in terms of which and how many barriers (low: mean 9.75, SD 1.83; high: mean 10.50, SD 2.38) and facilitators (low: mean 18.25, SD 4.13; high: mean 21.00; SD 3.92) they mentioned.

Conclusions: This study provides insights into factors influencing GPs' referrals to bPT as gatekeepers to depression care. Barriers and facilitators should be considered when designing implementation strategies to enhance referral rates. The findings should be interpreted with care because of the small and self-selected sample and low response rates.

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KEYWORDS

barriers and facilitators; general practitioners; depression; referral; blended therapy; internet-based intervention; mobile phone; psychotherapy; qualitative research

Introduction

Background

Approximately 350 million people worldwide are affected by major depressive disorder (MDD) annually [1]. It is the most common mental health disorder, with an estimated lifetime prevalence of 12.8% [2]. Prevalence rates of MDD in primary care patients range from 10% to 14% [3-6].

General practitioners (GPs) are considered most important in the management of depression because they are often the first point of contact in the pathways to care [7,8]. Accordingly, it is estimated that 60% to 71% of patients with MDD are treated by their GP [5,9-11]. However, a recent study [12] showed that 60% of patients with MDD under primary care did not receive guideline-oriented treatment; 54% were treated by their GPs with medication only (31%), counseling (45%), referral to specialized care (21%), and psychotherapy (10%). In general, referral rates of GPs to specialized care for depression vary between 16% and 58% [3,13-16]. In Germany, psychotherapy referral rates are low (8%-33%) [13,17,18], and only 17.3% of patients with mild or moderate depression and 3.6% with severe depression are treated with psychological psychotherapy in a 3-year period [10].

There are several reasons for not adhering to clinical guidelines in primary care. Factors that may hinder GPs in adequately treating depression include low rates (47%) of correct recognition and diagnosis of depression [19], insufficient time for care provision [20], self-reported insufficient knowledge relating to diagnosis or treatment and low skills [16,20], and higher self-confidence in providing medication [4,16]. Studies have also identified factors influencing GPs' referrals to mental health services [4,15,16,20-22]. These include characteristics of the disease (impairment, severity and duration of symptoms, and need for specialized treatment), patient (age, gender, and presentation of psychological complaints), GP (confidence in their abilities, insufficient time and insufficient skills to provide care, and need for clarification of diagnosis), and care system (lack of access to specialists, long distance or waiting time, personal communication, and medical exchange).

Some of the abovementioned barriers may be overcome by providing digital technologies as an additional treatment option. Digital approaches may help to improve access to specialists, decrease long waiting times, and reduce the high number of untreated patients [23,24]. Internet- and mobile-based interventions (IMIs) have been shown to be effective in treating MDD [25] and to yield results comparable with face-to-face psychological short-term treatments, when delivered as guided internet-based treatment [26].

Despite its potential, the uptake of evidence-based internet-delivered treatment remains limited [27,28], and not all patients are willing to use a digital stand-alone treatment [29,30]. For patients who are open to using technology-based treatments but also value personal contact, blended psychotherapy (bPT) might be a promising approach that combines IMIs with face-to-face treatment. This is a relatively new research field, and only a few studies have investigated the acceptance and effectiveness of blended treatments [31]. Previous studies indicate a potentially high acceptance and willingness to use bPT by both patients [32,33] and therapists [34-36]. Furthermore, randomized controlled trials (RCTs) on blended treatments indicated that the reduction of face-to-face psychotherapy sessions with equivalent replacement by IMIs did not lead to an inferior outcome when compared with traditional therapy [37-39]. Thus, implementing bPT could be an attractive alternative with the potential to reduce therapist time and increase the number of treated patients.

Given GPs' central role as gatekeepers in the management of depression, research on their perspectives as gatekeepers seems crucial. A recent study on the implementation of internet-based therapy services in routine care, in guided, unguided, or blended formats, suggested that GPs' low referral rates and unstable patient intake could be explained by GP skepticism and reservations and called for research on referrers' attitudes [40]. A study on Australian routine practice not only indicated a high GP satisfaction with web-based referrals and treatment services but also highlighted challenges in encouraging GPs' uptake [41]. Studies on GPs' attitudes toward depression IMIs identified benefits for implementation, such as a facilitated diagnosis, reduced workload, individualized treatment, shorter waiting time, and support for more patients [42,43]. Furthermore, GPs reported barriers to implementing IMIs, such as infrastructure requirements, privacy concerns, low awareness of electronic mental health (e–mental health) interventions, low confidence in prescribing IMIs, lack of training, uncertainty about the evidence base [42], and concerns that computer treatments are too impersonal and would not meet patient needs [44].

Objectives

The abovementioned insights refer to GPs' perspective on IMIs and show that research on bPT is scarce. To the best of our knowledge, no study has yet investigated GPs' perspectives on barriers to and facilitators for referrals to blended treatments. GPs may be more willing to refer to an IMI when it is combined with face-to-face psychotherapy, which is well known and trustworthy. At the same time, referrals might be facilitated by improved treatment availability and access to treatment options. However, given low GPs' referral rates to psychotherapy and the novelty of blended treatments, an assessment of factors determining GPs' referrals to bPT is needed. From this, implementation strategies can be designed to address these and maximize the uptake of bPT. This mixed methods study aimed to identify barriers and facilitators that influence the referral behavior of GPs to a bPT for MDD.

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Methods

Study Setting and Design of the RCT

This study was part of a mixed methods German study arm of the European Project E-COMPARED, which was the first multicenter study that evaluated the clinical and cost-effectiveness of a blended depression treatment compared with treatment as usual across 8 countries. The objective of the German RCT was to evaluate the effectiveness of bPT based on cognitive behavioral therapy (CBT) for adults with a diagnosis of MDD compared with GP routine care. Further information on the RCT can be found in the study protocol [45].

The trial was approved by the Ethics Committee of the German Society of Psychology and registered in the German Clinical Trials Register (DRKS00006866). All GPs provided informed consent to participate.

Patients were recruited in GP offices in primary care and randomly assigned to the treatment conditions, bPT (n=86) and GP care (n=87). Professionals were not blinded. The bPT was conducted by psychologists in an outpatient university clinic. GP care consisted of (1) initial screening of MDD, informing about treatment options and referring depressed patients to the study; (2) conducting routine care for the control group; and (3) completing questionnaires about the diagnosis and treatment of patients at baseline and postassessment (13 weeks). All GPs received a print booklet with information about bPT and trial procedures as well as recruitment material (eg, flyers, displays, posters) to inform and motivate their patients. Their effort was reimbursed with EUR 100 (US $117.6) per partaking patient. Further motivating activities were a kickoff meeting, newsletter, phone calls, and onsite visits.

Blended Internet-Based Psychotherapy

bPT was delivered as a short-term treatment (13 weeks) for MDD. It combined 6 internet-based CBT lessons (psychoeducation, behavioral activation, cognitive restructuring, problem-solving, physical exercise, and preventing relapse), daily assessments of mood, and cognitive and behavior-related parameters on a mobile app (eg, sleep habits, worries), as well as 6 biweekly face-to-face sessions with a psychologist and CBT therapist in training (Multimedia Appendix 1). Patients had free and password-encrypted access to a website with 10 weekly CBT-based web-based modules (text, videos, and exercises), mood graphs, a calendar, and a messaging system and independently edited the web-based modules at home. They received automated tailored web-based reminders. Therapists referred back and forward to web- and mobile-based content within face-to-face sessions to structure the treatment, monitored patients' treatment course on the internet, provided weekly web-based feedback on exercises and progress, or wrote reminder and motivation messages. A detailed description and a case report are published elsewhere [46].

Recruitment and Referrals

By the end of 2014, more than 1000 GPs were contacted through post, whose practices were located in the relevant catchment area for referrals to the university outpatient clinic (60 km). Overall, 137 GPs from 107 practices in Bavaria (Germany) agreed to refer to bPT. In the recruitment period from February 2015 to August 2016, 121 GPs referred to at least one patient, and 86 GPs had partaking patients in the RCT.

Successful referrals were operationalized as the number of patients who completed screening for MDD after being informed of it in GP offices. Owing to the study design, it was not possible to document the intended referrals onsite. Higher referral rates can be assumed; since some patients may not have followed the recommendation of their GP, the GPs had reported a high number of patients treated daily (mean 49, SD 22.84), and not all patients could be assigned to a GP.

The recruitment of GPs for this qualitative study took place shortly before the end of the study enrollment period (March to June 2016) by inviting 110 GPs from the trial population (those without study withdrawal) by email or telephone to participate in interviews. In total, 12 GPs (11%) took part in semistructured interviews. Of 110 GPs, 39 refused to participate; some were interested but had time constraints, and others could not be reached by telephone and emails with 3 reminders.

Design of the Qualitative Study and Data Collection

We used a qualitative method with a theory-based approach to gain insights into the experiences and perspectives of GPs regarding their referral behavior to bPT. This exploratory method is a recommended approach to identify barriers and facilitators for implementing interventions [47].

The semistructured interview guide (Textbox 1) was based on the theoretical domains framework (TDF), which provides a comprehensive theoretical assessment of implementation problems and professional behavior [48]. The 14 domains (eg, knowledge and intention) represent potential determinants for the change of behavior of GPs during the implementation of bPT as a new referral option. It enables researchers to identify the hindering and facilitating factors to support the implementation of evidence-based interventions. Items were evaluated by 3 experts in clinical psychology, e–mental health, and qualitative research to enhance validity. When needed, guided prompts enabled gathering of information, and field notes complemented data collection. Pilot testing of the interview guide with the first interview (IT) did not require any adjustments.

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Textbox 1. Theoretical Domains Framework and exemplary questions in the interview guide.

D01: Knowledge

- What do you know about blended psychotherapy (bPT) and its effectiveness?

D02: Skills

- Which skills and competencies do you consider as necessary to refer patients to bPT?

D03: Social/professional role and identity

- Do you see referring suitable patients to bPT as part of your role? Is doing referrals to bPT incompatible or in conflict with professional standards or your identity?

D04: Beliefs about capabilities

- How difficult or easy is it to refer patients to bPT? How confident are you that you can overcome existing barriers?

D05: Optimism

- Based on your experience, how confident are you that referrals to bPT will run optimally?

D06: Beliefs about consequences

- What do you think are the benefits of bPT?

D07: Reinforcement

- Do you think the benefits of bPT for patients are sufficient to justify referral being part of your normal workflow?

D08: Intentions

- How much of a priority is bPT in the care of patients with depression? How essential is your personal requirement to refer patients?

D09: Goals

- How do you feel about the goal to implement bPT into the health care system in a way that you could refer to it in the future?

D10: Memory, attention and decision processes

- Is referring to bPT something you usually do or remember to do? What helps or would help you to remember?

D11: Environmental context and resources

- Do you think there are sufficient resources available if you start referring more patients to bPT? Which barriers outside your practice can prevent referrals?

D12: Social influences

- Did colleagues or patients/relatives ever prompt or encourage you to refer to bPT? Did they discourage your referral? What reactions do you expect?

D13: Emotion

- Do you think bPT is something patients are willing to participate in? Does thinking about referrals to bPT evoke any concerns?

D14: Behavioral regulation

- Are there procedures or ways of working that encourage referrals to bPT?

The sample size was determined by the low response rates to interviews at the end of the RCT enrollment period. Hence, the sample size and composition could not be planned. In total, 3 interviewers conducted 4 interviews with GPs. IT trained 2 interviewers with a Bachelor of Science in Psychology in using the interview guide and gave feedback to their first interviews. The interviews were conducted through telephone between May 2016 and June 2016, whereas the GPs were at the workplace (n=9), at home (n=2), or in the car (n=1). The average duration of the interviews was 56 min (SD 15.26; minimum=36 and maximum=78). Interviews were audio recorded and transcribed verbatim, based on a transcription guide. Data were pseudonymized using code numbers.

Data Analyses

Qualitative Analysis

A qualitative content analysis was conducted, drawing on an inductive-deductive approach and using standardized methodical

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steps in qualitative research [49]. Codes were developed from the raw data and referred to themes relevant to the research question. The items were based on the TDF.

First, a list of codes was developed using 50% (n=6) of interview material, which involved identifying emerging themes, discussing the possible meanings of text excerpts, and arranging themes into categories within consensus meetings. Consensual coding was applied to enhance the quality of the coding process [50]; 2 independent coders developed and compared codes and discussed any differences to generate consensus on the codes.

Second, a further text retrieval was done to (1) label text related to the first draft of the code list, (2) specify subthemes, (3) add new emerging themes to the code list, and (4) target a higher level of abstraction of the codes. A paragraph was coded if it contained themes from one or more categories. IT gave written feedback to the coders regarding all labeled text frames to enrich the data interpretation through clinical expertise. The list of codes was revised and completed with additional definitions and exemplary statements. A preliminary code system, based on 50% (6 interviews) of the material, was developed and discussed in a consensus meeting among IT, SS, and the coders. They reached final agreement on code definitions and excerpts, the structure of the code system, and coding rules. This iterative research process aimed to finalize the code list to fit the data and to optimize the content and number of identified categories.

Third, all interview transcripts were independently coded by 2 coders in accordance with the code list. There was sufficiently moderate intercoder agreement with the coefficient kappa, k=0.71 [51]. Data saturation (a validity criterion of the codes list) was successfully reached, as each theme was mentioned by at least two GPs and no new themes emerged from the interview data. This indicated that no additional interviews should be conducted [52]. Key themes were defined as emerging themes mentioned by 100% of GPs.

Finally, to ensure the validity of the identified themes, the 12 GPs were questioned as to whether they agreed with the resultant barriers and facilitators via a survey. The themes were presented as a list. GPs agreed, on average, with 37 of 48 of all themes identified (mean 78%, SD 14%; minimum=44% and maximum=98%). The mean agreement rate per theme (ie, for each barrier or facilitator) was 78% (SD 19%; minimum=8% and maximum=100%). Thus, the identified barriers and facilitators yielded very good validation results.

Quantitative Analysis

A comparison of all barriers and facilitators and the percentage of all 12 GPs who mentioned these in the interviews and in the follow-up validation survey was conducted. Agreement rates per GP were analyzed.

Secondary quantitative analyses were conducted to evaluate whether there were any group differences in the identified barriers and facilitators. The interviewees were divided into 2 groups according to the following characteristics: “referral rates: high (n=4) versus low (n=8)” (cutoff by mean value=6), “experience years as licensed GP: high (n=6) versus low (n=6)” (cutoff by mean value=15), and “training in psychotherapy: yes (n=4) versus no (n=8).” A frequency table and descriptive statistics with 95% CIs were used to present differences in the barriers and facilitators between the abovementioned groups. Inferential statistics were not applied because of small samples and limited power. Power sensitivity analyses indicated that both equal (6/6) and unequal (8/4) small sample sizes would have the sensitivity to detect only a large proportional difference of 0.75 in a Fisher exact test and large effect sizes of d=1.96 (unequal) or 1.85 (equal) in a Mann-Whitney U test, each with a power of 80% and an alpha level of 5% (two tailed).

Independence tests of the interviewed sample (n=12) and the remaining RCT sample (n=64) were conducted using the Fisher exact test for categorical variables (because of cell frequencies <5) and using the t test or Mann-Whitney U test for continuous variables. The results of the nonparametric Mann-Whitney U test were reported because of unequal sample sizes, if both assumptions (normality of distribution and equality of variance) were not met. The test was applied for verification if the data were nonnormally distributed. All analyses were two sided, with an alpha level of 5%. Sensitivity power analysis for t tests, targeting unequal sample sizes (n=64 and n=12), an alpha level of 5% (two tailed), and 80% power, had yielded the sensitivity to detect an effect size of d=0.89.

Pearson correlations were conducted to determine the association between referrals and different continuous variables in the total RCT sample (n=76). The power analysis indicated that a sample size of 76 would have the sensitivity to detect an effect size of r=0.31, with a power of 80% (alpha level of 5%, two tailed) in a bivariate correlation.

The tool MAXQDA 12 (VERBI software, 2015) was used for the qualitative analysis and SPSS 25 (IBM SPSS Statistics, 2017) for the quantitative analysis. Power analyses were conducted using G*Power, version 3.1.9.7 [53]. A guideline for reporting qualitative studies (Consolidated Criteria for Reporting Qualitative Studies [COREQ] checklist) was applied (Multimedia Appendix 2) [54].

Results

Participant Characteristics and Referral Rates

Interviewed GPs were mainly men (8/12, 67%), with an average of 50.67 (SD 11.88) years and reported an average of 15.75 (SD 10.42) years of practice experience. Regarding their qualifications, 4 GPs had a license for psychotherapy and 9 had further education in psychosomatic basic care in addition to their university degree in medicine. GPs worked in both metropolitan (7/12, 58%) and rural (5/12, 42%) areas. Sociodemographic data for the remaining RCT sample (available for n=64) showed similar values, such as a proportion of 64% (41/64) being men, an average age of 52.14 (SD 8.73) years with 16.65 (SD 8.34) working years as a licensed GP. There were no statistically significant group differences in characteristics between the interviewed sample (n=12) and the RCT sample (n=64), all P≥.08 (see descriptive statistics in Table 1).

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Table 1. Sample characteristics of participants.

Characteristics of GPs[a]	RCT[b]-GP sample (n=64), mean (SD)	Interviewed GP sample (n=12)			*P* value[c]	Low referrer interviewees (n=8)[d], mean (SD)	High referrer interviewees (n=4)[d], mean (SD)
		Mean (SD)	Minimum	Maximum			
Age (years)							
	52.14 (8.73)	50.67 (11.88)	29	75	.62	51.50 (13.70)	49.00 (8.60)
Female, n (%)							
	23 (36)	4 (33)	N/A[e]	N/A	>.99[f]	3 (38)	2 (50)
Experience as licensed GP (years)							
	16.65 (8.34)	15.75 (10.42)	1	31	.94	15.50 (10.58)	16.25 (11.67)
Working in current practice (years)							
	14.82 (9.47)	14.29 (9.36)	1	28	.86	13.19 (8.70)	16.50 (11.62)
Training in psychosomatic care, n (%)							
	51 (80)	9 (75)	N/A	N/A	.14[f]	5 (63)	4 (100)
Training in psychotherapy, n (%)							
	7 (11)	4 (33)	N/A	N/A	.09[f]	3 (38)	1 (25)
Radius of patient catchment area (km)							
	14.72 (11.09)	16.67 (12.26)	3	50	.59	11.25 (6.27)	27.50 (15.00)
Number of daily treated patients							
	48.80 (22.81)	52.00 (24.06)	20	100	.69	49.17 (18.55)	56.25 (33.51)
Number of referrals to blended psychotherapy							
	2.75 (3.06)	6.33 (9.42)	0	26	.66[g]	1.38 (9.2)	16.25 (11.27)
Self-ratings on competences (range 1-5)[h]							
Diagnosing depression	3.81 (0.69)	4.08 (0.29)	4	5	.16[g]	4.13 (0.35)	4.00 (0.00)
Depression treatment with psychotherapy	3.10 (0.93)	2.92 (0.90)	2	4	.54	3.00 (0.93)	2.75 (0.96)
Supportive talk	3.76 (0.84)	4.08 (0.67)	3	5	.21	4.00 (0.54)	4.25 (0.96)
Treatment with pharmacotherapy	3.33 (0.54)	3.00 (0.85)	1	4	.08	3.13 (0.64)	2.75 (1.26)
Agreement with statements (range 1-5)[i]							
I am experienced in treating depression	3.75 (0.70)	3.67 (0.65)	3	5	.72	3.62 (0.74)	3.75 (0.50)
I carry out depression treatment because of long waiting periods for specialist care	4.30 (0.98)	4.42 (0.67)	3	5	.70	4.38 (0.74)	4.50 (0.58)

[a]GP: general practitioner.

[b]RCT: randomized controlled trial.

[c]Statistics regarding group differences between randomized controlled trial (n=64) and interviewed sample (n=12). A *t* test was used, if not otherwise specified. The results of *t* tests were verified if one requirement was not fulfilled.

[d]Groups were split by mean value (low referrers mean <6; high referrers mean ≥6).

[e]N/A: not applicable.

[f]The Fisher exact test was used for categorial variables.

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[g]The Mann-Whitney U test was used if both assumptions were not met because sample sizes are unequal.

[h]Scale from quite low (1) to quite strong (5).

[i]Scale from not applicable (1) to very applicable (5).

The patients treated with bPT (n=86) were aged on average 43.22 years (SD 13.07; range 19-70), mostly women (61%), highly educated (56%), and employed (74%). Overall, 71% had no prior experience with psychotherapy.

Of 698 successful referrals to bPT, 321 could be assigned to 121 GPs in the RCT. The majority of RCT-GPs (92/121, 76%) referred fewer than 3 patients to bPT during the 18-month study period, indicating a ceiling effect. However, there was a large variation between GPs in the number of referrals made (RCT sample: mean 2.65, SD 3.92; minimum=1, maximum=26; interview sample: mean 6.34, SD 9.42; minimum=0, maximum=26), and interviewed GPs had higher referral rates than those in the RCT. Table 2 shows the frequency distribution of GPs' referrals to bPT in the interviewed sample (n=12) and the RCT sample (n=121).

Table 2. Frequency distribution of GPs' referral rates to blended psychotherapy.

Referral rates	Randomized controlled trial-GP[a] sample (n=121), n (%)	Interviewed GP sample (n=12), n (%)
Number of referrals per GP		
0	0 (0)	1 (8)
1	63 (52.1)	4 (33)
2	29 (24)	2 (17)
3-5	20 (16.5)	1 (8)
6-8	5 (4.1)	2 (17)
12	1 (0.8)	0 (0)
21	1 (0.8)	0 (0)
26	2 (1.7)	2 (17)

[a]GP: general practitioner.

A significant moderately negative correlation was found between the number of referrals made and self-rated competence in delivering pharmacotherapy ($r(73)=-0.31$; $P<.001$), that is, GPs with higher self-confidence in delivering pharmacotherapy were less likely to make referrals to bPT. Correlations between referrals and demographics, medical experience, competence ratings, and depression management statement agreements were otherwise nonsignificant (Multimedia Appendix 3).

Qualitative Findings

Altogether, 19 barriers and 29 facilitators were identified and categorized into 4 main areas: (1) the *general practitioner*, (2) the *patient*, (3) factors influencing the routine in the *GP practice*, and (4) factors relating to *sociopolitical circumstances* that influence the implementation of a bPT for MDD in Germany as well as the referral process. In total, 77% (37/48) of the identified themes were mentioned by at least five or more interviewed GPs (42%), whereas 44% (21/48) of the themes were mentioned by at least eight GPs (67%).

Barriers to Referrals

Most emerging barriers (11/19, 58%) were assigned to the patient level. Five barriers (5/19, 26%) were named by at least nine GPs (75% of interviewees), whereas 2 barriers (2/19, 11%) were mentioned by all 12 GPs. These latter 2 key barriers are presented in the following section with a quotation illustrating the physicians' experiences, whereas all 19 barriers are described with a definition and supporting quotations in Table 3.

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Table 3. General practitioners' perceived barriers for referrals to blended internet-based psychotherapy (bPT) for depression.

Barriers (n=19)	GPs[a] (n=12)		Definition	Supporting quotations
	n (%)[b]	κ[c]		
Level of *general practitioner* (barriers n=4)				
Little knowledge about internet-based interventions	12 (100)	22	The GPs know little about the content and procedures of internet-based interventions or bPT[d]. Furthermore, they declare to have no profound scientific knowledge about their clinical effectiveness	"To date, I don't know anything about the efficacy of internet-based interventions." [GP059]
Lack of feedback on referral or treatment response	9 (75)	13	The GPs need more feedback on the effectiveness of bPT for a patient, and if necessary, recommendations for further treatment. Feedback is claimed to be an essential component of the communication between GPs and other professionals in health care	"It's important to be immediately informed of its effects on the patient [...] whether bPT was successful. Or conversely, what measures should be taken if the patient became seriously ill." [GP084]
Skepticism toward the internet-based intervention	6 (50)	10	The physicians are skeptical of the quality of internet-based interventions for depression. As a result, they prefer other treatment options for patients	"I would prefer traditional psychotherapy if there could be shorter waiting periods, because it's more sustainable, a long-term treatment and more personal." [GP026]
Lack of habit and routine	5 (42)	10	Referrals to bPT are not a habit and not yet normal for the everyday working routine. The integration of a new procedure takes time and is a complex process. The reasons for this include lack of time, lack of familiarity with the program, or no coverage by medical insurance	"The routine is still developing. It's not part of my role yet. [...] Referrals to bPT have not yet been embedded in my routine and my regular work, so to speak." [GP043]
Level of *patient* (barriers n=11)				
Lack of familiarity with technology, internet, and media	12 (100)	22	The GPs assume that some patients are not confident in using computers, mobile phones, and new technology. They might not be familiar with these devices or have little experience using them	"I imagine not all patients are tech-savvy. Even when you provide them with a smartphone, I think, they're scared of not being able to use new technologies." [GP007]
Disease-specific contraindication	10 (83)	20	The GPs assume that patients with certain diagnoses are not suitable for the internet-based intervention, for example, severe forms of depression, chronic clinical course, suicidality, lack of introspection skills, personality disorder, high comorbidity, or psychotic symptoms	"A referral is not an option if there is an acute suicide risk, a borderline disorder or eating disorders." [GP059]
Reservations and skepticism toward technology in treatment	9 (75)	14	The patients are skeptical of the treatment and whether therapy can be effectively implemented and delivered through internet technology	"Patients say 'Internet? That works for depression treatment? Really?' They are quite skeptical." [GP097]
Lower suitability for physically limited or older patients	8 (67)	9	Internet-based interventions for depression are often considered less suitable for patients with physical limitations. GPs would not refer older patients to internet-based interventions	"It's clear that older patients, who have bad eyesight, won't sit in front of their screen and do an internet-based intervention." [GP059]
Reservations regarding data safety	7 (58)	12	Patients express reservations regarding data safety with internet-based interventions for depression or this is assumed by the GP	"Patients are often very anxious about data safety when offering something via the Internet. They don't believe me when I tell them that their information stays confidential." [GP084]
Lack of internet access or a computer	5 (42)	7	Internet-based treatment is refused or cannot take place because patients do not have the technical equipment (mobile phone and computer with internet access)	"Well, apart from not having access to the internet and a lack of trust in data security, I can't think of any big barriers." [GP012]
Limited therapeutic relationship or personal contact	5 (42)	9	Internet-based intervention does not provide enough therapeutic contact for the patient. Interviewees mention that a good therapeutic relationship and good rapport cannot arise through internet-based interventions	"Maybe for some the internet-based intervention is too impersonal. Some patients might still prefer more human contact and a closer relationship." [GP007]

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Barriers (n=19)	GPs[a] (n=12)		Definition	Supporting quotations
	n (%)[b]	κ[c]		
Fear of stigmatization	3 (25)	4	Having depression and starting bPT causes unpleasant feelings within patients. They fear the consequences of a psychological disease in society	"When you name the disorder, it is often hard for patients to accept it. When you say 'Listen, the depression has to be treated and there is bPT,' the patient often doesn't like it." [GP059]
Personal effort required	3 (25)	5	Contributing actively and independently to the treatment can be burdensome for patients. It can be especially challenging for those with depression	"I say to the patients: 'You have to work, you use your PC at home.' [...] It involves personal effort and it is not as comfortable as sitting in the GPs' office and going home afterwards." [GP046]
Language barrier	3 (25)	4	Patients who are not able to speak German, which is needed for the intervention, cannot take part in the internet-based intervention. The GPs believe there is a need for translations into other languages for immigrants and refugees	"One disadvantage is that the intervention excludes refugees and immigrants because of the language. They're a big patient group. They need a translator." [GP026]
Little room for individualized treatment or personal issues	2 (17)	4	The limited number of face-to-face sessions and the therapists' orientation toward web-based modules leave little therapeutic room for personal issues and individualized treatment	"I had a patient that struggled with bPT. The face-to-face sessions were too attached to the internet part and he wanted to talk more about himself. It was too rigid for him." [GP007]
Level of *GP practice* (barriers n=1)				
Lack of time for explanations about the availability of bPT	3 (25)	3	The GPs and their office staff lack temporal resources to explain the new bPT that is available to patients	"When the counselling for depression treatment takes too much time, when I spend too much time explaining […] that there's something new and how it works, then I won't have enough time." [GP043]
Level of *sociopolitical circumstances* (barriers n=3)				
Low awareness of bPT as a therapeutic method	7 (58)	11	Public knowledge and awareness of internet-based interventions and bPT for depression is limited, and this reduces the willingness to use bPT	"Nobody asked me or reinforced to me that I should refer to bPT. That's too early. It isn't well-known enough yet." [GP046]
No reimbursement by health insurance	6 (50)	9	Health insurance companies do not cover the reimbursement of internet-based interventions	"Health insurers should pay for it and there should be contingencies" [GP007]
Organizational, bureaucratic, and legal requirements for care providers	5 (42)	6	Organizational, bureaucratic, or legal obstacles can avert the referral to bPT for depression. This includes the interference of health insurance companies, shortage of money, legal requirements, etc	"The bureaucracy and the legal requirements of §12 SGB V, that asks for 'efficiency principles', as well as the entire organization of the Association of Statutory Health Insurance Physicians are aggravating factors." [GP046]

[a]GP: general practitioner.

[b]The percentages give the proportion of all 12 general practitioners who mentioned the barrier.

[c]Number of excerpts (κ) show the number of statements regarding a barrier on a code level.

[d]bPT: blended psychotherapy.

All interviewed GPs reported feeling poorly informed about the content and the procedure of bPT and having little knowledge about the scientific evidence of the treatment, as one GP outlined:

> *I know nothing about the effectiveness of bPT. I have not read anything about it in GP journals.* [GP098]

All respondents agreed that patients who are not familiar with computers or smartphones and have little experience with technology might struggle with the technology-based treatment:

> *There are still people today who are not familiar with computers, especially in rural areas.* [GP053]

Facilitators for Referrals

The analysis revealed more facilitating than hindering factors on the levels of the GP as a person, GP practice, and sociopolitical circumstances. Of the identified 29 facilitators, 16 (55%) were mentioned by at least 75% (n=8) of GPs and 2 (7%) by all interviewees. Below, these 2 key facilitators are presented with an outlining statement. All 29 facilitators are described with a definition and supporting quotations in Table 4.

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Table 4. General practitioners' perceived facilitators for referrals to blended internet-based psychotherapy for depression.

Facilitators (n=29)	GPs[a] (n=12)		Definition	Supporting quotations
	n (%)[b]	κ[c]		
Level of *general practitioner* (facilitators n=11)				
No conflict with GP's role	12 (100)	16	Referral to a bPT[d] is not in conflict with professional standards and the GP's role identity. Interviewees integrate the referral into their job role without problems	"I don't see a role conflict. As a GP you're not a specialist for everything, therefore it belongs to my daily routine to refer patients to a specialist. My competence is recognizing patients being in need of a specialist." [GP084]
High level of self-efficacy regarding the referral	11 (92)	15	The GPs feel able to do the referral to bPT in a promising and successful way. They describe no difficulties for the referral process	"The referral to bPT is not very complicated. It already works quite well." [GP084]
Optimistic attitude	11 (92)	15	The interviewees are open toward the new internet-based approach. Physicians are confident that the bPT will work well and the treatment will be successful	"I am very confident that bPT can be a great support. Definitely." [GP007]
Support through information and training	11 (92)	19	The GPs would benefit from more information, further education and training, and the opportunity to try out the tool themselves. This increases the likelihood of a referral	"I think a 2-3 hours training session would be nice. A short introduction into the disorder, the diagnostic process of the GP and information about the blended treatment." [GP026]
Positive self-appraisal regarding own skills	9 (75)	10	The GPs rate their own skills as very high which are needed for a successful referral. Those include, for example, the diagnosis of depression and counseling techniques	"The main skill is actually interviewing. I learnt most the things by doing further educational courses. As a GP, my main weapon is talking." [GP084]
Positive beliefs about treatment success	9 (75)	12	The physicians expect the blended depression treatment to be associated with positive consequences for the patient	"I can imagine, that a certain group of patients could benefit a lot from it. [...] I think it is a step forward." [GP084]
Positive attention and decision-making process	9 (75)	16	Positive attention and decision-making processes are supported by the following: the referral option is remembered, GPs get reminders (flyers and mails) from the therapy institution, and patients give positive responses to the treatment	"I really remember it all the time. I have the flyer on my desk and every patient that seems suitable to me gets one from me." [GP026]
Expectation of social reinforcement	9 (75)	9	The GPs expect positive reactions within their social environment for the referral of patients to bPT	"I would expect interest and curiosity about bPT from others." [GP012]
Perception of patients' consent	9 (75)	9	The physicians feel that patients are willing to take part in blended depression treatment. They expect patients to give consent when they express a referral offer	"Yes, patients are willing to participate in the bPT." [GP007]
Positive emotions	8 (67)	8	Pleasant emotions arise when the GPs consider referring a patient to bPT for depression	"It feels good to be able to refer a patient to bPT." [GP007]
Personal contact with the therapists and provider	7 (58)	11	Personal contact with therapists and staff of the provider reinforces the GP's referral behavior	"It was helpful to know the staff." [H026]
Level of *patient* (facilitators n=9)				
Perceived patient suitability (eg, well-educated or young)	12 (100)	22	bPT is an up-to-date intervention, which is close to patients' everyday media use. It is especially suitable for people of a younger age and a medium to high level of education	"Patients with a higher educational level are more suitable." [GP012]
Intervention for minor-to-moderate depression or dysthymia	10 (83)	22	The GPs perceive bPT to be appropriate for patients who are affected by minor-to-moderate depression or dysthymia	"I would refer patients suffering from mild to moderate depressive disorders. I don't consider bPT to be sufficient for severe forms." [GP012]
Motivation and willingness for treatment	7 (58)	13	The interviewees are ready to recommend the blended treatment if the patient shows motivation and willingness to start the treatment	"If a patient shows interest and wants to be informed about the bPT, I am open and ready to recommend the offer." [GP012]

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Facilitators (n=29)	GPs[a] (n=12)		Definition	Supporting quotations
	n (%)[b]	κ[c]		
Smaller inhibition threshold and barrier for usage	7 (58)	15	Patients have fewer inhibitions about taking part in internet-based interventions for depression and taking advantage of this offer. One can reach new patient groups, who were not previously open for treatment	"Another facilitating factor is maybe the low threshold, particularly for younger patients, to contact a psychologist online." [GP012]
Time- and location-independent internet-based intervention	6 (50)	8	The internet-based components of the treatment are neither bound to place nor to time, so they can be easily integrated into daily life. The patient works through the internet-based modules in a flexible way	"The advantage is surely that bPT is not time bound, at least for the internet-based part of the treatment." [GP046]
Anonymity	5 (42)	7	Patients also participate because of the given anonymity of the web-based section of bPT and appreciate this anonymity	"The anonymity is an advantage. If patients can register on their own on an online platform, it will surely help. Some just have this threshold and are frightened to speak about their problem in face-to-face contact." [GP007]
Technical affinity	4 (33)	4	Working with technical tools and new media is an incentive to join internet-based interventions for depression. People who have an affinity for technical tools are attracted to this new technology	"Younger patients, who are often technophiles, are especially interested in bPT, I think." [GP012]
Preventive approach for subclinical symptoms	3 (25)	7	The GPs believe the bPT is suitable for subclinical symptoms of depression. It can also be used for prevention	"I think it is an in-between treatment. I need it for people diagnosed with a depressive adaptation disorder who are still at a beginning point with subclinical symptoms." [GP007]
Short duration of treatment	2 (17)	3	The treatment only lasts 13 weeks, which is a manageable amount of time for patients	"The behavior-centered working, six sessions in a short-term, therefore a manageable thing. I like that." [GP084]
Level of *GP practice* (facilitators n=3)				
Methods facilitating GPs' work and referral process	11 (92)	40	Working routines that help GPs to treat depressive patients and to refer them, for example, information flyer, poster in the waiting room, newsletter, standardized referral documents, digital feedback about diagnostic and treatment findings	"Concerning one patient, I underestimated the severity of the disorder and I received diagnostic feedback from his therapist. I called a neurologist for an appointment in the near term. I saw this positively since I don't claim that I can recognize everything." [GP084]
GPs' perception of a high demand	11 (92)	14	Additional treatment options for the referral of depressive patients are strongly needed in GPs' offices	"There is an increased prevalence of depression, especially in younger patients. Those providing outpatient therapy are overloaded. There is a high need." [GP098]
Saving GPs' office resources	7 (58)	14	Referrals to bPT saves GPs' resources. Patients can apply for therapy on their own via an web-based link. Physicians do not have to bridge the time with a treatment in their own office until a patient starts a traditional treatment	"Referrals to bPT are relatively time saving, don't need many resources, are quickly executed and actually quite feasible." [GP012]
Level of *sociopolitical circumstances* (facilitators n=6)				
Short waiting time for internet-based intervention	11 (92)	38	The waiting time for internet-based interventions is essentially shorter than for traditional face-to-face psychotherapy. Depressive patients can be treated promptly, and as such, psychological strain is reduced	"The main advantage is that there's no time delay. You can offer your patient a treatment immediately." [GP012]
Quick and easy availability	10 (83)	18	Internet-based intervention is quickly and easily accessible for patients without any large organizational and temporal effort	"Everybody can start the treatment very easily at home and almost immediately. The patient doesn't need to arrange an appointment for the first contact, he can start online." [GP059]

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Facilitators (n=29)	GPs[a] (n=12)		Definition	Supporting quotations
	n (%)[b]	κ[c]		
Additional therapy approach as new pillar in health care	9 (75)	21	The GPs benefit from the provision of an additional up-to-date treatment offer in the health care system. bPT can close the care gap and has the potential for nationwide coverage	"bPT closes a gap in our range of therapeutic treatments. It is a very good additional option. Access to psychotherapy is limited and everything additional is something positive." [GP026]
Integration within guidelines as evidence-based treatment	6 (50)	11	bPT for depression should be established in the health care system as an intervention with approved evidence. The GPs should be informed about the guidelines and the recommendation of bPT as a treatment for depression	"Well, GPs are treating patients according to guidelines and it would help, if bPT were to be integrated into these guidelines. We have to be sure, that we can work with this treatment without hesitation." [GP053]
Media coverage improves awareness and evaluation of bPT	3 (25)	5	Media reports about the possibility of bPT for depression as an approved therapeutic approach improves GPs' and patients' perceptions of it and their willingness to use it	"A kind of public relation would be helpful. I benefit from the media coverage. If my patients get aware of this bPT through TV reporting, then I can say 'Yes, I'm a part of it, too'." [GP084]
Bridging the waiting time for traditional psychotherapy	2 (17)	4	Long waiting times for specialized therapeutic care are a burden for the patient. Short-term bPT for depression can be used while patients wait for the start of a long-term traditional therapy. It helps to prevent the deterioration of symptoms	"I wonder if I should refer my patient first to your bPT short-term treatment and hope it will help, or should I choose a referral to a long-term psychotherapy with long waiting lists. I have to admit, I sometimes did both." [GP026]

[a]GP: general practitioner.

[b]The percentages give the proportion of all general practitioners who mentioned the facilitator.

[c]Number of excerpts (k) show the number of statements regarding a facilitator on a code level.

[d]bPT: blended psychotherapy.

All interviewed GPs perceived no role conflict between the referral to bPT and their professional identity and standards:

> *I see the referral to bPT as part of my role. I see it as a welcome opportunity to be able to offer the patient a quick and uncomplicated means of assistance here in the practice.* [GP059]

Each GP identified patient groups for whom the bPT suits well. They characterized these patients as those who are young and highly educated, used to work with computers and smartphones, and ready to integrate them into their treatment:

> *I think it is definitely suitable for younger patients and also for patients who are already at work and do not have that much time.* [GP083]

Quantitative Findings

Follow-Up Validation of Qualitative Findings

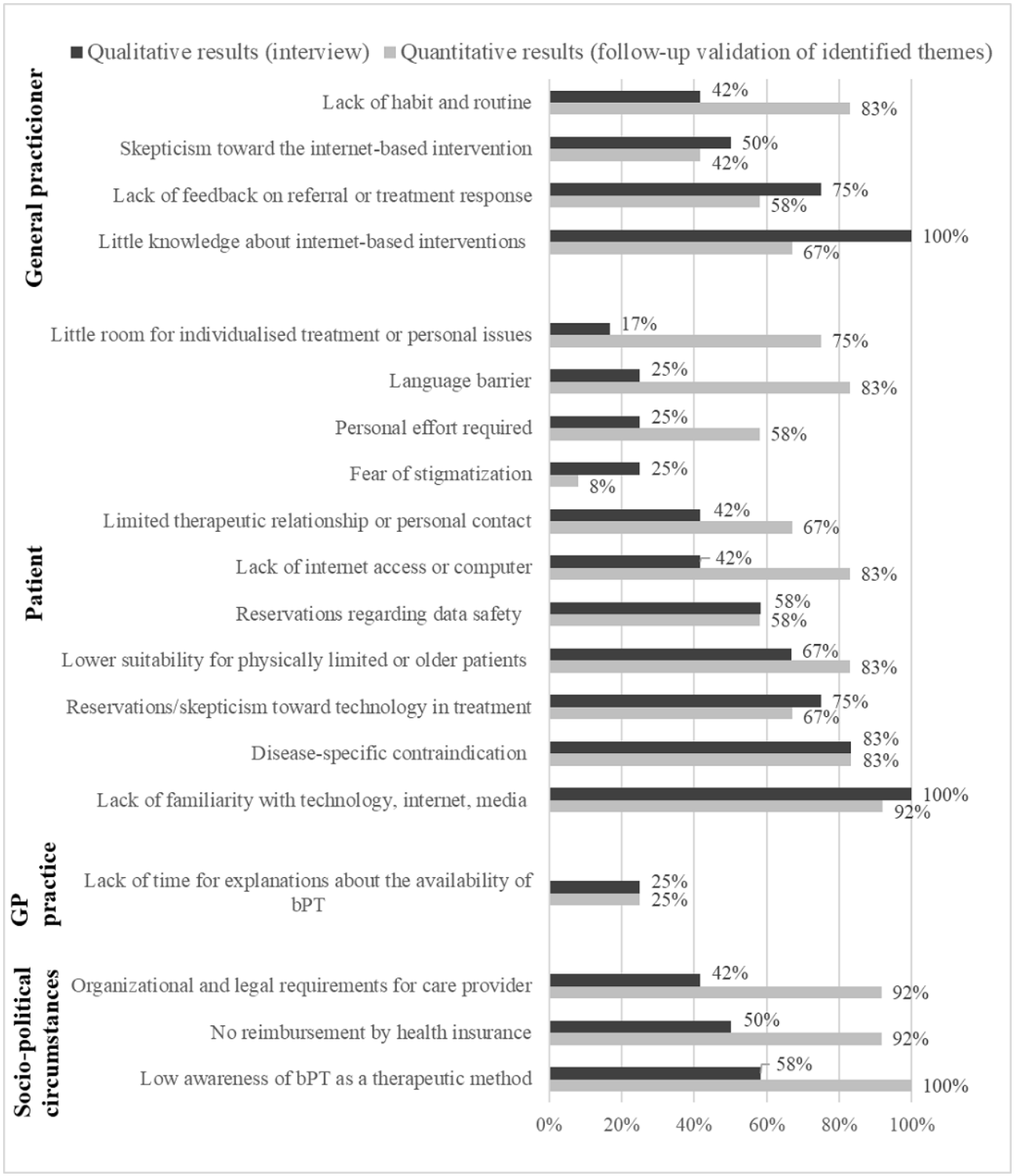
The follow-up assessment of the identified themes within the qualitative interviews showed a very high agreement rate between all 12 GPs of at least 75% for 34 (71%) of the identified barriers and facilitators. In total, 44 of 48 (92%) themes yielded an agreement rate of at least 58%, and 3 (6%) themes were agreed by all GPs. Only 2 (4%) themes had an agreement rate less than or equal to 25% of GPs.

Low awareness of bPT as a therapeutic method was the barrier, and *integration within guidelines as evidence-based treatment* and *short waiting time for internet-based intervention* were the facilitators, which resulted in the highest agreement rates. *Patients' fear of stigmatization* was the barrier, and *GPs' expectation of social reinforcement* was the facilitator with the lowest agreement rates.

All barriers, and the percentage of all 12 GPs who mentioned these in the interviews and in the follow-up validation survey of qualitative findings, are listed in Figure 1. The average proportion of GPs who mentioned these 19 barriers in the interview was 53% (SD 25%; minimum=17% and maximum=100%), whereas the mean agreement rate for barriers in the quantitative follow-up survey was 69% (SD 24%; minimum=8% and maximum=100%). When these 19 identified barriers were presented to GPs as a list, 53% obtained higher agreement rates than in the interviews.

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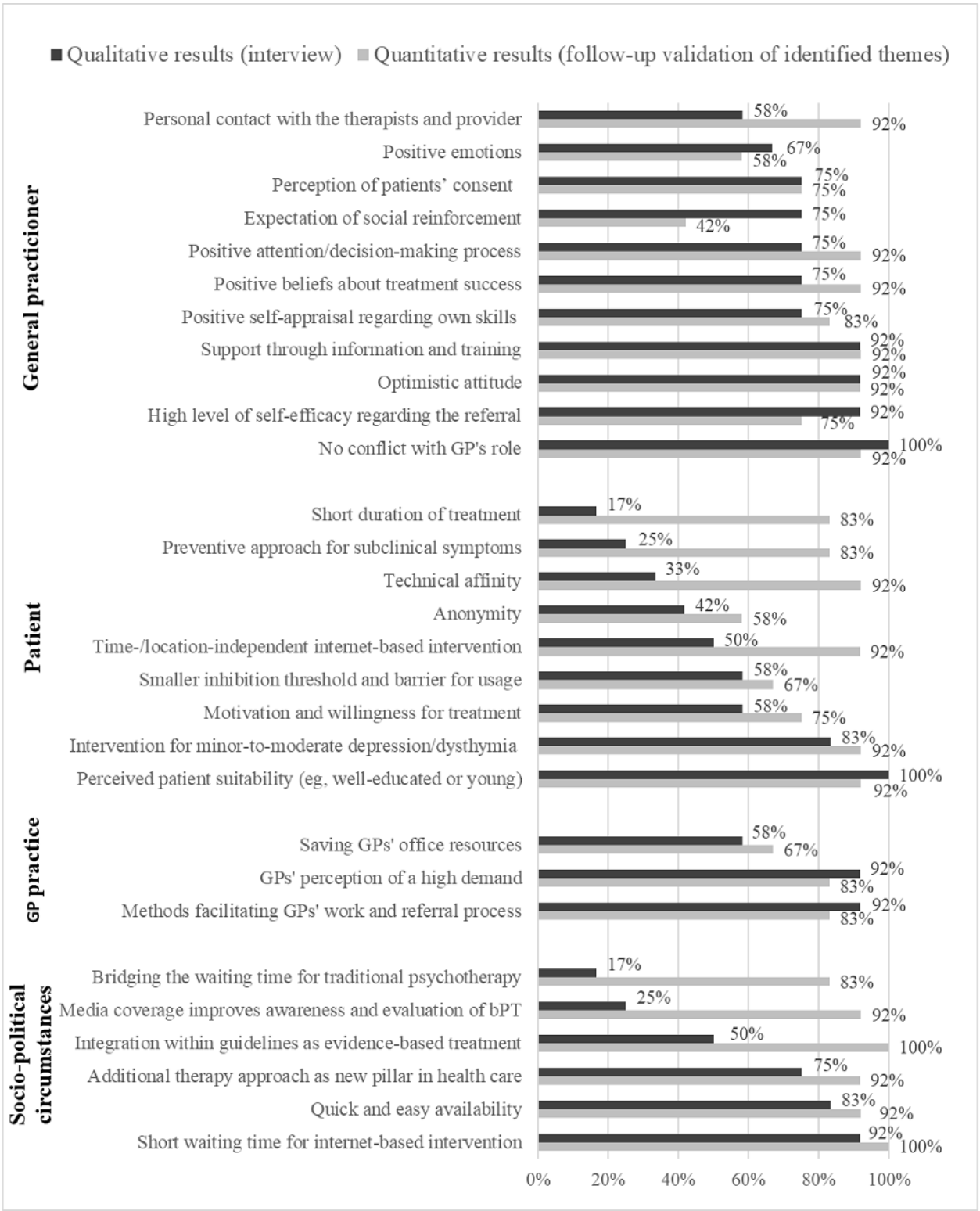
Figure 1. Frequency graphs of barriers for referrals to blended psychotherapy (bPT) mentioned in the interviews and in the follow-up assessment. GP: general practitioner.



All enabling factors and the percentage of all 12 GPs who mentioned the facilitator in the interview and the follow-up validation survey of qualitative findings are listed in Figure 2. The average proportion of GPs who mentioned these facilitators in the interview was 66% (SD 25%; minimum=17% and maximum=100%), whereas the mean agreement rate for facilitators in the quantitative follow-up survey was 83% (SD 14%; minimum=42% and maximum=100%). Overall, 66% of these 29 facilitators received higher agreement rates from GPs when presented as a list.

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Figure 2. Frequency graphs of facilitators for referrals to blended psychotherapy (bPT) mentioned in the interviews and in the follow-up assessment. GP: general practitioner.



Differences in the Barriers and Facilitators Perceived by GPs With Different Characteristics

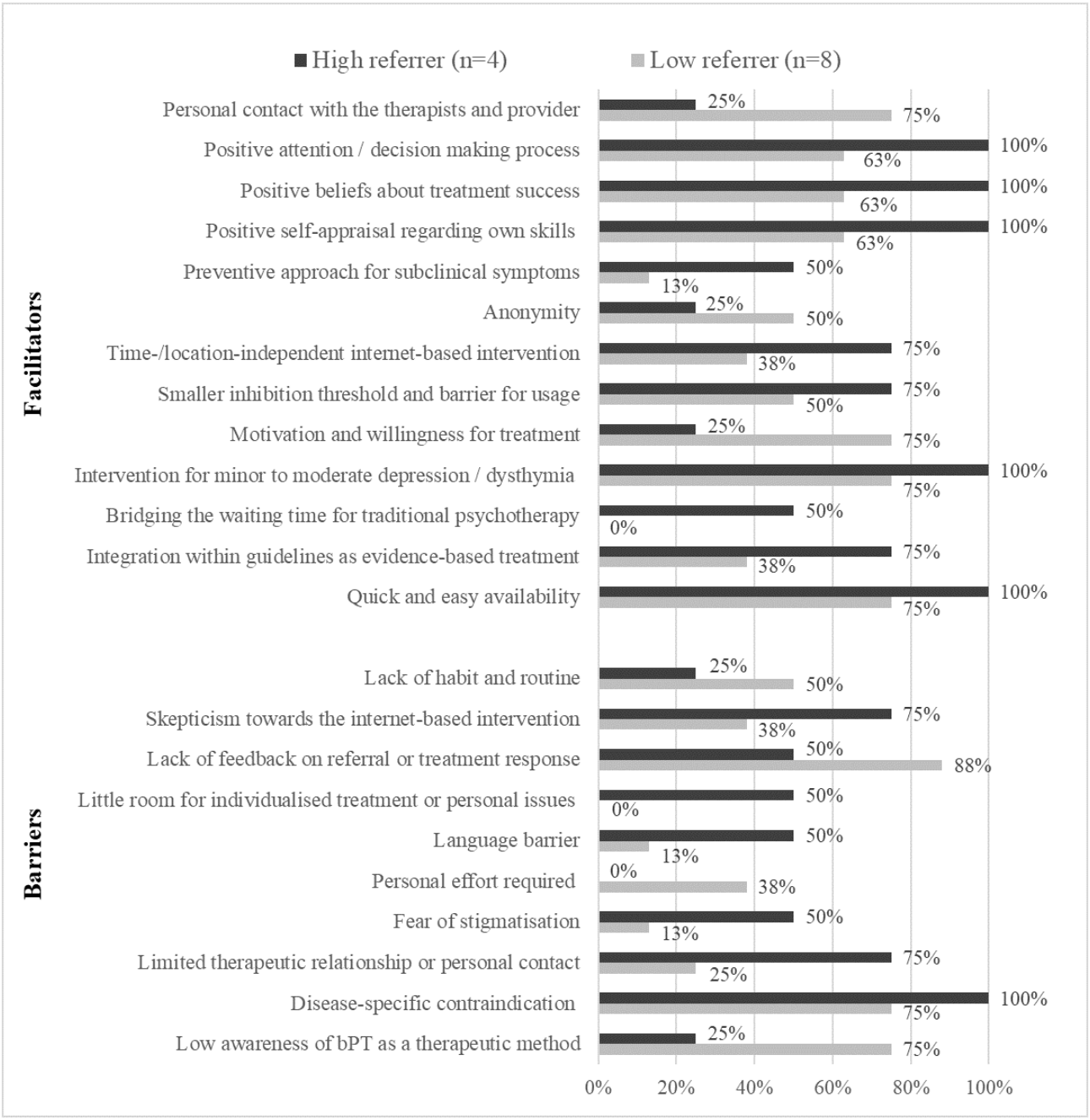
Frequency tables indicated there were differences between GPs with different characteristics (low or high referrers, low or high GP experience, and no or yes psychotherapist) in terms of whether they mentioned particular barriers and facilitators. Descriptive statistics and 95% CIs can be found in Multimedia Appendix 4.

Barriers (10/19) and facilitators (13/29) with a discrepancy of at least 25% among GPs with high versus low referral rates are shown in Figure 3. Those mentioned by more high referrers, with a difference of 50%, included *bridging the waiting time for traditional psychotherapy*, *little room for individualized treatment or personal issues*, and *limited therapeutic*

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relationship or personal contact. Low referrers more frequently mentioned with a difference of 50% *low awareness of bPT as a therapeutic method*, *personal contact with the therapists and provider*, and *patients' motivation and willingness for treatment*. Such meaningful differences were not found when comparing GPs with high or low experience and training or no training in psychotherapy.

Figure 3. Barriers and facilitators mentioned by high versus low referrers with group differences of ≥ 25%.



The GPs with low referral rates mentioned fewer barriers (mean 9.75, SD 1.83) and facilitators (mean 18.25, SD 4.13) than those with high referral rates (B: mean 10.50, SD 2.38; F: mean 21.00, SD 3.92). Both GP groups mentioned, on average, more facilitators than barriers.

Discussion

Principal Findings and Comparison With Prior Work

This mixed methods study investigated facilitators and barriers for referrals to bPT for depression from the perspective of GPs. The results should be interpreted in light of the fact that the sample was limited, small, self-selected, and unlikely to represent the full range of all GPs' experiences (because of low response rates). Although referral rates were quite low, they differed between GPs. The lower the RCT-GPs rated their pharmacotherapeutic skills, the more referrals they made. Interviewees referred more than double the number of patients than the RCT-GPs.

All 29 facilitating and 19 hindering factors were identified on the levels of GP, patient, GP practice, and sociopolitical circumstances. The most frequently named barriers by the

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interviewed GPs concerned the use of new technologies within blended treatments, as most assumed that some patients would not be familiar with internet and technology or would be skeptical and uncertain as to whether an internet-based intervention could help them. These findings are in line with earlier research on barriers to the use of bPT by psychotherapists [34,35,55,56] as well as IMIs by clinicians (psychiatrists or GPs or psychologists) [57] or by GPs [42]. Furthermore, GPs' concerns regarding data safety were also mentioned in previous research on bPT by GPs [58] and psychotherapists [34,35,55] as well as on IMIs by GPs [42] and psychotherapists [59].

The interviewed GPs reported not to be familiar with bPT, to have little knowledge of it, and to prefer more information and training. This is in accordance with the results of studies on bPT in GPs [58] and psychotherapists [56] and stand-alone IMIs in GPs [42,60] and health professionals [61]. GPs also asked for more feedback and professional exchange regarding the treatment, consistent with requests by professionals in previous research on IMIs [57] and with GPs' reported facilitators for referrals to IMIs [41].

GPs had positive beliefs about the treatment success of bPT as well as high self-efficacy levels for patient referrals, contrasting previous findings on IMIs for depression in GPs [42]. This might be because of a higher level of trust in familiar face-to-face treatments or to the scientific setting of the conducted bPT, which reduced uncertainties. The finding that GPs feel no conflict with their role was in contrast with psychotherapists' perceptions [36] but could potentially be explained through their gatekeeper function [40]. Other research suggested that GPs valued the feeling of being more skillful and professional when they blended IMIs with their depression treatment [58].

Further facilitators for referrals mentioned by the interviewed GPs relate to the health care system (eg, shorter waiting time, simple access, closing the treatment gap, feeling able to react to the high number of depressive patients in a better way) and are in line with research on IMIs with GPs [41,42] and bPT with GPs [58] and psychotherapists [34,35]. At the same time, GPs reported barriers such as little familiarity with treatment, missing reimbursement, and legal requirements, which correspond with research of IMIs in GPs [42] and of bPT in psychotherapists [34,55].

GPs' attitudes that patients are suitable for bPT if they are familiar with modern technologies or are affected by minor-to-moderate depression were in line with previous research on bPT with psychotherapists [34,35,56] and GPs [58] and on IMIs with professionals [57,61]. The latter corresponds with treatment guidelines for depression [7,8]. Nevertheless, there is evidence that patients with severe forms can benefit from IMIs compared with untreated controls [62]. Furthermore, GPs judged suicidality and psychotic symptoms as a contraindication for bPT, corresponding with the attitudes of psychotherapists [34,56], despite studies showing that suicidal thoughts [63,64] and positive psychotic symptoms [65] can be targeted successfully with IMIs.

The finding that GPs perceived younger patients to be more suitable for bPT compared with older patients is in accordance with research on IMIs in clinicians [57] and GPs [58] and on bPT in psychotherapists [34,35,55,56]. However, a meta-analysis indicated that older patients significantly profited from a stand-alone IMI for depression and to an even greater extent compared with younger patients [62].

The findings can be interpreted in the context of prior systematic reviews on barriers and facilitators and help to develop implementation strategies. First, they align with the 7 stages of the implementation process of an intervention (eg, physician, patient, and system barriers), which were identified using 256 publications to categorize barriers to optimal clinical practice in health care [66]. These stages could support the implementation of referrals to bPT in practice. Second, the findings fall under important groups of determinants relating to the use of e–mental health interventions [67] and suggest that these are considered valid by GPs in relation to bPT. The authors recommend that implementation practitioners consider such determinants to achieve better implementation results and use these to design and apply specific implementation activities. The research project ImpleMentAll aims to find evidence for such an intervention (the ItFits-toolkit) through the development, application, and evaluation of tailored implementation strategies in ongoing eHealth implementation initiatives [68].

Limitations and Strengths

This study has noteworthy limitations, such as low response rates of GPs to interview invitations (RCT-GPs: 12/110, 11%) and a limited sample size. This meant that further sampling to check the consistency of findings was not possible, and having a small sample size may have produced fewer themes and nuances in GPs' views than the 20 to 30 interviews suggested by guidelines [69]. Yet, sufficient data saturation was reached with 12 interviews. All themes were mentioned by at least two GPs and 45 themes (94%) were mentioned by at least three GPs, which suggests that the findings covered important topics. This is in line with a study that reached saturation with the 12th interview of 60 interviews [70]. Nevertheless, the results of this study represent the perceptions of a small number of interviewees and, as such, may not be representative or generalizable for the whole RCT or primary care GPs. For example, interviewed GPs conducted twice as many referrals (and with 3 times the amount of variance) as the larger sample of RCT-GPs, indicating a self-selection bias of the interview participants toward the Central Research Question. Interviewees may have had a higher motivation and openness to referrals and possibly perceived different barriers and facilitators than the group of RCT-GPs. Concordantly, such differences were found within the interviewed GPs between those with high and low referral rates. However, the mean value of the interviewees was biased by 2 participants having the highest referral rates (each 26), and the average referrals of the interviewees as well as RCT-GPs were both rather low (difference in means was 3.69). The low referral rates resulted in a ceiling effect and limited the mean difference between the groups with low and high referrals. This meant that GP group members with high referral rates potentially experienced referrals to bPT similarly to the low referral group, negatively impacting the ability to make meaningful between-group comparisons. The interpretation of quantitative group comparisons should be considered with care

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because of the small and unequal distributed subsamples. To avoid this limitation, future studies should plan the composition and size of the sample a priori. Furthermore, as low referral rates indicate a low degree of practice and the referral behavior occurred within a standardized RCT setting with an unfamiliar intervention, the perceived barriers and facilitators may not be representative of routine practice. As the GPs participated in the RCT, they may have been biased toward more positive views regarding technology-based treatments and research, indicating a selection bias. GPs in routine care and/or with more experience with bPT might express other attitudes and views. On the other hand, when implementing bPT as a referral option in primary care, these early insights will be important for the outcome. Further limitations include the failure to register the intended referrals by GPs. Referral rates per GP relied on patient self-report screening data and may reflect the successful number of referrals rather than the actual intended referrals.

The strengths of this work included the mixed methods approach, which enabled the research team to generate in-depth findings by using a theory-based interview guide, and validated qualitative findings with a survey. The consensus and iterative approach is used to develop codes, and independent coding with a moderate interrater agreement enhanced rigor in producing the results. Identifying GP subgroups and comparing differences between these provided an indication of whether barriers or facilitators differed in their importance to different GPs.

Implications for Clinical Practice and Future Research

Findings relating to barriers and facilitators could be used to design implementation strategies to support the integration of bPT as a referral option in clinical practice. The TDF is associated with the Behavior Change Wheel framework, which connects theoretical domains to 3 broad drivers of behavior: capability, opportunity, and motivation (COM-B model). It also connects these to specific intervention options [48,71], describes step-by-step how implementers can develop measures for behavioral change, and supports theory-based decision making [71]. Therefore, the study findings can be used to derive helpful, theory-based practical tips for developing effective intervention strategies for the implementation of bPT. Possible interventions include training and communication activities that can address the need for knowledge, attitudes, and misconceptions about bPT and expected patient reactions; legally required sophisticated IT solutions that reduce uncertainties regarding technology use and data safety; and stakeholder and policyholder involvement to drive the necessary adaptation of reimbursement or treatment guidelines.

In addition, future studies might explore barriers and facilitators in larger samples, invite GPs that have referred to bPT in routine care, and consider different delivery options of digital interventions (eg, guided IMIs). Furthermore, the roles of GPs as referrers to or users of blended treatments for different mental health disorders should be evaluated.

Conclusions

This study provides insights into barriers and facilitators determining GPs' referral behavior in relation to bPT for depression. The results indicate that GPs perceive bPT as an additional and valuable treatment delivery format. Having a central position in depression treatment, they experience positive consequences for their own professional group and for patient care when they are able to use bPT as a referral option. Thus, GPs appear to be ready as stakeholders to integrate digital interventions blended with face-to-face psychotherapy in their depression management. However, they experienced considerable barriers to their referrals, which might have led to their low referral rates in this study. Understanding and addressing their perceived barriers and facilitators might enhance their uptake of bPT as a referral option and therefore improve patients' access to specialized care.

On the basis of these findings, the following issues should be taken into account when developing an implementation strategy: (1) address the organizational, legal, and reimbursement requirements; (2) consider GPs' suggestions for implementation, such as the integration of bPT as an additional care pillar in treatment guidelines and the development of measures to increase familiarity with bPT and its advantages (eg, shorter waiting time, improved treatment availability); (3) save GPs' resources (eg, digital referral receipts, automated feedback about treatment findings, patient leaflet); (4) ensure fit with GPs' habits and routine activities (eg, interacting with information technology and reimbursement structures in health care); and (5) address GPs' need for information and training on bPT as well as personal contact and feedback in communication with therapists.

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Authors' Contributions

IT designed the study, developed the interview guide, recruited participants, collected the data, designed or contributed to the qualitative data analysis and interpretation within consensus meetings, performed the quantitative analysis, and drafted the manuscript. SS contributed as therapist and independent researcher to the discussion of emerging themes within consensus

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meetings as well as critically revised the manuscript. DE supervised the manuscript writing. MB and HR critically revised the manuscript. All authors have read and approved the final manuscript.

Conflicts of Interest

DE has served as a consultant on scientific advisory boards in the eHealth setting. DE is a stakeholder of the GET.ON Institute, which aims to implement science-based digital health interventions in routine care. IT and SS have received fees and travel costs for lectures or workshops in the eHealth setting from congresses and psychotherapy training institutes. HR and MB declare that they have no competing interests.

Multimedia Appendix 1
Description of the blended internet-based psychotherapy as intervention and screenshots of the Moodbuster website and app.
[DOCX File , 1470 KB - mental_v7i8e18642_app1.docx]

Multimedia Appendix 2
Consolidated Criteria for Reporting Qualitative Studies checklist. This table shows the COREQ checklist, a guideline for reporting qualitative studies.
[DOCX File , 41 KB - mental_v7i8e18642_app2.docx]

Multimedia Appendix 3
Correlations, means, SDs, and minimum/maximum of general practitioners' referrals and characteristics (randomized controlled trial; sample N=76). This table shows the correlations between the number of referrals and characteristics, self-ratings on competences, and agreements to statements about depression management.
[XLSX File (Microsoft Excel File), 14 KB - mental_v7i8e18642_app3.xlsx]

Multimedia Appendix 4
Descriptive statistics and 95% CI for different general practitioner groups and their mentioned barriers and facilitators (interviewed general practitioners N=12). The contingency tables show the frequency and total numbers of barriers and facilitators in each group (low/high referrers, low/high general practitioner experience, and psychotherapist yes/no).
[XLSX File (Microsoft Excel File), 30 KB - mental_v7i8e18642_app4.xlsx]

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Abbreviations

bPT: blended psychotherapy
CBT: cognitive behavioral therapy
E-COMPARED: European Comparative Effectiveness Research on Internet-based Depression Treatment
e–mental health: electronic mental health
GP: general practitioner
IMI: internet- and mobile-based intervention
MDD: major depressive disorder
RCT: randomized controlled trial
TDF: theoretical domains framework

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