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Contents

Original Papers

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Editorial / Patient Perspective

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Original Paper

Preliminary Evaluation of a Brief Web and Mobile Phone Intervention for Men With Depression: Men's Positive Coping Strategies and Associated Depression, Resilience, and Work and Social Functioning

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Abstract

Background: Previous research has identified that men experiencing depression do not always access appropriate health services. Web-based interventions represent an alternative treatment option for men, are effective in reducing anxiety and depression, and have potential for wide dissemination. However, men do not access Web-based programs at the same rate as women. Programs with content explicitly tailored to men's mental health needs are required.

Objective: This study evaluated the applicability of Man Central, a new Web and mobile phone intervention for men with depression. The impact of the use of Man Central on depression, resilience, and work and social functioning was assessed.

Methods: A recruitment flier was distributed via social media, email networks, newsletters, research registers, and partner organizations. A single-group, repeated measures design was used. The primary outcome was symptoms of depression. Secondary outcomes included externalizing symptoms, resilience, and work and social functioning. Man Central comprises regular mood, symptom, and behavior monitoring, combined with three 15-min interactive sessions. Clinical features are grounded in cognitive behavior therapy and problem-solving therapy. A distinguishing feature is the incorporation of positive strategies identified by men as useful in preventing and managing depression. Participants were directed to use Man Central for a period of 4 weeks. Linear mixed modeling with intention-to-treat analysis assessed associations between the intervention and the primary and secondary outcomes.

Results: A total of 144 men aged between 18 and 68 years and with at least mild depression enrolled in the study. The symptoms most often monitored by men included motivation (471 instances), depression (399), sleep (323), anxiety (316), and stress (262). Reminders were scheduled by 60.4% (87/144). Significant improvements were observed in depression symptoms (P<.001, d=0.68), depression risk, and externalizing symptoms (P<.001, d=0.88) and work and social functioning (P<.001, d=0.78). No change was observed in measures of resilience. Participants reported satisfaction with the program, with a majority saying that it was easy (42/51, 82%) and convenient (41/51, 80%) to use. Study attrition was high; 27.1% (39/144) and 8.3% (12/144) of the participants provided complete follow-up data and partial follow-up data, respectively, whereas the majority (93/144, 64.6%) did not complete follow-up measures.

Conclusions: This preliminary evaluation demonstrated the potential of using electronic health (eHealth) tools to deliver self-management strategies to men with depressive symptoms. Man Central may meet the treatment needs of a subgroup of depressed men who are willing to engage with an e-mental health program. With further research, it may provide an acceptable

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option to those unwilling or unable to access traditional mental health services. Given the limitations of the study design, prospective studies are required, using controlled designs to further elucidate the effect of the program over time.

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KEYWORDS

depression; eHealth; men; mental health

Introduction

Global prevalence estimates show that a substantial number of men are affected by depression [1,2]. Although women are diagnosed with depression more frequently [3,4], recent research acknowledges that men may express depression differently than women [5], with some pointing to higher rates of substance use disorders, relationship problems, and externalizing behaviors among men as evidence of "masked" depression [6]. Globally, prevalence estimates of depression in men vary between 3.8% and 6.4%, depending on the measurement and definition [2]; in 2012, the rate of male suicide (15 per 100,000) was nearly double the rate in women (8 per 100,000; [7]). In Australia, the estimated 12-month prevalence of mental or substance use disorders among men is 20.4% [8], and men die from suicide at nearly 4 times the rate of women [9].

At the same time, men are less likely to seek professional help for health problems; a recent review concluded that men's individual level of adherence to masculine role norms can significantly affect their help-seeking behavior and symptom management [10]. For some, beliefs about traditional masculinity can contribute to inhibiting emotions and perceived need for help [11]. Furthermore, the use of maladaptive coping strategies [12] is implicated in men's risk of attempting suicide [13].

Globally, there are calls for improved longitudinal data regarding changes in the rates of men's help-seeking behavior for mental health [14]. Whereas the proportion of Australian men seeking professional help for mental health and substance use problems increased significantly between 2006 and 2012 [15], men still access treatment at lower rates than women, and common mental health problems in men persist. Indeed, even when men see a health professional, they may not always disclose psychological distress [16]. Furthermore, men with more severe depression report higher perceived barriers to help-seeking [17], and there are persistent barriers to successful detection and management of depression [16,18]. For example, general practitioners (GPs) cite not having sufficient training in mental health and a lack of confidence in managing symptoms as specific barriers [19]. Thus, while access to services is improving, there are still men at risk of depression and suicide, who are unable to access appropriate care in a timely manner.

In recent years, the use of Web and mobile phone–based interventions has received considerable research attention [20]. Web-based cognitive behavioral therapy (CBT) programs targeting depression and anxiety are effective in reducing symptoms [21,22], are cost effective [23], have comparable treatment effects with face-to-face therapy [24], and can contribute to improvements in work and social functioning [25]. A systematic review concluded that mental health programs delivered via mobile phones could deliver reductions in depression, stress, and substance use, with the potential to improve treatment accessibility [26]. As a result, there are growing calls for the integration of effective e-mental health services with primary care, clinical, and community settings [27,28], with an emphasis on the importance of research rigor [26], the need for user involvement in the development stage [29,30], and an understanding of consumer preferences [31,32]. Research indicates that, on the whole, men do not take up Web-based interventions at the same rate as women [33], though reasons for this are not always clear. However, one study reported higher rates of acceptance of a Web-based intervention among young men than young women when the intervention was accessed via Internet from the home (as opposed to school; [34]). Thus, the question that arises is whether Web-based programs can be developed that target men and will be liked and used by men.

In this context, this research developed a brief intervention for men with at least mild depression following participatory-based design recommendations [35]. Men from around Australia were involved in two phases of research to identify the most effective self-care strategies they used to prevent and manage depression [36-38]. The results were used to develop and test a Web and mobile phone brief intervention for men with depression, in response to concerns that at-risk men in the community may not access traditional services in a timely manner. This study aimed to assess the feasibility of the intervention and to evaluate its relationship with symptoms of depression, resilience, and work and social functioning.

Methods

Recruitment

The study was promoted via the lead institute's professional and digital networks. The Black Dog Institute is a translational research center that incorporates research, clinical services, and community education and focuses on achieving reductions in the incidence of mental illness and suicide rates in Australia. The study was promoted as a "Research Study: 'Man Central'—an online tool for depression," and the recruitment flier worded potential participation as follows: "We will ask you to visit the study website and answer a few questions to see if the study is suitable for you. If you are enrolled in the study, you will be asked to complete initial study questionnaires and complete your registration with the program. You will then be asked to use the online program for a period of 4 weeks, while tracking your moods. At the end of 4 weeks, you will be asked to complete the second round of study questionnaires." Recruitment activities included circulation of a printed recruitment flier, social media publicity using Facebook and

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Twitter and links to the study on the lead institute's websites, email circulation of an electronic flier through the organizational networks of all the partners on the study, and an invitation email to men who had previously registered to the lead institute's volunteer research register. An email flier was also circulated via Mensheds Australia [39]. The promotional flier invited Australian men to visit the study website and register their interest in participating. This expression of interest was open between May and October 2014, and the study remained listed on the Black Dog Institute's website under "research opportunities" during this period. Once the development of the tool was complete, all men who had registered an expression of interest in knowing more about the study were contacted via their email address and invited to visit the study website where they could participate in screening procedures to assess their eligibility. At this time, the study was publicized again via the lead institute's social media pages with a link to the study website.

Men were eligible to participate if they scored at least 5 or more on the Patient Health Questionnaire-9 (PHQ-9; ie, mild depression), had a valid email address, could access the Internet via both a computer and a mobile phone, were aged 18 years or more, were resident in Australia, and were comfortable reading and writing English. Men were excluded on the following basis: no current depression or depression symptoms below the study threshold (PHQ-9 total score less than 5), frequent suicidal thinking (a score of 3 on item ix of the PHQ-9: "Thoughts that you would be better off dead or of hurting yourself in some way"), and/or psychosis (score of 2 or more on the Psychosis Screening Questionnaire).

Intervention

The Man Central intervention was delivered via an existing Web-based program, myCompass [25]. myCompass was developed by the Black Dog Institute and is fully automated and delivers a personalized intervention based on the assessment of user's symptoms at registration. Recommendations include a set of interactive, skill-based psychoeducational modules and cognitive/behavioral factors for self-monitoring. There is flexibility for users to select their own modules and self-monitoring dimensions if they wish. Additionally, access to a range of other resources, including self-monitoring reminders, mental health care tips and motivational statements delivered by email/short message service (SMS), a Web-based journal, and graphical reporting of self-monitoring data is provided.

There are currently 12 myCompass modules, including four core modules (eg, tackling unhelpful thinking), three recommended modules (eg, sleeping well), and six further modules that can be completed at the user's convenience (eg, communicating clearly and managing fear and anxiety). For this study, access to the existing 12 myCompass modules was restricted to ensure users' engagement with the new module (Man Central) only (see Figure 1). Man Central was developed for men with depression, based on the results from two previous phases of research exploring men's use of and preferred positive strategies to prevent and manage symptoms of depression, including suicidal ideation [36,37].

In line with the existing myCompass modules, Man Central is delivered without therapist support, although the content was developed by a clinical psychologist in close coordination with the research team (AF and EW), followed by a review by a senior clinical researcher (JC) and project leads (JP and KW). Principles of both CBT and problem-solving therapy were used to inform the development of the module exercises, with emphasis given to the words and examples used by men in the development phase of research.

The module comprises three brief interactive sessions and two home tasks ("Man Experiments") to facilitate skill generalization (Figure 2). Session 1 focuses on understanding the links between moods and behavior, as well as recognizing warning signs or changes in mood. Session 2 focuses on strategies used by other men, with the user choosing some to try. Session 3 focuses on staying on track, having tried new strategies, and building a plan for the future based on what worked well.

In general, each session incorporates initial education, concept examples, a case study example, and the user applying the ideas to their personal situation by entering information into the program in response to prompts. At the end of each session, users are introduced to a homework task, where they record the activity they have chosen, plan to practice the task, and can elect to receive reminders to do the activity through the week. Upon returning for the next module session, users review their "Man Experiment" and rate their enjoyment of it. Different feedback is offered by the program, dependent on whether the experiment went better or worse than expected or whether the user felt neutral about it.

Throughout all sessions and experiments, a traffic lights analogy is used to facilitate men's understanding of different moods and associated behaviors, which distinguishes between a Green Zone (ie, prevention), Orange Zone (ie, early intervention), and Red Zone (ie, management of a depressed mood). In addition, users learn skills regarding the identification of unhelpful strategies (ie, maintaining factors), awareness of predisposing factors and difficult situations, and choice of appropriate action. Figure 2 illustrates two case studies featuring the male characters who provide examples for men to consider when examining their own situations (Figure 2).

The "Man Experiments" encourage men to evaluate how well those activities suited them and their lifestyle, with a view to finalizing a mental "tool kit" of strategies to be used in tough times. The module concludes with the development of a personalized "traffic lights plan," which identifies moods, behaviors, warning signs, and appropriate helpful strategies that match a user's Green, Orange, and Red zones (Figure 3).

In addition to completing Man Central, participants were required to perform regular "mood monitoring" using the tracking features of the myCompass program, which allowed men to monitor up to the three symptoms, moods, or behaviors, while at the same time recording contextual data (eg, where they were, who they were with, and what they were doing). Tracking was an essential feature of the intervention, given its relationship with improved outcomes [40].

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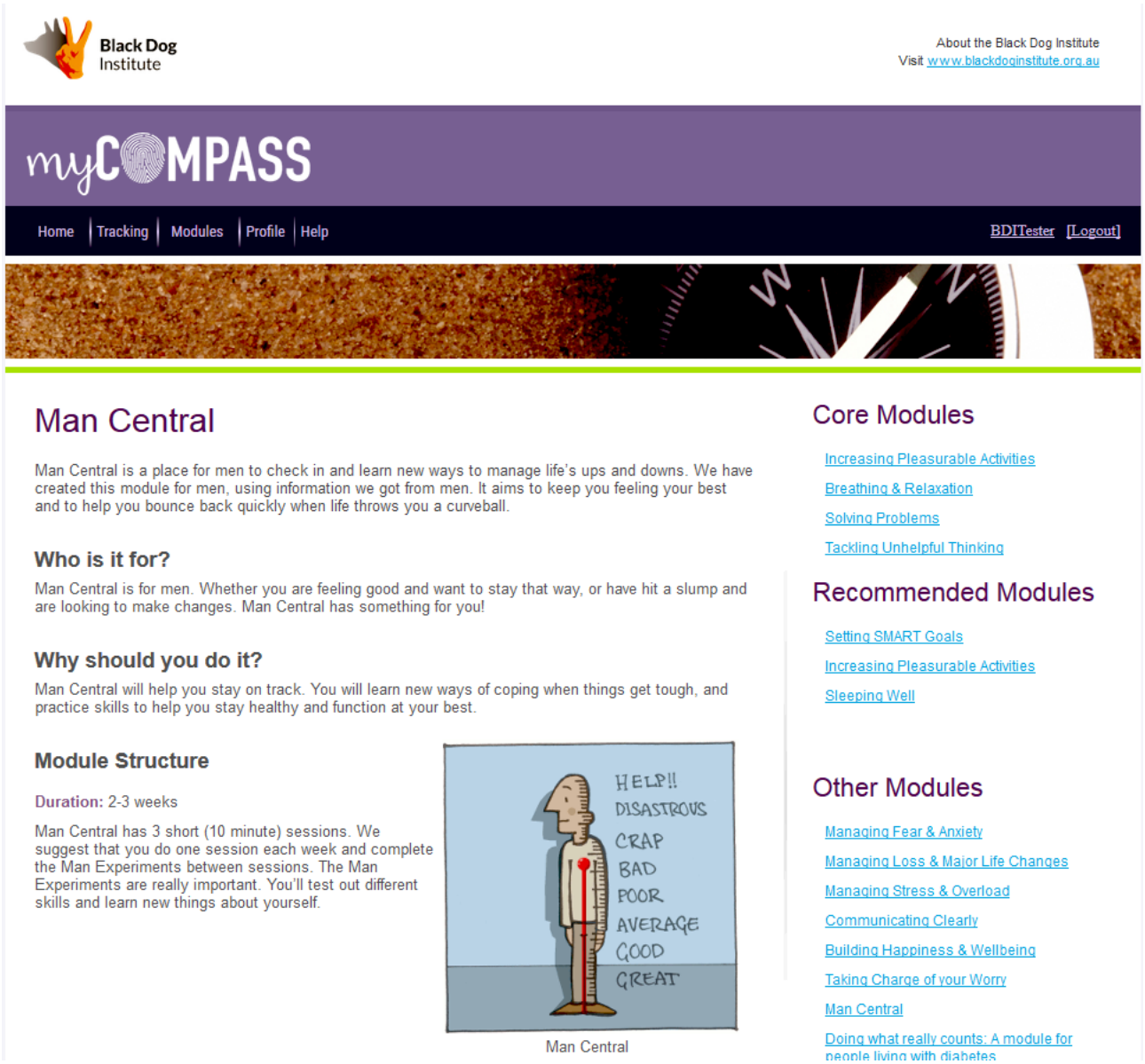
Figure 1. Home page of Man Central module on myCompass program.



Man Central

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Figure 2. Example of "Man Experiment" with case studies.

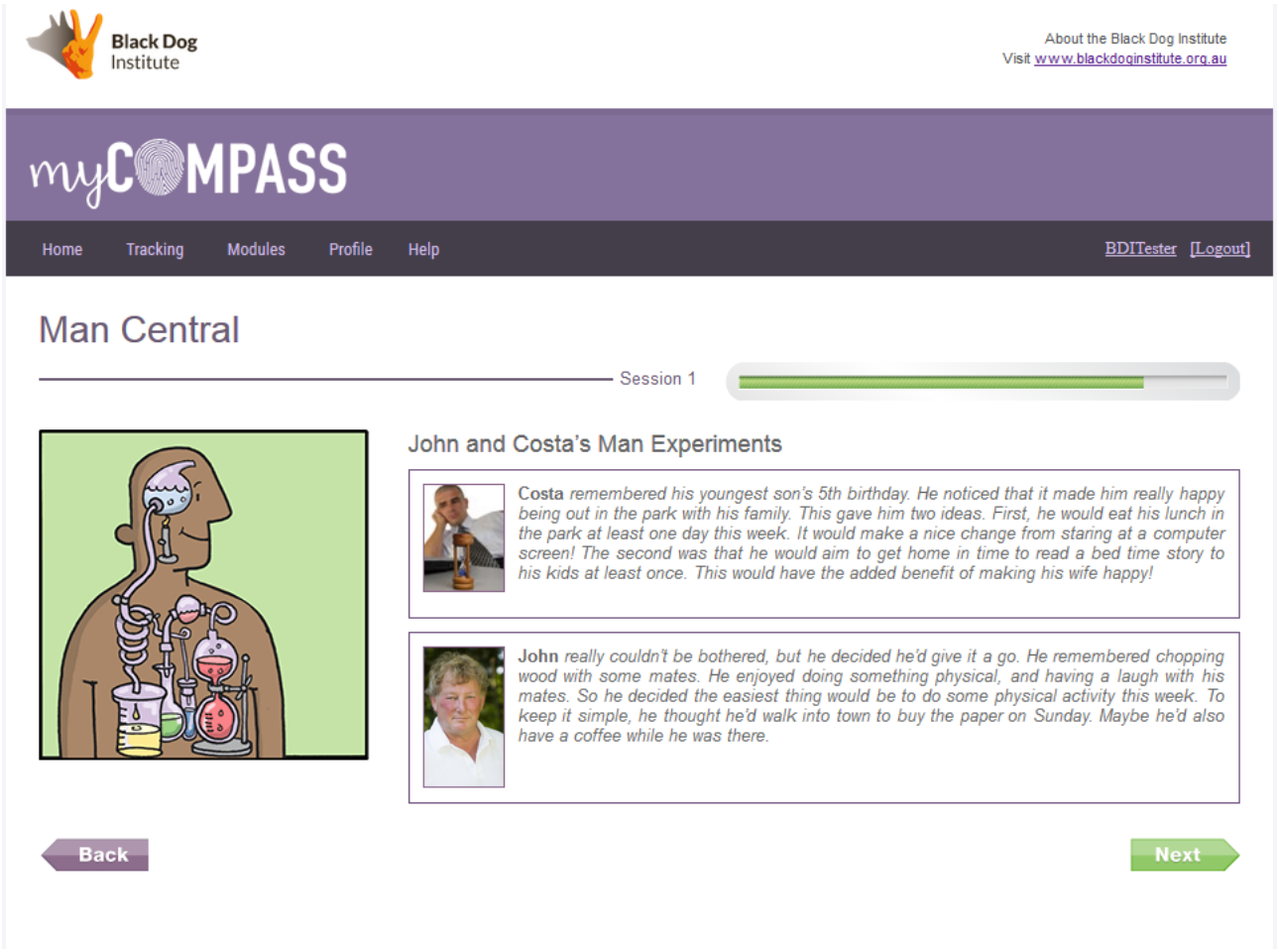
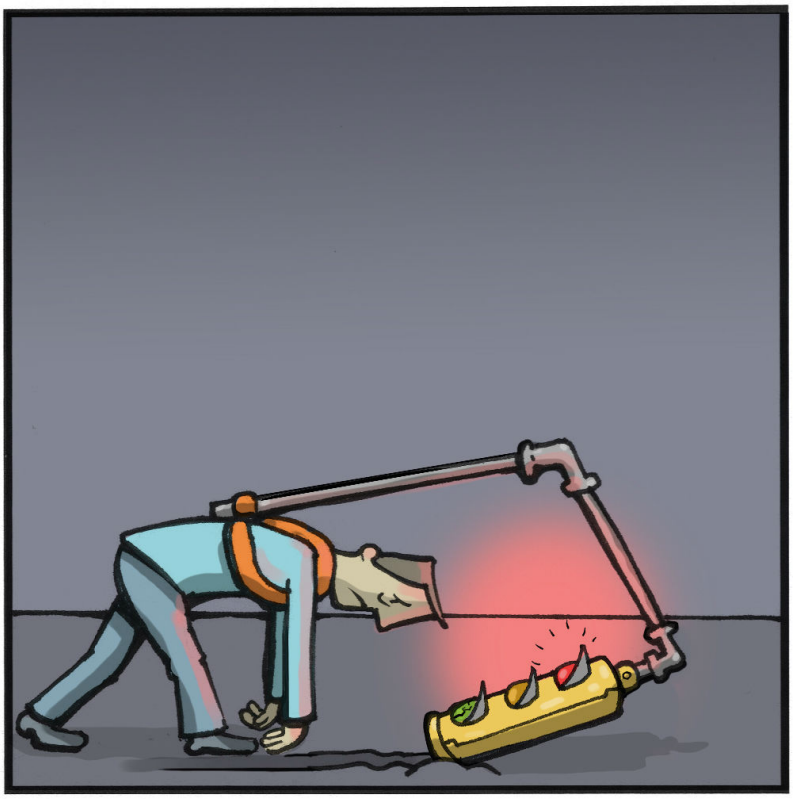


Figure 3. "Red Light"—traffic light imagery used in Man Central module.



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Design and Procedure

The preliminary evaluation used a single-group, repeated measures (pre-post) design to evaluate associations between the use of Man Central and the measures of depression, resilience, and work and social functioning. Interested men visited the study website to complete screening. Eligible participants who consented commenced baseline data collection immediately, followed by automated registration with myCompass.

Once enrolled in the study, users were instructed to complete mood monitoring for 4 weeks, one module session per week, and the two home tasks in between module sessions. Participants were contacted at regular intervals by the study team as per the following schedule: (1) within 3 days of registration, participants were welcomed into the study; (2) at 2 weeks, a reminder advised participants that they were at the halfway point and queried any technical problems; (3) at week 3, a reminder encouraged participants to complete the module; (4) at week 4, a reminder prompted participants to provide follow-up data; and (5) a final reminder advised participants that the study was complete and prompted follow-up data collection for anyone who had not completed the questionnaires. This was done based on previous research, which found that automated reminders could improve course-completion rates [41]. However, it should be noted that none of the contacts with the research team contained therapeutic information or support.

All data were collected online via a study-specific website, which was integrated with the myCompass program. Participants were compensated Aus $50 for their time, and access to the other myCompass modules was restored at the close of the study.

The study was approved by the UNSW Australia's Human Research Ethics Committee (HREC13077).

Measures

Participants provided standard demographic data (age, gender, relationship status, and location) at enrollment. Outcome measures were collected at baseline and follow-up, 4 weeks later. The primary outcome was symptoms of depression, as measured by the well-validated PHQ-9 [42-44], which asks how often a person has been bothered by particular symptoms in the previous 2 weeks. Total scores range from 0 to 27, with clinically significant cut points indicating mild (5-9), moderate (10-14), moderately severe (15-19), or severe (20+) depression.

Secondary outcomes included the assessment of externalizing symptoms of distress using the Male Depression Risk Scale (MDRS; [45]), which uses 22 items rated on an 8-point scale (0-7), with higher total scores indicating higher distress, and validated subscale scores are produced for emotional suppression, drug use, alcohol use, anger and aggression, somatic symptoms, and risk-taking. Functional impairments in work, home, leisure, and social activities were assessed via the Work and Social Adjustment Scale (WSAS; [46]). Participants rate 5 items on a 9-point scale (0-8) that generates a total score between 0 and 40, with higher scores indicating more severe impairment. The Connor-Davidson Resilience Scale (CD-RISC; [47]), which comprises 25 items rated on a 5-point scale (0-4), was used to assess psychological resilience. Total scores range between 0 and 100, with higher scores indicating higher resilience.

At follow-up, participants were also asked to rate their satisfaction with the myCompass program. Use of the intervention was monitored via the number of log-ins, symptoms monitored, and reminders sent.

Data Analysis

All data were analyzed using the Statistical Package for Social Sciences (SPSS) version 22.0 (IBM Corp; [48]). Descriptive statistics (mean, standard deviation [SD], and range) were obtained for all baseline data. Independent *t*-tests, chi-square tests, and bivariate and point biserial correlations were used to examine relationships between demographic data and primary and secondary outcomes and differences between those who completed or dropped out of the study. Changes in the primary and secondary outcome measures between baseline and follow-up were examined using linear mixed modeling analyses [49-51], which allows for the inclusion of cases with incomplete data, with centered baseline scores on primary and secondary outcomes entered into the model as covariates. Parameter estimates were obtained using the restricted maximum likelihood method (REML), Cohen *d* was used to estimate within-group effect size, and separate analyses estimated significant changes between baseline and follow-up at $P<.05$ level.

Results

Participants

In total, 254 men participated in screening, and 144 met eligibility criteria, enrolled in the trial, and completed baseline data collection. Participants were excluded because of incomplete screening questionnaires (41/254; 16.1%), reporting either no symptoms of depression or symptoms that fell below the study threshold for inclusion (32/254; 12.6%), not having access to the Internet via both mobile phone and computer (14/254; 5.5%), symptoms of psychosis (12/254; 4.7%), previous use of myCompass (6/254; 2.4%), being nonresident in Australia (3/254; 1.2%), and being female (1/254; 0.4%).

Table 1 shows the demographic and clinical features of the sample. Participants were aged between 18 and 68 years, and about one-third were married (53/144; 36.8%) or single (44/144; 30.6%). The majority (118/144; 81.9%) were located on Australia's Eastern seaboard. Just over half of the participants reported mild to moderate depression (82/144; 56.9%). With the exception of the MDRS emotion suppression subscale (mean: 20.3, SD: 4.5), where mean scores were on the higher end of the range, all MDRS subscale mean scores were below the midpoint. Mean scores on the CD-RISC (mean: 52.3, SD: 12.7) were at the midpoint of the scale, indicating midrange resilience. Participants' mean score on the WSAS (mean: 21.4, SD: 8.0) indicated some functional impairment. The majority (87/144; 60.4%) indicated that they found it "somewhat difficult" to do their work, take care of things at home, or get along with other people. Just over one-third (51/144; 35.4%) reported that it was "very" or "extremely difficult." Nearly half (70/144; 48.6%) of all participants reported that their ability to lead a normal life was impaired "markedly or very severely."

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Table 1. Sample characteristics.

Participant characteristics		(N=144)
Age in years, mean (SD)		40.47 (10.9)
Age group in years, n (%)		
	18-24	10 (6.9)
	25-34	34 (23.6)
	35-44	50 (34.7)
	45-54	35 (24.3)
	55+	15 (10.4)
Marital status, n (%)		
	Single	44 (30.6)
	De facto	26 (18.1)
	Married	53 (36.8)
	Divorced	21 (14.6)
PHQ-9[a] depression severity, n (%)		
	Mild	33 (22.9)
	Moderate	49 (34.0)
	Moderately severe	43 (29.9)
	Severe	19 (13.2)
MDRS[b] , mean (SD)		
	Total	61.9 (22.7)
	Emotion suppression	20.3 (4.5)
	Drug use	3.1 (5.9)
	Alcohol use	9.8 (9.7)
	Anger and aggression	11.8 (7.5)
	Somatic symptoms	10.3 (6.7)
	Risk-taking	6.7 (5.0)
CD-RISC[c] total, mean (SD)		52.3 (12.7)
WSAS[d] total, mean (SD)		21.4 (8.0)

[a]PHQ-9: Patient Health Questionnaire-9.

[b]MDRS: Male Depression Risk Scale.

[c]CD-RISC: Connor-Davidson Resilience Scale.

[d]WSAS: Work and Social Adjustment Scale.

Covariates and Study Attrition

Being in a relationship at baseline was weakly correlated with lower PHQ-9 scores (r^2=−.19, P=.02), higher CD-RISC scores (r^2=.238, P=.004), and lower total MDRS scores (r^2=−.278, P=.001). There were no other potential covariates identified.

There were no significant differences between those who provided complete follow-up data (39/144; 27.1%) and those who did not (105/144; 72.9%) on demographic factors or baseline measures of depression (PHQ-9, MDRS), resilience (CD-RISC), and functional impairment (WSAS).

Postintervention Study Outcomes

Table 2 shows mean scores on the outcome measures at baseline and follow-up, and results of the linear mixed modeling analyses. With the exception of CD-RISC scores, which remained unchanged, improvement was observed for all primary and secondary outcome measures, including depression (PHQ-9), work and social functioning (WSAS), depression risk (MDRS total), and all the subscales of externalizing symptoms of depression on the MDRS (emotion suppression, drug use, alcohol use, anger and aggression, risk-taking, and somatic symptoms). Also, shown in the last column are the within-group effect sizes at follow-up for all outcomes measures. Effect sizes are all within the moderate range, with the exception of the

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effect size for total MDRS score, which is in the high range [52].

Program Satisfaction and User Engagement

One-third of respondents (51/144; 35.4%) provided ratings of their satisfaction with the myCompass program post intervention. Of those, a majority reported that the program was easy to use (42/51; 82%), convenient to use (41/51; 80%), and easy to understand (35/51; 69%). Lower proportions agreed that the program kept their attention (28/51; 55%); improved their stress, low mood, or anxiety (24/51; 47%); or taught them skills to handle future problems (28/51; 55%). In general, participants reported that they found the tracking functions the most useful (eg, "tracking of moods gave me a comparison of how I was going, in a snapshot"), whereas the least useful parts of the program concerned difficulties with logging in (eg, "complex password to login in via mobile" or "login never worked") or a lack of clarity regarding how to use the module (eg, "too much info was a little overwhelming" or "understanding some of the instructions").

The majority of the participants (102/144; 70.8%) used the mood-monitoring features at least once and accessed the Man Central module at least once (93/144; 64.6%) during the 4-week period. The mean number of log-ins reported was 12 (SD: 15.8, range: 0-108), with 16.7% (24/144) logging in more than 20 times. The symptoms most often monitored by men included motivation (471 times), depression (399 times), sleep (323 times), anxiety (316 times), and stress (262 times). Reminders to monitor symptoms were scheduled by 60.4% (87/144), with an almost even split between email and SMS reminders.

There was no difference at baseline between men who did and did not log in to use Man Central during the intervention period, and the total number of log-ins to the program did not correlate with any primary or secondary outcome data obtained at baseline.

Table 2. Results of linear mixed modeling analyses: observed scores on primary and secondary outcome measures, and within-group effect sizes (Cohen *d*) post intervention.

Primary and secondary outcome measures of symptoms and functioning	Estimated marginal means		Test of fixed effects			Post intervention
	Baseline	Follow-up	Degrees of freedom	*F* statistic	*P* value	Cohen *d*
	Mean (standard error)	Mean (standard error)				
PHQ-9[a]	13.75 (0.18)	10.49 (0.35)	1,165	66.9	<.001	0.68
CD-RISC[b]	52.18 (0.54)	53.29 (1.0)	1,162	0.916	.34	−0.05
WSAS[c]	21.20 (0.28)	16.88 (0.55)	1,164	48.3	<.001	0.78
MDRS[d] total	62.1 (0.65)	46.56 (1.3)	1,165	117.7	<.001	0.88
MDRS emotion suppression	20.21 (0.17)	18.39 (0.32)	1,161	25.1	<.001	0.50
MDRS drug use	3.06 (0.13)	1.99 (0.24)	1,167	14.8	<.001	0.39
MDRS alcohol use	9.71 (0.23)	6.63 (0.43)	1,166	38.34	<.001	0.56
MDRS somatic	10.42 (0.26)	6.78 (0.50)	1,166	39.24	<.001	0.43
MDRS anger and aggression	11.91 (0.24)	8.28 (0.46)	1,164	47.77	<.001	0.50
MDRS risk-taking	6.78 (0.16)	4.54 (0.30)	1,164	43.63	<.001	0.43

[a]PHQ-9: Patient Health Questionnaire-9.

[b]CD-RISC: Connor-Davidson Resilience Scale.

[c]WSAS: Work and Social Adjustment Scale.

[d]MDRS: Male Depression Risk Scale.

Discussion

Principal Findings and Comparison With Prior Work

Symptoms of depression were significantly reduced among men with at least mild depression, after using the newly developed module, Man Central, via the myCompass program for 4 weeks. The effect size was moderate (*d*=0.68), indicating that Man Central may have a clinically relevant effect for depression symptoms among men with at least mild depression. A significant reduction was also observed for depression risk (*d*=0.88), alongside improvement in work and social functioning (*d*=0.78). These findings are concordant with previous research showing that brief Web-based interventions can improve depressive symptoms and reduce risk [23,25,53] and suggest that Man Central holds promise as a self-help tool for a subgroup of men with depression who engage with the program.

Man Central differs from currently available Web-based tools in that it specifically targets men, and its development benefitted from prioritizing extensive research into what men themselves say are effective strategies for preventing and managing depression. Thus, it delivers useful program content that relates directly to the users and does not solely rely on delivering standard manual-driven CBT. An initial review into men's coping strategies for depression and suicidality identified the

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use of maladaptive coping strategies as a predominant theme in the literature [38], with little exploration of what "effective coping" looks like from men's point of view. The development of Man Central sought to redress this imbalance by specifically identifying and incorporating those positive strategies that men find preferable or already use effectively [36,37], while also recognizing other research that emphasizes (1) the importance of incorporating notions of "masculinity" into CBT psychoeducation for interventions that are better received among men [54], and (2) men's preferences for self-reliance and independent problem solving, particularly among those men who do not access clinical services early in the course of illness [13,55].

Although it is true that these positive strategies are likely to be useful for both men and women and may have similarities with previously identified strategies for coping with depression (eg, self-care through diet, exercise, and sleep hygiene; helping other people; using humor to reframe situations and negative thinking; and setting goals and completing small achievements; [56]), the design of the module refined these ideas with men's input and with men's acceptance specifically in mind.

Three key features of the module may enhance the likelihood of its uptake among men who are reluctant to engage with standard clinical services, which are as follows: (1) the language used in the module repeatedly emphasizes the role that other men, rather than distant "clinicians," played in creating the examples and module content; (2) the module allows for complete self-guided learning, which may be important for those men who prefer to solve problems independently; and (3) it culminates in creating a personal, individualized step-by-step plan that can be modified based on individual experimentation. This last point is particularly important, as our prior research showed that aside from advising men to talk about their problems, the most common piece of advice given by men to other men in a similar situation was to create a specific concrete plan to follow during times of stress [36]. As such, it is likely that Man Central is acceptable to men, especially as the log-in problems and reportedly confusing instructions have since been rectified.

Notably, the largest effect size observed here related to the MDRS, where scale items explicitly reflect externalizing features of depression thought to be more specific to men's experiences (as opposed to the more standard clinical features of the PHQ-9). Thus, given the symptom improvement observed here, delivery of Man Central via the myCompass program may represent an alternative avenue for men to access treatment and employ useful self-care in managing their mental health.

No change was observed post intervention in resilience, in contrast to previous research, suggesting positive associations between treatment, increased resilience, global improvements, and symptom reductions [47,57]. It may be that as this sample already had midrange resilience scores at baseline, the capacity for improvement in resilience was limited or that the active ingredients in the module failed to have any effect on the measures of resilience. Another possibility is that the brief format of the intervention did not provide a therapeutic "dose" large enough to facilitate improvements in resilience. One previous study [58] reported gains in resilience in a 4-week time frame, which matched the time frame used in this study. However, we note that that research prescribed 2 hours of psychoeducation per week, whereas the time prescribed per week for Man Central was significantly less than 2 hours. Alternatively, resilience promotion among men with depression may require interventions that more directly encourage specific skill development that the module content does not adequately target, especially where depression is recurrent. For example, recent work [59] theorizes that with each recurrent episode of depression, people become less resilient and more sensitive to negative effects of less powerful stressors. This work argues that the following three resilience factors should be targeted in depression management: (1) successful stress management (or "stress-recovery"); (2) flexibility (employing different approaches in different contexts to maximize chances of success); and (3) positivity (competence, positive adaptations, and positive emotions during adversity). Alongside this, three types of intervention are recommended to improve resilience among depressed populations: stress inoculation training, positivity training, and meditation. Though the intervention focused on the positive strategies men use to proactively manage their mental health, these are not necessarily analogous to the intervention types (eg, positivity training) specified by previous work as relating to resilience building in depressed populations [59]. Likewise, identified dimensions of resilience, such as self-efficacy, self-control, and persistence through setbacks [60], may not be adequately targeted by the exercises in the module.

With regard to program engagement, and in line with other myCompass studies, the most popular program feature for the men in our study was symptom tracking [40]. In particular, the symptom tracked most often by the participants was motivation. One possibility is that difficulties with motivation constitute a salient or "core" feature of the depression experience for men, with changes in motivation potentially indicative of significant changes in mood. Further work is needed to determine whether (1) active self-monitoring of motivation is especially clinically relevant for men with depressive symptoms, (2) consistently monitoring motivation levels alongside changes in mood has any predictive or treatment value for self-managing mental health, or (3) motivation levels in men should be prioritized by treating clinicians, lest they be missed by current diagnostic and screening criteria. If so, this could be incorporated into preventive activities, self-management plans, and relapse prevention strategies for men in clinical settings. Furthermore, future research into developing the program could investigate the potential to incorporate psychoeducation strategies that focus on enhancing motivation levels as an ideal place to start for men who have not engaged with health services.

Limitations

This preliminary evaluation was exploratory in nature and therefore has considerable limitations in drawing any causal associations. First, the study's quasi-experimental single-group design prevents attributing improved symptoms and functioning solely to the intervention. For example, it is possible that our results reflect the natural course of remission of symptoms with the passage of time. Nevertheless, reductions in depression

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symptoms have been reported in controlled studies of myCompass previously [25]. When looking specifically at depression symptoms or work and social adjustment, the within-group effect sizes reported for attention-control and wait-list groups in that controlled trial were comparatively smaller (*d* range=0.01-0.27) than the effect sizes reported here, so it is possible that the use of Man Central accelerates the natural time course for men.

Second, adherence to the program was low, with almost one-third of participants not accessing the Man Central module. In addition, study attrition was high. Man Central is a purely self-help program (that is, without therapist or peer support), and low rates of program adherence and high rates of dropout attrition are not uncommon in studies of unguided interventions [61,62], potentially introducing selection bias and complicating interpretation of study findings. Nevertheless, our inspection of potential biases because of these factors yielded few differences between participants who did and did not access the module and did and did not complete postintervention questionnaires. Previous studies have found that adherence can be related to disease severity [63], but this was not the case in this sample. Similarly, it has been suggested that those who do not complete Web-based interventions may have derived benefit before dropping out [64], but it is not possible to infer that from the current data. All participants were invited to give feedback on why they did or did not use the program, but very few responded and of those who did, none reported specific complaints about the content of the program.

Some research suggests that human involvement, in the form of therapist or peer support, in Web-based interventions can reduce attrition rates, particularly among those with low levels of social support [64]. Future studies might seek to determine the impact of these features on program engagement and impact among men with depression. However, given the reluctance of some men to seek support for mental health difficulties, it is crucial to balance such an approach with the privacy and anonymity afforded by the independent and automated nature of the current program design.

Implications and Conclusions

The results indicate that men with at least mild depression are interested in the possibility of using Web-based interventions for self-management of their mental health. We initially sought to recruit only 30 men to test the program but received expressions of interest from more than 300 men. Though not all who expressed interest were eligible, it nevertheless indicates that the idea of using electronic health (eHealth) tools to monitor and manage mental health is palatable to men and that using social media publicity and email fliers to recruit men to studies does pique the interest of some men. Similarly, the present intervention seems to provide an acceptable delivery format, in that the men used the program on both their phone and their computers; logging in multiple times from different locations and making use of multiple program features, including mood monitoring, reminders, and the Man Central module itself.

Given the well-documented low uptake of face-to-face psychological services for men and the increased risk of suicide among men with untreated mood disorders [13,65], it is crucial to establish other avenues of treatment, particularly for those men who might be isolated from other sources of support in their daily lives. Whereas the study lacked the tight controls of a randomized controlled trial, our findings show that Web-based delivery of practical skills and strategies, supported by real-time symptom monitoring, is a potential solution for reaching some men.

We note, however, that it is unclear from the data presented here whether the men who would engage with a service delivered in this way represent a distinct subgroup of men, with definable demographic or clinical features, or whether the recruitment approach and intervention failed to satisfy the expectations and needs of men more generally. Thus, we suggest that controlled investigation of the impact of Man Central is warranted, with an aim to determine: (1) the active program elements and required “dose” for symptom improvement, (2) the conditions under which symptoms gains are greatest (eg, guided vs unguided Internet interventions), (3) the factors governing adherence and program engagement, (4) the possible characteristics of consumers who do or do not wish to access treatment delivered via Web-based interventions, and (5) the relative benefit of delivering tailored interventions to men, as compared with nontailored interventions targeting the same factors.

As is the case for all Web-based interventions, future research will also need to examine and establish the best way to recruit men to such services if they are to be effectively scaled up for population-wide delivery. In particular, whereas this intervention may be useful to some men, it remains to be seen how such services should be promoted. Although there are recent developments in terms of “stepped-care” approaches to service delivery that seek to incorporate the prescription of eHealth tools as a part of initial treatment plans [66], such approaches still rely upon engaging with a health service at some point. Though large proportions of men do visit a GP, establishing uptake of eHealth into primary care is still in the early stages, and this approach would not effectively address the needs of those men who are alienated from all health services. In this case, we suggest future research should examine the potential for community delivery of Web-based mental health services through organizations that may not be specific to mental health but are already engaged with men in some way, for example, MenSheds Australia [39]. Similarly, recent policy recommendations support engaging men, particularly young men, where they are already engaged in community activities (eg, sport, schools, and workplaces) and using existing digital platforms to more effectively target Web-based treatment to men who are already looking for information online [67].

Regardless of these concerns, this study shows that by incorporating men’s preferences with a particular emphasis on developing a personalized plan for the future (something men strongly advised [36]), Man Central has the strong potential to deliver a useful and promising treatment alternative for men with depression who may not access traditional mental health services. As with all Web-based interventions, it will be crucial to establish the best ways to disseminate the program to reach those populations who are most in need of assistance.

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Conflicts of Interest

None declared.

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Abbreviations

CBT: cognitive behavior therapy
CD-RISC: Connor-Davidson Resilience Scale
eHealth: electronic health
GP: general practitioner
MDRS: Male Depression Risk Scale
PHQ-9: Patient Health Questionnaire-9
REML: restricted maximum likelihood
SD: standard deviation
SMS: short message service
SPSS: Statistical Package for Social Sciences
WSAS: Work and Social Adjustment Scale

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Original Paper

Assessing the Equivalence of Paper, Mobile Phone, and Tablet Survey Responses at a Community Mental Health Center Using Equivalent Halves of a 'Gold-Standard' Depression Item Bank

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Abstract

Background: The computerized administration of self-report psychiatric diagnostic and outcomes assessments has risen in popularity. If results are similar enough across different administration modalities, then new administration technologies can be used interchangeably and the choice of technology can be based on other factors, such as convenience in the study design. An assessment based on item response theory (IRT), such as the Patient-Reported Outcomes Measurement Information System (PROMIS) depression item bank, offers new possibilities for assessing the effect of technology choice upon results.

Objective: To create equivalent halves of the PROMIS depression item bank and to use these halves to compare survey responses and user satisfaction among administration modalities—paper, mobile phone, or tablet—with a community mental health care population.

Methods: The 28 PROMIS depression items were divided into 2 halves based on content and simulations with an established PROMIS response data set. A total of 129 participants were recruited from an outpatient public sector mental health clinic based in Memphis. All participants took both nonoverlapping halves of the PROMIS IRT-based depression items (Part A and Part B): once using paper and pencil, and once using either a mobile phone or tablet. An 8-cell randomization was done on technology used, order of technologies used, and order of PROMIS Parts A and B. Both Parts A and B were administered as fixed-length assessments and both were scored using published PROMIS IRT parameters and algorithms.

Results: All 129 participants received either Part A or B via paper assessment. Participants were also administered the opposite assessment, 63 using a mobile phone and 66 using a tablet. There was no significant difference in item response scores for Part A versus B. All 3 of the technologies yielded essentially identical assessment results and equivalent satisfaction levels.

Conclusions: Our findings show that the PROMIS depression assessment can be divided into 2 equivalent halves, with the potential to simplify future experimental methodologies. Among community mental health care recipients, the PROMIS items function similarly whether administered via paper, tablet, or mobile phone. User satisfaction across modalities was also similar. Because paper, tablet, and mobile phone administrations yielded similar results, the choice of technology should be based on factors such as convenience and can even be changed during a study without adversely affecting the comparability of results.

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KEYWORDS

mobile phone; tablet; PROMIS; depression; item response theory; outcomes tracking; PORTAL; TeleSage; behavioral health; special issue on computing and mental health

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Introduction

As Internet and electronic survey administration technologies have shown many advantages and benefits relative to paper forms, computerized administrations of diagnostic and outcome measures have grown in popularity [1]. Recent studies have shown that participants often prefer the electronic version of an assessment to traditional paper surveys [2,3]. Additionally, electronic data entry has been shown to minimize errors that occur during traditional paper data collection [1,4]. In many situations, however, patients and research participants alternate between paper and electronic data collection (EDC) mediums as needed, such as when certain parts of a facility differ in regards to wireless connectivity, or when it is unknown what device an end-user may use to complete a survey sent as a link in an email. In cases such as these, researchers need to know whether the administration technology meaningfully affects results and whether these technologies can be used interchangeably within a single study. If administration method does not significantly impact assessment results and user satisfaction, the least expensive, most user-friendly, or most convenient form of administration technology can be employed without risk of jeopardizing assessment validity.

Several authors have provided evidence that the results of assessments administered via EDC methods are equivalent to results of those administered via the traditional paper-and-pencil method [1-3,5-9]. Additionally, a 2008 meta-analysis found equivalence between paper- and computer-administered self-report assessments [10]. Similar to prior research, this study investigates whether results of self-report assessment differ based on mode of administration; however, this study improves upon past research in several ways.

First, many studies have used a test-retest design, using the same items or instrument for both assessment periods [5,7-9]. This can be problematic because if the same items are administered sequentially, results may be impacted by a lingering memory effect. Furthermore, when time-delay methods are used to decrease this memory effect, if is not possible to determine whether changes in response are due to changes in modality or changes in symptoms over time. This study provides a method for overcoming these challenges.

A second way that this study improves upon past research in the field is in regard to psychometric equivalence versus face validity equivalence. Previous research has been done using the Patient-Reported Outcomes Measurement Information System (PROMIS) depression item bank (the same items that are used in the current study), which demonstrated the psychometric reliability and validity of these items [2]. While it is true that any 2 sets of items drawn at random from the PROMIS depression item bank should be psychometrically equivalent, clinicians rely on constellations of symptoms to diagnose and understand psychiatric disorders. Thus, from a clinical perspective, it is necessary to have equivalence on the symptom level, as well as psychometrically.

To address both of these concerns, this study created 2 psychometrically equivalent halves of the PROMIS depression item bank. The 2 halves (called Form A and Form B) had no overlapping questions, which eliminated the risk of lingering memory effects within participants. Additionally, to the greatest extent possible, the halves were created to assess similar depression symptoms, which is crucial for an assessment to have clinical significance. We hypothesize that the within-person validity of assessment will be similar across administration modality.

Methods

Item Set Generation

The PROMIS depression item bank is a set of 28 self-report items that use a Likert-scale with 5 options that range from “Never” to “Always” indicating how often the patient experiences each symptom [11]. Item response theory (IRT) parameters have been established for the PROMIS items using the graded response model (GRM) [12]. IRT parameters describe the probability of a given response to an item as a function of the respondent’s true standing on a trait or domain (for an overview of IRT and its importance in the field of psychiatry, see Yang and Kao [13]). Thus, IRT allows for estimation of this trait score (theta), and the associated standard error, using any combination or number of items. These PROMIS item parameters and the IRT algorithm were programmed into the TeleSage IRT engine, which runs on the TeleSage data collection platform, called PORTAL. The IRT algorithms were created with assistance from Seung Choi, who also assisted with development of the PROMIS assessment center algorithms [14]. For this study, we chose to use the PROMIS items and parameters due to the rigor that was used in their development and their proven relevance in the field [12].

Dividing the PROMIS depression item bank into 2 nonoverlapping analogous subsets of 14 items created the item sets used in this study. Although a perfect correspondence of content within pairs was not possible, Dr Brodey, a psychiatrist with clinical experience, paired the most similar items together based on criteria from the Diagnostic and Statistical Manual of Mental Disorders, fifth edition (DSM-5). For example, sadness was paired with depression. Sadness and depression are represented by unique PROMIS items but are included in a single DSM-5 criterion [15]. The members of each pair were then divided into Form A and B (see Textboxes 1 and 2). Dividing the PROMIS items based on face validity preserves psychometric equivalence while maximizing clinical equivalence and relevance. The test information curves were derived from the de-identified data set used in the original PROMIS validation [12]. Upon first analysis, one of the item sets provided slightly more information than the other, so one pair was chosen and the 2 items in that pair were switched to the opposite form. The test information curve for the final item sets can be seen in the Results section.

Data Collection Tool

Electronic health records (EHR) are a ready means of housing and sharing quantitative health information. We used the Health Insurance Portability and Accountability Act of 1996 (HIPAA)-compliant security technologies and an HL7 protocol for the bidirectional exchange of data between the community

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mental health systems' EHR and the TeleSage database, via the TeleSage PORTAL.

Recruitment and Summary of Participants

Following full institutional review board (IRB) approval of this study, participants were recruited via flyers that were posted at an outpatient community mental health center serving severe and persistently mentally ill clients in the Memphis, TN area. Clients were excluded if they were younger than 18 years of age. Participants were advised that they would be paid US$10 in the form of a Target gift certificate regardless of whether or not they completed the study. All 129 participants who began the study completed it. The ages of the participants ranged from 18 to 72 years with an average of 43 years. The participants were more often African-American (109/129, 84.5%), non-Hispanic (123/129, 95.3%), and female (83/129, 64.3%). This is representative of the public sector population served by the clinic used in this study. The demographic characteristics in mobile phone and tablet groups were very similar across age, sex, race, and ethnicity (Table 1).

Textbox 1. Division of Patient-Reported Outcomes Measurement Information System depression bank items into Form A.

Question text:

- I felt hopeless.
- I felt unhappy.
- I felt sad.
- I felt guilty.
- I withdrew from other people.
- I felt like a failure.
- I felt discouraged about the future.
- I felt ignored by people.
- I found that things in my life were overwhelming.
- I felt that my life was empty.
- I felt disappointed in myself.
- I had trouble making decisions.
- I felt that I was not needed.
- I felt worthless.

Textbox 2. Division of Patient-Reported Outcomes Measurement Information System depression bank items into Form B.

Question text:

- I felt I had no reason for living.
- I felt that nothing could cheer me up.
- I felt depressed.
- I felt that I was to blame for things.
- I had trouble feeling close to people.
- I felt that I was not as good as other people.
- I felt that I had nothing to look forward to.
- I felt lonely.
- I felt emotionally exhausted.
- I felt that nothing was interesting.
- I felt worthless.
- I felt pessimistic.
- I felt that I wanted to give up on everything.
- I felt upset for no reason.

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Table 1. Demographics of the full sample and of the mobile phone and tablet administration groups[a] (see Multimedia Appendix 1).

Demographics	Full Sample (N=129)	Mobile phone (N=63)	Tablet (N=66)
Age; mean (standard deviation)	43 (12)	43 (11.28)	44 (12.63)
Sex; N (%)			
Female	83 (65)	41 (65)	42 (64)
Male	45 (35)	22 (35)	23 (36)
Race; N (%)			
Asian	1 (1)	1 (2)	0 (0)
African-American	109 (86)	52 (83)	57 (86)
Caucasian	17 (13)	9 (14)	8 (12)
Ethnicity; N (%)			
Non-Hispanic	123 (98)	59 (98)	64 (98)
Hispanic	2 (2)	1 (2)	1 (2)

[a]Missing values: sex (1 in tablet group), race (1 in mobile phone group, 1 in tablet group), and ethnicity (3 in mobile phone group, 1 in tablet group)

Assessment Modality Assignment and Administration

HIPAA standards were maintained throughout the data collection process. Participants were divided into an 8-cell randomization and independently randomized into groups based on (1) modality of the electronic assessment administration (mobile phone vs tablet), (2) order of assessment modality (paper first vs electronic first), and (3) order of assessment subset presentation (Form A first vs Form B first). All modalities of the surveys were self-administered. The study coordinator at the clinical site provided paper forms, and the electronic assessments were provided via the Internet (using clinic Wi-Fi and a Samsung tablet [n=63] or mobile phone [n=66]) via the TeleSage PORTAL. The site study coordinator entered all the paper surveys into the TeleSage PORTAL by using the rapid data entry interface. TeleSage obtained demographic data on each participant by automatically matching participants with their NetSmart EHR. The PORTAL system integrated with the clinic EHR, allowing the direct importation of demographics from the EHR and direct export of the clinical report to the EHR. The demographic data for each individual, including age in years, sex, race, and ethnicity, were prepopulated into the study assessments without error via the PORTAL system. Assessment reports were generated and exported to the EHR in real time. After completing both survey modalities, 38 consecutive participants filled out a short satisfaction survey (on paper) regarding the technologies they used. The survey asked participants to compare their satisfaction with the paper survey versus the electronic survey, and it asked about satisfaction with the specific electronic modality they used. All questions used a 5-point Likert-scale format of “Strongly Agree” to “Strongly Disagree.” Participants also completed survey items that asked about their technology ownership and usage.

Statistical Analysis

Scores are evaluated on a theta scale, based on PROMIS community norms and defined from −4.0 to 4.0, where 0 is the mean, and positive scores indicate depression. The PORTAL’s IRT module estimated a trait score (theta) in real time for each of the 2 surveys taken by each individual using the GRM and the maximum likelihood estimation calculation method [12]. The theta scores were subsequently analyzed using mixed-effects models with a random intercept, which allowed for variance in the severity of depression symptoms reported by participants. Additionally, participants were repeated in the data set, which allowed the model to take within-subject dependencies across administrations into account. Fixed-effects predictors included modality (paper, mobile phone, tablet), item set (Form A or B), and the interaction between modality and item set.

To gain a more intuitive understanding of trends seen in the data, *t* tests were also performed. While *t* tests do not take into account all dependencies in the data, they do allow for a more direct comparison of within-subject variation (repeated measures *t* tests of Form A vs B, paper vs mobile phone, and paper vs tablet) and between-subject variation (an independent groups *t* test of mobile phone versus tablet; Multimedia Appendix 1).

Results

Item Set Generation

Using the methodology described previously, it was possible to create 2 psychometrically equivalent halves of the PROMIS depression item bank. Figure 1 depicts the test information plots for Form A and B, based on item data from the original PROMIS validation [12]. Table 2 shows a summary of the IRT scale (theta) scores, overall, and based on variables of interest (Multimedia Appendix 1).

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Figure 1. Item response theory test information plot for Forms A and B (see Multimedia Appendix 1).

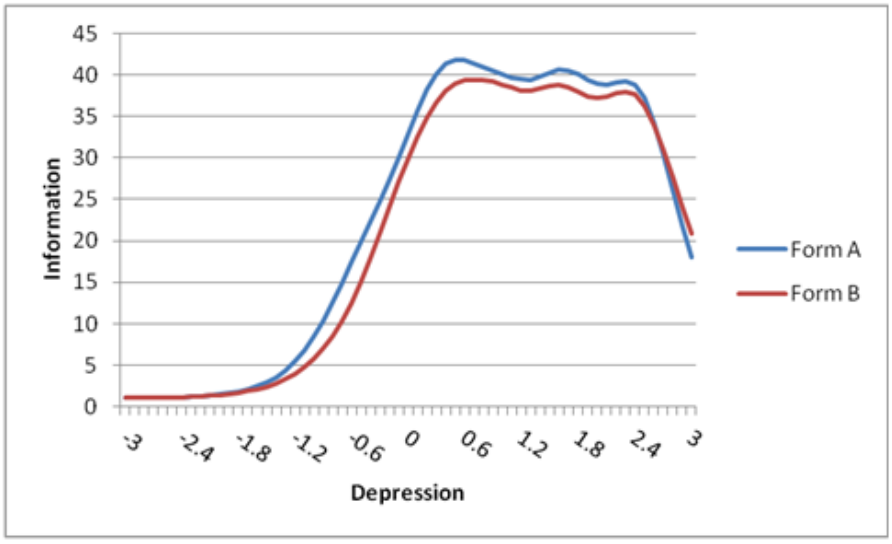

Table 2. Summary of item response theory scale scores, overall and by variables of interest (see Multimedia Appendix 1).

Condition	N	Mean	Standard deviation
Overall	258	0.91	0.98
Modality			
Paper	129	0.91	0.87
Mobile phone	63	0.89	1.04
Tablet	66	0.93	1.11
Form			
A	129	0.92	0.91
B	129	0.90	1.04
Modality × Form			
Paper × A	65	0.85	0.92
Paper × B	64	0.98	0.82
Mobile phone × A	32	0.93	1.02
Mobile phone × B	31	0.85	1.08
Tablet × A	32	1.05	0.79
Table × B	34	0.81	1.34

Statistical Analyses

Dr RJ Wirth, of Vector Psychometric Group, completed all statistical analyses. The wording of this section was taken from Dr Wirth's report (see Multimedia Appendix 1). For the full data analyses, the first model included modality, form, and the modality-by-form interaction as predictors. Results showed a statistically nonsignificant interaction, indicating that the difference between forms did not depend on modality; $F_{2,125}$=0.44, P=.64. For parsimony, the nonsignificant modality-by-form interaction was dropped and a second, main effects only model was estimated using modality and form as predictors. Results from this main-effects model demonstrated that there was not a statistically significant effect of either form, $F_{1,126}$=0.06, P=.81, or modality, $F_{2,126}$=0.16, P=.85 on the provided IRT scale scores for depression.

Similar results were obtained for the model using only data from unflagged observations, which resulted in the removal of 12 subjects for a reduced N of 117. Initial model results showed a statistically nonsignificant interaction, indicating that the difference between forms did not depend on modality; $F_{2,113}$=0.39, P=.68. For parsimony, the nonsignificant modality-by-form interaction was dropped and a second model was estimated with only modality and form as main effect predictors. Results from this model again demonstrated that there were no statistically significant effects due to either form, $F_{1,114}$=0.15, P=.70, or modality, $F_{2,114}$=0.23, P=.79 on depression scores.

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The data was also analyzed using *t* tests. While *t* tests do not model as many dependencies in the data, they are often easier to interpret. The results of the repeated-measures *t* tests (comparing the means of Form A and B, as well as paper vs mobile phone scores and paper vs tablet scores) are shown in Table 3. The results of the independent groups *t* test (comparing mobile phone vs table scores) are shown in Table 4. The results of the *t* tests support the general findings of the previously reported analysis of the variance; no statistically significant differences were found among any of the modality comparisons or across forms.

Post-Assessment Satisfaction and Technology Usage and Experience Survey

After completing both the electronic and the paper assessments, 38 participants in our study received a paper satisfaction survey. Of the mobile phone and tablet groups, 62% (39/63) and 61% (40/66), respectively, responded that they agreed or strongly agreed with the following statement: “It was easier to read the questions on the mobile phone/tablet (than on the paper form).” Of the mobile phone and tablet groups, 61% (38/63) and 72% (48/66), respectively, responded that they disagreed or disagreed strongly with the following statement: “It took me longer to take the survey on the mobile phone/tablet (than on the paper form).” Of the mobile phone and tablet groups, 50% (32/66) and 48% (32/66), respectively, responded that they agreed or strongly agreed with the following statement: “Overall, It was easier to take the survey on the mobile phone/tablet (than on the paper form).” Of the mobile phone and tablet groups, 66% (42/63) and 67% (44/66), respectively, responded that they agreed or strongly agreed with the following statement: “In the future, I would be equally willing to take a survey on paper or using the mobile phone/tablet.” These results indicate that overall, the participants felt that the technologies were largely equivalent.

Analysis of the technology usage and experience survey showed that technology access in the 2 groups was essentially equivalent. Personal computer ownership was 22% (14/63) for the mobile phone group and 18% (12/66) for the tablet group. The mean observed duration for assessment completion on both the mobile phone and tablet was very similar (3.61 and 3.41 minutes, respectively). The mean duration for paper administration was 1.66 minutes. The mean duration of Parts A and B electronic survey administrations were very similar (3.57 and 3.43 minutes, respectively).

Table 3. Group descriptives and associated *t* test values for repeated measures planned comparisons (see Multimedia Appendix 1).

Group	N	Mean	Standard deviation	Degrees of freedom	*t*	*P*	Cohen
Form A	129	0.92	0.91				
Form B	129	0.90	1.04				
Difference		0.01	0.59	128	0.25	.80	0.02
Mobile Phone Group							
Paper	63	0.85	0.93				
Mobile phone	63	0.89	1.04				
Difference		−0.03	0.66	62	0.42	.68	0.04
Tablet Group							
Paper	66	0.97	0.81				
Tablet	66	0.93	1.11				
Difference		0.04	0.53	65	0.68	.50	0.04

[a]Cohen *d* was calculated using original group standard deviations, rather than difference standard deviation [16].

Table 4. Group descriptives and *t* test results for the mobile phone versus tablet independent groups comparison (see Multimedia Appendix 1).

Group	N	Mean	Standard deviation	Degrees of freedom	*t*	*P*	Cohen
Mobile phone	63	0.89	1.04				
Tablet	66	0.93	1.11				
Difference		−0.04	1.08	127	−0.2	.84	0.04

Discussion

Principal Results

This study found no significant difference between the 2 item sets created from the PROMIS depression item bank; therefore, Forms A and B functioned equivalently in our sample. This suggests that in the future, researchers can administer Forms A and B to the same participant, in the same visit, without results being biased by a memory effect. Future studies could implement the methodology used in this study to assess the equivalence of additional technologies (eg, interactive voice response and smart eye wear [17,18]), or the equivalence of different administration settings (eg, the clinician’s office vs a patient’s home). Additionally, using multiple equivalent item groups may improve methodologies involving regularly repeated longitudinal assessments, by reducing any memory bias.

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We also found no significant differences between EDC method and paper, or between mobile phone and tablet. The negligible effect sizes of the differences between assessment modalities suggest that these technologies functioned equivalently within our sample, which is consistent with previous literature [1-3,5-10]. These findings imply that clinicians and researchers can administer the PROMIS depression items to public sector mental health recipients via mobile phone, tablet, or paper, without impacting the reliability of the information gathered from each modality, and can even shift between survey administration technologies during a study without fear of significantly affecting the validity of the survey responses or confounding the study results.

Along with modality and form equivalence, the satisfaction survey reveals that there was no modality (electronic or paper) that participants clearly preferred. This was a surprising finding because the EDC methods took, on average, approximately twice as long as the paper surveys. We do not have clear evidence explaining this variation, but it may be that the EDC modality was relatively novel for many participants, thus it took them extra time to learn how to navigate the electronic surveys. Despite the time difference, a majority of the participants disagreed or disagreed strongly with the statement that it took longer to complete their EDC method. This suggests that patients/participants may not be averse to longer surveys if the surveys are administered electronically.

Limitations

Many of the recruited clients suffered from schizophrenia. This may have impaired their ability to respond to survey questions. Additionally, this study was conducted with the PROMIS items, which were designed to be short and easy to interpret. Thus, the results might not generalize to more complex question formats.

Comparison With Prior Work

There are several strengths of the current study that expand upon work done previously. While there has been work done using the PROMIS depression item bank and alternate methods of administration, this may be the first study to use nonoverlapping, equivalent item sets [2]. This methodology could be applied to other instruments in which modality equivalence has been found, to provide greater strength to these studies [3,5,7,8]. One study used 2 different self-report instruments to assess depression and compare modalities, but the authors found significant main effects and interaction effects based on the order in which the 2 instruments were administered [6]. While using 2 different but psychometrically equivalent instruments may have eliminated the risk of memory effect in the previous study, it could have benefitted from the methodology in this study—administering nonoverlapping items from the same assessment (to decrease the effects of administration order) [6].

Additionally, several prior studies have found that participants prefer using an EDC method to a paper survey [2,3,8]. The current study did not have results that are consistent with these studies, suggesting that user preference can change.

Suggestions for Future Research

Future work should investigate the equivalence of data collected in different settings. With the PORTAL software, clients can easily be administered a survey in their homes via an email or text link (this study's IRB approval required that all data be gathered within a health care setting). Future research in the public sector mental health care field would benefit from further research of user preference. Finding a modality that most patients are satisfied with could increase both study participation rates and the accuracy of diagnoses, especially if a self-report diagnostic assessment can be administered at home using EDC methods.

Conclusions

The current study found that, in a population of mental health care recipients, 3 different self-report assessment modalities (mobile phone, tablet, paper) yielded essentially identical assessment results and essentially equivalent satisfaction levels. This suggests that, at least for the PROMIS depression assessment and public sector mental health recipients, the choice of survey administration technology in future studies can be based on cost and convenience. The results may open the way for more accurate technology comparisons among depressed patients.

Acknowledgments

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Conflicts of Interest

ISB and BBB are the sole owners of TeleSage, Inc., which is the company that developed and hosts the PORTAL system used in this study.

Multimedia Appendix 1

Statistical report from Dr RJ Wirth.

[PDF File (Adobe PDF File), 88KB - mental_v4i3e36_app1.pdf]

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Abbreviations

DSM-5: Diagnostic and Statistical Manual of Mental Disorders, fifth edition
EDC: electronic data collection
EHR: electronic health record
GRM: graded response model
HIPAA: Health Insurance Portability and Accountability Act of 1996
IRB: institutional review board
IRT: item response theory

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PROMIS: patient-reported outcomes measurement information system

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Original Paper

Internet-Delivered Cognitive Behavioral Therapy for Children With Pain-Related Functional Gastrointestinal Disorders: Feasibility Study

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Abstract

Background: Pain-related functional gastrointestinal disorders (P-FGIDs; eg, irritable bowel syndrome) are highly prevalent in children and associated with low quality of life, anxiety, and school absence. Treatment options are scarce, and there is a need for effective and accessible treatments. Internet-delivered cognitive behavior therapy (Internet-CBT) based on exposure exercises is effective for adult and adolescent irritable bowel syndrome, but it has not been evaluated for younger children.

Objective: The objective of this study was to assess acceptability, feasibility, and potential clinical efficacy of Internet-CBT for children with P-FGIDs.

Methods: This was a feasibility study with a within-group design. We included 31 children aged 8-12 years and diagnosed with P-FGID, according to the ROME III criteria. Mean duration of abdominal symptoms at baseline was 3.8 years (standard deviation [SD] 2.6). The treatment was therapist-guided and consisted of 10 weekly modules of exposure-based Internet-CBT. The children were instructed to provoke abdominal symptoms in a graded manner and to engage in previously avoided activities. The parents were taught to decrease their attention to their children's pain behaviors and to reinforce and support their work with the exposures. Assessments included treatment satisfaction, subjective treatment effect, gastrointestinal symptoms, quality of life, pain intensity, anxiety, depression, and school absence. Data were collected at pretreatment, posttreatment, and 6-month follow-up. Means, standard errors (SEs), and Cohen *d* effect sizes were estimated based on multi-level linear mixed models.

Results: Most children 25/31 (81%) completed 9 or 10 of the 10 treatment modules. Almost all children, 28/31 (90%), reported that the treatment had helped them to deal more effectively with their symptoms, and 27/31 (87%) children declared that their symptoms had improved during the treatment. Assessments from the parents were in accordance with the children's reports. No child or parent reported that the symptoms had worsened. We observed a large within-group effect size on the primary outcome measure, child-rated gastrointestinal symptoms from pretreatment to posttreatment (Cohen d=1.14, P<.001, 95% CI 0.69-1.61), and this effect size was maintained at 6-month follow-up (Cohen d=1.40, P<.001, 95% CI 1.04-1.81). We also observed significant improvements from pretreatment to posttreatment on a wide range of child- and parent-rated measures including quality of life, pain intensity, anxiety, depression, and school absence. All results remained stable or were further improved at 6-month follow-up.

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Conclusions: This study shows that children with longstanding P-FGIDs, and their parents, perceive exposure-based Internet-CBT as a helpful and feasible treatment. The included children improved significantly despite a long duration of abdominal symptoms before the intervention. The treatment shows potential to be highly effective for P-FGIDs. The results need to be confirmed in a randomized controlled trial (RCT).

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KEYWORDS

cognitive therapy; behavior therapy; functional gastrointestinal disorders; abdominal pain; irritable bowel syndrome

Introduction

Pain-related functional gastrointestinal disorders (P-FGIDs) according to the Rome III criteria are characterized by persistent or recurrent abdominal pain without an organic explanation. P-FGIDs include irritable bowel syndrome (IBS), functional abdominal pain (FAP), and functional dyspepsia (FD). IBS is most common and is by definition associated with fecal disturbances. In FAP, pain is often the only symptom, and in FD the pain is located in the upper abdomen and is often accompanied by symptoms like early satiety and nausea [1]. P-FGIDs affect about 13% of all children [2] and are associated with anxiety, depression [3], school absence, parental work absence, low quality of life [4], and extensive health care visits [5]. Support for the efficacy of medical [6] and dietary [7] treatments is weak, and there is a lack of treatment options in regular health care for these children. Cognitive behavior therapy (CBT) has been shown to be effective for P-FGIDs [7], but since CBT often includes multiple components, it is unclear which ones are effective [8]. A newly published Cochrane review concludes that identifying active components of psychological interventions in treatments for recurrent abdominal pain is an area of priority [9].

One potentially efficacious psychological intervention for pediatric P-FGIDs is exposure therapy. This treatment is based on a model proposing that P-FGID-related stimuli have been associated with pain, fear, or other unpleasant feelings such as losing control (ie, a respondent conditioning process [10,11]). The stimuli are typically avoided to reduce these experiences (ie, an operant conditioning process). Avoided stimuli can include abdominal symptoms, certain foods that are associated with abdominal symptoms, and situations in which abdominal symptoms are perceived as particularly intolerable. The avoidance prevents the child from gaining new and possibly contradictory experiences of the stimuli, which in turn contributes to maintenance of the fear of the stimuli and maintenance of the symptoms. This is consistent with what has been shown in adult studies: avoidance and control of symptoms seem to maintain the abdominal problems [12,13]. Exposure-based CBT includes exercises where the patient provokes the feared stimuli and approaches avoided situations in a graded manner. Examples of exposure exercises are eating symptom-provoking foods, postponing toilet visits, participating in previously avoided activities in the presence of symptoms, and decreasing medication for abdominal symptoms. Exposure therapy may be perceived to be difficult or aversive for children to engage in, and studies show that psychologists, even those using a behavioral approach, are often hesitant to include exposure in their treatments [14]. However, our previous study of exposure-based CBT in face-to-face format showed that children were adherent to the treatment and considered the exposure exercises to be helpful in dealing with symptoms [15]. Exposure-based CBT has also been proven effective for adults and adolescents with IBS [16-19] and shows promising results for children with P-FGIDs [15].

Parents are probably the most important contextual factor for younger children, and parents' behavioral responses and coping mechanisms have been related to children's pain symptoms [20]. In an experimental study, Walker et al [21] showed that parental attention to their child's pain expressions increased both the child's pain complaints and self-assessed abdominal symptoms after the experiment. It is therefore important to address parental behavior in a treatment for children with P-FGIDs, and this approach has been used in several treatment studies [22-24]. In exposure-based CBT, parents facilitate and encourage their child's work with exposure exercises and reinforce and model adaptive behavior.

One major challenge in somatic health care is that the availability of CBT-trained psychologists is low [25]. Internet-delivered CBT (Internet-CBT) could be a viable option to make effective treatments more available to children. Internet-CBT has several advantages compared with therapy delivered in face-to-face format, such as being independent of geographical distance, requiring less therapist time, and being cost-effective [26]. Internet-CBT has also been shown to enable an as good working alliance between children and therapists as CBT delivered face-to-face [27]. Furthermore, the standardized format of Internet-CBT makes it possible to deliver the treatment with high treatment fidelity, and families are able to participate in the treatment without taking time off from school or work [8]. Exposure-based Internet-CBT has been shown to be effective for adult and adolescent IBS [16-19] and promising for adolescents with P-FGIDs [28]. It has also been proven effective for other disorders in children and adolescents like anxiety disorders [29] and obsessive compulsive disorder (OCD) [30]. However, to the best of our knowledge, there are no studies of exposure-based CBT delivered via Internet for children aged 8-12 years with P-FGIDs [8]. In this study, we therefore aimed to assess the feasibility, acceptability, and potential clinical efficacy for such a treatment in preparation for a forthcoming randomized controlled trial (RCT).

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Methods

Design

This was a feasibility study with a pre- posttest design that included 31 children with P-FGIDs who were 8-12 years old. The study is reported according to the TREND statements for evaluations with nonrandomized designs. It was approved by the regional ethics review board in Stockholm, Sweden July 24, 2015 (2015/969-31) and registered at ClinicalTrials.gov June 17, 2015 (NCT02475096).

Inclusion Criteria

The inclusion criteria were (1) age ≥8 and <13 years; (2) IBS, FAP, or FD diagnosis according to the Rome III criteria; (3) no more than 40% school-absenteeism; (4) stable dose since at least one month if treated with psychopharmacological medications; and (5) normal reading and writing skills (the child and the parent responsible for treatment and assessments). Exclusion criteria were (1) nonfunctional medical conditions that better explained the child's abdominal symptoms (eg, celiac disease), (2) other ongoing psychological treatment, and (3) severe psychosocial or psychiatric problems that needed immediate attention. School-absenteeism of more than 40% (criteria [c]) was considered an acute and serious problem in need of more intensive care than an Internet-delivered intervention study can offer. Excluded children in need of other care were referred to other health care providers.

Procedure

Participants were included in a nation-wide recruitment from August 2015 to January 2016. Follow-up assessments were collected from June to November 2016. The study was conducted at the Child and Adolescent Psychiatry Research Center in Stockholm. Physicians within primary, secondary, or tertiary care, who were informed about the study via emails and lectures, referred children to the study. Physicians signed a health form in which they confirmed the P-FGID diagnosis and reassured that basic work-up had been normal (normal linear growth and no involuntary weight stagnation or loss, negative tests for transglutaminase lgA antibodies, and in case of diarrhea for fecal calprotectin). The parents were contacted via telephone, and inclusion and exclusion criteria were assessed. The P-FGID phenotype was confirmed by a self-assessment version of the Rome III form that was completed by the families via the Internet and in a clinical interview at the research clinic conducted by the study's psychologists. During the clinical interview, psychiatric disorders were assessed with the Mini-International Neuropsychiatric Interview for Children and Adolescents (MINI-KID) [31,32]. Written informed consent was obtained from the parents, and verbal informed consent was obtained from the child. During one part of the interview the child was asked questions without the parents present in the room. These questions concerned school, friends, family, and if the child had ever been mistreated. After the clinical interview, the child was either included or excluded. A child and adolescent psychiatrist (ES) and pediatric gastroenterologist (OO) were available for consultation if there were uncertainties regarding the child's mental or physical health.

Intervention

The therapist-guided Internet-CBT used in this study was based on the treatments for adults and adolescents developed by members of the research group [28,33]. It was adapted for children and tested in a face-to-face treatment study before this trial [15]. The treatment consisted of ten modules for the children and ten modules for the parents, delivered once a week. An overview of the treatment is presented in Table 1.

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Table 1. Overview of the treatment.

Module	Child	Parent
1	Psycho-education about abdominal symptoms. Explanatory model of symptoms and treatment (Figure 1). Mapping avoidant and controlling behaviors. Setting goals.	The role of parental attention. Validating the child's experience and shifting focus. Mapping parental behaviors. Handling worry and frustration.
2	The role of thoughts. A short mindfulness exercise, "SOL" (Stop, Observe, Let go). Building an exposure hierarchy.	"Golden moments"—spending quality time with the child without focusing on abdominal symptoms.
3	Functional analyses. Psycho-education about exposure. Exposure exercises.	Supporting the child in the treatment. Introduction of token game. Increasing school attendance.
4	Review of first exposure exercises. Toilet habits. Functional analyses. Exposure exercises.	How to handle parental stress. Plan for own recreational activities.
5	Review of the treatment sessions 1-4. Exposure exercises.	Review of the treatment sessions 1-4. Inventory of parental challenges.
6	Functional analyses of goal-directed behaviors. Exposure exercises, increasing the difficulty—level up.	Solving problems with the treatment together with the child.
7	Functional analyses of goal-directed behaviors. Review of the goals. Exposure exercises.	Functional analyses of parental behavior with emphasis on the interaction between parent and child. Functional analysis of goal-directed behaviors.
8	Positive analyses of goal-directed behaviors. Increasing the difficulty—exposure to multiple stimuli.	Review of treatment, part I. Rewarding yourself for the hard work with the treatment.
9	Quizzes of the treatment. Review of what has been accomplished so far.	Review of treatment, part II. Lessons learned. Review of parental challenges.
10	Review of avoidant and controlling behaviors, goals, and hierarchy. Maintenance and relapse prevention.	Review of parental behaviors. Maintenance and relapse prevention.

One parent was responsible for the treatment and was instructed to review the child's modules together with the child and to share the content of the parental and child modules with the other parent. The parent responsible for the treatment also completed the parental self-assessments. All children and parent modules included homework exercises that were reviewed in the subsequent module. Case examples were used throughout the children's modules, modeling the exercises, including behavior mapping, goal setting, and exposure exercises.

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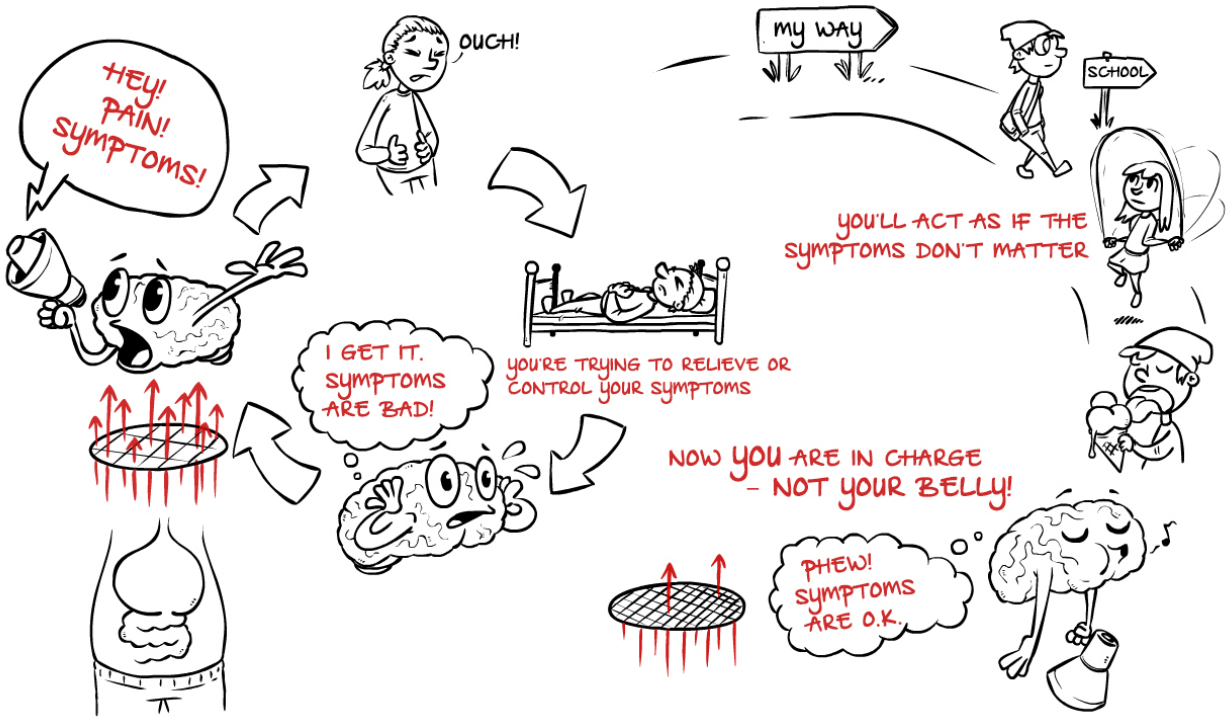
Figure 1. Explanatory model of abdominal pain and treatment presented to the child (translated from Swedish).



Children's Modules

An explanatory model of the maintenance of abdominal symptoms and the exposure-based treatment approach was presented as an animated film (Figure 1).

The model uses a metaphor of a porous filter between the stomach and the brain to explain the children's hypersensitivity toward abdominal signals. The brain is compared with a loudspeaker that amplifies the abdominal signals because they are perceived as important or even dangerous. The increased hypervigilance is explained as a consequence of the behavioral responses to control or avoid the symptoms, for example, resting, avoiding activities, or rushing into the bathroom. These behaviors confirm the importance or danger of the abdominal signals, leading the brain to become more attentive toward the signals: a vicious circle has been established. Exposure to abdominal symptoms is presented as a means to break the vicious circle. During the exposure exercises, the children provoke pain and other abdominal symptoms and engage in goal-directed behaviors with the long-term purpose of decreasing symptoms and regaining control. The children are told that one major purpose of the treatment is that they, and not their bellies, should be in charge.

Figure 2. Screenshot from the treatment platform showing the mindfulness exercise "Stop, Observe, and Let go" (translated from Swedish).

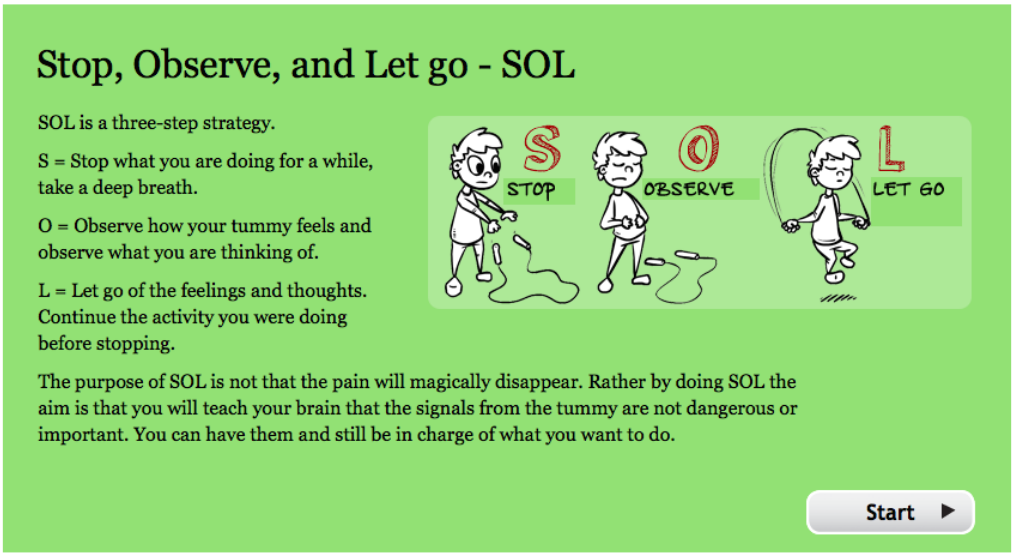


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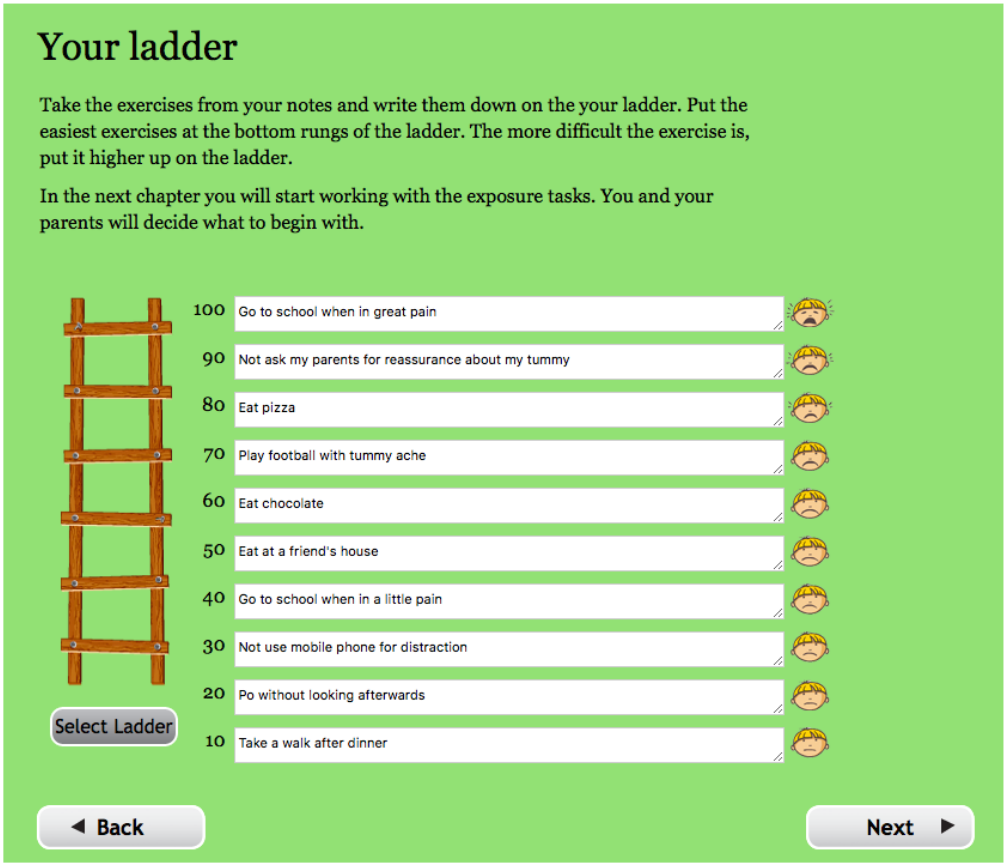
Figure 3. Screenshot from the treatment platform showing a hierarchy of exercises (translated from Swedish).



A short mindfulness exercise "SOL" was presented as a way to increase the effect of the exposures and to engage in goal-directed behaviors. Thoughts were presented as something that is difficult to control and that one way to handle catastrophic thoughts is to observe them and identify them as unhelpful and try not letting them interfere with ongoing behavior. The children were taught to (1) stop what they were doing, (2) observe their thoughts and symptoms for a short while, and (3) let go: continue to do whatever they were doing, in the presence of the thoughts and symptoms. SOL is presented in Figure 2.

The children mapped their avoidance and controlling behaviors. Exposure exercises that aimed to break these behaviors were planned and placed on a hierarchy; see Figure 3. The hierarchies were used to increase the difficulty of the exposures as they advanced through the treatment. Functional analyses of avoidance and controlling behaviors, as well as positive analyses for goal-directed behaviors were conducted throughout the treatment.

Parents' Modules

The parents received information on how attention and giving privileges may reinforce the child's perception of pain and pain behavior. Common strategies used in parenting programs were introduced as a means to reinforce children's adaptive behaviors [34,35]. The strategies included validating the child's experience of abdominal symptoms and then shift focus to the activity; spending quality time together without focusing on the stomach, so called "golden moments," see Figure 4; taking breaks if the parent was unable to act in a calm way when the child expressed symptoms; and using encouragement as well as a token game to reinforce the child's work with exposures. The token game consisted of a printed game board where the child marked completed exposures with a pen and received small rewards for every fourth to eighth exposure on the way to the goal, where the child usually received a somewhat larger reward. The parents were given examples of rewards, such as letting the child choose what to have for dinner or to play a game together. The overall aim of the parental modules was to help the parents support the child with the exposure exercises and to reduce reinforcement of behaviors that are counter-productive to the exposure-based approach, such as avoidance and control of symptoms.

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Figure 4. Screenshot from the treatment platform showing golden moments (translated from Swedish).

Therapists

Every family had an assigned clinical psychologist whom they had met during the initial clinical interview. New treatment modules were provided every Friday, and the participants were instructed to complete the modules during the weekend. On Mondays, the psychologists reviewed the work and provided written feedback within the platform. On the other weekdays, the psychologists reminded participants that had been inactive and had an ongoing communication with the participants via the platform. All therapists (ML, MB, and JH) were licensed psychologists with 8-9 years of experience of CBT and had 1-4 years of experience of Internet-CBT with children and adolescents. ML provided supervision on demand to the other psychologists throughout the study.

Outcome Measures

The assessments were self-administered and provided via a secure platform over the Internet. The child and the parent responsible for the treatment made assessments at screening, pretreatment, posttreatment, and at 6-month follow-up. Some measures were assessed weekly during treatment by the children: Pediatric Quality of Life Inventory Gastrointestinal Symptom Scale (PedsQL Gastro), FACES Pain Rating Scale, pain-free days, and IBS-Behavioral Responses Questionnaire (IBS-BRQ), whereas parents assessed IBS-BRQ weekly; see descriptions of the measures below. The weekly assessments were included as a part of the piloting of a forthcoming randomized trial. Therefore, only a figure of the weekly assessments of the main outcome was included in this study (Figure 8). Parents were instructed to help their child during the assessment if they needed help, without influencing the child's answers. The pediatric initiative on methods, measurement, and pain assessment in clinical trials (PedIMMPACT) recommendations for clinical trials for recurrent pain were used as guidelines in choosing measurements for the study [36].

Child-Rated Outcome Measures

PedsQL Gastro rated by the child was the primary outcome. It is a 9-item scale assessing last month's gastrointestinal symptoms. The scale was developed to assess symptoms that are common in P-FGID disorders [37]. The 5-point scale ranges from never (0) to almost always (4). The items are reversely scored and transformed to a 0-100 scale, with higher scores indicating less symptoms.

Pediatric Quality of Life Inventory (PedsQL QOL) is a 23-item scale assessing quality of life for children aged 8-12 years, showing good validity and reliability [38]. The scoring is identical to PedsQL Gastro. Higher scores indicate greater quality of life.

Faces Pain Scale-Revised (FPS-R) was used to assess pain intensity. Human faces showing pain expressions corresponding to numbers from no pain (0) to worst pain (10) help the child rate last week's worst pain intensity. The scale has been validated for children [39].

Pain-free days was assessed by asking about how many days last week the child had no pain or only so little pain that he or she felt okay [36].

Child Depression Inventory-Short version (CDI-S) assesses depressive symptoms in children. For each of the 10 items, there are three statements corresponding to 0, 1, or 2 points, with higher scores indicating more problems with depressive symptoms [40,41] .

Spence Children Anxiety Scale (SCAS) is a 45-item scale that assesses anxiety in children aged 8-12 years [42]. In this study, a hitherto unpublished short version with 18 items was used (SCAS-S). The frequency of anxiety symptoms is rated on a 4-point scale, with answers ranging from never (0) to always (3).

Visceral sensitivity Index (VSI) assesses gastrointestinal specific anxiety and was a process variable in this study [12]. It was developed for adults with IBS, and some wordings were

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changed to fit the pediatric P-FGID population. It comprises 15 items and is rated on a 6-point scale ranging from strongly disagree (0) to strongly agree (5).

IBS-BRQ is validated for adults with IBS and has shown high internal consistency for that group (Cronbach alpha=.86) [43]. In this study, a child-adjusted version of the scale with 11 items was used. The scale assesses avoidant behavior and controlling of symptoms and was a process variable in this study. The items are rated on a 7-point scale with only endpoints defined: never (1) and always (7).

The catastrophizing subscale of the Pain Response Inventory was used to assess maladaptive coping by catastrophizing. It consists of 5 items rated in 5 points ranging from never (0) to always (4) [44].

Children's Somatization Inventory-24 (CSI-24 *)* is a 24-item scale that assesses perceived severity of somatic symptoms. Items include symptoms such as headache, sore muscles, and gastrointestinal symptoms. It is a 5-point scale with responses ranging from not at all (0) to a whole lot (4). CSI-24 has been evaluated for a pediatric population and was found to be psychometrically sound [45]. Seven of the items assess gastrointestinal symptoms and were reported as a separate subscale, CSI-24 (gastro), as has been done in other studies [22,46].

Insomnia Severity Index-Child version (ISI-C) was used to assess problems with sleep. It comprises seven items covering different aspects of sleep problems and is rated on a 5-point scale from no problems or not at all (0) to very large problems or very much (4) [47].

Pressure Activation Stress Scale (PAS) assesses stress in children. It comprises 11 items rated on a 5-point scale ranging from never (0), to always (4) [48].

School absence was assessed with the question: "How many hours last month were you absent from school due to pain?" with the responses on a 4-point scale: 0 hours (0), 1-5 hours (1), 6-10 hours (2), and more than 10 hours (3)[15].

Client Satisfaction Questionnaire-8 (CSQ-8) was used to measure different aspects of treatment satisfaction. It is an 8-item scale where questions are rated from 1-4, corresponding to different answers for the questions [49].

Subjective Assessment Questionnaire (SAQ) assesses the participant's subjective perception of the treatment effect by asking one question about how severe the symptoms are after treatment compared with before treatment. It is a 7-point scale ranging from very much better (6) to very much worse (0) [50].

Parent-Rated Outcome Measures

Parents completed parental versions of PedsQL Gastro, PedsQL QOL, FACES Pain Rating Scale, pain-free days, CSI-24, school absence, SAQ, and CSQ-8 described above and the following measures.

Parental work absence was assessed with the question: "How many days in the last month have you or another adult been home from work due to your child's abdominal problems?" The responses were rated on a 4-point scale: 0 days (0), 1-5 days (1), 6-10 days (2), and more than 10 days (3).

Adult responses to children's symptoms (ARCS) is a 29-item scale with 4 points (1-4) [51]. Endpoints are defined as never (1) and always (4). Parents are asked how often they respond with certain behaviors when their child has abdominal pain. ARCS is analyzed in subscales and was a process variable in this study. We used the subscales Protect and Monitor (age-adjusted versions), which have been shown to be sensitive to change [52,53].

Patient health questionnaire-9 (PHQ-9) assesses the parent's own depressive symptoms in 9 items rated on a 4-point scale ranging from not at all (0) to almost every day (3) [54].

Generalized anxiety disorder assessment-7 (GAD-7) is a 7-item scale that assesses the parents' symptoms of anxiety [55]. Like PHQ-9, the scale ranges from not at all (0) to almost every day (3).

Adverse events (AE) assess negative effects associated with the treatment. Each negative effect was described in free-form text and its severity from no negative effect (0) to very negative effect (3) was rated on two scales, how much the event affected the child at the time of its occurrence, and how much it affected the child at the time of the assessment (ie, to what extent the effect lingered) [18].

Data Analyses

All analyses were performed in R (R Foundation for Statistical Computing), except for the McNemar test that was performed in Stata 13 (StataCorp LP). Pretreatment, posttreatment, and six-month follow-up data were included in piecewise linear mixed models analysis using all available data, that is, analyses were based on intent-to-treat. Separate slopes were estimated for the pre- to posttreatment assessment (Slope 1) and posttreatment to six-month follow-up assessment (Slope 2). Slopes 1 and 2 were then summed to form the estimated overall pre to six-month follow-up improvement. Cohen *d* within-group effect sizes were calculated by dividing the estimated change scores with the model-implied standard deviation. Effect sizes were categorized as suggested by Cohen [56]: d=0.2 represents a small effect size, d=0.5 a medium effect size, and d=0.8 a large effect size. CIs and *P* values for the effect sizes were obtained using bootstrap with 5000 replications. An improvement of ≥30% on the primary outcome measure was used to define clinically significant change, which is consistent with recommendations and cut offs used in other studies [57,58].

Results

Participants

There were 61 children referred to the study of which 30 were excluded or declined to participate; see the participants flow through the study (Figure 5). Of the 31 children included in the study, 19 were girls. The mean duration of abdominal symptoms was 3.8 years (range 0.3-11.0). Complete baseline characteristics are presented in Table 2.

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Table 2. Patient characteristics at baseline (N=31).

Characteristics	Mean	n (%)	Range
Age (years)	10.7		8-12
Duration abdominal problems (years)	3.8		0.3-11
Girls		19 (61)	
Born in Sweden		30 (97)	
Parental heredity[a]		10 (32)	
Medication for abdominal symptoms[b]		12 (39)	
School absence last month[c]		25 (81)	
Distance from home to clinic (kilometers)	172		5-907
Rome III diagnosis			
Irritable bowel syndrome		18 (58)	
Functional abdominal pain		11 (35)	
Functional dyspepsia		2 (6)	
Psychiatric comorbidity (MINI-KID[d])			
Any psychiatric comorbidity		10 (32)	
Anxiety disorder		7 (23)	
Depression		2 (6)	
Suicidal thoughts (all low level)		2 (6)	
Attention deficit disorder		1 (3)	
Referring care unit			
Primary care		2 (6)	
Secondary care		19 (61)	
Tertiary care		10 (32)	
Education, parents			
High School <3 years		2 (6)	
High School ≥3 years		8 (26)	
College		20 (64)	
Other		1 (3)	

[a]At least one parent with abdominal problems.

[b]Polyethylene glycol, lactitol monohydrate, simeticone, sterculia, and calcium carbonate or magnesium hydroxide.

[c]Due to abdominal pain.

[d]MINI-KID: Mini-International Neuropsychiatric Interview for Children and Adolescents.

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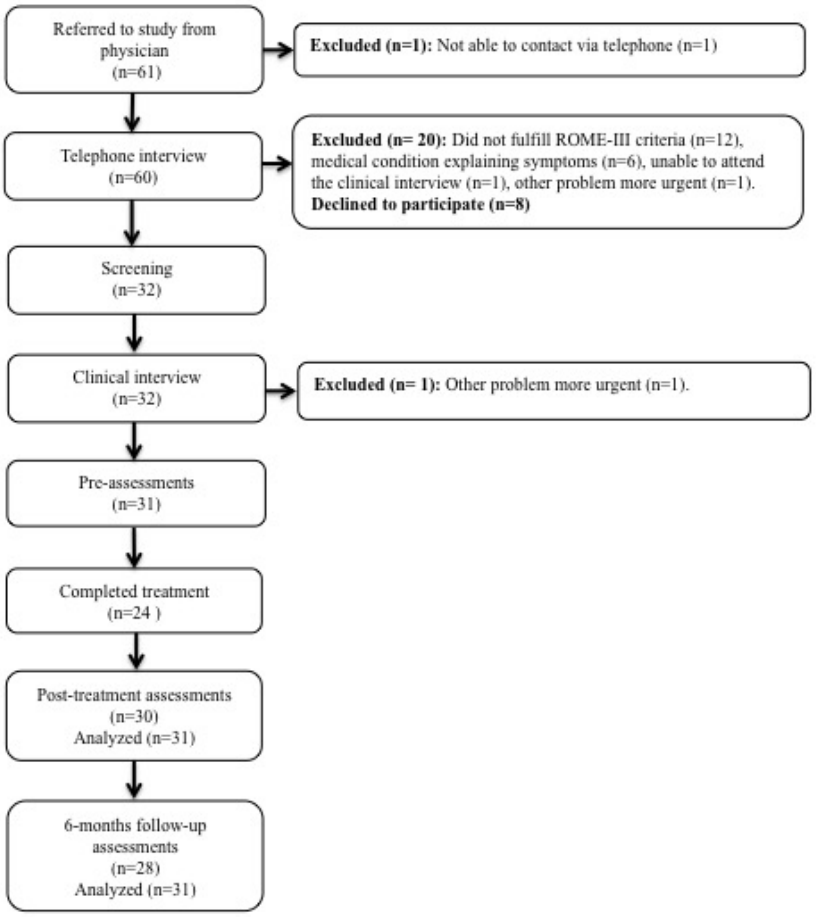
Figure 5. Participants flow through the study.



Attendance and Attrition

The mean number of modules that the children and their parents took part of was 8.6 and 8.8 of 10 modules, respectively. Most children and their parents completed 9-10 modules, 24/31 (77%), and were considered treatment completers. The noncompleters (n=7) were dyads where both children and parents completed 2-7 modules. Modules completed are illustrated in Figures 6 and 7. At the posttreatment assessments, there was almost no data attrition, 1/31 (3%). The one participant who did not respond to the posttreatment assessment was a noncompleter. At 6-month follow-up the data attrition was 3/31 (10%). Two of the participants who did not provide follow-up data were noncompleters, and one was a completer. Mean therapist time for the whole treatment was 165 (standard deviation [SD] 64.0) min per family, representing a mean of 19 min per week in treatment (mean therapist time divided by mean number of modules completed).

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Figure 6. Number of modules completed by each of the 31 children. Dyads of children and parents share the same numbers on the x-axis in Figure 6 and 7.

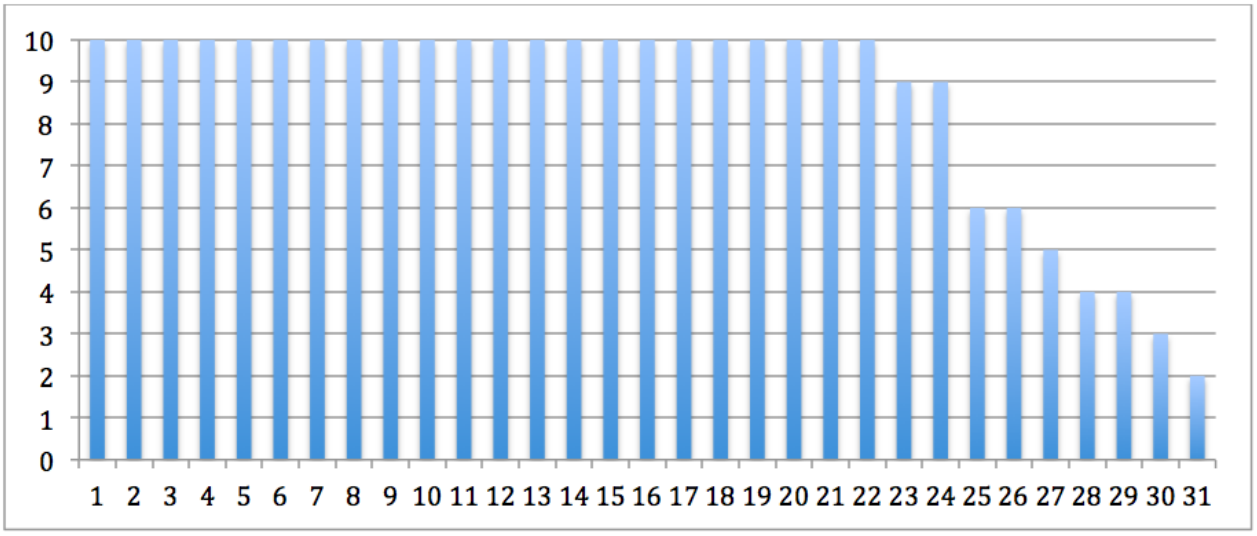

Figure 7. Number of modules completed by each of the 31 parents. Dyads of children and parents share the same numbers on the x-axis in Figure 6 and 7.

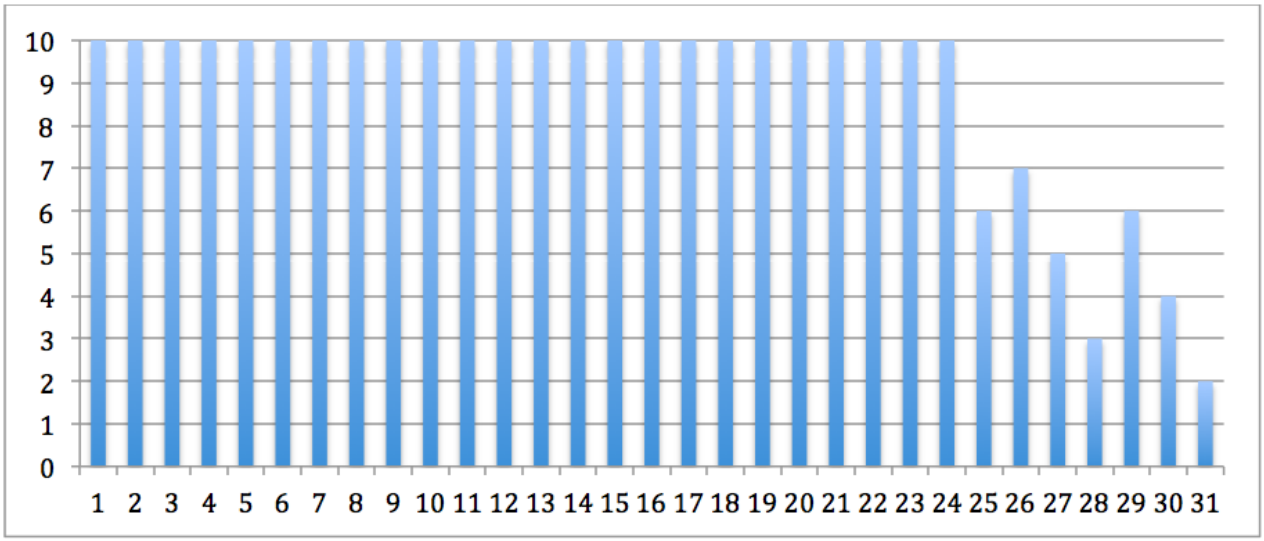

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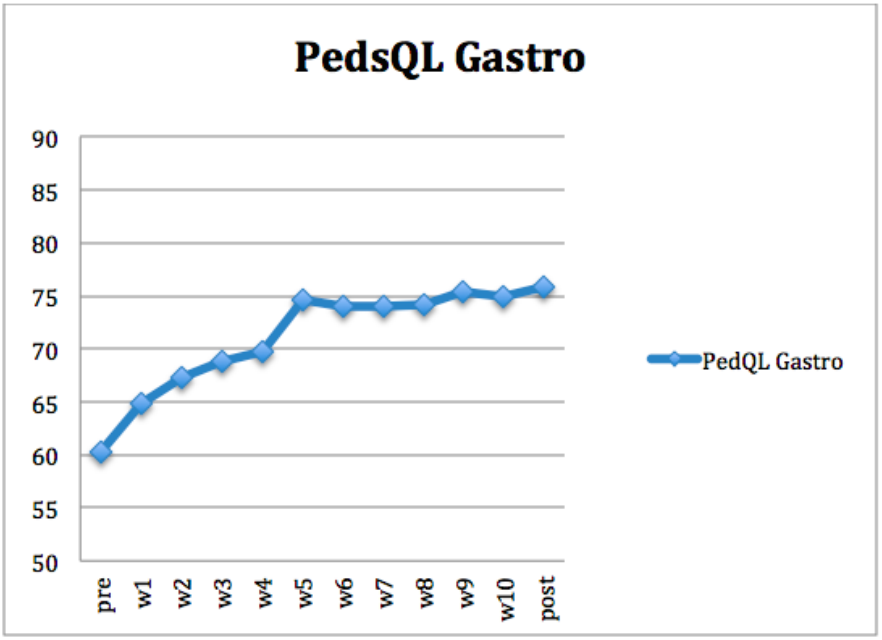
Figure 8. Observed means of child-rated gastrointestinal symptoms measured by PedsQL Gastro at pretreatment, every week during treatment, and at posttreatment. The scale ranges from 0-100, and the range in the sample was 25-100.



Treatment Satisfaction and Subjective Treatment Effect

The children reported an average total score on the CSQ (range 8-32) of 25.1 (SD 5.1) and the parents an average total score of 28.1 (SD 4.4). Most children were satisfied with the support from the psychologist (28/31, 90%) and reported that the treatment had helped them deal more effectively with their symptoms (27/31, 87%). The children rated their mean subjective treatment effect on the SAQ (range 0-6) as 4.7 (SD 1.0), and the parents rated their child's mean subjective treatment effect as 5.0 (SD 1.0). Of the 30 children who completed the postassessments, 26 reported that their symptoms had improved, and 4 reported that they were about the same as before treatment. These assessments were similar for the parents where 27 parents rated that their child's symptoms had improved, and three rated that the symptoms were about the same as before treatment. No child or parent reported that the symptoms had worsened.

Child-Rated Outcomes

Estimated means and SEs for all measures are presented in Table 3. Effect-sizes and their 95% CIs and *P* values are presented in Table 4. There was a significant pre- to posttreatment change on the primary outcome measure child-rated gastrointestinal symptoms (PedsQL Gastro). This change was maintained at 6-month follow-up. The within-group effect size was large d=1.14 (P<.001) from pre- to posttreatment and also from pretreatment to follow-up, d=1.40 (P<.001). At both posttreatment and at 6-month follow-up, 15/31 (48%) children reached clinically significant change on the primary outcome measure, defined as 30% improvement. The children who reached clinically significant change at posttreatment had a mean change score of 28.1 (SD=7.0, range=16.7-41.7) from pretreatment to posttreatment. For the children who reached clinically significant change at 6-month follow-up, the mean change score from pretreatment was 28.7 (SD=7.3, range=19.4-41.7). PedsQL Gastro was also assessed every week during treatment (Figure 8). All measures showed statistically significant improvement between pre- and posttreatment, except ISI-C (sleep problems) and PAS (stress) that showed improvement between pretreatment and 6-month follow-up. We also observed large effect sizes between pretreatment and posttreatment for quality of life (PedsQL QOL), gastrointestinal symptoms (CSI-24 [gastro]), and the process variables gastrointestinal specific anxiety (VSI) and avoidant behavior (IBS-BRQ). At 6-month follow-up, these effect sizes remained large and the effect sizes for pain intensity (FACES Pain Rating Scale), pain-free days, catastrophizing, and school absence had also become large compared with pretreatment. We observed a significant improvement of the effect sizes between posttreatment and 6-month follow-up for pain intensity (FACES Pain Rating Scale) d=0.56 (P=.01), catastrophizing d=0.69 (P<.001), gastrointestinal symptoms (CSI-24 [gastro]) d=0.40 (P=.03), and stress (PAS) d=0.57 (P=.006).

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Table 3. Estimated means and standard errors at pretreatment, posttreatment, and 6-month follow-up reported by children.

Outcome measure	Pretreatment		Posttreatment		6-month follow-up	
	Mean	(SE[a])	Mean	(SE)	Mean	(SE)
PedsQL Gastro[b,c]	60.30	(2.41)	75.63	(2.44)	79.08	(2.49)
PedsQL QOL[c,d]	72.48	(1.89)	85.75	(1.92)	87.56	(1.97)
FACES Pain Rating Scale	6.87	(0.43)	5.09	(0.44)	3.74	(0.45)
Pain-free days/week[c]	2.45	(0.36)	3.84	(0.36)	4.35	(0.38)
CDI-S[e]	2.90	(0.41)	1.92	(0.42)	1.86	(0.42)
SCAS-S[f]	12.45	(1.34)	10.27	(1.35)	9.13	(1.38)
VSI[g]	10.74	(1.06)	5.33	(1.07)	3.45	(1.10)
IBS-BRQ[h]	29.87	(1.67)	18.91	(1.69)	17.96	(1.74)
Catastrophizing	6.81	(0.67)	4.61	(0.67)	2.04	(0.69)
CSI-24[i]	15.48	(1.64)	11.78	(1.65)	9.17	(1.67)
CSI-24 (gastro)[j]	7.74	(0.62)	4.88	(0.63)	3.50	(0.64)
ISI-C[k]	6.03	(0.83)	5.19	(0.84)	3.97	(0.86)
PAS[l]	11.65	(1.20)	10.28	(1.22)	6.48	(1.25)
School absence[m]	1.45	(0.18)	0.81	(0.19)	0.59	(0.19)

[a]SE: standard error.

[b]PedsQL Gastro: Pediatric Quality of Life Inventory Gastrointestinal Symptom Scale.

[c]PedsQL Gastro, PedsQL QOL, and pain-free days are reversely scored. Higher scores indicate improvement.

[d]PedsQL QOL: Pediatric Quality of Life Inventory.

[e]CDI-S: Child Depression Inventory-Short version.

[f]SCAS-S: Spence Children Anxiety Scale-Short version.

[g]VSI: Visceral Sensitivity Index.

[h]IBS-BRQ: Irritable Bowel Syndrome-Behavioral Responses Questionnaire.

[i]CSI-24: Children's Somatization Inventory.

[j]CSI-24 (gastro): Children's Somatization Inventory-24 (gastro).

[k]ISI-C: Insomnia Severity Index-Child version.

[l]PAS: Pressure Activation Stress Scale.

[m]School Absence was rated in intervals of hours absent from school last month. 1=1-5 hours, 2=6-10 hours, and 3=more than 10 hours.

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Table 4. Effects sizes for child-reported outcomes.

Outcome measure	Pre-post			Pre-FU6		
	Cohen *d*	(95% CI)	*P* value	Cohen *d*	(95% CI)	*P* value
PedsQL Gastro[a]	1.14[b]	0.69-1.61	<.001	1.40[b]	1.04-1.81	<.001
PedsQL QOL[c]	1.26[b]	0.82-1.72	<.001	1.43[b]	0.95-1.97	<.001
FACES Pain Rating Scale	0.74[b]	0.34-1.17	<.001	1.30[b]	0.81-1.74	<.001
Pain-free days	0.70[b]	0.25-1.17	=.002	0.95[b]	0.42-1.49	<.001
CDI-S[d]	0.43[b]	0.08-0.79	=.006	0.45[b]	0.06-0.87	=.005
SCAS-S[e]	0.29[b]	0.03-0.59	=.04	0.44[b]	0.06-0.87	=.002
VSI[f]	0.92[b]	0.56-1.31	<.001	1.24[b]	0.80-1.72	<.001
IBS-BRQ[g]	1.18[b]	0.76-1.65	<.001	1.28[b]	0.84-1.78	<.001
Catastrophizing	0.59[b]	0.17-1.00	=.002	1.29[b]	0.88-1.73	<.001
CSI-24[h]	0.41[b]	0.05-0.74	=.005	0.69[b]	0.43-0.97	<.001
CSI-24 (gastro)[i]	0.82[b]	0.49-1.17	<.001	1.22[b]	0.91-1.52	<.001
ISI-C[j]	0.18	−0.20 to 0.53	=.31	0.44[b]	0.11-0.69	=.01
PAS[k]	0.20	−0.16 to 0.60	=.31	0.77[b]	0.38-1.22	<.001
School absence	0.62[b]	0.26-1.05	<.001	0.84[b]	0.49-1.29	<.001

[a]PedsQL Gastro: Pediatric Quality of Life Inventory Gastrointestinal Symptom Scale.

[b]Significant effect sizes.

[c]PedsQL QOL: Pediatric Quality of Life Inventory.

[d]CDI-S: Child Depression Inventory-Short version.

[e]SCAS-S: Spence Children Anxiety Scale-Short version.

[f]VSI: Visceral Sensitivity Index.

[g]IBS-BRQ: Irritable Bowel Syndrome-Behavioral Responses Questionnaire.

[h]CSI-24: Children's Somatization Inventory.

[i]CSI-24 (gastro): Children's Somatization Inventory (gastro).

[j]ISI-C: Insomnia Severity Index-Child version.

[k]PAS: Pressure Activation Stress Scale.

School Absence

Before treatment, 25 of the 31 children (81%) reported that they had had some absence from school in the previous month related to abdominal symptoms. At posttreatment, 14 children (45%, 14/31) reported absence from school related to abdominal symptoms, and at 6-month follow-up, only 10/31 (32%) children reported absence from school in the previous month due to abdominal symptoms. McNemar tests showed that the differences in school absenteeism between pretreatment and posttreatment, and pretreatment and 6-month follow-up, were significant; P=.002 and P<.001, respectively. Of the 25 children who reported school absence at pretreatment, 10 children reported that they had no school absence at posttreatment, and 11 children reported that they had no school absence at 6-month follow-up. All children who reported no school absence at pretreatment also did so during the later assessments.

Rome III Criteria

At posttreatment, 6/31 (19%) children did not fulfill Rome III criteria according to their self-assessments any longer, and at 6-month follow-up, 16/31 (52%) no longer fulfilled the criteria. The distribution of the Rome III diagnosis at the different time points is presented in Table 5.

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Table 5. Patients fulfilling Rome III criteria for different pain-related functional gastrointestinal disorders (P-FGID) diagnoses at pre, post, and 6-month follow-up.

Disorder	Pretreatment	Posttreatment	FU6
IBS[a]	19	4	2
FAP[b,c]	11	17	8
FD[c,d]	2	3	2
No P-FGID[e]	0	6	16

[a]IBS: irritable bowel syndrome.

[b]FAP: functional abdominal pain.

[c]Participants migrated between diagnoses, which explains the increase in functional abdominal pain (FAP) and functional dyspepsia (FD) between pre- and posttreatment.

[d]FD: functional dyspepsia.

[e]P-FGID: pain-related functional gastrointestinal disorders.

Parent-Rated Outcomes

All parent-rated outcomes showed statistically significant improvements from pre- to posttreatment, except PHQ-9 (parental depression). Estimated means and SEs for all measures reported by parents are presented in Table 6. Effect-sizes and their 95% CIs and *P* values are presented in Table 7.

Table 6. Estimated means and standard errors at pretreatment, posttreatment, and 6-month follow-up reported by parents.

Outcome measure	Pretreatment		Posttreatment		6-month follow-up	
	Mean	(SE[a])	Mean	(SE)	Mean	(SE)
PedsQL Gastro[b,c]	57.62	(2.22)	74.54	(2.25)	77.46	(2.29)
PedsQL QOL[c,d]	69.57	(2.05)	82.79	(2.07)	85.95	(2.12)
FACES Pain Rating Scale	6.19	(0.44)	3.91	(0.45)	3.03	(0.46)
Pain-free days/week[c]	2.32	(0.37)	3.71	(0.38)	5.20	(0.39)
CSI-24[e]	13.97	(1.08)	8.46	(1.09)	6.95	(1.11)
CSI-24 (gastro)[f]	8.55	(0.58)	5.29	(0.58)	3.55	(0.60)
School absence[g]	1.58	(0.19)	1.01	(0.19)	0.55	(0.19)
Work absence[h]	0.65	(0.10)	0.34	(0.10)	0.05	(0.10)
ARCS[i]protect	11.35	(0.88)	5.16	(0.90)	4.41	(0.92)
ARCS monitor	10.10	(0.57)	4.82	(0.58)	3.99	(0.59)
PHQ-9[j]	4.29	(0.74)	3.45	(0.74)	2.40	(0.75)
GAD-7[k]	3.26	(0.49)	1.90	(0.50)	1.83	(0.51)

[a]SE: standard error.

[b]PedsQL Gastro: Pediatric Quality of Life Inventory Gastrointestinal Symptom Scale.

[c]PedsQL Gastro, PedsQL QOL, and pain-free days are reversely scored. Higher scores indicate improvement.

[d]PedsQL QOL: Pediatric Quality of Life Inventory.

[e]CSI-24: Children's Somatization Inventory-24.

[f]CSI-24 (gastro): Children's Somatization Inventory (gastro).

[g]School Absence was rated in intervals of hours absent from school last month. 0=0 hours, 1=1-5 hours, 2=6-10 hours, and 3=more than 10 hours.

[h]Work Absence was rated in intervals of days home from work last month due to the child's abdominal problems. 0=0 days, 1=1-5 days, 2=6-10 days, and 2=more than 10 days.

[i]ARCS: Adult Responses to Children's Symptoms.

[j]PHQ-9: Patient Health Questionnaire-9.

[k]GAD-7: Generalized Anxiety Disorder-7.

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Effect sizes were large from pretreatment to posttreatment for gastrointestinal symptoms (PedsQL Gastro), pain intensity (FACES Pain Rating Scale), quality of life (PedsQL QOL), somatization (CSI-24), and the process variables assessing parental responses to their children's symptoms (ARCS protect and monitor). At 6-month follow-up, all measures showed significant improvements compared with pretreatment. All effect sizes were large from pretreatment to 6-month follow-up, except for parental depression (PHQ-9) and parental anxiety (GAD-7). We observed a significant improvement of the effect sizes between posttreatment and 6-month follow-up for pain-free days d=0.72 (P<.001), gastrointestinal symptoms (CSI-24 gastro) d=0.54 (P=.004), school absence d=0.44 (P=.006), and work absence d=0.52 (P=.02).

Table 7. Effects sizes for parent-reported outcomes; Cohen *d*, (95% CI), and *P* values.

Outcome measure	Pre-post			Pre-FU6		
	Cohen *d*	(95% CI)	*P* value	Cohen *d*	(95% CI)	*P* value
PedsQL Gastro[a]	1.37[b]	0.83-1.96	<.001	1.60[b]	1.03-2.22	<.001
PedsQL QOL[c]	1.16[b]	0.70-1.69	<.001	1.44[b]	0.93-1.97	<.001
FACES Pain Rating Scale	0.93[b]	0.46-1.42	<.001	1.29[b]	0.81-1.72	<.001
Pain-free days	0.67[b]	0.27-1.08	<.001	1.38[b]	0.90-1.88	<.001
CSI-24[d]	0.92[b]	0.44-1.38	<.001	1.17[b]	0.46-1.72	<.001
CSI-24 (gastro)[e]	1.02[b]	0.56-1.44	<.001	1.56[b]	1.18-1.96	<.001
School absence	0.55[b]	0.22-0.97	<.001	0.99[b]	0.60-1.49	<.001
Work absence	0.55[b]	0.00-1.11	=.01	1.07[b]	0.68-1.54	<.001
ARCS[f]protect	1.26[b]	0.67-1.79	<.001	1.41[b]	0.74-2.00	<.001
ARCS monitor	1.65[b]	0.96-2.35	<.001	1.91[b]	1.15-2.68	<.001
PHQ-9[g]	0.21	−0.13 to 0.50	=.16	0.46[b]	0.09-0.75	=.002
GAD-7[h]	0.50[b]	0.19-0.77	=.004	0.52[b]	0.20-0.83	=.003

[a]PedsQL Gastro: Pediatric Quality of Life Inventory Gastrointestinal Symptom Scale.

[b]Significant effect sizes.

[c]PedsQL QOL: Pediatric Quality of Life Inventory.

[d]CSI-24: Children's Somatization Inventory-24.

[e]CSI-24 (gastro): Children's Somatization Inventory (gastro).

[f]ARCS: Adult Responses to Children's Symptoms.

[g]PHQ-9: Patient Health Questionnaire-9.

[h]GAD-7: Generalized Anxiety Disorder-7.

Medication for Abdominal Symptoms

At pretreatment, 12 children were on medications for their abdominal symptoms. At posttreatment, 6 of the children had stopped taking medications, and 6 children were still taking them. None initiated new medications during treatment.

Adverse Events

Parents reported that 7 children had experienced an adverse event during the treatment. These events were sleep problems (n=2), increased problems with defecation when decreasing medication for constipation (n=1), lack of time for school homework and other obligations (n=1), longer toilet visits (n=1), increasing number of conflicts due to the treatment exercises (n=1), and feelings of panic once when doing a difficult exposure exercise (n=1). One event was rated as having a big negative impact at the time (sleep problems), two as having medium negative impact at the time (longer toilet visits and increasing number of conflicts and resistance to do the exercises), two as having a small negative impact at the time (sleep problems and difficulty with decreasing medication for constipation), and two were rated as having no impact at the time of the occurrence (lack of time for school homework and other obligations and feelings of panic once when doing a difficult exposure exercise). At the posttreatment assessments, three parents rated that their child was still affected by the adverse events, one with a medium negative impact (sleep problems) and two with a small negative impact (sleep problems and longer toilet visits).

Discussion

Main Results

To the best of our knowledge, this is the first study of exposure-based Internet-CBT for children aged 8-12 years with P-FGIDs. The results showed that children and their parents perceived exposure-based Internet-CBT as a feasible, acceptable, and helpful intervention. The within-group effect size was large

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on the primary outcome measure of gastrointestinal symptoms, from pretreatment to posttreatment, and almost all secondary measures showed significant improvements. Results were maintained or further improved at 6-month follow-up. These results add to the support for exposure-based Internet-CBT for adults and adolescents with IBS [17,19,59,60]. Comparison with other studies in the field is complicated by differences in research designs and by different ways of reporting results: effect sizes are not frequently reported and even mean raw scores are reported differently across studies. In the largest study of CBT for pediatric P-FGIDs conducted by Levy [22], Cohen *d* effect sizes were reported only at 12-month follow-up [61]. The within-group effect sizes in Levy's study were comparable with our results. Even though the intervention studied by Levy was brief, therapist time per family in treatment was similar between Levy's and our intervention. In a newly published study of hypnotherapy for children with P-FGIDs [62], the within-group reductions of pain intensity and frequency were large. However, that study reported more modest results on anxiety, depression, and quality of life. We observed larger improvements on these outcomes in this study, especially quality of life. Thus, with the important limitation in mind that the present study did not include a control group and thus causal inferences cannot be drawn, the observed within-group effects are at par with previous studies in the field, indicating potential efficacy of the treatment format and content.

Strengths and Limitations

Among the strengths of the study were low attrition (with only one child's assessments missing at posttreatment and three at 6-month follow-up) and high compliance to the treatment. Another strength was the consistent results on the wide range of outcome domains assessed, including abdominal symptoms, quality of life, pain intensity, pain-free days, depression, anxiety, gastrointestinal-specific anxiety, avoidant behaviors, catastrophizing, somatization, sleep, stress, and school absence, and for parents also work absence, responses to the child's symptoms, parental depression, and parental anxiety. The outcome domains used in the study reflect the extent of problems associated with P-FGIDs and are based on the recommendations for assessments in clinical trials for pediatric recurrent pain [36]. The external validity of this study is strengthened by the fact that participants were recruited via primary, secondary, and tertiary health care for children, and few exclusion criteria were used. In this study, psychiatric comorbidity was assessed with a structured interview (MINI-KID) [31,32] conducted by psychologists. It would have been interesting to compare the psychiatric comorbidity in this study with other studies in the field. Unfortunately, we have found only one other treatment study for children with P-FGIDs where the psychiatric comorbidity was assessed and presented [46]. In that study, the psychiatric comorbidity was comparable with what was observed in our study. Hopefully, psychiatric comorbidity will be assessed and presented thoroughly in future studies to enable comparison and discussion.

The most important limitation of the study is the within-group study design. This design was chosen to match the aims of the study: to assess the acceptability, feasibility, and preliminary within-group effect sizes, before conducting an RCT.

Possible Mechanisms and Clinical Implications

CBT for children with P-FGIDs typically include multiple components, and thus, several possible mechanisms of treatment [22,46,63]. In this study, we had a distinct focus on exposure to abdominal symptoms and associated stimuli. Fear and avoidance of these stimuli have been established as key maintaining factors in adult IBS [64], and this is likely an important mechanism also for children with P-FGIDs. We observed large effect sizes on the process variables related to decreased avoidance (IBS-BRQ), decreased gastrointestinal-specific anxiety (VSI), and decreased parental protectiveness and monitoring (ARCS protect and ARCS monitor). These results support a model where interoceptive and in-vivo exposure exercises and changed parental responses to children's symptoms lead to reduced fear and avoidance and thereby symptom improvements. Future studies should perform mediation analyses on these variables to explore how they interplay and affect symptoms.

Pediatric P-FGIDs have been associated with societal costs, such as extensive health care visits [5], school absence, and parental time off work [4]. This study shows that school absence and parental work absence can be affected by the treatment, but because of the study design (with no control condition), no comprehensive health economic evaluation was conducted. Future studies should thoroughly assess and take into account economic factors, when designing and conducting clinical trials for this population, to investigate if there are societal benefits as well as benefits for the families taking part of the treatment [36].

Considering the large effect sizes on the primary outcome measure, the high level of acceptability as rated by both children and parents, and the limited amount of therapist time required, this treatment is highly promising in reducing symptoms, improving quality of life, and increasing accessibility to psychological treatments for children with P-FGIDs.

Conclusions

This is the first study where children aged 8-12 years with P-FGIDs were treated with therapist-guided exposure-based Internet-CBT. The children and their parents perceived the treatment as acceptable, feasible, and helpful. Despite the long duration of abdominal pain before start of the intervention, improvements were statistically significant on almost all measures from pretreatment to posttreatment, and at 6-month follow-up, all measures showed significant improvements from pretreatment. The within-group effect size on the primary outcome measure PedsQL Gastro was large from pretreatment to posttreatment, and the results were maintained at 6-month follow-up. We conclude that this treatment may be highly feasible and clinically effective. The results need to be confirmed in an RCT.

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Acknowledgments

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Conflicts of Interest

None declared.

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Abbreviations

ARCS: Adult Responses to Children's Symptoms
CBT: cognitive behavioral therapy
CDI-S: Child Depression Inventory-Short version
CSI-24: Children's Somatization Inventory-24
FAP: functional abdominal pain
FD: functional dyspepsia
GAD-7: Generalized Anxiety Disorder-7
IBS: irritable bowel syndrome
IBS-BRQ: Irritable Bowel Syndrome-Behavioral Responses Questionnaire
Internet-CBT: Internet-delivered cognitive behavior therapy
ISI-C: Insomnia Severity Index-Child version.
MINI-KID: Mini-International Neuropsychiatric Interview for Children and Adolescents
PAS: Pressure Activation Stress Scale
PedIMMPACT: the Pediatric Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials
PedsQL Gastro: Pediatric Quality of Life Inventory Gastrointestinal Symptom Scale
PedsQL QOL: Pediatric Quality of Life Inventory
P-FGID: pain-related functional gastrointestinal disorder
PHQ-9: Patient Health Questionnaire-9
RCT: randomized controlled trial
SCAS-S: Spence Children Anxiety Scale-Short version.
SOL: stop, observe, and let go
VSI: Visceral Sensitivity Index

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Original Paper

Comparison of Self-Reported Telephone Interviewing and Web-Based Survey Responses: Findings From the Second Australian Young and Well National Survey

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Abstract

Background: Web-based self-report surveying has increased in popularity, as it can rapidly yield large samples at a low cost. Despite this increase in popularity, in the area of youth mental health, there is a distinct lack of research comparing the results of Web-based self-report surveys with the more traditional and widely accepted computer-assisted telephone interviewing (CATI).

Objective: The Second Australian Young and Well National Survey 2014 sought to compare differences in respondent response patterns using matched items on CATI versus a Web-based self-report survey. The aim of this study was to examine whether responses varied as a result of item sensitivity, that is, the item's susceptibility to exaggeration on underreporting and to assess whether certain subgroups demonstrated this effect to a greater extent.

Methods: A subsample of young people aged 16 to 25 years (N=101), recruited through the Second Australian Young and Well National Survey 2014, completed the identical items on two occasions: via CATI and via Web-based self-report survey. Respondents also rated perceived item sensitivity.

Results: When comparing CATI with the Web-based self-report survey, a Wilcoxon signed-rank analysis showed that respondents answered 14 of the 42 matched items in a significantly different way. Significant variation in responses (CATI vs Web-based) was more frequent if the item was also rated by the respondents as *highly sensitive* in nature. Specifically, 63% (5/8) of the *high sensitivity* items, 43% (3/7) of the *neutral sensitivity* items, and 0% (0/4) of the *low sensitivity* items were answered in a significantly different manner by respondents when comparing their matched CATI and Web-based question responses. The items that were perceived as *highly sensitive* by respondents and demonstrated response variability included the following: sexting activities, body image concerns, experience of diagnosis, and suicidal ideation. For *high sensitivity* items, a regression analysis showed respondents who were male (beta=−.19, *P*=.048) or who were not in employment, education, or training (NEET; beta=−.32, *P*=.001) were significantly more likely to provide different responses on matched items when responding in the CATI as compared with the Web-based self-report survey. The Web-based self-report survey, however, demonstrated some evidence of avidity and attrition bias.

Conclusions: Compared with CATI, Web-based self-report surveys are highly cost-effective and had higher rates of self-disclosure on sensitive items, particularly for respondents who identify as male and NEET. A drawback to Web-based surveying methodologies, however, includes the limited control over avidity bias and the greater incidence of attrition bias. These findings have important implications for further development of survey methods in the area of health and well-being, especially when considering research topics (in this case diagnosis, suicidal ideation, sexting, and body image) and groups that are being recruited (young people, males, and NEET).

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KEYWORDS

survey methods; youth; mental health; online behaviors; information disclosure

Introduction

Over the past decade, the Australian government and nongovernment organizations have invested heavily in computer-assisted telephone interviewing (CATI) and face-to-face interview methodologies [1-4]. Of these, CATI has proved more popular than face-to-face surveys as it has greater cost-effectiveness, has good geographical coverage without the need of travel, and maintains a personal interaction between the interviewer and the survey respondent, while also offering random digit dialing (RDD) for sample selection. However, in more recent years, changes in technology have resulted in some new challenges to using telephone surveying [5]. Landline telephone use has decreased because of mobile phone popularity. This has hindered sample stratification, which was traditionally enabled by an association between landlines and geographic locations. Decreasing CATI response rates and increased sampling bias have also been attributed to the use of certain technologies including do not call registers and the use of voicemail and caller identification [6]. With the rapid uptake of the Internet over the past decade, facilitated by better connectivity (eg, Wi-Fi and national fiber optics networks), Web-based self-report surveying has become increasingly popular for its potential to efficiently yield much larger samples at a much lower cost [7]. Despite this popularity, research comparing respondent answers in youth-focused mental health surveys when using CATI versus Web-based self-report surveys is limited.

There are some subgroups of the population that may find Web-based self-report surveys particularly advantageous. Research has suggested that young people are more comfortable using the Internet than other subsamples of the population [8]. The Internet is also widely accessible to nearly all young people [1,9]. Since 2008, our research group has focused on national surveys relating to mental health and technology use of young people. These have been carried out using both CATI [1,10] and Web-based self-report surveys [1,10-12]. Results from the First Australian Young and Well National Survey [1] showed that young people's responses differed based on methodologies (CATI vs Web-based self-report survey). For example, there was a higher proportion of young people reporting psychological distress online compared with CATI (59% vs 21% *high* to *very high* distress).

Another subsample that Web-based self-report surveys may benefit comprises men and boys. Research has suggested that males have poorer mental health knowledge and higher mental health stigma than females [8], and they are also more reluctant to disclose sensitive mental health information [13]. Alongside further investigation into general response differences when comparing CATI with Web-based self-report surveys, gender differences in responding warrants further investigation. This line of inquiry follows our previous research into young men and their technology use, mental health help-seeking, and stigma [1,11,12,14].

There are other advantages and disadvantages to collecting self-report data online versus CATI. For example, particular challenges arise when survey questions contain information that is considered sensitive in nature. According to Tourangeau and Yan [15], survey questions can be labeled as "sensitive" if respondents perceive them as intrusive or an invasion of privacy, they raise fears about the potential repercussions of disclosing the information, or if they trigger social desirability concerns. Examples of sensitive topics that appear in the literature include illicit drug use, abortion and, sexual behavior [15].

There is evidence to suggest that with the presence of an interviewer, a social desirability effect occurs, whereby respondents minimize more unpleasant disclosures to maximize social acceptability and respectability [16]. Responses to more sensitive items may be reported at a higher rate online than via the telephone. For example, higher levels of alcohol consumption have been reported by college students answering online compared with those responding via the telephone [17]. More importantly, most prior research in this domain has relied on the researchers' judgments about which items are sensitive (consider the study by Kreuter et al [18] as an exception). Therefore, what is considered sensitive from respondents' perspective and how this influences their responses requires further research.

For the Second Australian Young and Well National Survey 2014 (Second National Survey, 2014), we sought to more thoroughly compare a CATI with a Web-based-self-report survey. This subsidiary study had three main aims, which were to assess whether (1) there were within-subject response differences between the CATI and the Web-based self-report survey; (2) sensitive items demonstrated greater variability across the different methodologies (CATI vs Web-based survey) compared with nonsensitive items; and (3) particular respondent subsamples demonstrated greater variability in their responses between methodologies based on the sensitivity of the items.

Methods

Design and Sample

This research was a subsidiary study that formed part of a larger national research project in Australia, the Second National Survey (2014). A within-subjects design was used in this substudy to assess response differences of respondents using matched items at two time points delivered via two different methodologies (CATI vs Web-based self-report survey).

To participate in this substudy, respondents were recruited from the larger Second National Survey (2014). Cross-sectional CATI using RDD to fixed landlines and mobile phones (N=1400) and a Web-based self-report survey (N=2416) were used to explore young people's experiences of mental health and well-being

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and their use of information and communication technology. The sampling and methods used in the CATI and the Web-based self-report survey for the larger Second National Survey (2014), followed the First Young and Well National Survey 2012, which have been described in further detail elsewhere [1].

At the end of both the CATI and the Web-based self-report survey, respondents were asked to provide an email account if they would be willing to be contacted again for research purposes on the same topic. Second National Survey (2014) CATI respondents who gave consent to be contacted again (N=674) were sent an email link to a smaller Web-based self-report survey with specific items drawn from the Second National Survey (2014) selected for this substudy. The Second National Survey (2014) Web-based respondents who gave consent to be contacted again and provided their telephone details (N=104) were contacted via telephone and were asked the same matched items selected for this substudy. Hence, respondents in this substudy completed the same set of questions on two occasions (via CATI and Web-based self-report survey), and the order of survey completion was counterbalanced. Consecutive recruitment took place until 100 useable cases were completed by respondents at these two time points (CATI and Web-based self-report survey). Study flow is shown in Figure 1. This study received ethics approval from The University of Sydney Human Research Ethics Committee (Protocol No. 2014/741).

Items

The initial Second National Survey (2014) was administered using both a CATI and a Web-based self-report survey and included up to 81 questions, depending on the skip pattern. Questions included demographics, general health and well-being, mental health, health perceptions of Australian youth, use of the Internet, online and communication risks (eg, digital abuse such as bullying and sexting), happiness and resilience, social networking and relationships, as well as use of mobile phones, apps, and social media. To address the primary aim outlined in this substudy, 19 questions (42 items and subitems in total) were selected to be administered using both the CATI and the Web-based self-report survey to the same respondent on two occasions. These items were purposively selected to provide a range of potentially sensitive and nonsensitive items that were both personal and nonpersonal in nature. Selected items are presented in Multimedia Appendix 1. The Second National Survey (2014) results from both the CATI and the Web-based self-report survey full samples for these selected matched items are included in Multimedia Appendix 2 as frequency statistics.

To address the secondary and tertiary aims relating to understanding item sensitivity, the final item of the survey, administered at the second time point only, asked respondents to rate the sensitivity of some of the earlier items. Similar to Kreuter and colleagues [18], this question read: "Questions sometimes have different effects on people. We'd like your opinions about some of the questions in this survey. Please indicate the degree to which you think each of the following items might make people falsely report or exaggerate their answers?" Respondents rated each sensitivity question on a 5-point Likert scale of 1= *strongly disagree* to 5= *strongly agree*.

Statistical Analysis

Data were analyzed using IBM's Statistical Package for the Social Sciences (SPSS) version 21.0. A Wilcoxon signed-rank test was conducted to address the primary aim of the study. This analysis was used to determine whether respondents' median scores differed for each repeated matched item at the two measurement points (CATI and Web-based self-report survey). This test was used, as the sample could not be assumed to be normally distributed. There was sufficient sample size (a priori minimum N=94, actual sample achieved N=101) as determined by G*Power 3.1 (a priori Cronbach alpha=.05, minimum effect size=0.3, power=0.8; [19]). Multiple response categorical items were collapsed to meet assumptions of the Wilcoxon signed-rank test that the dependent measurements were at least of ordinal scale (which includes dichotomous measures). This included collapsing: Q3, main educational and vocational activity (not in employment, education, or training [NEET] vs in employment, education, or training [EET]); Q4, highest level of education (tertiary vs nontertiary); and, Q12 and Q13, weekday and weekend Internet use (regular hours use vs late night use [11pm to 5am]). All Likert scale items and dichotomous categorical items were not transformed at this point. Missing values ("Don't know" or "Refused") were excluded from analysis, except where stated in Table 1, to meet the required ordinal scale assumption.

To address the secondary aim of the study, a number of analyses assessing item sensitivity were performed. First, the sensitivity items (adapted from Krueter et al [18]) were collected at the second survey time point using two different methodologies (CATI and Web-based self-report survey). Thus, a Mann-Whitney *U* test was used to examine if there were any significant differences in responses between the two methodologies for each sensitivity item. Following this, items were aggregated by their median score into *high sensitivity*, *neutral sensitivity*, and *low sensitivity* groups. Each item that received a median score of 4 was allocated to the *high sensitivity* group, as the majority of respondents "agreed" that people might falsely report or exaggerate their answers. An item with a median score of 3 indicated *neutral sensitivity*, as the majority of respondents "neither agreed nor disagreed" that people might falsely report or exaggerate their answers. Finally, an item that received a median score of 2 was categorized into the *low sensitivity* group, as the majority of respondents "disagreed" that people might falsely report or exaggerate their answers. Within these three established groups (*low*, *neutral*, and *high*), a difference score between the CATI and the Web-based self-report survey was calculated. This was carried out by determining whether the respondent provided the same response using the two methodologies (difference score=0) or provided a different response (difference score=1) for each identical item collapsed onto dichotomous measures.

To address the tertiary aim of the study, each item's difference score was then aggregated into a total difference score for each sensitivity group (*low*, *neutral*, and *high*), and the mean score was taken as each sensitivity group had varying numbers of

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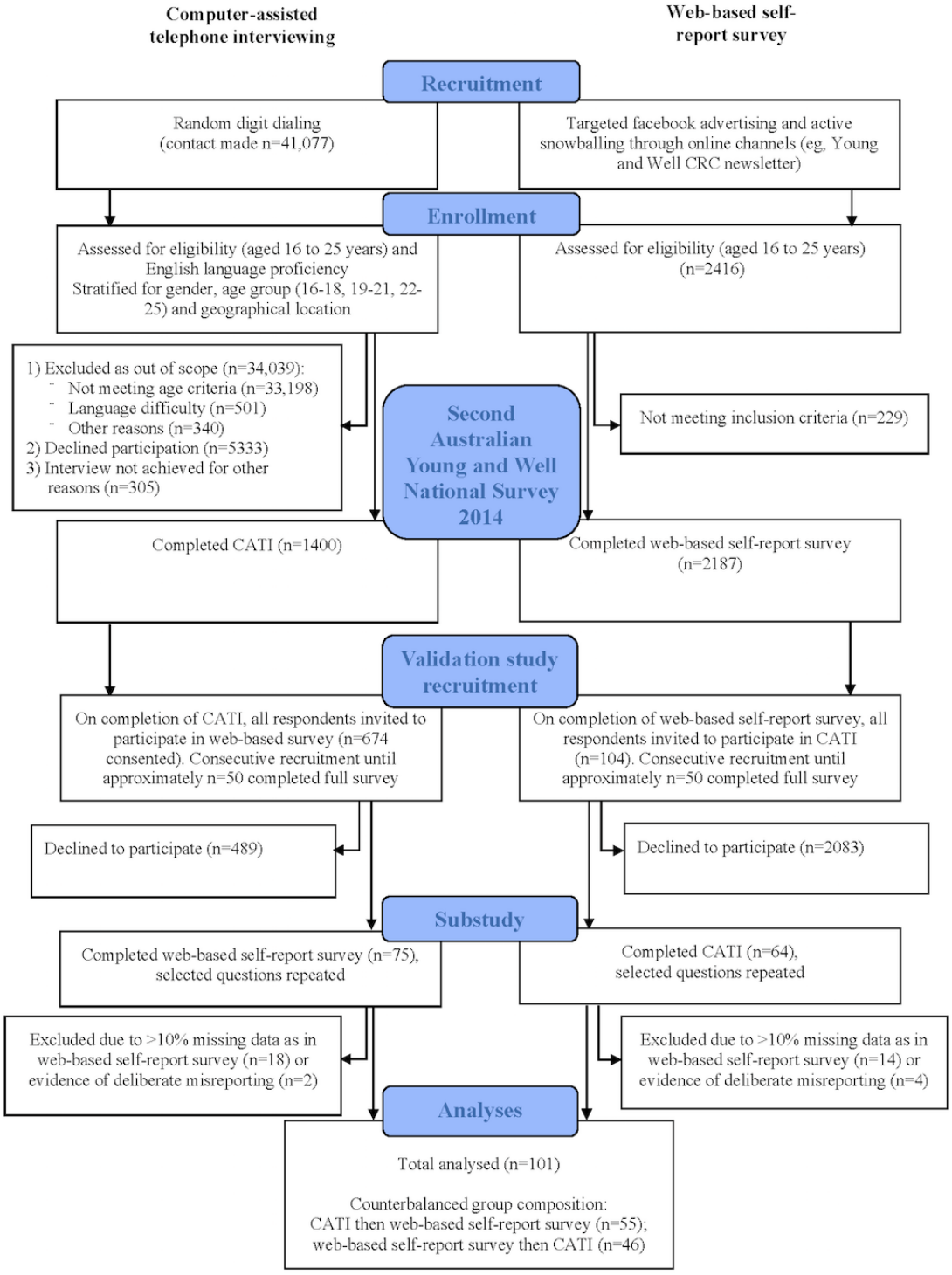
items. Subsequent regression analyses were used to examine the association between demographic or biographic items and the total mean differences score for the sensitivity groups (*low*, *neutral*, and *high*). There was sufficient sample size (a priori minimum N=89, actual sample achieved N=101) calculated using G*Power 3.1 ([19]; a priori Cronbach alpha=.05, minimum effect size=0.2, power=0.9, predictors=5). Five demographic or biographic predictors that met regression model assumptions of linearity, homoscedasticity, independence, and normality (evaluated using standard residuals-based diagnostic procedures) included gender (males vs females), age, educational attainment (tertiary vs nontertiary), main vocational and educational activity (NEET vs EET), and the order of survey administration (CATI first vs Web-based self-report survey first).

Figure 1. Study flow.



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Results

Sample

A total of 139 respondents completed both the CATI and Web-based self-report survey. Of these, 32 cases (23.0%, 32/139) were discarded as too much data were missing from one administration (>10% of data missing on one administration in the Web-based sample), and a further 6 cases (4.3%, 6/139) were discarded because of obvious misreporting (ie, unreasonable values for some or all data fields). All missing data and misreporting cases were from the Web-based self-report survey. Of the discarded cases, approximately half were female (55%, 21/38). Overall, 101 respondents provided sufficient data for analysis. Of these remaining cases, 61 (60.4%) were female, 40 (39.6%) were male, 55 (54.5%) completed the CATI before the Web-based self-report survey, and 46 (45.5%) completed the Web-based self-report survey before the CATI.

CATI Versus Web-Based Response Differences (Primary Aim Findings)

Results from the Wilcoxon signed-rank test by matched item (see Multimedia Appendix 1) showed that 14 of the matched items demonstrated significant median differences between the CATI and Web-based self-report survey. The vast majority of these matched items (13/14, 93%) that demonstrated significant differences were consistently ranked in the same direction. Specifically, respondents endorsed the item when asked via CATI less frequently than when answering online. These items included main educational and vocational activity (NEET: CATI item endorsement=5.0% vs Web-based self-report survey=17.8%; *P*=.002), experience of diagnosis (mental health or behavioral: CATI item endorsement=25.0% vs Web-based self-report survey=31.6%; *P*=.03), suicidal ideation (thought of taking own life: CATI item endorsement=11.1% vs Web-based self-report survey=18.4%; *P*=.02), multiple sexting activity responses, searching for information relating to a health problem (mental health or substance use problem: CATI item endorsement=61.4% vs Web-based self-report survey=74.3%; *P*=.002), help-seeking waiting periods (less than 4 weeks: CATI item endorsement=66.3% vs Web-based self-report survey=72.0%; *P*=.003), and body image (CATI item endorsement=34.7% vs Web-based self-report survey=65.3%; *P*<.001). Only one item "Do you think cyberbullying is a serious problem for young people?" had higher respondent endorsement in the CATI than Web-based self-report survey (CATI item endorsement=93.1% vs Web-based self-report survey=80.6%; *P*=.02).

Item Sensitivity (Secondary Aim Findings)

The Mann-Whitney test determined that there were no differences between CATI and Web-based self-report respondent ratings of sensitivity items. Table 1 shows the perceived sensitivity of each item, as rated by the respondent, and their subsequent sensitivity group allocation based on median scores. All items that demonstrated significant differences in the initial Wilcoxon signed-rank test were found to be in the *high sensitivity* or *neutral sensitivity* group, with no differences found in the *low sensitivity* group. A greater proportion of *high sensitivity* domains (5/8, 63%) demonstrated significant differences between surveying methodologies in the Wilcoxon signed-rank test compared with the *neutral sensitivity* (3/7, 43%) and *low sensitivity* (0/4, 0%) domains.

Item Sensitivity by Subgroup (Tertiary Aim Findings)

The linear regression models for each of the sensitivity groupings (*low*, *neutral*, and *high*) are presented in Table 2. For the *low sensitivity* group, none of the demographic or biographic variables were significant in explaining the regression model's variance ($F_{5,95}$=0.45, *P*=.81, R^2_{adj}=−.03). For the *neutral sensitivity* group, 8% of the variance was significantly accounted for in the regression model ($F_{5,95}$=2.8, *P*=.02, R^2_{adj}=.08). Two variables significantly explained the variance, which included age (beta=.28, *P*=.03) and EET status (beta=−.26, *P*=.01). Those who were older or NEET had higher total mean difference scores for *neutral sensitivity* items. That is, they more frequently reported differently online than they did in the CATI for *neutral sensitivity* items. For the *high sensitivity* group, 14% of the variance was significantly accounted for in the regression model ($F_{5,95}$=4.3, *P*=.001, R^2_{adj}=.14). Two variables significantly explained the variance, which included sex (beta=−.19, *P*=.048) and EET status (beta=−.32, *P*=.001). Those who were male or NEET had higher total mean difference scores for *high sensitivity* items. That is, they more frequently reported differently online than they did in the CATI when answering *high sensitivity* items.

For males, items with the highest difference in item responses were Q20ii, whether body image is an issue that concerns them personally (CATI: 5/39, 13% vs Web-based self-report survey: 18/40, 45%); Q18v, whether they have seen other people perform acts of a sexual nature on their mobile phone, smartphone, or the Internet (CATI: 11/40, 28% vs Web-based self-report survey: 22/40, 55%); and Q19i, whether they had sent someone a sexual message on their mobile phone, smartphone, or the Internet (CATI: 13/40, 33% vs Web-based self-report survey: 21/40, 53%).

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Table 1. Perceived sensitivity of survey items.

Survey item[a]	Perceived sensitivity			Sensitivity grouping
	N	Median	Mean (standard deviation)	
16ii. In the past 12 months, how often have you cyber-bullied someone?	93	4	4.01 (1.03)	High
19. In the past 12 months, have you done these things (sexting activities) on your mobile, smartphone, or the Internet?	93	4	3.94 (1.08)	High[b]
5. How would you rate your overall mental health in the past 4 weeks?	90	4	3.83 (0.82)	High
18. In the past 12 months, have you had any of these things (sexting activities) happen to on your mobile, smartphone, or the Internet?	93	4	3.75 (1.06)	High[b]
7. In the past 12 months have you ever thought about taking your own life?	91	4	3.74 (1.07)	High[b]
6. Have you ever been diagnosed with a mental health or behavioral problem?	91	4	3.74 (0.85)	High[b]
16ii. In the past 12 months, how often have you been cyber-bullied?	94	4	3.51 (1.12)	High
2. Do any of the following issues concern you personally (eg, alcohol, body image, and depression)?	93	4	3.44 (1.07)	High[b]
4. What is your highest level of education?	93	3	3.00 (1.12)	Neutral
14. Have you ever used the Internet to find information for a mental health, alcohol, or substance use problem?	92	3	2.98 (1.15)	Neutral[b]
17. Do you think sexting is a serious problem for young people your age?	91	3	2.91 (1.21)	Neutral
9. Would you know where to get help if you, or someone you knew, was feeling suicidal?	88	3	2.88 (1.19)	Neutral
8. How long do you think a mental health or behavioral problem needs to be present before a young person should seek help?	88	3	2.76 (1.09)	Neutral[b]
3. Main current activity	93	3	2.69 (1.17)	Neutral[b]
15. Do you think cyberbullying is a serious problem for young people?	93	3	2.63 (1.20)	Neutral
11. How often do you use the Internet?	98	2	2.66 (1.39)	Low
12. When are you most active online on a normal weekday or workday?	96	2	2.35 (1.27)	Low
13. When are you most active online on a normal weekend or nonworkday?	97	2	2.34 (1.22)	Low
1. Do you use the Internet?	97	2	2.25 (1.30)	Low

[a]Ordered from most sensitive to least sensitive items. Sensitivity grouping is based on median score.

[b]Denotes items that demonstrated at least some significant difference in respondent answers when using the CATI and the online self-report survey (as measured by the Wilcoxon singed-rank test).

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Table 2. Multiple regression models for total mean difference scores in high sensitivity, neutral sensitivity, and low sensitivity groups.

Variable	*t*	*P* value	Beta	95% CI	*F*	*df* [a]	*P* value	Adjusted R^2
High sensitivity					4.30	5,95	.001	.14
Sex	−2.00	.048	−.19	−0.10 to 0.00				
Age	−1.14	.26	−.14	−0.02 to 0.05				
EET[b] status	−3.29	.001	−.32	−0.16 to −0.04				
Educational attainment	0.80	.42	.10	−0.04 to 0.09				
Order of survey completion	−1.41	.16	−.13	−0.08 to 0.01				
Neutral sensitivity					2.81	5,95	.02	.08
Sex	1.32	.19	.13	−0.02 to 0.08				
Age	2.17	.03	.28	0.00 to 0.02				
EET status	−2.62	.01	−.26	−0.15 to −0.02				
Educational attainment	−1.90	.06	−.25	−0.13 to 0.00				
Order of survey completion	1.26	.21	.12	−0.02 to 0.08				
Low sensitivity					0.45	5,95	.81	−.03
Sex	0.59	.56	.06	−0.03 to 0.05				
Age	0.32	.75	.04	−0.01 to 0.01				
EET status	0.51	.61	.06	−0.04 to 0.07				
Educational attainment	−0.06	.96	−.01	−0.06 to 0.05				
Order of survey completion	1.03	.31	.11	−0.02 to 0.06				

[a]df: degrees of freedom.

[b]EET: education, employment, or training.

Discussion

Principal Findings

The key findings of this research demonstrated that significant variation in responses (CATI vs Web-based) was more frequent if the item was also rated by the respondents as *highly sensitive* in nature. For these *high sensitivity* items, a regression analysis showed that male and NEET respondents were significantly more likely to provide different responses on matched items when responding in the CATI as compared with the Web-based self-report survey.

The primary aim of this study was to determine whether differences in survey responses arose using a within-subjects design that delivered the survey via two distinct methodologies; CATI versus Web-based self-report survey. Of the total 42 matching demographic, mental health, and well-being questions asked at the two counterbalanced survey time points, 14 (33%) demonstrated significant differences in respondent answers. These findings suggest that CATI and Web-based surveying approaches do not always yield corresponding results for the same individual surveyed. Importantly, the overall trend was that the Web-based self-report survey resulted in higher levels of disclosure or item endorsement.

The secondary aim explored potential reasons for these differences in respondent answers by examining item sensitivity. Respondent-rated *high sensitivity* items in this study included cyberbullying behavior, sexting activities, overall mental health, suicidal ideation, mental health diagnosis, and personally concerning issues such as body image. Of these, sexting activity, suicidal ideation, experiencing a mental health diagnosis, and body image concerns were endorsed significantly more frequently in the Web-based self-report survey compared with the CATI.

Previous studies have found that respondents report more socially undesirable sexual behavior in self-administered questionnaires than interviewer-administrated surveys [20,21]. Although related to these previous studies, no known research has compared Web-based self-report surveys with CATI for sexting behavior. This finding is important as survey-based research into sexting activities often cites social desirability bias as a key limitation to their findings [22,23]. Moving to Web-based self-report survey platforms may help to provide a more accurate understanding of the sexting landscape.

Similarly, no known research has compared CATI and Web-based self-report surveying methodologies when looking at questions relating to body image concerns. Our research found that, for males, this was the most underreported item in the CATI when compared with the self-report Web-based survey. Research has shown that for men in particular, body image is a difficult topic to discuss, especially when disclosing their insecurities, as they may be inexperienced at discussing how they feel about the way that they look [24]. Compared with surveys with an interviewer present, Web-based reporting may allow people, especially men, to open up more freely about any body image concerns they are experiencing.

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When compared with interviewer-administered surveys, self-report computer-based surveying has been found to increase respondents' reports of mental health symptoms [25]. Contrary results, however, have been reported in other studies on mental health symptomology [26], and other research has found no difference between the rates of reporting depression symptoms [27]. There was no difference in overall mental health ratings in this substudy when comparing surveying methodologies despite this item being rated as a *highly sensitive* item. Respondents did, however, report significantly higher rates of suicidal ideation and diagnosis in the self-report Web-based survey. One reason for this difference may be attributed to both suicidal ideation and the experience of a mental health diagnosis being harder to disclose to an interviewer than a person's overall mental health. This may be compounded by the response options provided, in that overall mental health provided a range of response options on a 5-point Likert scale (ranging from very bad to very good), whereas suicidal ideation and mental health diagnosis elicited binary responses of "yes" or "no."

Overall, a larger proportion of items deemed by respondents as more sensitive had greater susceptibility to variance, as compared with those that were rated as having *low sensitivity*. With the exception of one item, all items demonstrating significant differences were more frequently endorsed using the Web-based self-report survey than the CATI. To some extent, this finding supports the research highlighting that more personal, unpleasant, or self-stigmatizing disclosures are minimized in the presence of an interviewer and are more frequently endorsed online (eg, [16,17,28]). Interestingly, the one item endorsed significantly more frequently in the CATI related to cyberbullying being a serious concern for young people. Although this may simply be due to the question being more general and not specific to the individual, this may also be due to the effect of social desirability; a respondent endorsing that cyberbullying is an issue may be associated with a belief that greater social approval will be provided by the interviewer who is researching the topic.

These findings are highly relevant to youth mental health and well-being surveys, as such surveys typically involve sensitive questions, and research has suggested that young people have a fear of stigma relating to mental health problems, as well as increased concerns regarding confidentiality [29]. Web-based surveys may help minimize these concerns. It is also important to consider how young people use technology and the influence this use may have on self-disclosure of sensitive information. Today, young people are known to disclose significant amounts of sensitive information through social networking and texting. For example, a recent study suggests that adolescents disclose more on social media and use privacy settings less than adults [30]. Given their propensity to use social media and online channels to discuss sensitive information with others, young people arguably generalize these behaviors to other online scenarios such as responding to surveys. Thus, current trends in use of these mediums for self-disclosure may be instilling in this generation a greater willingness to disclose in online formats [31]. Web-based self-report surveys may pose challenges with some other populations, including those less familiar with technology, those with language or literacy issues, and those less likely to have readily available and affordable Internet access (eg, the elderly and those with a lower socioeconomic status). The question of Internet access and acceptability, however, does not appear to be an issue for young Australians, who are native to technology in their daily lives, with 99% reporting daily Internet use in our larger Second National Survey (2014) in both the CATI and the Web-based self-report survey.

The tertiary aim of the study was to examine the impact item sensitivity had on specific subgroups. Results showed that those who were male and those who were NEET were more susceptible to variance in disclosure of highly sensitive items. These groups exhibited a higher endorsement of items when answering a Web-based self-report survey. Research comparing gender differences in responses with sensitive items using Web-based self-report and CATI surveying methodologies is lacking. However, Web-based survey research has reported that in situations where privacy is perceived to be greater, men have significantly higher disclosure rates when asked sensitive questions, whereas women maintain a stable disclosure rate irrespective of the privacy condition [32]. Thus, in this substudy, the anonymity of the Web-based self-report survey may be seen as influencing men's willingness to disclose more sensitive information. In general, research suggests that men are reluctant to disclose sensitive mental health information [13]. This may be attributed to the greater levels of mental health stigma men experience. For example, a 2015 systematic review [33] reported that compared with women, men were disproportionately deterred to seek help for their mental health because of stigma, with disclosure concerns the most commonly reported stigma barrier. Similarly, in depression assessments, males tend to underreport symptoms of depression that should require medical attention [34]. Overall, the findings of increased levels of disclosure for males in this substudy suggest that Web-based self-report surveys may be useful to assist males to disclose more openly.

Item sensitivity ratings explain at least some variability across survey methodologies; however, sensitivity ratings do not explain all variability between the two methodologies. Some matched items (such as a respondent's mental health rating over the past 12 months) were not significantly different between the CATI and the Web-based self-report survey within this substudy, although differences were expected. This particular item showed considerable differences in the larger Second National Survey (2014) samples, with CATI respondents reporting better overall mental health (eg, the CATI median rating was "good" with 39.6% of respondents reporting this score, whereas the Web-based self-report survey median rating was "moderate," representing 32.4% of respondents). As no differences in these items were found in this substudy, the disparities found in the full Second National Survey (2014) may be attributed in some capacity to recruitment methods when sampling online. In particular, avidity bias may be involved as those with a greater interest in, or experience with, a survey topic are more likely to respond [35]. In the Web-based self-report Second National Survey (2014) sample, it may be that people with a lived experience of mental health problems were more likely to want to participate in a study focused on

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health and well-being, which explains the higher distress levels compared with the CATI.

In online recruitment, there is no social desirability pressure (albeit unspoken, unintentional, and subconscious) from an interviewer to initially take part in a study, unlike when contacted by the CATI through RDD. Interviewer presence may also explain the attrition bias that arose in the Web-based self-report survey sample. Specifically, in this substudy, all cases that were excluded because of missing data arose from Web-based surveying, that is, respondents are far less likely to terminate a CATI.

Strengths and Limitations

A key strength of this study was that respondents completed matched questions via the CATI and the Web-based survey. The wording of the questions and response categories were as identical as possible for each methodology to ensure consistency and comparability of responses. A further strength was the inclusion of ratings of item sensitivity at the end of the survey. This is important as sensitivity groupings were therefore based on the respondents' perceptions rather than researchers' assumptions. Despite these strengths, this was a comparative study of CATI vs Web-based self-report survey responses without the possibility of external validation with some objective criterion. We are essentially interpreting the results according to the "more-is-better" assumption for socially undesirable behavior and the "less-is-better" assumption for socially desirable behavior, respectively [28].

In terms of sampling, the strength of the study lay in the initial random sampling of respondents. A major limitation, however, was that the respondents then volunteered to take part in the second survey. As described above, this may result in avidity bias. Future studies should consider embedding random sampling across both survey time points into the study design. Furthermore, for a fine-grained comparison, an additional two control samples could have been included in the design of the study. In this future design, participants would complete the identical questions on two occasions but use the same surveying methodology (CATI vs CATI and Web-based vs Web-based).

Conclusions

The CATI, although a popular methodology, may be susceptible to underreporting when eliciting sensitive demographic or biographic, mental health, and well-being information from young people. Therefore, there may be some benefits to using Internet-based self-report surveys in research with young people when collecting data on sensitive issues, especially those related to body image concerns, suicidal ideation, and viewing or receiving sexual content online. However, there are also disadvantages in using Web-based surveys, which are important to take into consideration, particularly because of the concerns around nonrepresentative sampling due to avidity and attrition bias. Overall, researchers must consider the best fit in survey format with the population being studied [23]. In the case of researching sensitive mental health and well-being questions with young people (especially males and those who are NEET), a Web-based self-report survey may facilitate improved rates of self-disclosure.

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Conflicts of Interest

IBH has been a commissioner in Australia's National Mental Health Commission since 2012. He is the codirector, Health and Policy at the Brain and Mind Centre, University of Sydney. The Brain and Mind Centre operates early-intervention youth services at Camperdown under contract to headspace. He has previously led community-based and pharmaceutical industry–supported (Wyeth, Eli Lily, Servier, Pfizer, and AstraZeneca) projects focused on the identification and better management of anxiety and depression. He is a member of the Medical Advisory Panel for Medibank Private, a board member of Psychosis Australia Trust, and a member of Veterans Mental Health Clinical Reference Group. He is the chief scientific advisor to, and an equity shareholder in, Innowell. Innowell has been formed by the University of Sydney and PricewaterhouseCoopers (PwC) to deliver the Aus $30m Australian Government–funded "Project Synergy." Project Synergy is a 3-year program for the transformation of mental health services through the use of innovative technologies. JMB is the CEO of, and an equity shareholder in, Innowell.

Multimedia Appendix 1

Mean rank differences between identical items administered using CATI and an online self-report survey.

[PDF File (Adobe PDF File), 87KB - mental_v4i3e37_app1.pdf]

Multimedia Appendix 2

Second Australian Young and Well National Survey 2014 results and sub-study results.

[PDF File (Adobe PDF File), 39KB - mental_v4i3e37_app2.pdf]

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Abbreviations

CATI: computer-assisted telephone interviewing
EET: employment, education, and training
NEET: not in employment, education, or training
RDD: random digit dialing
SPSS: Statistical Package for the Social Sciences

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Original Paper

Effectiveness of Optional Videoconferencing-Based Treatment of Alcohol Use Disorders: Randomized Controlled Trial

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Abstract

Background: Treatment of alcohol use disorders (AUDs) is characterized by an adherence rate below 50%. Clinical research has found that patient adherence enhances treatment effect; hence, health authorities, clinicians, and researchers strive to explore initiatives contributing to patients receiving treatment. Concurrently, videoconferencing-based treatment is gaining ground within other addiction and psychiatric areas.

Objective: The aim of this study was to test whether optional videoconferencing increases adherence to and effectiveness of AUD treatment in a randomized controlled trial (RCT). We hypothesized that the intervention would decrease premature dropout (the primary outcome), as well as increase successful treatment termination, treatment duration, and treatment outcome (secondary outcomes).

Methods: We conducted this study in the public outpatient alcohol clinic in Odense, Denmark, between September 2012 and April 2013. It was an RCT with 2 groups: treatment as usual (TAU) and treatment as usual with add-on intervention (TAU+I). The TAU+I group had the option, from session to session, to choose to receive treatment as usual via videoconferencing. Data consisted of self-reported responses to the European version of the Addiction Severity Index (EuropASI). We collected data at baseline, at follow-up at 3, 6, and 12 months, and at discharge.

Results: Among consecutive patients attending the clinic, 128 met the inclusion criteria, and 71 of them were included at baseline. For the primary outcome, after 180 days, 2 of 32 patients (6%) in the TAU+I group and 12 of 39 patients (31%) in the TAU group had dropped out prematurely. The difference is significant (P=.008). After 365 days, 8 patients (25%) in the TAU+I group and 17 patients (44%) in the TAU group had dropped out prematurely. The difference is significant (P=.02). For the secondary outcomes, significantly more patients in the TAU+I group were still attending treatment after 1 year (P=.03). We found no significant differences between the 2 groups with regard to successful treatment termination and treatment outcome.

Conclusions: The results indicate that offering patients optional videoconferencing may prevent premature dropouts from treatment and prolong treatment courses. However, the small sample size precludes conclusions regarding the effect of the intervention, which was not detectable in the patients' use of alcohol and severity of problems.

Trial Registration: The Regional Health Research Ethics Committee System in Denmark: S-20110052; https://komite.regionsyddanmark.dk/wm258128 (Archived by WebCite at http://www.webcitation.org/6tTL3CO6u)

(JMIR Ment Health 2017;4(3):e38) doi:10.2196/mental.6713

KEYWORDS

treatment of alcohol use disorders; alcoholism; videoconferencing; effectiveness; adherence; patient compliance; premature dropout; patient dropouts

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Introduction

Treatment of alcohol use disorders (AUDs) is characterized by an adherence rate below 50% [1,2], with 50% of the patients dropping out within the first month of treatment [3,4]. Clinical research has found that the largest alcohol behavior change occurs at the beginning of a treatment course [5] and that patient adherence enhances treatment effect [6]. Hence, health authorities, clinicians, and researchers strive to explore initiatives contributing to patients receiving the planned amount of treatment. Even though research on the optimal duration of treatment is sparse, to our knowledge, no studies found evidence for an increased effect of longer treatment courses compared with shorter courses, such as 3 and 6 months [7-9]. The Danish clinical guideline for the treatment of alcohol dependence [10] recommends a 3-month course of therapy with the possibility of extension. However, most treatment institutions in Denmark have, so far, recommended 6 months of treatment in general or even longer, and this is still often the case.

Videoconferencing-based treatment, either alone or combined with face-to-face treatment such as blended care, has shown great potential for enhancing treatment and recovery within substance use and psychiatric areas, as it decreases barriers of time and distance [11,12]. The field of videoconferencing-based treatment of AUDs is relatively new, and the few existing studies were predominantly small pilot and feasibility studies, which found high levels of patient satisfaction and acceptance [13-19]. Furthermore, they found that videoconferencing may offer the potential to meet some of the challenges AUD treatment is facing regarding barriers [15,16], especially for patients who live at a considerable distance from the clinics [17-19] or have other psychiatric diagnoses [14]. Moreover, these earlier studies found videoconferencing-based assessment and treatment to be highly credible [13,14] and even as effective as face-to-face treatment, with similar relapse and attrition rates [13].

In supplement to the existing studies on videoconferencing-based treatment of AUDs, we have conducted a small randomized controlled trial (RCT) in a real-life setting. The purpose was to examine the effectiveness of optional videoconferencing-based AUD treatment on a laptop with wireless Internet and a videoconferencing client. To our knowledge, this is the first study where AUD patients could opt in on videoconferencing for as many sessions as they chose. However, studies regarding Web-based blended therapy for psychiatric disorders have, for example, examined designs with optional modules [20], with the opportunity to step up treatment if the patient felt it was necessary [21], and using a personal blend [22], enhancing patients' self-management [12]. Similarly, a qualitative study nested within the RCT found that patients being offered videoconferencing may have experienced it as a means to enhance their autonomy and empowerment, with the ability to choose freely between the two formats having a positive impact on the treatment course [23]. Also, a mixed methods study linked to the RCT found that patients felt more satisfied with the treatment and prolonged their treatment courses when they had the opportunity to receive sessions via videoconferencing [24]. Therefore, it seems highly relevant to examine whether the opportunity of receiving all or some of the treatment course by means of videoconferencing can increase adherence to, and thereby the effectiveness of, AUD treatment.

Aim

The aim of this study was to test whether optional videoconferencing increases adherence to and effectiveness of AUD treatment in an RCT.

Hypotheses

We hypothesized that the intervention would decrease the number of patients who dropped out prematurely. We tested this by measuring premature dropout at 6-month follow-up (the primary outcome). Additionally, we hypothesized that the intervention would increase the number of patients terminating their treatment course successfully, increase the proportion of patients still attending a treatment course after 6 months from 45% to 70%, and increase treatment outcome. We tested this by measuring successful treatment termination, treatment duration, and the difference in alcohol characteristics from baseline to 1 year into the treatment course (secondary outcomes).

Methods

Design

The study was an RCT with 2 groups: treatment as usual (TAU) and treatment as usual with add-on intervention (TAU+I).

Sample

All consecutive patients who attended the public outpatient alcohol clinic in Odense, Denmark, between September 2012 and April 2013 were eligible to participate in the study. Inclusion criteria were age 18 years or older, harmful alcohol use or alcohol dependence syndrome according to the *International Classification of Diseases, Tenth Revision* (*ICD-10*), and written informed consent. Exclusion criteria were dementia, psychoses, and lack of sufficient Danish language skills. We registered the study with The Regional Committees on Health Research Ethics for Southern Denmark (S-20110052; Multimedia Appendix 1 [25]).

Setting

In the outpatient clinic, an interdisciplinary team of social workers, nurses, and psychiatrists conducts the AUD treatment, based on clinical guidelines [26]. The treatment is free of charge and based on face-to-face therapy sessions and pharmacology, if needed [27]. At the beginning of the treatment course, the patients are offered detoxification and motivational interviewing [28]. When they are free of withdrawal symptoms and if they decide to attend a psychosocial treatment course, the patients undergo an assessment interview using the European version of the Addiction Severity Index (EuropASI) [29,30]. Based on an algorithm using the results of the assessment interview, consultant psychiatrists refer the patients to individual psychosocial treatment. This may consist of cognitive behavioral therapy, supportive consultations, family therapy, or contract treatment [31]; as such, there is no difference in the effect of each offer. Treatment is conducted by well-trained and closely supervised nurses and social workers. The length of each

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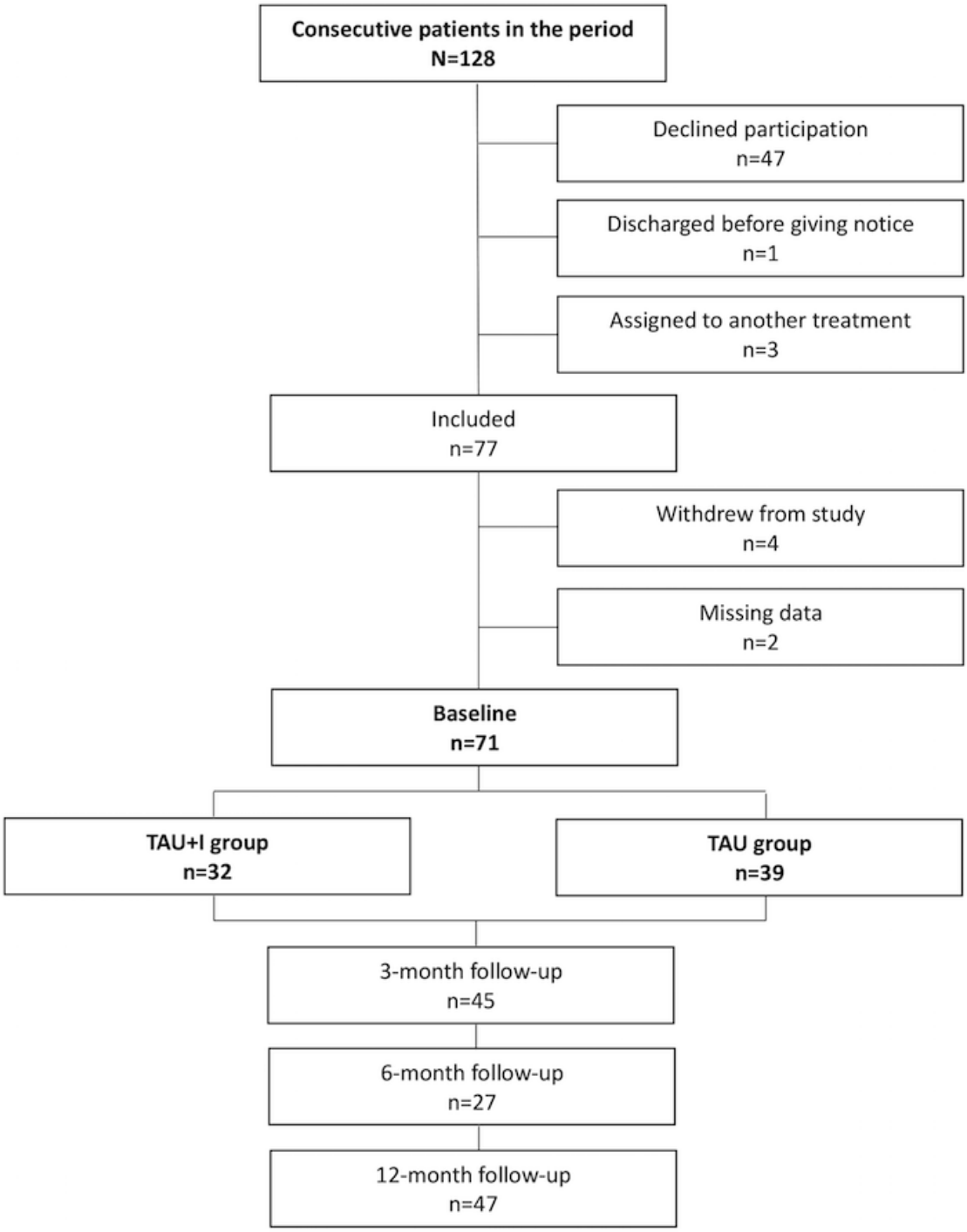
treatment course is individually planned. The duration of a typical successful treatment course is about 7 months. One treatment session lasts between 30 and 60 minutes. Session frequency is 1 to 3 times a week at the beginning of the course and 1 session every other week later in the course [32].

Recruitment and Randomization

We recruited patients during the assessment interview and systematically offered participation to consecutive patients who decided to attend a psychosocial treatment course and met the inclusion criteria. We included patients who decided to participate in the study and randomly assigned them during the assessment interview; we were aiming at recruiting 140 patients, with 70 in each group. Randomization was carried out by the administrative staff, who were not affiliated with the study. The patients drew a nontransparent envelope packed by an independent person. The envelope contained information about their group placements, either the TAU group or the TAU+I group, with their entailments. Figure 1 shows the recruitment and randomization process.

Figure 1. Flowchart of the recruitment process. TAU: treatment as usual; TAU+I: treatment as usual with add-on intervention.



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Treatment as Usual

The TAU group received treatment as usual face-to-face at the clinic. Treatment was conducted as described in the Setting section above, according to clinical guidelines.

Treatment as Usual With Add-On Intervention

The TAU+I group also received treatment as usual. In addition, they were offered optional videoconferencing and were, from session to session, able to choose to receive treatment as usual via videoconferencing. Hence, the offer of receiving treatment by optional videoconferencing was the intervention in this study. We chose this approach, of patients opting in on videoconferencing as opposed to having all patients receive treatment via videoconferencing, in order to offer the patients the opportunity to make the choices. Each patient in the TAU+I group was equipped with a laptop with wireless Internet and a Cisco TelePresence videoconferencing client (Cisco Systems, Inc, San Jose, CA, USA). Prior to scheduling the first treatment session, we instructed the patients in the use of the equipment and conducted a test to ensure that the equipment was fully functional. Before each therapy session, the patients had the choice between treatment as usual at the clinic and treatment as usual via videoconferencing from any location. If the patients opted for a session via videoconferencing, they just needed to turn on the equipment. If the therapist went to fetch the patients from the waiting room, only to discover them absent, the therapist would then call them via videoconferencing.

Measures

The Addiction Severity Index (ASI) was developed especially for assessment, treatment, and research in addiction [29,33]. Studies have demonstrated the ASI to be a valid instrument [34,35]. The EuropASI [30] provides sociodemographics, alcohol measures, and composite scores for 9 potential problem areas in the patients' life circumstances. The composite scores reflect the severity of the problems during the last month preceding the assessment interview. The composite scores range from 0 to 1; the higher the score, the greater the severity [29].

Baseline measures were EuropASI sociodemographics about age, sex, higher/continuing education, employment, and cohabitation; EuropASI alcohol measures regarding dependence, age at onset of excessive use of alcohol (≥5 units a day, at least 3 days a week during the last 30 days), years of excessive alcohol use in life, days of alcohol use in the past month, and days of excessive alcohol use in the past month; and EuropASI composite scores regarding alcohol use, drug use, economic status, employment, legal status, family status, social status, medical status, and psychiatric status. The composite scores were computed according to the EuropASI [30].

The primary outcome was premature dropout at the 6-month follow-up. Secondary outcomes were successful treatment termination, treatment duration (measured by the number of days in treatment), and alcohol characteristics, consisting of 12-month follow-up alcohol use and severity (measured by the number of days of alcohol use and excessive alcohol use in the past month preceding the interview), and composite scores regarding alcohol use, employment, legal status, family status, medical status, and psychiatric status.

Data Collection

Baseline data were collected by the therapists at the assessment interview at treatment start prior to the randomization. Follow-up data were collected by the therapists as part of the routine treatment course as long as the patients attended treatment, at the status sessions at 3, 6, and 12 months, and at discharge. We collected additional 1-year follow-up data. To collect the data, we used letters, telephone calls, and personal contacts to secure the highest possible participation rate [36].

In addition, we collected data on the actual use of videoconferencing, and from questionnaires on nonparticipation and satisfaction, and semistructured interviews with participants in the TAU+I group, therapists, and collaborators. We used these additional data for separate analyses of nonparticipation, satisfaction, patient perspectives, and therapist perspectives on the use of videoconferencing.

Statistics

We conducted the analyses in this study using SAS Enterprise Guide 7.1 (SAS Institute Inc) and Stata v14 (StataCorp LLC).

The power was calculated in Stata. The primary outcome was the number of patients still attending treatment 6 months after the assessment interview. The calculation was based on numbers from the clinic in 2010 showing that the proportion of patients still attending treatment after 7 months was 45%. We expected the intervention to increase the proportion of patients still attending a treatment course after 6 months from 45% to 70%. For a significance level of 5% and a power of 80%, 140 patients should be included, with 70 in each group.

Baseline variables, sex, higher/continuing education, employment, cohabitation, and dependence were categorical; hence, we used Pearson chi-square tests for relationships between variables. The variables higher/continuing education and dependence had an expected frequency of 5 or less in one cell; hence, we used Fisher exact test. The rest of the variables were continuous; hence, we used the Shapiro-Wilk *W* test for normal data to check for normally distributed data. None of the continuous variables were normally distributed; hence, we used 2-sample Wilcoxon rank sum (Mann-Whitney) tests to compare the means of not normally distributed interval-dependent variables for 2 independent groups.

We tested the primary outcome, premature dropout at 6-month follow-up, by means of a Kaplan-Meier survival analysis using Wilcoxon test statistics.

Secondary outcomes were regarding successful treatment termination, treatment duration, and alcohol characteristics. We tested successful treatment termination by means of a logistic regression analysis. We tested treatment duration by means of a Kaplan-Meier survival analysis at 6-month and 12-month follow-ups. We tested differences in alcohol characteristics from baseline to 1-year follow-up using per-protocol analyses; however, due to missing data, we used last observation carried forward. The variables were continuous; hence, we used the Shapiro-Wilk *W* test for normal data to check for normally distributed data. The variable employment was normally distributed; hence, we used a 2-sample *t* test with equal variances

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to compare means. The rest of the continuous variables were not normally distributed; hence, we used 2-sample Wilcoxon rank sum (Mann-Whitney) tests to compare means. We made no corrections for multiple comparisons.

Results

Participants

Our goal was to recruit 140 participants, but we succeeded in recruiting only 71 participants. As the flowchart in Figure 1 shows, 128 consecutive patients entered psychosocial AUD treatment during the period of recruitment. A total of 47 patients declined to participate in the study, 3 patients were assigned to another treatment, and 1 patient was discharged before giving notice. After inclusion, a further 4 patients withdrew from the study, and data were missing for 2. Hence, only 71 patients completed the baseline assessment interview and were randomly assigned: 39 patients to the TAU group and 32 patients to the TAU+I group.

Table 1. Baseline sample characteristics, by randomization group (N=71).

Characteristics	TAU[a] group (n=39)	TAU+I[b] group (n=32)	*P* value
EuropASI[c] sociodemographics			
Age in years, mean (SD)	47.3 (12.4)	46.0 (13.5)	.64
Sex (female), n (%)	10 (26)	9 28)	.81
Higher/continuing[d] education (yes), n (%)	30 (77)	28 (88)	.36
Employed[e] (yes), n (%)	20 (51)	11 (34)	.15
Cohabiting (yes), n (%)	22 (56)	20 (63)	.60
EuropASI alcohol measures			
Alcohol dependence[f] (yes), n (%)	32 (82)	28 (87)	.74
Age in years at onset of excessive[g] use of alcohol, mean (SD)	31.31 (13.72)	32.25 (14.83)	.73
Years of excessive alcohol use in life, mean (SD)	16.28 (10.51)	13.09 (11.79)	.09
Days of alcohol use in the past month, mean (SD)	18.44 (10.89)	20.44 (10.37)	.44
Days of excessive[g] alcohol use in the past month, mean (SD)	15.54 (11.53)	18.25 (10.24)	.31
EuropASI composite scores[h]			
Alcohol use, mean (SD)	0.68 (0.22)	0.72 (0.19)	.51
Drug use, mean (SD)[i]	0.02 (0.08)	0.05 (0.12)	.1
Economic status, mean (SD)	0.54 (0.45)	0.65 (0.45)	.33
Employment, mean (SD)	0.38 (0.41)	0.44 (0.39)	.54
Legal status, mean (SD)[j]	0.01 (0.04)	0.04 (0.15)	.24
Family status, mean (SD)	0.22 (0.27)	0.11 (0.21)	.09
Social status, mean (SD)[j]	0.08 (0.19)	0.08 (0.19)	.90
Medical status, mean (SD)	0.29 (0.40)	0.29 (0.39)	.94
Psychiatric status, mean (SD)	0.20 (0.20)	0.24 (0.26)	.80

[a]TAU: treatment as usual.

[b]TAU+I: treatment as usual with add-on intervention.

[c]EuropASI: European version of the Addiction Severity Index.

[d]Some respondents with continuing education attended high school first; some did not.

[e]Not necessarily full time.

[f]According to the *International Classification of Diseases, Tenth Revision* (*ICD-10*).

[g]≥5 units a day in at least 3 days a week during the last 30 days.

[h]EuropASI composite scores vary from 0 (no problem) to 1 (extreme problem) in the 30 days preceding the interview.

[i]On the basis of 69 observations.

[j]On the basis of 70 observations.

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Baseline

Table 1 shows baseline characteristics of the participants. The 2 groups received the same variation of treatment offers. The average participant was about 47 years old, most were male, and more than half were cohabiting. A majority had higher/continuing education but less than 50% were employed. More than 80% had a diagnosis of alcohol dependence syndrome according to the *ICD-10*. The 2 groups did not deviate from each other according to EuropASI sociodemographics, alcohol measures, and composite scores. It seems that the allocation of patients to the 2 groups resulted in 2 similar groups with regard to sociodemographic and alcohol characteristics. Therefore, we assumed that the randomization was successful.

Use of Videoconferencing

Records of the use of the intervention showed that 16 of the 32 patients (50%) in the TAU+I group used the laptop with videoconferencing for a total of 60 treatment sessions; however, 37 (62%) of the sessions had technical problems. Mostly, these problems consisted of poor sound quality, which was solved by using telephones for the sound.

Primary Outcome: Premature Dropout

The termination status of the patients in this study fell into 2 categories. The first category is premature dropout, consisting of patients who did not appear at the discharging session but were expected to return, patients who were discharged after not appearing at the treatment sessions, and patients who were discharged by their own wish (at a time considered by the therapist as being too early).

Figure 2 shows premature dropout by the means of a survival analysis. The plot shows the number of days the TAU group and the TAU+I group stayed in treatment or the number who successfully terminated treatment. After 180 days in treatment, 2 of 32 patients (6%) in the TAU+I group and 12 of 39 patients (31%) in the TAU group had dropped out prematurely. The difference is significant (*P*=.008). After 365 days, 8 patients (25%) in the TAU+I group and 17 patients (44%) in the TAU group had dropped out prematurely. The difference is significant (*P*=.02).

Secondary Outcomes

Successful Treatment Termination

The second category of termination status is successful treatment termination, consisting of patients who completed their treatment course as planned or still were in treatment at the discharging session. Upon completion of their treatment course, 21 of 39 patients (54%) in the TAU group and 19 of 32 patients (59%) in the TAU+I group had successfully terminated treatment. The difference is not significant (*P*=.64). The crude odds ratio for successful termination is 1.25 (95% CI 0.48-3.25) for the TAU+I group. When adjusted for employment and sex, the odds ratio for successful termination is 1.57 (95% CI 0.57-4.37).

Treatment Duration

Figure 3 shows that after 6 months, 24 of 32 patients (75%) in the TAU+I group and 24 of 39 patients (62%) in the TAU group were still attending treatment. After 1 year, 14 of 32 (44%) patients in the TAU+I group and 7 of 39 (18%) patients in the TAU group were still in treatment. The difference is significant (*P*=.03).

Figure 2. Primary outcome: premature dropout; survival curves (*P*=.008; successful terminations censored), by randomization group (N=71; treatment as usual [TAU] group: n=39; treatment as usual with add-on intervention [TAU+I] group: n=32).

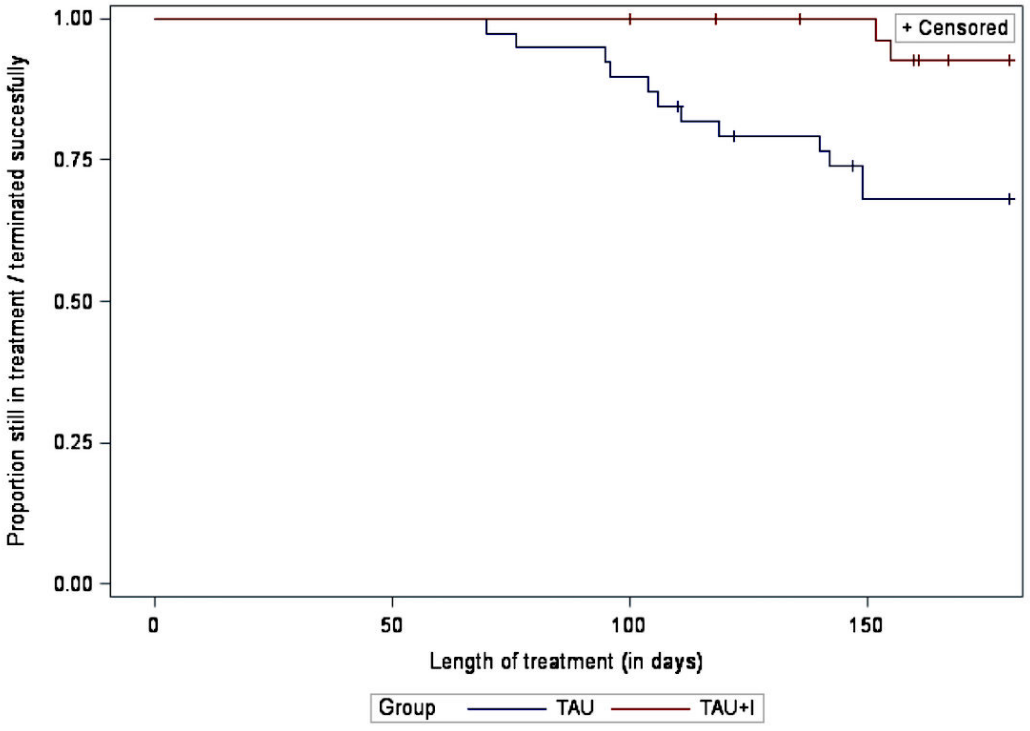

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Figure 3. Secondary outcome: treatment duration; survival curves (*P*=.03), by randomization group (N=71; treatment as usual [TAU] group: n=39; treatment as usual with add-on intervention [TAU+I] group: n=32).

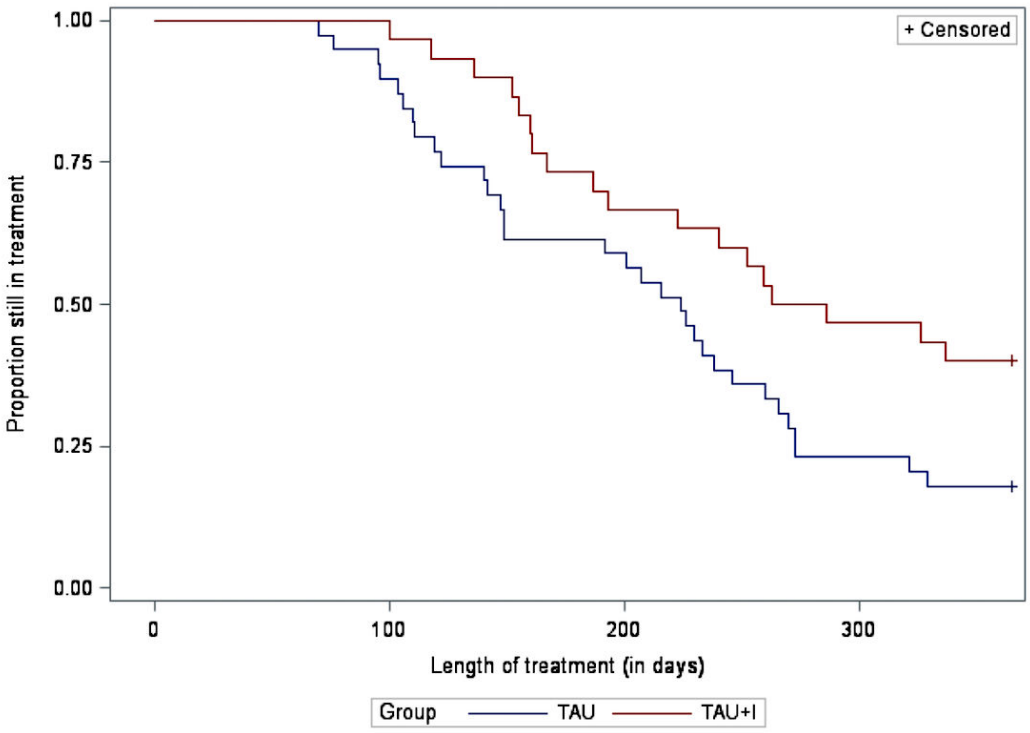

Table 2. Changes from baseline to 12-month follow-up, by randomization group (N=71).

Measures	TAU[a] group (n=39)	TAU+I[b] group (n=32)	*P* value
EuropASI[c] alcohol measures			
Days of alcohol use in the past month prior to interviews, mean (SD)	–12.44 (10.53)	–13.75 (12.40)	.64
Days of excessive[d] alcohol use in the past month prior to interviews, mean (SD)	–12.26 (11.29)	–13.47 (11.79)	.68
EuropASI composite scores[e]			
Alcohol use, mean (SD)	–0.48 (0.26)	–0.49 (0.33)	.59
Employment, mean (SD)	–0.05 (0.33)	–0.05 (0.42)	.97
Legal status, mean (SD)[f]	–0.01 (0.03)	–0.01 (0.05)	.21
Family status, mean (SD)	–0.09 (0.25)	–0.02 (0.25)	.52
Medical status, mean (SD)[g]	0.07 (0.42)	–0.03 (0.21)	.14
Psychiatric status, mean (SD)	–0.04 (0.24)	0.00 (0.21)	.42

[a]TAU: treatment as usual.

[b]TAU+I: treatment as usual with add-on intervention.

[c]EuropASI: European version of the Addiction Severity Index.

[d]≥5 units a day in at least 3 days a week during the last 30 days.

[e]EuropASI composite scores vary from 0 (no problem) to 1 (extreme problem) in the 30 days preceding the interview.

[f]On the basis of 70 observations.

[g]On the basis of 69 observations.

Alcohol Characteristics

Table 2 shows differences from baseline to 1-year follow-up for selected alcohol measures and composite scores. We found no significant differences.

Discussion

The results of this study indicate that the offer of optional videoconferencing may prevent premature dropout, in which patients attend only the first couple of sessions and then drop out. One reason why patients in the TAU+I group had significantly fewer premature dropouts may have been that they

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were more satisfied with their treatment course, having been given the opportunity to choose (before each session) whether to receive treatment via videoconferencing [24]. This may have led to increased experiences of flexibility and autonomy, making the patients feel more empowered [23], which, in turn, may have prevented dropouts. Similar notions were reported in a study on Web-based blended care therapy, where patients had positive perceptions of the Web-based sessions, especially regarding enhancing their self-management [12]. Hence, videoconferencing may have encouraged adherence to treatment and prevented premature dropouts. This is especially interesting, since previous research found that the largest alcohol behavior change occurred at the beginning of a treatment course [5]. Previous research also found that patient groups with a general lack of dependability (eg, no job stability, psychiatric illness, and prior discharges from hospitals) tend to drop out prematurely. However, patients functioning too poorly or too well may both equally increase dropout rates. This study investigated videoconferencing as a means to reduce premature dropout, but videoconferencing is, of course, only one of many initiatives that may be used. Other useful examples include reduction of waiting time at the beginning of the treatment course [9,26], treatment matching [6,37], explanation of the anticipated treatment [9], use of clinical guidelines [26,38-41], a less focal and talkative therapist at the beginning of the treatment course [9], engagement of relatives in the treatment process [9], aggressive pursuit [9], use of attendance contracting and prompting [42], and contact with no-shows [43].

The Danish clinical guideline for treatment of alcohol dependence [10] recommends treatment courses of 3 months' duration with the possibility of extension; hence, we chose to measure 6 and 12 months after treatment start, allowing most patients to have completed the treatment course. In 2010, 45% of the patients attending the clinic were still in treatment after 6 months. We expected this intervention to increase this proportion from 45% to 70%. After 6 months, 75% of the patients in the TAU+I group were still attending treatment, which exceeds the expected increase. However, also after 6 months, 62% of the TAU group were still attending treatment, which well exceeds the proportion from 2010. Nonetheless, it may be an ongoing issue to offer treatment courses that comply with cost effectiveness; hence, in a review from 2014, Littrell [9] explored outcome findings regarding length of treatment. Several reviews have correlated treatment duration with outcome and found that patients who remain in treatment longer have better outcomes. Hence, it seems that patients who drop out have poorer outcomes. However, some of these studies did not consider whether the duration was shorter because of planned termination or premature dropout. Studies where patients were randomly assigned to longer or shorter treatment durations, and studies comparing shorter versus longer treatment programs, have not found any differences in outcomes, except for patients with lower socioeconomic standing [9]. More than 80% of the patients in this study had alcohol dependence syndrome diagnosed according to the *ICD-10*. Evidently, patients with severe drinking problems, and without social support, benefit from treatment [9]; hence, research suggests that patients with moderate or severe levels of alcohol dependence should be referred to and encouraged to attend treatment [44].

Despite significantly fewer premature dropouts in the TAU+I group, it was not possible to detect any significant differences in the effect of the treatment after 1 year with regard to alcohol consumption. There could be several reasons why outcome did not differ between the 2 groups. For instance, patients without the option of videoconferencing, but still motivated to attend face-to-face sessions, may have been more motivated in general and thereby produced better outcomes. In contrast, those who had the option could have been less motivated in general, less willing to appear face-to-face, and more willing to use the videoconferencing option instead. Another reason may have been that the poor technical quality of the equipment the patients were provided with, especially the sound where phones were often used instead, may have caused the patients to need further sessions. This would, unintentionally, have increased treatment duration, as these patients probably did not fully benefit from the videoconferencing treatment sessions due to poor technical quality and hence only maintained their treatment status quo. Here, those who put up with the poor technical quality of the equipment handed to them would probably have been more motivated to change, compared with those who did not. A few previous studies on videoconferencing-based treatment of AUDs have addressed attendance and effect. Frueh et al found that 13 out of 14 patients who completed their study remained abstinent throughout the treatment [13]. Staton-Tindall et al [16] found no significant differences between the intervention group and the comparison group receiving motivational enhancement therapy via videoconferencing. However, sessions 3 to 5 (focusing on change) of the intervention significantly reduced the likelihood of using alcohol by 72% and predicted fewer drinking days, fewer drinks per week, and fewer days experiencing problems with alcohol during the follow-up period; however, both motivational enhancement therapy and videoconferencing were part of the intervention [16].

Strengths and Limitations

The most important strength of this small RCT is that it was carried out as an effectiveness study in a real-life setting, where consecutive patients seeking ordinary AUD treatment at the outpatient clinic were offered participation in the study. Studies conducted among a treatment-seeking population are unique and rarely seen. If an experimental intervention in a research study is likely to be implemented and upscaled in real-life praxis, it is an advantage that the research has been carried out among alcohol patients attending an operating clinic. Effectiveness studies generate results that can inform clinical practice [45,46], and examination of the intervention's effectiveness, when implemented within an everyday clinical setting, is an important part of establishing an evidence base for a particular treatment [47].

However, as a consequence, the findings of this study may not be as positive as findings from other studies with other prerequisites. Most of the previous studies on videoconferencing-based AUD treatment were small feasibility studies or randomized studies with paid patient participation. Our sample was, nevertheless, fairly similar to them regarding sociodemographic and alcohol measures [13-15,17]. Since the study is representative, it can be generalized to the extent of treatment-seeking patients with harmful alcohol use or alcohol

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dependence, at the higher severity end, attending clinics in Denmark and other countries with a similar organization of, and distances between, clinics.

A severe limitation of this study is that we were unable to include the number of patients estimated in the power calculations prior to study start. The relatively low number of participants may have been due to patient rates being lower than expected, compared with the same time period in previous years in the same setting. Also, it may have been due to the participation rate being lower than expected, based on participation rates in other studies conducted in the same setting. In alcohol treatment and research, it is a common challenge to recruit and maintain patients for studies, as well as for treatment [48]. Unwillingness to participate in research studies has been reported as becoming more and more common [36], especially regarding studies performed over the Internet [49]. Thus, more patients than anticipated may simply have declined participation because of the technical element in the study. As a consequence, the small sample size in this study is a limitation for the significance of the results and may, thereby, have consequences for the inferential conclusions that can be drawn from the results.

It is a huge strength that data on premature dropout and treatment termination were available for all but 2 patients; however, it may be a limitation that we have 1-year follow-up data for only 66%. Prior studies have reported follow-up participation rates below 60% with no evidence of bias [36], and the use of last observation carried forward is a conservative approach to secure validity. In comparison, previous studies on videoconferencing-based AUD treatment have reported relatively good session attendance and successful intervention engagement, as well as completion rates similar to face-to-face treatment [13,15,16], completion rates ranging from 50% to almost 100% [14,15,17], and follow-up rates of up to 90% [16,18]. This may be due to the fact that most of the prior studies were small pilot and feasibility studies or RCTs, where participants were even paid to participate. These recruitment processes may have biased participation in the prior studies in a positive direction compared with participation in effectiveness studies like ours, where participants were consecutive patients seeking treatment for alcohol problems in a real-life setting.

It may be a limitation to the study that the results were based on self-reported EuropASI data. Even though general population surveys have found alcohol consumption to be underreported, and the accuracy of an individual's report may be difficult to determine, the literature suggests that, from a group perspective, self-reports of alcohol use from clinical and nonclinical samples are accurate provided that people are interviewed under the following conditions: alcohol-free when interviewed; given written assurances of confidentiality; interviewed in a setting encouraging honest reporting; asked clearly worded objective questions; and provided with memory aids [50].

Furthermore, it may be a limitation to this study that we analyzed psychosocial treatment as a single treatment approach, even though it consists of 4 different psychosocial treatment forms. Since the offers were equally effective and the 2 groups received the same variation in treatment offers, we did this to limit the different outcome possibilities as opposed to limiting any broad inferences about the effects of offering videoconferencing.

Moreover, it may be both a strength and a limitation to have chosen videoconferencing as an option in order not to force any patient to use it. None of the previous similar studies have used *optional* videoconferencing; however, blended care is commonly used in psychiatric treatment. Here, patients reported advantages such as having met the therapist before or during the treatment course [12], and optional use of videoconferencing, throughout the treatment course, offers similar advantages.

Conclusion

The aim of this study was to test whether optional videoconferencing increases adherence and effect in AUD treatment. We tested this by examining premature dropout (the primary outcome), as well as successful treatment termination, treatment duration, and alcohol characteristics (secondary outcomes). The results indicate that offering patients optional videoconferencing may prevent premature dropouts from treatment and prolong treatment courses. However, the small sample size precludes conclusions regarding the effect of the intervention, which was not detectable in the patients' use of alcohol and severity of problems. Even though videoconferencing did not, in this study, seem to lead to a more effective treatment course, it may be a tool to increase adherence. Thus, future research is warranted on how videoconferencing and treatment duration may influence adherence and effect in AUD treatment.

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ABB, AM, and KT conducted the statistical analyses. KT drafted the manuscript. ASN repetitively revised the manuscript critically for important intellectual content. All authors approved the final version to be published.

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Conflicts of Interest

None declared.

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Multimedia Appendix 1

CONSORT-EHEALTH checklist V1.6.1.

[PDF File (Adobe PDF File), 519KB - mental_v4i3e38_app1.pdf]

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Abbreviations

ASI: Addiction Severity Index
AUD: alcohol use disorder
EuropASI: European version of the Addiction Severity Index
ICD-10: International Classification of Diseases, Tenth Revision
RCT: randomized controlled trial
TAU: treatment as usual
TAU+I: treatment as usual with add-on intervention

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Original Paper

Mobile Mindfulness Intervention on an Acute Psychiatric Unit: Feasibility and Acceptability Study

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Abstract

Background: Aggression and violence on acute psychiatric inpatient units is extensive and leads to negative sequelae for staff and patients. With increasingly acute inpatient milieus due to shorter lengths of stay, inpatient staff is limited in training and time to be able to provide treatments. Mobile technology provides a new platform for offering treatment on such units, but it has not been tested for feasibility or usability in this particular setting.

Objective: The aim of this study was to examine the feasibility, usability, and acceptability of a brief mindfulness meditation mobile phone app intended to reduce anger and aggression in acute psychiatric inpatients with schizophrenia, schizoaffective disorder, or bipolar disorder, and a history of violence.

Methods: Participants were recruited between November 1, 2015 and June 1, 2016. A total of 13 inpatients at an acute care state hospital carried mobile phones for 1 week and were asked to try a commercially available mindfulness app called Headspace. The participants completed a usability questionnaire and engaged in a qualitative interview upon completion of the 7 days. In addition, measures of mindfulness, state and trait anger, and cognitive ability were administered before and after the intervention.

Results: Of the 13 enrolled participants, 10 used the app for the 7 days of the study and completed all measures. Two additional participants used the app for fewer than 7 days and completed all measures. All participants found the app to be engaging and easy to use. Most (10/12, 83%) felt comfortable using Headspace and 83% (10/12) would recommend it to others. All participants made some effort to try the app, with 6 participants (6/12, 50%) completing the first 10 10-minute “foundation” guided meditations.

Conclusions: This is the first known study of the use of a commercially available app as an intervention on acute psychiatric inpatient units. Acutely ill psychiatric inpatients at a state hospital found the Headspace app easy to use, were able to complete a series of meditations, and felt the app helped with anxiety, sleep, and boredom on the unit. There were no instances of an increase in psychotic symptoms reported and there were no episodes of aggression or violence noted in the record.

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KEYWORDS

mindfulness; meditation; mHealth; psychiatry; mobile phone; aggression; violence; schizophrenia; bipolar disorder; psychotic disorders

Introduction

Despite the lack of consistency in accurate measurement, it is clear that violence on psychiatric inpatient units is a significant problem. In a recent meta-analysis of 35 studies involving more than 23,000 acutely ill psychiatric inpatients in the United States, Iozzino [1] reported that the pooled proportion of patients engaging in at least one act of violence while hospitalized was 17%. The hypothesized and measured costs to staff and patients are manifold. The most obvious cost to staff is physical injury [2,3]. One state hospital in the United States recently reported that of the 425 assaults of staff in 2014, 394 resulted in a workplace injury, and from 2012 to 2014, the hospital logged 5600 cumulative days of missed work [4]. Additional problems related to inpatient violence include decreased workplace morale, job dissatisfaction, increased staff turnover [3,5], increased use of coercive practices [2,6], decreased patient satisfaction and engagement with care [7], plus increased readmission rates [8].

Agitation, impulsivity, and disorganized thinking are cited as common causes of, or contributors to, patient aggression [9,10]. There are effective cognitive behavioral therapies (CBT) for addressing aggression and violence [11,12]. However, these rely on an intact cognitive capacity, which is often impaired in those with serious mental illness (SMI). A number of other potential problems with CBT for anger and aggression in people with SMI have been raised, including the need for introspective ability and self-awareness, as well as a perception that there is a problem with anger or aggression [11].

In several small studies, mindfulness-based therapies (MBT) have successfully reduced impulsivity and agitation, which underpin aggression and violence [11,13-16]. Mindfulness interventions have been proposed as alternatives to CBT for use with people who have cognitive impairment or disorganized thinking, as mindfulness improves emotion regulation without requiring the cognitive restructuring emphasized in CBT [17,18]. Mindfulness-based interventions teach an alternative “aware and observing” approach related to sensations, thoughts, and feelings so as to promote *acceptance of* rather than *reacting to* everyday life, especially during high-stress situations. Importantly, MBT have been used safely and successfully to improve quality of life in persons with SMI, particularly in those with treatment-resistant hallucinations [18-23], as well as to address aggression in a small number of individuals with SMI [24-26]. Mindfulness-based stress reduction has been shown to reduce contributors to aggression, such as impulsivity, stress and anxiety, negative mood states, and depression, among individuals with SMI and active psychotic symptoms [19].

In mental health care, mobile technologies such as mobile phones are being used more frequently to induce individuals to engage in increased self-monitoring and treatment outside of the provider’s office [27-29]. Mobile technologies are portable and computationally powerful, and therefore have the potential to provide the right dose of the right intervention at the right time of individualized evidence-based mental health treatment. Mobile health approaches are just beginning to be tested in people with SMI; however, early work has demonstrated that this treatment approach is feasible and acceptable to psychiatric outpatients [30-32] and inpatients [33-35]. These pioneering studies demonstrate that people with SMI can successfully use mobile technology as long as the technology is user-friendly, intuitive, and engaging, and the treatment model includes self-management components that are independent of clinician engagement [36].

Using a mindfulness app on mobile phones to address violence on acute psychiatric units addresses several needs in the field. Although effective cognitive behavioral interventions have been developed to address this problem, they are difficult, if not impossible, to provide on an acute inpatient unit due to increased symptom acuity, decreased lengths of stay, and lack of staff time and training. Using an *existing*, *commercially available* mindfulness app in this context has other potential advantages. From a research standpoint, there is far less cost and time needed to develop the initial intervention. Additionally, this app can be used by inpatients whenever and wherever they need an intervention, providing another potential coping skill that can be used even after discharge and independent of the research project. Unlike apps specifically designed for research studies, this commercially available and relatively inexpensive app would be readily available to discharged individuals.

Demonstrating that a mindfulness mobile phone app can provide engaging treatments that inpatients with SMI can access when they want is innovative because it combines 2 techniques, mindfulness and mobile technology, each of which has been independently and successfully used in this population, but not in this combination. This study sought to determine the feasibility of utilizing a mindfulness mobile phone app by acutely ill psychiatric inpatients with schizophrenia, schizoaffective disorder, and bipolar disorder. It also sought to determine how patients felt about using the mindfulness app.

Methods

The Committee for Protection of Human Subjects at Dartmouth College and New Hampshire Department of Health and Human Services approved the study. Participants provided informed consent. Study participants were recruited primarily by daily screening of the hospital census by the research assistant (RA) between November 1, 2015 and June 1, 2016.

Participants

Patients diagnosed with schizophrenia, schizoaffective disorder, or bipolar disorder, aged 18-65 years, with a recent (within the 6 months before admission) history of aggression or violence were eligible for the study. Participants were screened for reading at least at a 6th grade level. Exclusion criteria included having a hearing, vision, or major motor difficulty that made it

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impossible for them to use a mobile phone. People with guardians were excluded. Inpatients were compensated US $50 for completing the 7-day study.

Study Flow

A total of 50 individuals were approached, 27 declined to participate (54%) and 13 enrolled (26%). The average length of stay at the hospital is quite short and the level of symptom acuity is high; therefore, many potential participants were too ill to complete the competency screener when approached initially and those who were able to participate were often close to their day of discharge and were unlikely to stay the full 7 days required for the study. One participant was discharged unexpectedly before completing the 7 days of the intervention and we were unable to meet with him in time to complete the follow-up assessment before he left the hospital, thus the final sample included 12 participants. Of these 12, 10 used the app for the 7 days of the study and completed all measures. Two additional participants used the app for fewer than 7 days and completed all measures. Data from all 12 participants are included in this paper.

Procedures and Measures

Trained research staff met with interested individuals and described the study in detail. If the candidate continued to be interested, the RA reviewed the consent form and administered a short competency screener to assess whether they understood what the study entailed. The RA administered the word knowledge section of the WRAT-4 (Wide Range Achievement Test 4) [37] to evaluate whether candidates were at least at a 6th grade reading level. After giving their informed consent, the enrolled participants completed the baseline assessments and were provided with a mobile phone with phone functions and camera disabled (in order to reduce the likelihood of confidentiality violations) to use for the 7 days of the study. At the first visit, baseline demographic measures and study measures of mindfulness, anger, and cognition were also conducted.

Participants were taught how to use Headspace, a mobile phone app that aims to teach beginners the basic concepts of mindfulness through simple guided meditations.

The Headspace app has an initial “Take 10” program that consists of 10 10-minute meditations guided by a male voice identified as “Andy.” Completing the initial 10 guided meditations unlocks access to more materials, including a “Series Library,” and 3 “Foundation Level” packs that make up a total of 30 sessions. The 10 sessions in the Foundation Level 1 are all 10 minutes long. The 10 sessions in Foundation Level 2 can be completed as either 10- or 15-minute sessions. The 10 sessions in Foundation Level 3 can be completed in 10-, 15-, or 20-minute sessions. Levels 2 and 3 are not required, but encouraged. Headspace data collected include number of sessions completed, a breakdown of the type of sessions, the average session length, and total time spent in meditating. The RA instructed participants to follow the daily mindfulness exercises feature of the “Take 10” program for at least 10 minutes a day over 7 days.

Quantitative Data Collection

At the end of the study, participants completed a rating scale adapted from a previous work by Ben-Zeev et al [32] that assessed acceptability and usability of the app. The study augmented these quantitative findings with qualitative methods to examine study participants’ experiences using the Headspace app.

Qualitative Data Collection

The investigators created a semistructured interview based on previous work done by one of the authors (DBZ) using an interview topic guide that followed the “funnel structure” described by Krueger and Casey [38]. Questions in the interview were designed to elicit study participants’ attitudes toward and positive and negative experiences using the app. Questions also addressed how participants used the app on the unit, what barriers hindered use, and what facilitated use. The RA then asked each participant a series of semistructured interview questions about their experiences with the app. Interview questions focused on users’ views of the amount of time they spent engaged in mindfulness practice, or the “dose” of the intervention, whether they felt the intervention was interesting, engaging, or useful, and what negative effects, if any, they encountered. Finally, participants were asked for their reflections on how the experience and/or the app might be improved.

Statistical Analyses

Simple statistics were used to describe the study sample. The audiotaped interviews were transcribed, and the Principal Investigator and RA read all transcripts and listened to the interviews to identify prominent issues, ideas, and perspectives that emerged from the data. Transcripts were reviewed by multiple analysts to develop an initial codebook, based on categories from the interview guide as well as content present in participants’ responses. The transcripts were then coded to find and label relevant text passages with the appropriate qualitative codes. Related codes were then grouped into the broader categories presented in the results. Through an iterative process of discussing emergent codes and re-reading transcripts, they reached a consensus on the main findings [39]. Five main themes emerged from this study: (1) usability of the app and equipment, (2) therapeutic applications, (3) barriers to use, (4) suggestions for program adaptation, and (5) endorsement of use for peers.

Results

The study group included 12 participants (males, N=10, 83%; whites, N=11, 92%; mean age 33.4 [SD 10.7]; mean total years of education 12.6 [SD 2.6]). The majority of participants were unemployed (9/12, 75%). All participants had prior psychiatric hospitalizations, 5 (5/12, 42%) within the past year. Twelve participants completed the pre- and posttest assessments, including the usability and acceptability questionnaire and the qualitative interview. The most common diagnosis of the participants was schizoaffective disorder (6/12, 50%). There were equal numbers of participants with diagnoses of bipolar disorder (3/12, 25%) and schizophrenia (3/12, 25%).

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Table 1. Participant usability and acceptability questionnaire.

Statement	Strongly disagree n (%)	Disagree n (%)	Neutral n (%)	Agree n (%)	Strongly agree n (%)
I would use the app often	1 (8)	1 (8)	2 (17)	6 (50)	2 (17)
It was too complicated	4 (33)	8 (67)	0 (0)	0 (0)	0 (0)
It was easy to use	0 (0)	0 (0)	1 (8)	4 (33)	7 (58)
I felt confident using it	0 (0)	0 (0)	1 (8)	4 (33)	7 (58)
I felt comfortable using it	0 (0)	0 (0)	2 (17)	3 (25)	7 (58)
It was easy to learn	0 (0)	0 (0)	0 (0)	5 (42)	7 (58)
The info was easy to understand	0 (0)	0 (0)	1 (8)	4 (33)	7 (58)
I could see the screen	0 (0)	0 (0)	2 (17)	2 (17)	8 (67)
I had enough meditation time	0 (0)	2 (17)	4 (33)	2 (17)	4 (33)
I did not have enough meditation time	6 (50)	3 (25)	2 (17)	1 (8)	0 (0)
I did not like the voice	6 (50)	5 (42)	1 (8)	0 (0)	0 (0)
I did like the voice	0 (0)	0 (0)	3 (25)	5 (42)	4 (33)
The app made my voices worse	10 (83)	2 (17)	0 (0)	0 (0)	0 (0)
The app made me more anxious	7 (58)	5 (42)	0 (0)	0 (0)	0 (0)
The app made me less anxious	0 (0)	0 (0)	1 (8)	9 (75)	2 (17)
The app helped me focus	0 (0)	0 (0)	3 (25)	6 (50)	3 (25)
The app did not help me focus	5 (42)	7 (58)	0 (0)	0 (0)	0 (0)
The app helped me manage symptoms	0 (0)	1 (8)	3 (25)	5 (42)	3 (25)
The app made me more upset	7 (58)	4 (33)	1 (8)	0 (0)	0 (0)
The app functions the way I want	0 (0)	0 (0)	1 (8)	8 (67)	3 (25)
I would use the app in the future	0 (0)	2 (17)	2 (17)	5 (42)	3 (25)
The app was fun to use	0 (0)	1 (8)	2 (17)	5 (42)	4 (33)
I would recommend the app to others	0 (0)	0 (0)	2 (17)	6 (50)	4 (33)
I was comfortable with the info collected on the app	0 (0)	1 (8)	1 (8)	7 (58)	3 (25)
I was worried about the privacy of my info	2 (17)	5 (42)	0 (0)	5 (42)	0 (0)
I found it easy to keep the phone with me	1 (8)	3 (25)	0 (0)	5 (42)	3 (25)

Quantitative Results

The quantitative results from the usability and acceptability questionnaire are shown in Table 1. Participants were asked to rate each statement on a scale from 1 (strongly disagree) to 5 (strongly agree), with 3 rated as neutral.

Qualitative Results

Usability

Uniformly, all participants endorsed that both the phone and the app were user-friendly, regardless of age. Elements that contributed to usability included that the app was easy to learn, the information provided was easy to understand, and the screen was clear. This is important in light of published results that people with SMI may require special adaptations to mHealth interventions to accommodate cognitive impairment and neurological deficits produced by medications [40,41]. Only 1 participant reported difficulty in navigating from one section of the app to another, as in below:

> *My overall impressions were that the app is very streamlined. The interface is very easy to use, even for someone who's potentially like an older user, someone over the age of 50 or 60. Um, for me it was very simple and almost mindless to navigate into the app.*

In general, people felt it was relatively easy to keep the mobile phone with them on the unit. Anecdotally, before initiation of the study, unit staff had previously hypothesized that participants would be losing, misplacing, or even throwing the phones away; however, it turned out that over time, staff became invested in the project to the extent that they were reminding participants to charge their phones and were prompting them to use the app when they became agitated. Of note, no phones were lost and only 1 was broken during this study of acutely ill participants with SMI. When asked how the phone was broken, the

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participant stated that he sat on the phone when it was in his pocket, and thus the screen cracked. There was no other collateral information available regarding the phone breaking, including nothing in staff notes about an aggressive act using the phone.

Therapeutic Applications

Most of the participants reported using the skills they learned using the Headspace program; for example, some noted having increased awareness of their body and surroundings and that they were better able to focus. Participants commented on using the app to help fall asleep in particular. They also said they used the breathing techniques to help control anger, decrease anxiety, and improve mood. While measures of state and trait anger did not change significantly after the intervention, participant references to the app helping control their anger is promising for future studies:

> *Helped me dealt with the day's events. If I had too much trouble during the day, then I would just go to my room and uh, do some coloring or think about what Headspace did for me in the morning and concentrate on something entirely than what's going on out in the dayroom.*

Interestingly, several people indicated that the app helped with boredom or getting through the day during their involuntary stay at the hospital. This is consistent with other findings that the treatment environment is a major contributor to aggression, especially when there is a lack of activity or variation in activity [42,43]. We know from the literature that periods of inactivity and boredom are consistent with an increased likelihood of aggression and violence [43]; therefore, this study reinforces the idea that interventions that alleviate boredom could conceivably be used to reduce aggression in future research, as in the following cases:

> *Headspace helped keep the days filled with positive activities.*
>
> *I was looking forward to the 10 minute session in the morning, because I would get up and say, "Geez, you know, I got something to do this morning, I got, I got my uh, my Headspace to look forward to."*

For all but one person, active symptoms were not identified as a barrier to use of the app. Several participants endorsed the idea that a mindfulness intervention would lead to an increased awareness of symptoms while simultaneously allowing the participant to "let go" of emotional attachment to symptoms, as follows:

> *I think it actually highlighted some of my symptoms that are, not in a bad way, it's just...I am more aware of, um, intrusive thoughts and things like that, you know, um, so, in a good way, it helped me to learn a little bit more about how my brain works and some of the faults that I have...*
>
> *The...way he described meditation..., as your mind starts to wander, it's almost like he knew..."All right, his mind's wandering now," like...and if your mind wanders, bring it back to your breathing...*

Barriers to Use

The most common response to questions about barriers to use was that the hospital units were too noisy and the atmosphere was not private enough to engage in the meditation app, as in below:

> *Um, I, I really couldn't find a really good place to not hear anything. I...because in, in this mental institution kind of thing, you can't really find a good place to like sit down and actually relax. but I-, I could sometimes but when I could it helped out a lot.*
>
> *Well, thing was, was because I had my roommate, and I had people in the hallway constantly, so it was kinda hard to always be on point with it.*

Another barrier to enjoyment of use was having less control over the app. Unfortunately, the lack of a wireless connection in the hospital led to a more cumbersome process for moving from one Headspace "level" to another once the next level was unlocked; participants reported that needing to wait for the RA to unlock the next level for them was somewhat frustrating. Several participants did not like the advertisements for purchasing Headspace embedded in the program. Only 1 participant reported technological difficulties in trying to use the program on one occasion. Only 1 person indicated that he felt his illness may have interfered with his ability to participate fully in the study:

> *Uh, just because, uh, just because of my own personal, uh, problems that I have with thinking clearly. Uh, I feel like it's, uh, just not as effective on me as it may be on a lot of other people.*

Although 5 participants agreed with the statement "I was worried about the privacy of my information" on the Usability and Acceptability Questionnaire, this was not a recurring theme in the qualitative interviews. In fact, when asked if there were any other issues he wanted to bring up at the end of the qualitative interview, 1 participant stated:

> *Just please try to keep my identity and private information private, 'cause we live in a world where there is no real privacy.*

Despite the reported obstacles, including the noise and crowding on the units, most of the participants managed to find ways to use the Headspace app. This level of participation in an activity that required some concentration and commitment from study participants is remarkable, given that participants were involuntarily admitted individuals with symptomatic SMI.

Program Adaptation Suggestions

Participants had several creative ideas for adapting the intervention for future use. A number of participants suggested making the program more interactive with other participants, which is a feature normally available for Headspace; however, as mentioned previously, the hospital does not currently have WiFi capability and thus this feature was not an option. In addition, participants recommended having other activities available on the phone, such as games. One participant stated that the equipment was somewhat obtrusive, with a large phone and "big giant headphones:"

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> *You might be able to scale it down to a point where you could fit it onto something portable, way portable, way more portable.*

Another common theme for adaptation recommendations was to increase the flexibility of the app itself to include more choices, such as what type of voice would be heard during the guided meditations, as well as to have a bigger variety of meditations that were aimed at particular problems that patients were seeking to address, as in below:

> *Um add, um, a woman speaker, like um, like a uh-, like you can, like right in the beginning, do you want to listen to a woman or do you want to listen to a man?*
>
> *Um, if you had certain categories to choose from, what mood setting and what situation you might have gone through before the session*

One person eloquently described the potential benefits of having readily accessible feedback on participation in the app:

> *Like if there was an opportunity to go and take a little survey before and after a meditation or before and after a course I think that would, uh, I think that can make a difference, too. Seeing all those little bar graphs, those little digital bar graphs for some people it's just like wow the, uh, the numerics of everything, the metrics or everything really amaze a lot of people out there in the digital world, so I think that would, with keeping the s-, with the graphical user interface staying similar I think, uh, if th-, if those metrics were added people would just, they would, it would make Headspace pop really.*

The recommendation for increased interaction with peers and for having games and other features on the phones is consistent with the hypothesis that patients have a lot of "down time" on the units and could conceivably be bored.

Endorsement of Use for Peers

Most participants said they would recommend Headspace to others. They commented on their own use of the breathing techniques, increased ability to focus, and having an increased awareness of their surroundings. Several participants endorsed having had philosophies consistent with mindfulness before engaging in the study, as follows:

> *Whatever thoughts are happening, accept 'em, you know, he said that a lot. You just kind of accept what's going on, but you do it in a nice, relaxed way.*

Participants felt it was refreshing to be offered something they could use by themselves at their own pace that did not involve medications or formal face-to-face interactions.

Discussion

Principal Findings

Out of 5 psychiatric inpatients, 1 engages in at least one act of violence during their stay [1], resulting in negative effects on staff and patients. There is a critical need for effective interventions that reduce aggression and violence and can be delivered to acutely ill psychiatric inpatients within a brief inpatient stay. With increasingly acute inpatient milieus due to shorter lengths of stay, inpatient staff has limited training and time to be able to provide such treatments. Mobile technology provides a new platform for offering treatment on such units, but it has not been tested for feasibility or usability in this particular setting. The objective of this study was to determine feasibility, usability, and acceptability of a brief mindfulness meditation mobile phone app intended to reduce anger and aggression in acute psychiatric inpatients with schizophrenia, schizoaffective disorder, or bipolar disorder, and a history of violence.

To our knowledge, this study reports on the first deployment of a commercially available app as an intervention on acute psychiatric inpatient units. Overall, participants with active affective and psychotic symptoms were able to understand and use a mobile mindfulness app during their admission to an inpatient psychiatric unit. There was no evidence of worsening of symptoms or induction of psychotic symptoms as a consequence of app use. Qualitative data indicate that the majority of participants liked the app for many reasons, including that it gave them "something to do" and seemed to provide a sense of mastery or control over something during an involuntary hospitalization.

Of note, many participants indicated that he app helped them relax enough to sleep better. Use of nonpharmacologic approaches to address sleep, anxiety, and even agitation could potentially reduce polypharmacy attributable to pro re nata (*prn*) medications on inpatient units. *prn* medications are given to between 70% and 90% of all psychiatric inpatients [44], and are hypothesized to lead to increased morbidity due to increased likelihood of drug interactions, dependence or misuse, and polypharmacy [45]. The literature supports that insomnia and anxiety are two of the three most common reasons for distribution of *prn* medications [46]. Some findings indicate that patients that use *prn* s end up feeling a loss of autonomy or feeling coerced [47]. Using skills instead of medications to address anxiety, insomnia, aggression, and mood is safer and more likely to lead to better results over the long term [48]. Encouraging patients to use such alternatives gives them more of a sense of empowerment and agency in managing their own symptoms, participating in their own care [46], and encourages a more collaborative relationship with providers [49]. Many psychiatric (and nonpsychiatric) patients understandably want to use "natural" means for therapy, reducing their exposure to potentially noxious side effects of, and interactions between, psychotropic medications

Several patients noted the benefit of having "something to do" on the unit. Boredom is reported as a precursor to aggression and violence on inpatient psychiatric units by patients themselves in qualitative studies [43]. Ostensibly, psychiatric inpatient units are the most intensive treatment modality in mental health care. Yet, patients report that they are bored on psychiatric units, with a limited range and quality of available activities and difficulty in getting time to talk with staff [43]. In one UK study, 40% of psychiatric inpatients reported not participating in social or recreational activity and 30% in no structured activity at all during their admissions [50]. With

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shorter hospital stays and more acutely ill patients, staff activity involving direct patient care tends to be more "putting out fires" involving a minority of severely ill patients on the unit, rather than engaging in proactive care for all patients [51,52]. mHealth interventions offer an alternative mode of treatment that may also alleviate the tedium of being on an inpatient unit.

Limitations

This study has several limitations including a small sample size and brief data collection period (driven by the short average length of hospitalizations). There is research supporting that groups of at least five are sufficient to identify most usability problems [53,54]. However, studying larger groups would likely provide more information [55]. There is also the potential for biased responses in the qualitative interviews and the Usability and Acceptability Questionnaires, as they were conducted by the study team's RA rather than by an independent interviewer, due to funding limitations. Future studies should include a qualitative interviewer who is not part of the study team in order to minimize the likelihood of such bias. One would generally expect that over time, participants would have improved functioning due to use of medications and other therapies. However, it was clear from the interviews that several participants had ongoing thought disorganization and hallucinations.

There were some difficulties related to hospital policy regarding mobile phones; charging phones required that staff help participants, as there is a prohibition on having cords on the unit for safety reasons. Not having access to a wireless connection meant that there was no ability to use what could be the most powerful features of Headspace, interaction with others using the app, keeping track of one's progress, and competing with others.

This work supports the idea that it is feasible to offer acutely psychiatrically ill inpatients a commercially available mindfulness meditation app and that the patients are able to use the app with few difficulties. The next step is to study the potential relationship between use of the app and inpatient aggression and violence. Future work will involve a more rigorous evaluation of a mindfulness intervention and its effects on aggression and violence on psychiatric units.

Conclusions

This is the first known study of the use of a commercially available app as an intervention on acute psychiatric inpatient units. As such, acutely ill psychiatric inpatients with SMI were able to use the app, navigating through it without much reported difficulty, and described using the mindfulness techniques to help with sleep and anxiety while on the unit. This is an example of an mHealth intervention that could potentially deliver individualized treatment when it is needed in an environment where the staff may be too busy to work one on one with the hospitalized person. Further study is warranted based on these findings.

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Conflicts of Interest

Although Headspace, Inc., provided free use of their product (as they often do for research teams), they were not involved in the conduct, analysis, or reporting of the research in anyway. Moreover, none of the authors possess any type of financial relationship with Headspace, Inc., that might be considered in any way a conflict of interest. Dr Ben-Zeev has an intervention content licensing agreement with Pear Therapeutics.

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Abbreviations

CBT: cognitive behavioral therapies
MBT: mindfulness-based therapies
prn: pro re nata
RA: research assistant
SMI: serious mental illness
WRAT-4: Wide Range Achievement Test 4

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Original Paper

Development and Evaluation of Digital Game-Based Training for Managers to Promote Employee Mental Health and Reduce Mental Illness Stigma at Work: Quasi-Experimental Study of Program Effectiveness

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Abstract

Background: To counteract the negative impact of mental health problems on business, organizations are increasingly investing in mental health intervention measures. However, those services are often underused, which, to a great extent, can be attributed to fear of stigmatization. Nevertheless, so far only a few workplace interventions have specifically targeted stigma, and evidence on their effectiveness is limited.

Objective: The objective of this study was to develop and evaluate a digital game-based training program for managers to promote employee mental health and reduce mental illness stigma at work.

Methods: We describe the empirical development of Leadership Training in Mental Health Promotion (LMHP), a digital game-based training program for leaders. A 1-group pre-post design and a 3-month follow-up were used for training evaluation. We applied multilevel growth models to investigate change over time in the dependent variables knowledge, attitudes, self-efficacy, and intentions to promote employee mental health in 48 managers of a global enterprise in the United Kingdom. Participants were mainly male (44/48, 92%) and ranged in age from 32 to 58 (mean 46.0, SD 7.2) years.

Results: We found a positive impact of the Web-based training program on managers' knowledge of mental health and mental illness (P<.001), on attitudes toward people with mental health problems (P<.01), and on their self-efficacy to deal with mental health situations at work (P<.001), with the exception of intentions to promote employee mental health, which was initially high.

Conclusions: Results provide first evidence of the effectiveness of LMHP to positively affect managers' skills to promote employee mental health at work. Furthermore, the high rate of participation in LMHP (48/54, 89%) supports the use of digital game-based interventions to increase user engagement and user experience in mental health programs at work.

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KEYWORDS

stigma; mental health; workplace; prevention; health promotion; leadership; eHealth; Internet

Introduction

Due to their high prevalence (1 in 4) [1], the economic impact of mental health problems such as depression can be considerable for employers globally. In high-income countries, the trend of sick days lost due to mental health problems has been growing in recent years [2]. Resulting total work loss due to sickness absence, lost at-work productivity, and turnover are estimated to cost £26 billion a year in the United Kingdom alone [3].

To counteract the negative impact of mental health problems on business, organizations are increasingly investing in mental health promotion, prevention, and intervention efforts [4]. For example, many organizations have implemented employee assistance programs (EAPs), which typically offer assessment, counselling, and referral services to employees with work-related or personal problems [5]. Others offer stress reduction programs such as meditation or relaxation interventions [6].

However, there are a few drawbacks worth discussing with regard to the current practice of workplace mental health promotion. First, most interventions aiming to promote employee mental health focus on the employee level (such as in stress management) while neglecting the organizational level (working conditions) [7,8]. However, many factors that positively affect employee mental health are related to the social environment at work, such as the working culture, level of social support, and leadership style [9]. Second, with regard to leadership, few efforts have considered the special role of managers in organizations [10,11]. Because they are in close contact with employees, managers are in the best position to spot signs of deteriorating mental health early and to provide support. Unfortunately, however, many leaders lack training in the management of workplace mental health and thus are ill-equipped to support affected individuals adequately [12]. Third, utilization rates of EAPs are generally low [5,13]. Despite the availability of effective mental health interventions, the majority of affected individuals choose not to seek help [14]. A major barrier that strongly contributes to the underuse of EAPs is the stigma associated with mental illness [15,16].

Stigma is defined as (1) the lack of knowledge of mental health problems and treatments, (2) prejudicial attitudes, and (3) the lack of supportive behavior, or anticipated or real acts of discrimination against people with mental health problems [14]. Despite its far-reaching impact on employees' willingness to seek help, current practices in mental health promotion largely fail to address stigma specifically [17]. Therefore, as of yet, efforts in mental health promotion do not seem to reach their primary aim, early and effective treatment, satisfactorily [18]. Instead, raising awareness of the importance of mental health, reducing stigma, and creating an organizational culture of acceptance, diversity, and respect may be a necessary prerequisite for the acceptance, use, and, thus, effectiveness of mental health interventions such as EAPs [19].

While the majority of stigma reduction programs targeted the general population—for example, in public health campaigns—there is growing interest in the effectiveness of workplace antistigma interventions [20,21]. A systematic review [17] found that workplace antistigma interventions can have a positive impact on employees' knowledge, attitudes, and supportive behavior toward people with mental health problems. However, limitations became apparent: (1) most interventions targeted the public sector, (2) half of the studies included did not target all 3 dimensions of stigma, which is key in achieving ultimate behavioral change, (3) there is a lack of evidence concerning the sustainability of workplace antistigma interventions due to insufficient follow-up beyond pre- and postintervention assessments, and (4) most interventions were delivered face-to-face, thus having only a limited reach and impact on stigma among the wider workforce.

The dissemination of digital interventions, however, could be a powerful strategy to facilitate widespread behavioral and cultural change in organizations [22]. Compared with face-to-face interventions, digital interventions have many advantages, such as greater reach, reduced barriers to access, increased participant engagement and adherence to treatment, and flexible and self-paced learning, as well as being more cost effective [23]. However, most digital health promotion efforts so far have targeted physical rather than mental health and mainly focused on the treatment of specific disorders in a subgroup (eg, depression in teenagers) [24-26]. Evidence on digital interventions aiming to prevent mental health problems is still scarce and even more so with regard to the workplace setting [27,28]. This study, therefore, aimed to address some of the limitations of current practices in mental health promotion and of research on stigma reduction. We followed 2 objectives: (1) to develop a digital game-based intervention to train leaders of a private sector organization to effectively manage employee mental health by addressing all 3 dimensions of stigma in order to prevent mental health problems and promote an open, inclusive, and supportive working culture, and (2) to evaluate the intervention in terms of its effectiveness and mid-term sustainability in a pilot study.

Specifically, we hypothesized that our digital game-based intervention, called Leadership Training in Mental Health Promotion (LMHP), would lead to (1) improved mental health knowledge, (2) increased positive attitudes toward people with mental health problems, (3) increased self-efficacy to deal with mental health situations at work, and (4) improved intentions to promote employee mental health at work in managers undertaking the training.

Methods

Objective 1: Intervention Development

The intervention was developed in a collaborative effort between the department of psychosocial health and well-being of a large global private sector company, which employed around 348,000 employees in more than 100 countries in 2015, and the Chair

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for Public Health and Health Services Research of Ludwig-Maximilians-University (LMU) in Munich, Germany.

Approach

In developing LMHP, we followed a systematic approach similar to intervention mapping [29] for designing theory- and evidence-based health promotion programs. Specifically, we took several steps, from analyzing the problem of mental illness stigmatization and effective change methods [17], to assessing the needs for managerial training on mental health, and, finally, to developing the training, as well as an implementation and evaluation plan.

Content

We developed training content based on a review of workplace training programs on mental health [30-33] and on consultations with subject matter experts in the field of health management, human resources, and training and development. Furthermore, we carried out a needs assessment via 14 semistructured interviews (7 managers, 7 employees) in the participating organization, investigating managerial training needs in terms of preferred content and mode of delivery (unpublished data). Results indicated a particular need for managers to be trained in spotting warning signs of mental distress, and in how to interact with and support affected employees.

Format

While e-learning is well established in larger enterprises, Web-based training in its most common form, animated slidecasts, is losing more and more in attractiveness and acceptance [34]. To counteract low participant engagement [35], LMHP was developed as a simulation game, a Web-based training program combining elements of both games and simulations [36]. By creating a real in-person environment with all the complexities of the formal and particularly social interactions typically found in the workplace, the program provides managers with the opportunity to directly apply what they learned about people management and to practice new skills in a safe virtual environment [37]. This way, managers can get a sense of the potential impact of different leadership styles on employee mental health without having to worry about real-world consequences.

Gamification

To facilitate an innovative and engaging learning experience [35], we used a subtle form of gamification in LMHP to fit the sensitivity of the training content. Gamification is defined as "the use of game design elements in non-game contexts" [38]. For example, while we refrained from providing badges for achievements or enabling competition between players, we did include several gamification strategies that were found to increase engagement and learning [39]. Those involved providing a storyline and clear goals, including the capacity to overcome challenges by learning; providing feedback on performance; showing progress (in terms of how leader behavior affects employee mental health over time); and reinforcing learning by allocating points (eg, for quiz questions answered correctly).

Objective 2: Intervention Evaluation

The goal of this pilot study was to evaluate the effectiveness of a digital game-based training program for managers, which we developed to promote employee mental health and reduce mental health-related stigma at work, using a 1-group pre-post design and a 3-month follow-up. The pilot study was carried out at a defined site of the participating organization near Oxford, United Kingdom.

Participants

All managers of this site were invited to take part in LMHP and its associated research study. To be included, participants had to be of working age (between 18 and 65 years) and be managing at least one employee at the time of the training. Informed consent was obtained from all individual participants included in the study.

Procedure

Invitations to participate in LMHP were sent out by email approximately a week in advance of the scheduled Web-based training. This invitation notified participants about the study's objectives, potential risks, data protection, etc.

Participants were then sent a personal link that allowed (1) participants to give their informed consent to participate in this study, (2) participants to access the training program for a limited time period of 3 weeks, (3) participants to access the pre- and postquestionnaire immediately before (T1) and after (T2) completion of the training, and (4) the researchers to allocate responses at T1, T2, and T3 to an individual. However, the link did not include any information that could be used to identify participants. At T3 (12 weeks after training completion), participants were resent their personal link in order to fill in a follow-up questionnaire to evaluate the first mid-term effects of the intervention.

Any communication about the training initiative (eg, invitations), as well as personal links to training and questionnaires, was sent out via email by a human resources staff member of the participating organization, who was not involved in the study. Questionnaires were completed anonymously online, and responses were tracked and stored safely at the external training provider. The external training provider then replaced participants' email addresses with a random, unique 3-digit identifier and posted the data back to the researchers at LMU Munich. To increase response rates, the external training provider informed the human resources staff member of the participating organization about any nonresponders so that he could send out reminders. The researchers were never told the names of individual respondents, and the human resources staff member in the participating organization never saw any completed questionnaires or individually identifiable data.

Ethics

Ethical approval for the study was given by the Ethics Committee of LMU Munich, Germany. All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional or national research committee and with the 1964 Declaration of

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Helsinki and its later amendments or comparable ethical standards.

Outcome Measures

Demographic questions included age, sex, level of education, marital status, whether they currently lived alone, and whether they knew someone with a mental health problem and had been diagnosed with or treated for a mental health problem themselves.

Other outcome measures matched the knowledge, attitudinal, and behavioral dimensions of stigma as defined above. We administered 4 validated instruments. To all of them, a 5-point Likert scale ranging from 1 ("strongly disagree") to 5 ("strongly agree") was applied. We calculated global scores on all instruments using sum scores, with higher scores indicating a better outcome, with the exception of stigmatizing attitudes. All measures were administrated at all 3 time points.

Knowledge

We assessed knowledge about mental health problems using the first 6 items, which are related to stigma, of the 12-item Mental Health Knowledge Schedule (MAKS) [40]. An example item is "Psychotherapy can be an effective treatment for people with mental health problems." Sum scores ranged from 6 to 30.

Additionally, we developed a set of 7 quiz questions to test participants' knowledge on specific training content of LMHP, with 3 answer options, of which 1 was correct. An example item is "Which statement about business costs related to mental disorders is correct?" In this case, sum scores ranged from 0 to 7.

Attitudes

We assessed attitudes in the workplace toward coworkers who may have a mental illness using the 23-item Opening Minds Scale for Workplace Attitudes (OMS-WA), an adapted version of the Opening Minds Scale for Health Care Providers (OMS-HC) [41]. OMS-WA consists of 5 subscales: 6 items on avoidance, 5 on perceived dangerousness, 5 on work beliefs and competencies, 4 on helping, and 3 on responsibility of people with mental health problems. During evaluation, we considered attitudes as a whole, with sum scores ranging from 23 to 115, as well as the individual subscales, with sum scores ranging from 6 to 30 for avoidance, 5 to 25 for perceived dangerousness, 5 to 25 for work beliefs and competencies, 4 to 20 for helping, and 3 to 15 for responsibility. An example item is "I would try to avoid a coworker with a mental illness."

Behavior

To assess behavioral change in leaders, we used proxy variables (eg, self-efficacy to deal with mental health situations at work and intentions to promote employee mental health), since in a 3-month period not very many mental health situations are likely to arise at work where leaders could possibly demonstrate actual support. However, prior research found that enhanced intentions and high self-efficacy increase the likelihood that a person will engage in newly learned behaviors [42].

In this study, we measured self-efficacy with regard to managing employee mental health by a previously adapted version of the 9-item New General Self-Efficacy Scale [30,43]. Items included "When facing difficulties related to employee mental health, I am certain that I will handle them appropriately." Sum scores ranged from 9 to 45.

To assess participants' intentions to promote employee mental health, we used a previously adapted 3-item version of a safety scale designed to assess managers' safety promotion intentions [30,44]. An example item is "I want to apply what I learn about employee mental health to my work setting." Sum scores ranged from 3 to 15.

Statistical Methods

We used descriptive statistics (mean, median, SD) to describe the study population. Multilevel growth models (with random intercept) were applied to investigate change over time in the dependent variables knowledge, attitudes, self-efficacy, and intentions to promote employee mental health [45]. An advantage of multilevel growth models is that missing data can be handled flexibly (using likelihood-based estimation) and thus allowed incorporation of all available data. First, we used time as a fixed factor in the models, as pre- and postmeasurements were collected on the same day for each participant and variability in time from post- to follow-up measurements was very low across participants. Second, we investigated whether selected participant characteristics (age, educational level) predicted initial status. We applied the forward modelling approach, starting with models without any predictors (model A) and adding potential explanatory variables as fixed effects at subsequent steps (models B and C). To select the best model, we considered reductions of deviance (–2*log likelihood) and of Akaike information criterion and Bayesian information criterion values, with smaller values indicating a better-fitting model. We computed change as the difference in relation to the baseline (T1) score. Parameter estimates and standard errors (SE) are reported. Effects were judged significant at alpha≤.05, unless otherwise noted. Statistical analyses were performed using IBM SPSS 23.0 and SPSS MIXED (IBM Corporation).

Results

Objective 1: Intervention Development

Taking all formative research described above into consideration, we designed LMHP in a way to train managers in (1) understanding mental health and mental illness, (2) spotting warning signs, (3) taking early and appropriate action, and (4) monitoring and self-monitoring.

Digital Game-Based Learning

The training consisted of one single session, which took between 1.5 and 2 hours to complete, thereby meeting managers' expectations of a particularly concise and time-efficient training format as expressed during interviews (see formative research described above). The setting was the office hub where, over a virtual time period of 7 weeks, the player was put into the position of a manager. During that time period, it was the manager's task to supervise a virtual team and manage employee mental health effectively.

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Table 1. Outline of content and psychological constructs covered in the virtual scenarios of the Leadership Training in Mental Health Promotion program.

Scenario	Objective	Knowledge	Attitude	Skills
1. Psychological well-being	Promotion of mental health	Create awareness of the importance of mental health at work and that stress or mental illness affects everyone	Develop more positive attitudes toward promoting mental health at work	Communication and behavioral strategies to ensure that healthy employees stay healthy
2. Acute stress	Prevention of mental illness	Create awareness that acute stress can result in psychological as well as physical symptoms	Develop more positive attitudes toward discussing the topic of stress more openly at work and to promote employee mental health	Communication, identification of warning signs, support strategies
3. Chronic stress	Prevention of mental illness	Create awareness that persistent stress has severe detrimental effects on the body and the mind and, if not dealt with, can lead to long-term sickness absence	Develop more positive attitudes toward employees with mental health problems with regard to avoidance, work competency, responsibility, and helping	Communication, identification of warning signs, and support and referral strategies
4. Mental Illness	Rehabilitation and return to work	Create awareness of common mental health problems and of return-to-work policies and procedures	Develop more positive attitudes toward employees with mental health problems with regard to perceived dangerousness, work competency, responsibility, avoidance, and helping	Communication, planning a successful return to work, workplace accommodations, monitoring, actively counteracting stigma and discrimination, facilitating open discussions

The virtual team consisted of 4 employees showing diverse psychological profiles; thus, each represented a different mental health scenario likely to appear in real office life. Scenarios contained examples of the promotion of mental health, the prevention of mental illness, and the rehabilitation of employees with common mental health problems such as anxiety or depressive disorders (see Table 1). Due to their relatively low prevalence rates, more severe mental disorders such as psychosis were not addressed in this workplace training. All scenarios required managers to develop and practice their skills in spotting warning signs, taking (early) action, and monitoring employees while building knowledge of mental health and mental illness and more positive attitudes toward employees with mental health problems at the same time (see Table 1).

For example, to sensitize managers in the recognition and identification of warning signs, certain hints were placed into the virtual work environment (eg, medication, uneaten lunch, or work piling up on an employee's desk) that may or may not signal a growing underlying mental imbalance. Once the manager had spotted something unusual or alarming, he or she could choose to engage in a conversation with the respective employee. Different dialogue options were provided to choose from, which were more or less appropriate given the sensitivity of a certain topic. Depending on how the manager behaved, the respective employee chose to either shut down and end the conversation or open up and share further information the manager needed to be able to offer appropriate and effective support.

To ensure continuous learning and improved self-efficacy to manage mental health situations at work, the player was provided with instant feedback regarding his or her actions after the end of each conversation. Furthermore, a video of an actual affected employee of the participating organization sharing his or her experience with burnout was shown automatically to every player. The personal testimonial was presented in a way to counter prominent stereotypes of people with mental health problems and with a strong focus on the road toward recovery and well-being, thus involving many features considered fundamental to reducing stigma [46]. This video formed a very powerful part of the training, since contact with people with lived experience (face-to-face or video-based) is argued to be the strongest method to tackle mental illness stigma [47].

Mental Health Toolbox

Next to scenario-based learning, LMHP also offered a mental health toolbox that provided managers with practical information on topics found to be relevant to manage a given scenario successfully. The toolbox was presented in a way to improve managers' knowledge of mental health and mental illness, improve their attitudes toward employees with mental health problems, and train them in skills to deal with mental health situations at work effectively. Topics of the mental health toolbox focused on 4 main areas: what mental health and mental illness mean, how to recognize signs of mental distress, how to start a conversation, and how to support affected employees effectively (see Table 2). Furthermore, the toolbox aimed to facilitate the application of newly learned skills in real everyday office life. For example, checklists with warning signs or guidelines for conversations on mental health could be downloaded as pdf files and serve as useful aids in interactions with employees.

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Table 2. Outline of content and psychological constructs covered in the Mental Health Toolbox of the Leadership Training in Mental Health Promotion program.

Focus areas of training		Module	
A	Understanding mental health and mental illness	A1	Mental health affects us all
		A2	Understanding mental health and mental illness
		A3	Economic impact of mental illness
		A4	Risk factors and treatment of mental disorders
B	Recognizing signs of mental distress	B1	What is stress?
		B2	Work-related stressors and resources
		B3	Warning signs
		B4	Common mental disorders at work
C	Starting the conversation	C1	Stigma: a barrier to help-seeking
		C2	Communication techniques
		C3	Guidance for leaders
		C4	In-house support services
D	Supporting effectively	D1	Key role of managers
		D2	Providing support
		D3	Return to work
		D4	Self-care

Theoretical Foundation and Underlying Models

The idea behind the training—for example, the progression of employees' mental state in scenarios—followed the principles of the mental health continuum model [48,49]. This model postulates that mental health is spread out along a continuum, meaning that people are not either mentally healthy or mentally ill, but that they can move in and out of further phases in between.

In LMHP, we used an adapted version of the mental health continuum model to suit our specific needs. Each phase of this continuum (health, acute stress, chronic stress, and illness) is assigned certain warning signs and recommended actions to take as an affected individual but also as a manager supporting affected employees. In this way, mental health becomes more concrete, which, in turn, facilitates managers' understanding of mental health and warning signs.

On several occasions during the training, the manager was asked to assess each employee's mental state along the phases of the mental health continuum model. Afterward, the player was given feedback on an employee's actual mental state and on other parameters the manager influenced with his or her behavior, such as perceived managerial support or an employee's willingness to seek professional help. This exercise was designed to improve managers' self-efficacy in identifying warning signs and to strengthen their intentions to promote employee mental health.

Objective 2: Intervention Evaluation

Participants

Figure 1 shows the flow of participants at each stage of the study. Of 54 managers working at the site, 48 (89%) accepted our invitation, completed the baseline questionnaire, and took part in the training. Of the 48 participants, 47 (98%) completed the postquestionnaire immediately after the training and 38 (79%) responded to the follow-up questionnaire 3 months later. Complete data from 3 waves were available for 37 (77%) participants and from at least two waves for 47 (98%) respondents.

Descriptive Analysis

Table 3 presents baseline demographic characteristics of the sample population: 92% of participants were male (44/48). Participants ranged in age from 32 to 58 (mean 46.0, SD 7.2) years. Among the 48 participants, 48% (23/48) had a university degree, 77% (37/48) were married, and 88% (42/48) were not living alone. Furthermore, 63% (30/48) knew someone with a mental health problem and 10% (5/48) had been diagnosed with or treated for a mental health problem themselves. Finally, 17% (8/48) received further training on mental health between the postevaluation and follow-up evaluation.

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Figure 1. Flow diagram showing progress through the phases of the trial.

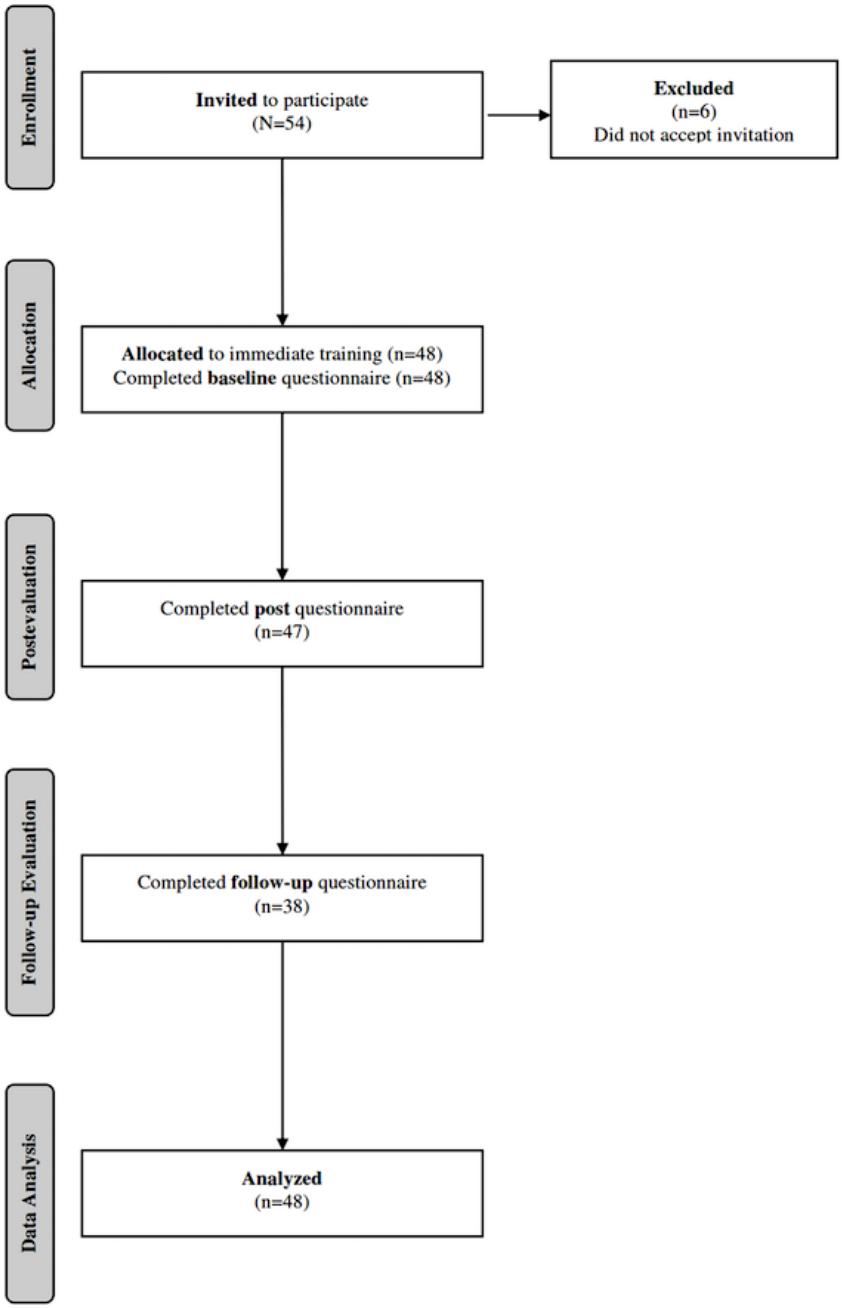

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Table 3. Baseline demographic characteristics of the sample population (n=48).

Characteristics	Data
Age in years, mean (SD), median	46.0 (7.2), 45.5
Age groups[a], n (%)	
<45.5 years	24 (50)
≥45.5 years	24 (50)
Sex, n (%)	
Male	44 (92)
Female	4 (8)
Education level attained, n (%)	
Graduate degree	11 (23)
Bachelor's degree	12 (25)
Nonuniversity certificate	13 (27)
High school	10 (21)
Less than high school	2 (4)
Education groups[a], n (%)	
University degree	23 (48)
Nonuniversity degree	25 (52)
Marital status	
Married	37 (77)
Divorced or separated	6 (13)
Single	3 (6)
Common-law relationship	2 (4)
Living alone, n (%)	
No	42 (88)
Yes	5 (10)
Prefer not to answer	1 (2)
Know someone with mental health problem, n (%)	
No	13 (27)
Yes	30 (63)
Prefer not to answer	5 (10)
Been diagnosed with or treated for mental health problem, n (%)	
No	41 (85)
Yes	5 (10)
Prefer not to answer	2 (4)
Received further training postintervention, n (%)	
No	30 (63)
Yes	8 (17)
Missing values	10 (21)

[a]Variables included in multilevel analysis (model C).

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Table 4. Descriptive statistics for respondents who participated at all 3 time points[a] (n=37).

Measures	Wave 0		Wave 1		Wave 2	
	Mean	SD	Mean	SD	Mean	SD
Knowledge (MAKS[b])	22.1	2.6	24.2	2.5	24.0	2.8
Knowledge (quiz)	4.4	1.4	5.6	1.4	4.9	1.2
Attitude total	45.9	10.7	43.1	11.5	42.3	10.3
Attitude avoidance	11.4	3.6	10.1	3.0	9.8	3.2
Attitude dangerousness	10.5	3.0	9.3	3.3	9.1	2.7
Attitude work	10.9	3.0	11.2	3.3	10.4	3.1
Attitude help	8.0	1.6	8.0	2.2	8.6	2.7
Attitude responsibility	5.0	2.0	4.5	1.6	4.4	1.7
Self-efficacy	31.5	3.6	34.7	3.4	34.2	2.9
Promotion intentions	12.2	1.3	12.4	1.2	12.3	1.2

[a]Wave 0, baseline; wave 1, postintervention; wave 2, 3-month follow-up.

[b]MAKS: Mental Health Knowledge Schedule.

Multilevel Analysis

Table 4 shows the mean scores of knowledge, attitudes, self-efficacy, and intentions to promote employee mental health at the 3 time points. In general, observed baseline scores indicated that, before the intervention, managers had quite good knowledge of mental health, fairly positive attitudes toward people with mental illness, and a high level of self-efficacy, as well as intentions to promote employee mental health.

Table 5 and Table 6 show the results of the multilevel analysis. Adding age and education (refer to Table 3) to the models neither showed significant effects regarding initial status nor improved the goodness of fit. Thus, in the following, we focused on results of model A intercept and, particularly, model B intercept and time. Overall, the B models had good fit. These models indicated that knowledge of mental health and mental illness (measured by MAKS and the quiz) and self-efficacy to deal with mental health situations at work significantly increased over time and that this effect remained significant over the 3-month period (see Table 5). Regarding stigmatizing attitudes, attitudes (total scale; Table 5) and attitude subscales related to avoidance, perceived dangerousness, and responsibility (Table 6) significantly decreased over time with these effects also being sustained 3 months later. However, attitudes related to work and competency beliefs and to helping people with mental health problems did not change over time (Table 6). Moreover, managers' intentions to promote employee mental health did not change over time (Table 5).

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Table 5. Mixed models (with random intercept) considering knowledge assessed by MAKS[a], knowledge assessed by quiz, attitude (total), self-efficacy, and intentions to promote employee mental health as the dependent variable (n=48).

Dependent variable and predictors of change over time	Model A: unconditional means model		Model B: unconditional growth (with time)		Model C: time & age & education	
	Parameter estimate (SE)	*P* value	Parameter estimate (SE)	*P* value	Parameter estimate (SE)	*P* value
Knowledge (MAKS)						
Fixed effects						
Intercept (initial status)	23.27 (0.324)	<.001	21.98 (0.372)	<.001	21.84 (0.572)	<.001
Time (rate of change)						
Wave = 1			2.16 (0.335)	<.001	2.16 (0.335)	<.001
Wave = 2			1.88 (0.361)	<.001	1.87 (0.361)	<.001
Age					–0.09 (0.641)	
Education					0.38 (0.642)	
Variance components						
Level 1: within-person (residual)	4.13 (0.633)	<.001	2.65 (0.407)	<.001	2.65 (0.407)	<.001
Level 2: in intercept	3.51 (1.052)	.001	3.99 (1.024)	<.001	3.95 (1.017)	<.001
Goodness of fit						
Deviance	623.88		585.60		585.23	
AIC[b]	629.88		595.60		599.23	
BIC[c]	638.55		610.05		619.47	
Knowledge (quiz)						
Fixed effects						
Intercept (initial status)	5.01 (0.138)	<.001	4.38 (0.191)	<.001	4.36 (0.259)	<.001
Time (rate of change)						
Wave = 1			1.36 (0.239)	<.001	1.36 (0.239)	<.001
Wave = 2			0.55 (0.256)	.03	0.53 (0.256)	.04
Age					–0.34 (0.263)	
Education					0.38 (0.642)	
Variance components						
Level 1: within-person (residual)	1.86 (0.284)	<.001	1.36 (0.208)	<.001	1.36 (0.208)	<.001
Level 2: in intercept	0.24 (0.211)		0.40 (0.197)	.04	0.33 (0.185)	
Goodness of fit						
Deviance	474.48		446.59		443.09	
AIC	480.48		456.59		457.09	
BIC	489.15		471.04		477.32	
Attitude (total)						
Fixed effects						
Intercept (initial status)	43.77 (1.511)	<.001	46.13 (1.633)	<.001	47.93 (2.601)	<.001
Time (rate of change)						
Wave = 1			–3.49 (1.095)	.002	–3.49 (1.095)	.002
Wave = 2			–4.08 (1.185)	.001	–4.06 (1.185)	.001
Age					–1.09 (3.002)	
Education					–2.64 (3.004)	
Variance components						

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Dependent variable and predictors of change over time	Model A: unconditional means model		Model B: unconditional growth (with time)		Model C: time & age & education	
	Parameter estimate (SE)	*P* value	Parameter estimate (SE)	*P* value	Parameter estimate (SE)	*P* value
Level 1: within-person (residual)	33.47 (5.147)	<.001	28.33 (4.356)	<.001	28.34 (4.361)	<.001
Level 2: in intercept	97.211 (22.562)	<.001	99.63 (22.644)	<.001	97.43 (22.218)	<.001
Goodness of fit						
Deviance	949.58		935.62		934.70	
AIC	955.58		945.62		948.70	
BIC	964.26		960.07		968.93	
Self-efficacy						
Fixed effects						
Intercept (initial status)	33.59 (0.396)	<.001	31.54 (0.507)	<.001	31.14 (0.742)	<.001
Time (rate of change)						
Wave = 1			3.62 (0.551)	<.001	3.62 (0.551)	<.001
Wave = 2			2.78 (0.225)	<.001	2.77 (0.592)	<.001
Age					0.47 (0.801)	
Education					0.36 (0.801)	
Variance components						
Level 1: within-person (residual)	11.28 (1.752)	<.001	7.18 (1.113)	<.001	7.20 (1.119)	<.001
Level 2: in intercept	3.41 (1.714)	.046	5.16 (1.685)	.002	5.03 (1.670)	.003
Goodness of fit						
Deviance	728.85		691.95		691.39	
AIC	734.86		701.95		705.39	
BIC	743.53		716.40		725.62	
Promotion intentions						
Fixed effects						
Intercept (initial status)	12.46 (0.151)	<.001	12.31 (0.185)	<.001	12.08 (0.269)	<.001
Time (rate of change)						
Wave = 1			0.36 (0.192)		0.36 (0.192)	
Wave = 2			0.08 (0.207)		0.07 (0.207)	
Age					0.00 (0.292)	
Education					0.48 (0.292)	
Variance components						
Level 1: within-person (residual)	0.91 (0.140)	<.001	0.87 (0.135)	<.001	0.88 (0.136)	<.001
Level 2: in intercept	0.76 (0.233)	.001	0.76 (0.231)	.001	0.70 (0.220)	.001
Goodness of fit						
Deviance	421.88		418.22		415.58	
AIC	427.88		428.22		429.58	
BIC	436.55		442.67		449.81	

[a]MAKS: Mental Health Knowledge Schedule.

[b]AIC: Akaike information criterion.

[c]BIC: Bayesian information criterion.

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Table 6. Mixed models (with random intercept) considering attitudes regarding avoidance, dangerousness, workability, helping, and responsibility as the dependent variable (n=48).

Dependent variable and predictors of change over time	Model A: unconditional means model		Model B: unconditional growth (with time)		Model C: time & age & education	
	Parameter estimate (SE)	*P* value	Parameter estimate (SE)	*P* value	Parameter estimate (SE)	*P* value
Attitude avoidance						
Fixed effects						
Intercept (initial status)	10.50 (0.439)	<.001	11.44 (0.492)	<.001	11.69 (0.773)	<.001
Time (rate of change)						
Wave = 1			–1.37 (0.390)	.001	–1.37 (0.390)	.001
Wave = 2			–1.66 (0.422)	<.001	–1.66 (0.422)	<.001
Age					–0.39 (0.880)	
Education					–0.12 (0.881)	
Variance components						
Level 1: within-person (residual)	4.43 (0.681)	<.001	3.60 (0.554)	<.001	3.60 (0.555)	<.001
Level 2: in intercept	7.63 (1.926)	<.001	8.00 (1.932)	<.001	7.95 (1.924)	<.001
Goodness of fit						
Deviance	659.03		641.77		641.55	
AIC[a]	665.03		651.77		655.55	
BIC[b]	673.70		666.22		675.78	
Attitude dangerousness						
Fixed effects						
Intercept (initial status)	9.72 (0.404)	<.001	10.60 (0.440)	<.001	11.33 (0.688)	<.001
Time (rate of change)						
Wave = 1			–1.32 (0.308)	<.001	–1.32 (0.308)	<.001
Wave = 2			–1.52 (0.333)	<.001	–1.51 (0.333)	<.001
Age					–0.40 (0.791)	
Education					–1.10 (0.792)	
Variance components						
Level 1: within-person (residual)	2.96 (0.454)	<.001	2.24 (0.345)	<.001	2.25 (0.345)	<.001
Level 2: in intercept	6.76 (1.615)	<.001	7.03 (1.614)	<.001	6.67 (1.543)	<.001
Goodness of fit						
Deviance	616.80		593.42		591.23	
AIC	622.80		603.42		605.23	
BIC	631.47		617.87		625.46	
Attitude workability						
Fixed effects	10.68 (0.409)	<.001	10.83 (0.472)	<.001	11.83 (0.707)	<.001
Intercept (initial status)						
Time (rate of change)						
Wave = 1			–0.08 (0.415)		–0.08 (0.415)	
Wave = 2			–0.47 (0.451)		–0.46 (0.452)	
Age					–1.24 (0.791)	
Education					–0.78 (0.792)	
Variance components						

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Dependent variable and predictors of change over time	Model A: unconditional means model		Model B: unconditional growth (with time)		Model C: time & age & education	
	Parameter estimate (SE)	*P* value	Parameter estimate (SE)	*P* value	Parameter estimate (SE)	*P* value
Level 1: within-person (residual)	4.20 (0.642)	<.001	4.13 (0.632)	<.001	4.14 (0.635)	<.001
Level 2: in intercept	6.50 (1.666)	<.001	6.58 (1.676)	<.001	5.98 (1.565)	<.001
Goodness of fit						
Deviance	652.52		651.35		647.93	
AIC	658.52		661.35		661.93	
BIC	667.21		675.84		682.21	
Attitude helping						
Fixed effects	8.07 (0.241)	<.001	8.17 (0.315)	<.001	8.00 (0.452)	<.001
Intercept (initial status)						
Time (rate of change)						
Wave = 1			1.16 (0.587)		–0.51 (0.365)	
Wave = 2			0.31 (0.484)		0.31 (0.392)	
Age					0.38 (0.479)	
Education					–0.04 (0.479)	
Variance components						
Level 1: within-person (residual)	3.32 (0.507)	<.001	3.17 (0.484)	<.001	3.16 (0.482)	<.001
Level 2: in intercept	1.58 (0.594)	.008	1.61 (0.587)	.006	1.59 (0.580)	.006
Goodness of fit						
Deviance	577.25		572.78		572.15	
AIC	583.25		582.78		586.15	
BIC	591.92		597.24		606.39	
Attitude responsibility						
Fixed effects						
Intercept (initial status)	4.68 (0.248)	<.001	5.08 (0.274)	<.001	4.99 (0.428)	<.001
Time (rate of change)						
Wave = 1			–0.62 (0.208)	.004	–0.61 (0.208)	.004
Wave = 2			–0.69 (0.225)	.003	–0.68 (0.225)	.003
Age					0.54 (0.489)	
Education					–0.37 (0.490)	
Variance components						
Level 1: within-person (residual)	1.18 (0.181)	<.001	1.02 (0.157)	<.001	1.02 (0.157)	<.001
Level 2: in intercept	2.52 (0.611)	<.001	2.58 (0.612)	<.001	2.49 (0.591)	<.001
Goodness of fit						
Deviance	491.42		479.80		478.11	
AIC	497.42		489.80		492.11	
BIC	506.09		504.25		512.34	

[a]AIC: Akaike information criterion.

[b]BIC: Bayesian information criterion.

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Discussion

Principal Results

In this study we targeted the development and pilot evaluation of a digital game-based training program for managers to promote employee mental health and reduce mental illness stigma at work. Our study contributes to strengthen the evidence base that interventions targeting leaders may be effective in improving mental health literacy and reducing mental illness stigma in the workplace. In line with prior research and our hypotheses, we found statistically significant improvements in managers' knowledge of mental health and mental illness, attitudes toward people with mental health problems, and self-efficacy to deal with mental health situations at work, with the exception of intentions to promote employee mental health [50-52]. While these results can only be considered preliminary until replicated in a controlled trial, they nevertheless highlight some interesting findings that will help inform, first, the future development of effective antistigma interventions in the workplace and, second, relevant stakeholders such as personnel in human resources or health management about the benefits of investing in stigma reduction efforts.

Knowledge of mental health and mental illness is a key stigma component and a common target of antistigma interventions, as it enables recognition and is thus essential to the prevention of mental health problems [47]. In line with previous studies [53,54], we found improvements in managers' knowledge of mental health and mental illness (MAKS and quiz). Research shows that improved knowledge of mental health problems strongly influences a person's ability not only to recognize signs of mental illness, but also to seek help and support others in seeking help, and to accept treatment [55].

Evidence of the potential impact of workplace antistigma interventions on managers' attitudes toward people with mental health problems is generally mixed [17]. While some studies did not find any significant change in overall attitudes toward people with mental health problems [53,54], others reported improvements [56,57]. In our study, we evaluated not only overall attitude but also specific aspects of attitude, namely avoidance, perceived dangerousness, beliefs about workability and competencies, helping, and responsibility. While we found decreasing overall stigmatizing attitudes in managers over time, this did not apply to attitudes related to beliefs about workability and competency of people with mental health problems, nor to attitudes related to helping. An important finding of our study is therefore that a more thorough evaluation of attitudes considering specific themes, such as perceived dangerousness or social avoidance, is necessary and may be crucial to a better understanding of the effectiveness of antistigma interventions.

Behavioral change is key to creating an open and supportive work environment [58]. While public health efforts have often failed to change behavior, antistigma interventions in the workplace were suggested to be particularly promising because they allow for clear instructions with regard to how one is expected to behave in specific situations at work [21]. In line with prior studies, we found LMHP to have a positive impact on managers' self-efficacy to deal with mental health situations at work (eg, provide support) [51,59]. This is very important, since, even more so than knowledge, the level of self-efficacy strongly influences whether a person will engage in learned behaviors [42,60].

An open question is why LMHP did not lead to improvements in attitudes related to beliefs about workability and competency of people with mental health problems, and in managers' intentions to promote employee mental health. One potential reason might be that managers in our sample already had quite positive attitudes at baseline regarding workability and competency of people with mental health problems, as well as intentions to promote employee mental health, which left little room for improvement postintervention. Moreover, even though people with mental health problems can function productively at work, the literature shows that employers' beliefs about the workability and competency of people with mental health problems are often poor and may be particularly hard to change [61]. Somewhat surprisingly, attitudes related to helping employees with mental health problems if they, for example, got behind in their work were and remained relatively negative despite the training. This could be related to managers' concerns about the equity of the distribution of responsibilities and meeting productivity pressures [62]. Having in mind how important these outcomes are to reduce stigma and given that many people with mental health problems are either unemployed but want to work or are working [63,64], we recognize that LMHP and other future workplace antistigma interventions might need to incorporate modules that address those aspects more specifically.

Due to a lack of sufficient follow-up in relevant prior studies, conclusions regarding the effectiveness of workplace antistigma interventions over the long term are limited [17]. However, the few studies that conducted a follow-up reported that changes achieved in people's knowledge, attitudes, and behavior were, in part, sustained over time [30,53,54,56,65,66]. We also found that effects of LMHP on managers' knowledge, attitudes, and self-efficacy were largely sustained over a 3-month period (Table 5 and Table 6). While still being significantly different from baseline values, scores seemed to slightly decrease again from post- to follow-up assessment, indicating a potential need for booster sessions and further measures.

While the use of digital game-based interventions in mental health promotion is scarce and especially so in the workplace, research in other settings such as schools shows promising effects, including significant improvements in students' psychological well-being and increased engagement in a learning program [27,28,67]. While existing efforts, however, mainly focus on risk prevention [67,68], LMHP trained managers equally in how they can contribute to reducing symptoms of mental illness in employees and in how to enhance their psychological well-being. Digital mental health promotion interventions need to shift their traditional focus on treatment and risk prevention of mental health problems to emphasizing positive psychology, healthy leadership, and the strengthening of individual resources in healthy people in order to be of greater relevance and applicability for organizations. Compared with other nongamified workplace mental health interventions with often low participant rates [27,66], this study confirmed the

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growing evidence that digital game-based interventions may increase user engagement and learning attainment, thus making it an attractive strategy to facilitate widespread behavioral and cultural change in organizations [34].

Strengths and Limitations

This pilot study contributes to strengthen the evidence base of (digital) workplace antistigma interventions. Previous efforts in mental health promotion have largely neglected the role of leaders and instead have focused on employee-level interventions to address stress at work [7,10]. A marked strength of this study is therefore its focus on managers. Additionally, it addressed (1) a lack of research in private sector organizations, (2) a lack of interventions targeting all 3 dimensions of stigma, and (3) a lack of long-term follow-up that characterizes the available literature. Furthermore, this study could help explain prior mixed findings on attitudinal change by investigating the impact of LMHP on attitudes related to specific themes rather than on a single attitude scale [17]. To the best of our knowledge, LMHP is the first digital game-based training for managers aiming to promote employee mental health and reduce mental illness stigma at work. Thus, this pilot adds to the small pool of digital workplace mental health promotion and antistigma interventions [33], providing further evidence suggesting, first, that brief Web-based interventions can be as effective as more time-consuming face-to-face equivalents, which often do not match business demands [22], and second, that incorporating gamification into the learning strategy can increase participant engagement [34].

This pilot study has some limitations that must be mentioned. First, the study lacked a control group due to formal restrictions of the participating site. To what extent observed changes were due to the intervention is therefore questionable. To account for that, we recorded whether managers participated in further interventions during the study time, and the majority did not (30/48, 63%). Second, to measure knowledge, we developed our own quiz, which was not validated. Therefore, we used a second standardized instrument (MAKS, see Methods) and found similar change patterns in knowledge over time with both instruments. Third, while the OMS-WA as an adapted version of the OMS-HC [25] has been used extensively in program evaluations [66], an evaluation of the psychometric properties of this measure has yet to be published. However, a validation study of OMS-WA is under review. Fourth, the intervention was carried out in the United Kingdom and, thus, participants might have been presensitized as a result of increased stigma reduction efforts that have been going on in the United Kingdom in the past decade [31,69-71]. This might explain the good baseline values and small changes over time and ultimately may have led to an underestimation of the real training impact. Future evaluations should aim to investigate the effectiveness of LMHP in countries where mental illness stigma might be particularly strong and prevailing and where evidence about the effectiveness of antistigma interventions is scarce [72]. Fifth, we collected no data from employees on mental health, intentions to seek help, and perceived management support, nor on actual help-seeking in this study. However, in this pilot, we specifically wanted to gain first evidence on the effectiveness of LMHP before investigating any potential indirect effects on employees. Sixth, we collected no information on user satisfaction with the digital game-based training that would allow us to make objective inferences about acceptance of and engagement with the training. However, some pretests were done to rule out any technical obstacles that could possibly undermine user satisfaction, and the digital game-based training solution was developed based on suggestions made by employees of the participating organization during semistructured interviews upfront. Furthermore, we received a vast amount of positive feedback on LMHP unofficially on completion of the pilot trial, which seems to be mirrored in the high participation rate of 89% (48/54).

Implications for Future Research

Future analysis of data on employees and on EAP utilization, sickness absence rates, or the frequency and duration of disability claims before and after using the training program is essential in evaluating the full impact of LMHP. As the ultimate goal of the training was to create an inclusive and supportive working culture where employees feel comfortable to talk about mental health openly and seek help (early), it would be valuable to include employees' perceptions on whether they feel supported by leaders, and whether and how that changed after the training. Investigating a change in objective data related to employee help-seeking would help establish the business case of investing in antistigma interventions in the workplace.

Even though we cannot be certain, it is very unlikely that a single intervention may be sufficient to end mental illness stigma and change the working culture in an organization. Hence, future research should explore whether training managers is an effective means of supporting employees with mental health problems or whether other interventions targeting employees instead or dual approaches (eg, campaign and training) may be more efficient to achieve cultural change in the long term. Finally, to increase the generalizability of our findings, workplace antistigma interventions targeting employees of different hierarchies in different types of workplaces are needed. Another appealing contribution of future research would be to compare different training formats (game-based vs standard Web-based vs face-to-face) and their effect on user engagement and learning attainment. In general, more digital workplace mental health interventions are needed that incorporate elements of positive psychology and focus on keeping employees healthy, motivated, and productive.

Conclusions

This pilot study provides first evidence on the effectiveness of LMHP, demonstrating its ability to positively affect managers' knowledge, attitudes, and self-efficacy to deal with mental health situations at work. Further evaluation is needed to investigate potential beneficial effects on employees' perceptions of management support, on their acceptance and use of existing mental health interventions (eg, EAP), and on the working culture in an organization. The benefits of digital game-based learning, such as increased participant engagement and reach, make it an effective strategy to facilitate widespread behavioral and cultural change in organizations.

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Conflicts of Interest

None declared.

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Abbreviations

EAP: employee assistance program
LMHP: Leadership Training in Mental Health Promotion
LMU: Ludwig-Maximilians-University Munich
MAKS: Mental Health Knowledge Schedule
OMS-HC: Opening Minds Scale for Health Care Providers
OMS-WA: Opening Minds Scale on Workplace Attitudes

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Original Paper

Peer Communication in Online Mental Health Forums for Young People: Directional and Nondirectional Support

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Abstract

Background: The Internet has the potential to help young people by reducing the stigma associated with mental health and enabling young people to access services and professionals which they may not otherwise access. Online support can empower young people, help them develop new online friendships, share personal experiences, communicate with others who understand, provide information and emotional support, and most importantly help them feel less alone and normalize their experiences in the world.

Objective: The aim of the research was to gain an understanding of how young people use an online forum for emotional and mental health issues. Specifically, the project examined what young people discuss and how they seek support on the forum (objective 1). Furthermore, it looked at how the young service users responded to posts to gain an understanding of how young people provided each other with peer-to-peer support (objective 2).

Methods: Kooth is an online counseling service for young people aged 11-25 years and experiencing emotional and mental health problems. It is based in the United Kingdom and provides support that is anonymous, confidential, and free at the point of delivery. Kooth provided the researchers with all the online forum posts between a 2-year period, which resulted in a dataset of 622 initial posts and 3657 initial posts with responses. Thematic analysis was employed to elicit key themes from the dataset.

Results: The findings support the literature that online forums provide young people with both informational and emotional support around a wide array of topics. The findings from this large dataset also reveal that this informational or emotional support can be viewed as directive or nondirective. The nondirective approach refers to when young people provide others with support by sharing their own experiences. These posts do not include explicit advice to act in a particular way, but the sharing process is hoped to be of use to the poster. The directive approach, in contrast, involves individuals making an explicit suggestion of what they believe the poster should do.

Conclusions: This study adds to the research exploring what young people discuss within online forums and provides insights into how these communications take place. Furthermore, it highlights the challenge that organizations may encounter in mediating support that is multidimensional in nature (informational-emotional, directive-nondirective).

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KEYWORDS

adolescence; Internet; social media, mental health; qualitative research

Introduction

It has been suggested that 75% of all mental illness emerges before the age of 25 [1]. Mental health can impact all aspects of young people's lives, including their relationships, educational attainment, and quality of life [2]. Despite the high prevalence of mental health in young people, this is not matched with the level of service use [3]. Indeed, getting young people

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to access health services can be a challenge, especially services related to mental health [4].

Online Versus Offline Support

The Internet affords a number of features the offline world does not. Research has found many of these features are important for young people seeking health information and offering support [5]. One feature of the Internet is that social cues are limited [6], which allow users to engage with those with whom they would otherwise not do so in the offline world [7], and it produces a hyperpersonal interaction [8]. A reduction of social cues facilitated contact in an online mental health forum, thus overriding differences with peers, such as gender, ethnicity, and disability [9]. The study also found that anonymity of the mental health forums was important, as this increased self-disclosure of forum users [9]. The anonymous nature of the Internet encourages the disinhibition effect [10], in that, people disclose and reveal more about themselves online than they would offline. Disinhibition is viewed to have a positive effect in online mental health forums [11]. Indeed, the features of anonymity, accessibility, and control (in terms of self-disclosure: what and how much people disclose) enables the Internet to provide a safe place to seek help [12]. Online counseling support has been perceived to be more confidential by young people than offline [5,13], with fewer risks, such as parents being informed. The Internet not only provides access to content around issues but also access to people in a similar situation, with no geographical restrictions. It also allows people to offer support, both professional and/or peer support [14]. Therefore the Internet has the potential to help young people by reducing the stigma associated with mental health and enabling young people to access services and professionals which they may not otherwise have been able to access. In general, the Internet can offer young people support through professional and peer support, as well as provide a referral to appropriate services [15].

Online Platforms: An Alternative to Face-to-Face Support

It is generally recognized that young people do not tend to access health services and health professionals, especially in regard to their mental health [4]. Reasons for this lack of access include the stigma associated with mental health issues [4], as well as issues around confidentiality and access [16]. The Internet plays a salient part in people's lives, and it is not just utilized by certain populations or for certain applications. Although it is recognized that a digital divide still exists in terms of who has access and how people use the Internet [17], research suggests that in the United Kingdom there are few young people who do not use the Internet [17]. Furthermore, accessing health information online is viewed as a confidential and convenient way to access information, which young people may find difficult to access offline, and as such, the Internet has become a primary source for general information and health information to young people [16,18].

What Does Previous Research Tell Us?

In regard to mental health, research has considered online forums for young people suffering a number of mental health symptoms and conditions; these include self-harm [19,20], depression [15], those with suicidal thoughts [21,22], and young people with mentally ill parents [23]. The way in which young people use online forums is of increasing interest to researchers. Help-seeking behaviors related to how individuals gain information and support around issues linked to their physical and mental health needs is of particular interest. A notable benefit of online support groups is that the groups are available 24/7, which enables users to receive support and advice when more traditional resources are unavailable [24]. Online support groups also offer the convenience of support from similar people from within their own homes [25]. Research has started to explore the effects of online support for young people with mental health problems and other health issues with results indicating that online forums provide them with emotional and informational support [15,26-28], they can decrease isolation and stress [15,28], and reduce symptoms such as depression [21] and self-harm [20]. In a study looking at the viability of online blogs as a research methodology for young people with arthritis, Prescott et al [29] found that the online environment gave them space and empowerment to express their own ideas and concerns. The young people in the study found blogging to be therapeutic and enabled them to provide detailed thoughts, feelings, and experiences beneficial to researchers of an often hard to reach sample. Indeed, earlier research of an online university mental health community found participants benefited from the therapeutic benefit of writing [11]. Ultimately, online forums have the potential to provide a private and emotionally safe environment; this is especially so for forums that are moderated [30]. Furthermore, online forums maybe particularly appealing to young males who tend to have lower levels of help-seeking behavior than their female counterparts [4].

Peer Support

Research has found forums beneficial to young people as it provided a safe place for them to share, offer, and receive emotional and informational support, again supporting earlier research on the supportive nature of online forums [15]. Recent research investigating online forums for young people with cancer [26] found both the requests for support, and the support provided, were found to be either informational support (which included themes such as medical aspects of treatment, advice to relieve fear, side-effects, and diet) or emotional support (which included themes such as keep fighting, I know what it's like, and non-cancer users providing support). Similarly, research found young people exchanged emotional and informational support, coping, and identity management issues online [27]. The study also found young people used the forum to discuss non-cancer related topics such as music, sports, and friendships. Through the discussion of non-cancer-related topics, the group was able to build a strong community and provide each other with a sense of normality. The study found that many young people with cancer felt they could not talk to their offline friends and many had lost friends since diagnosis. This suggests that young people may not have access to offline peer-to-peer support and proves a potential reason why young people may value online peer support. This is an important finding of online forums, since it is often thought or assumed that young people seek informal support from friends or family members more so than from formal support mechanisms [4]. If this informal

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support is not so easily available offline, then online forums have a potentially vital role in the lives of young people who are vulnerable, isolated, or in some way marginalized.

Online self-help groups can provide a sense of normality to young people [23]. Knowing others have been or are currently going through a similar situation provides a sense of being normal and provides the opportunity to share experiences and feelings [23]. Online forums can provide social contact and support as a supplement to, rather than a replacement of, traditional health services. It was also revealed that professional involvement in forums was a valued aspect [9]. Suggesting forums benefit from some form of professional moderation, a view supported by Webb et al [31] who found a moderated online forum for young people in Australia to be a positive, unique, and helpful experience for young people suffering mental health problems. However, despite the benefits of forums being moderated, in a study aimed at bringing young people and health professionals together via an online forum for young people who self-harm, health professionals did not actively engage in the forum [20]. Reasons for the nonengagement included lack of confidence, private-professional boundaries, role clarity, duty of care, and accountability. Nevertheless, despite this lack of engagement by health professionals, the young people in the research shared their experiences and developed a strong community online. More research needs to consider barriers health professionals may face reaching young people through online forums.

Help-seekers have been found to provide support for others, suggesting young people adopt dynamic roles when using online forums that allow them to tell their stories and develop an online community of support [22]. It has been recommended that online support groups and forums should encourage active involvement to facilitate emotional relief and distress [21]. Active participation in support groups involves posting initial messages, responding to others, or receiving replies [21].

McKiernan et al (2017) [32] found that a small percentage of forum users directly requested advice or information (directive queries) from others and concluded that forum users were either uncomfortable with or not interested in receiving suggestions on how to behave. Instead, they were more interested in other people's experiences and opinions to help them make their own decisions regarding their actions (nondirective queries). Although it was uncommon for forum users to use directive queries, when considering both moderator and user queries, moderators were more likely to use nondirective queries to elicit experience and opinion suggesting a facilitative role. One major problem that young people could face when bonding online with other young people with mental health issues could be a negative mood induction (or triggering) due to hearing about difficulties in other people's lives [33,34]. Other issues which may impact young people's use of forums that needs to be taken into consideration include data security, technical issues, and user safety [35].

It is evident that online support groups can support and empower young people, help them develop new friendships, share personal experiences, communicate with others who understand, provide information and emotional support, and most importantly help them feel less alone and normal. Often online communities develop for young people who do not feel supported in the offline world or they may want to discuss issues they feel embarrassed to share with their offline friends due to risk of stigma or embarrassment [23,28,36,37]. It is, therefore, important to understand online mental health forums for young people with a variety of concerns and needs. Furthermore, it is essential to consider the way that individuals engage with these services and how individuals may be supported to receive and provide support.

The aim of this research is to gain an understanding of how young people use online forums for their emotional and mental health issues and to gain an insight into how they support each other through this forum that is part of a wider online counseling service. The data covers a 2-year period, providing rich in-depth analysis on the ways young people interact. Specifically, the project examined what the forum users discussed and how they sought support through this platform (objective 1). Furthermore, it looked at service users' responses to initial posts to gain an understanding of how peer-to-peer support was provided (objective 2).

Methods

Kooth is an online counseling service for young people aged 11-25 years experiencing emotional and mental health problems. It is based in the United Kingdom and provides support that is anonymous, confidential, and free at the point of delivery. Kooth offers young people a number of services including drop-in and one-to-one chats with fully trained counselors, a themed moderated message forum, a secure Web-based email, and an online magazine. Young people register on the site using an anonymous user name.

The Forum Data

The themed moderated forums on Kooth are relationships, bullying, eating disorders, depression, self-harm, health, friends, family, and ideas for Kooth. Despite having themed forums, the dataset was initially analyzed afresh by the researchers, rather than keeping the data within the themes devised by the Kooth site. This was undertaken by the researchers so as to allow the data to lead the theming, an inductive approach to data analysis [38,39], and capture any areas not outlined in the organization's framework. The quotes have been kept in full to give a transparent flavor of the communication.

Kooth provided the researchers with all the forum posts (1 dataset) between a 2-year period (initial posts, posted on the forum from December 12, 2013 to December 31, 2015) that resulted in a dataset of 622 initial posts, 3657 initial posts and responses, 8 moderator initial posts, and 113 moderator posts and responses. The dataset was then divided into 2 datasets for deeper analysis of posters as well as the responses. These will briefly be discussed in turn below.

The first dataset was the initial posts (the help-seekers' posts; 622 posts), analyzed to understand the issues young people wanted to discuss or seek support for, as well as to understand how young people started conversations and posts on this site (objective 1).

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The second dataset included both the initial posts from individuals we will refer to as posters and the responses to each of the posts from individuals we will refer to as responders. This was the largest dataset with 3657 posts analyzed, to gain an understanding of how young people provided each other with peer-to-peer support (objective 2). Young people set up a username to post on the forum. Since the young people are posting on the forum for genuine, rather than research purposes, the research team decided not to include any username details so that all quotes are unidentifiable and completely anonymous. Due to the anonymity of the site, no participant information is available.

Data Analysis

In total, the overall datasets included 160 unique posters (dataset 1) and 1320 unique posts (posters—the person who initiated the post on the forum, and responders—people who responded or commented on the initial post) overall (dataset 2). The most comments on a post was 170, and the least was one (a few posts received no response); however, most posts received between two and ten comments. All data was analyzed using Nvivo version 10 software (QSR International). The qualitative approach used to analyze each of the datasets was thematic analysis [38]. All authors reviewed the themes and discussed at length to refine the themes, the subthemes, and the hierarchy. This refining process helps to demonstrate the overall trustworthiness within the data analysis [40]. To ascertain and increase intercoder reliability and the reliability of the results, the raw data was read by all authors to develop a coding framework and code book. Once the code book was established, author KU, employed as a research assistant on the project, coded the datasets accordingly.

Ethical and Research Approvals

Approval for the study was received by University of Bolton Research Ethics Committee in January 2016.

Results

The results will be discussed in terms of addressing objective 1 from dataset 1 first, then objective 2 from dataset 2. The analysis revealed the following themes and topics (Table 1) related to the two objectives and datasets. Table 1 shows the main themes, topics, and an example quote from the interview analysis.

What Young People Discuss

Young people discussed a range of mental health (such as anxiety, depression, panic attacks, eating disorders, suicide, and self-harm) and physical health issues (such as pregnancy, periods, cancer, diabetes, and epilepsy). They also discussed numerous issues related to interpersonal relationships, which included friendships, sexual relationships, family issues, death, isolation or loneliness, and bullying. Other issues that were frequently discussed included those related to school (anxious about school, too much school work, and not fitting in), sexuality (coming out and confused), and identity issues (self-esteem or confidence, appearance, and being different). Although this is not a complete list of the issues discussed, it is apparent that the themes suggested on the forum do not limit, or in any way restrict, the discussions on the forum.

It was also observed that the young people in the forum frequently posted and responded to noncounseling-related issues. For instance, there are a number of posts discussing topics such as music, film, and pets, and there are plenty of jokes on there too. These discussions suggest a sense of community and friendship, aside from the problem specific supportive element of the forums, being developed on the forum and also the sense of wanting to share. Interestingly, there is discussion of Internet and social media use, with security or privacy issues, the benefits of anonymity, as well as the ability and benefits of sharing with others online in a similar situation as highlighted in the example quote in Table 1.

How Young People Seek Support

In terms of how the young people seek support, posters tended to approach this in one of two ways. Either by direct request for advice, with a themed heading followed by a post with more detail about the specific advice they require, or a direct question within the post itself. The example quote in Table 1 is by a young person asking for advice on how they can cope with panic attacks. Indeed, the title header of the post states this is what the poster is seeking advice on, which is then followed by more detail on the issue and further detail on the specific advice they are seeking. In this instance it's about seeking advice on how to deal with them, in particular how to cope during class.

Other ways the young people sought advice was by finding other young people on the forum who shared similar feelings or were in a similar situation to themselves. Through doing this, young people were able to start a dialogue relevant to their concerns and issues and hopefully gain support through the responses received. Many posters provide detailed background information when seeking support or advice as shown in the example quote in Table 1.

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Table 1. Objectives and themes.

Objectives		Example quote
Objective 1		
What young people discuss	Mental health issues, physical health issues, interpersonal relationships, school-related issues, sexuality, identity issues, noncounseling-related issues	I use Instagram to talk to people who have the same sort of feelings as me. I think it is a good thing because it has helped me get a better understanding of what exactly it is that I'm feeling and sort of a sense of security because I know I have people I can talk to and I know I'm not alone with this. I think problems occur when people pretend to be someone that they aren't...
How young people seek support	Direct request for advice	How to cope with panic attacks? -Lately all my panic attacks have been getting worse and extremely frequent. I'm getting them in school especially. How do you cope with them personally? And, what do you do if you get them in class? Their really getting in the way of everything, and I don't know how to deal with this anxiety anymore.
	Seeking others in a similar situation or with similar feelings	My parent has depression, advice? So I'm 17 and old enough to understand what and how bad depression can be. But I never expected for my mum to be diagnosed with it. You can only do so much; I'm 17 and still find it a daily struggle to watch someone I love and care for with every breath go through such an awful illness. What are your thoughts do you have any advice?
	Offering support	Adoption: Hi, I am X 2754. I am adopted and don't always believe my parents love me. Because of this, I know it's hard being adopted and people who are adopted all understand this. We may all experience separation and flashback anxiety; I have terrible anxiety, always constantly thinking my birth parents are trying to track me down and are watching my every move. It's hard to overcome these anxieties. I just think to myself, "try to get on with life; you only live once, don't let it overtake you when you're still young also don't waste your life because you're in this situation, make the most of life whilst you still can. Never think that your family now don't love you; they OBVIOUSLY DO, OTHERWISE THEY WOULDN'T HAVE ADOPTED YOU IN THE FIRST PLACE." I hope I help people with anxiety and panic attacks who suffer from these because of being adopted that you only live once, and don't let it be misery but happiness. Good luck to you all; let adoption strive forward.
Objective 2		
Emotional support	Nondirective emotional support	I can completely relate to all of these comments. I have attempted before but now I feel like they don't treat my feelings seriously like if I'm not hurting or trying to take my life although it still comes to mind that I'm not feeling a certain way...nobody around me understands me. But on kooth, I feel like the community does. At least on here, there are people who can say that it isn't just you Yano. You don't have to go it alone. We take you seriously. You are exactly who you are supposed to be and you fit perfectly into your own spot in life, even though it may not feel like it, you are important to a lot of people.
	Directive emotional support	I have had a fair few panic attacks in my life and I understand how HORRIBLE they are. My first panic attack was when my insomnia was getting seriously bad and I started panicking about not sleeping and I just lost it. From my personal experience I would recommend, 1, talking to someone about it, what you're going through, helpful ways of dealing with it, and also to get your worries off your chest, which can help a lot trust me. 2, tell people. The more people know, the more people can help you when you are in that state. But only tell people you know very well and trust.

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Objectives		Example quote
Informational Support	Nondirective informational support	I found papyrus and the Samaritans particularly good as I emailed them when I was having a hard time living and still am but they're very helpful and it's not just for suicide you can talk about anything with them and they'll listen and they're good to vent for. As I've been self-harming for three years and only recently noticed how bad I've gotten and how different I am to others and they helped me get to the root of my problems and gave me the courage to see a doctor as did the counsellors on kooth who then gave me a cahms referral [camhs stands for Child and Adolescent Mental Health Services, a specialist NHS service].
	Directive informational support	Can you confront your friends about this? Or find an interest you both share? You don't need to be a normal teenager, and if they're treating you like this, then they are not the friends they seem. It may seem easier said than done but how about joining a club to make new friends. A typical response, yes, but joining a club is one of the best ways to meet people who share your interests. And if there are no clubs in your area that support your interests, how about starting one. As for your diabetes, if you can't confront your father about this, is there someone who can? Can you contact your mother in any way? Or perhaps you could visit your local GP surgery or school nurse for some advice on coping with your illness. Good luck.

Not all of the posters sought support; many posters instead offered support in their opening post. Through starting a communication on the forum on a specific topic relevant to them allows others to comment and receive support. Responses to advice giving posts include seeking further advice and further developing some kind of friendship. For example, it can be seen from the following response that the opening, initial post provided an opportunity for others to seek advice and support:

> *I have a friend that is adopted and sometimes when there upset I don't know what to say something and I am scared to say something about my home life in front of her I don't know how to cheer her up when she is upset Can you help Btw I think you're really brave telling this.*

Many young people provided support from personal experience, telling their story in a cautionary way for others to learn from. The following poster is sharing their experience of self-harm and informing others what it is like to self-harm; discussing the emotional battle they have gone through, the physical implications, and warning people against it, as in the quote below:

> *I don't know how to deal with it-Hi I feel so horrible about self-harm. At the minute I'm really trying to stop cutting myself so much because it suddenly hit me hard when I looked at myself in the mirror. My legs are full of scars a deep purple scar on my arm and there is now a new one on my wrist. Okay the one on my arm just looks like an accident, but I now know how it would look to other people. No matter how hard I try, I can't cover or fade them. The depression and anxiety around it has grown worse, and I think more about cutting. Please guys, if you have not yet self-harmed and you are considering it, just think could you look at your injury every day? Do you want to create a cycle? If you want to get better, just start by asking yourself these questions because doing something like self-harm has harsh consequences that might make things worse.*

In light of previous research, it could be posited that posters offering support rather than seeking it are perhaps gaining from the therapeutic benefits of writing and sharing their experiences with others in this online context. The encouraging responses in terms of how their advice has been positively received may also provide posters with emotional support as well as through the gratitude observed in responses, such as, *Your advice is very kind thank you for posting this,* and *Thank you for your last piece its important people know that.* However, the data does not allow us to determine if this is an actual goal of the posters.

Support on the Forum

The main forms of support provided by responders on the forum can be classified as emotional and informational support. When examining this further, this emotional and informational support can be viewed as being provided either in a directive or nondirective way. For instance, nondirective emotional support would involve the responder sharing an experience and not explicitly following this with advice, whereas directive emotional support would involve the responder sharing an experience while also advising on what to do. Similarly, nondirective informational support involves the responder sharing information and not providing explicit advice, while when offering directive informational support the responder shares information while also suggesting the poster do something. Figure 1 illustrates the support provided from the forum data analysis.

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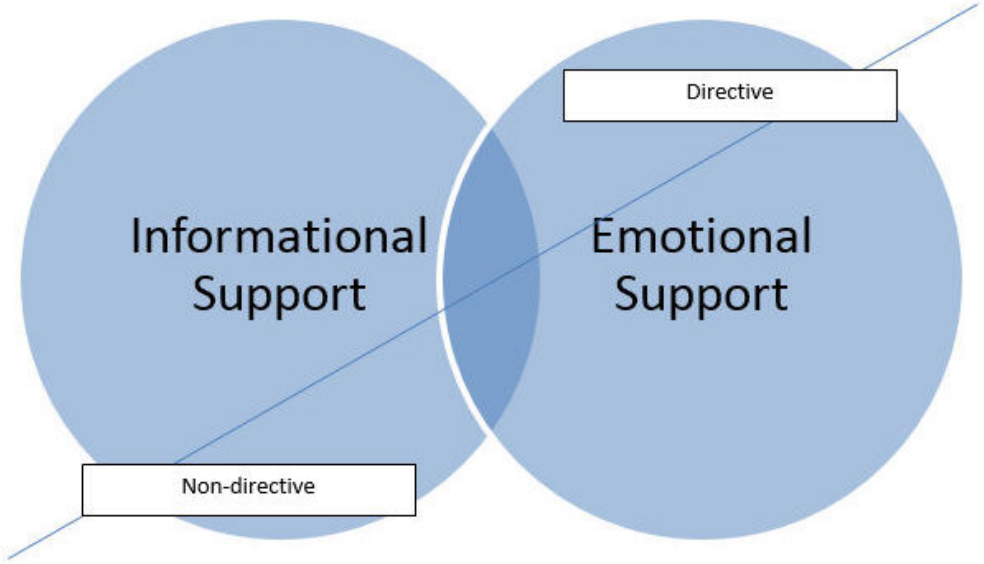
Figure 1. Type of Support.



Emotional Support

The emotional support theme includes responses such as you are not alone, things will get better, it's not your fault, don't worry about what people say or think, empathizing, sympathizing, understanding, how to grow from the experience, it's normal, you're perfect the way you are, and I'm here if you want to talk. There were also a number of encouraging phrases used such as be yourself, do what is best for you or makes you happy, believe in yourself, be brave, have confidence in yourself, and look to the future. Some of these responder posts are encouraging but cautious. For instance, the following responder, despite being emotionally supportive and providing encouragement to the poster, is suggesting they wait until they are older before they make any decisions, as in the quote below:

> *Do what comes naturally to you I'd say; wait a few years after school and puberty and your hormones. I know I probably sound like I'm just saying it's a phase but honestly it could well be.*

Nondirective Emotional Support

A lot of the responders shared their own personal experiences in a nondirective way to provide or offer emotional support to posters. In the example quote in Table 1, the initial poster had described feeling alone and describes suffering from depression with little support from offline sources. One of the responders provides nondirective emotional support, expressing how they too have previously felt in a similar situation and how the community online can help as it had helped them previously. The response is supportive and encouraging. It is encouraging in that the responder is supporting the poster to reach out to people online, expressing that they will be taken seriously in this online environment, and they are a community who understands and supports. There are many examples of this type of emotional support where the support is provided by the responders showing empathy and knowledge through their own experience of being in a similar situation or experiencing similar experiences or emotions.

Directive Emotional Support

The forum data contained less directive emotional support compared with nondirective; however, this type of emotional support was provided on occasion. The blurred boundaries between nondirective and directive support were evident in the data. The example quote in Table 1 provides an example of a responder commenting on a post with nondirective emotional support. The responder in the first instance is describing how they understand due to having themselves gone through a similar situation or experience, in this case, panic attacks. The responder then moves on to provide the poster with some more directive practical advice by suggesting they talk to someone about it, highlighting how talking about it had helped them in the past.

Informational Support

Informational support in the form of practical advice is provided frequently on the site. For example, how to deal with a condition or issue, to provide others with information on a topic, or where to seek further help or answers.

Nondirective Informational Support

Responders frequently provided information to posters that they themselves found useful when they were going through similar difficulties based on experiences and emotion. Responders tended to provide a level of personal detail to provide the informational support or suggestions on how to help the situation as highlighted in the quote in Table 1. It can be seen from this quote that the responder is not just suggesting to the poster to contact the organizations mentioned but is instead telling the poster how useful they found them when they were going through a difficult time. The responder is disclosing to the poster their personal story to provide this information rather than simply stating who may be able to help.

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Directive Informational Support

Although there are frequent examples of nondirective informational support as exemplified above, it was more frequently observed that young people offered more directive forms of informational support. In the example provided in Table 1, the poster had discussed having a number of issues and not knowing where or who to turn to. One responder offers support in the form of directive informational support suggesting the people they may be able to contact such as friends, general practitioner (GP) surgery, or school nurse. In contrast to the nondirective informational support, this response has no personal story to support why they are suggesting the advice they are or indeed why they think the poster should contact certain people as evidenced from the example quote for the nondirective informational support. It is however clear that the advice, although lacking in any personal background story, or experience, is empathic in nature, and the responder is trying to provide the poster with some encouragement and support.

Despite the variety of issues discussed on the forum, analysis revealed that some mental health or emotional issues tended to get a particular response. Table 2 illustrates the issues that received specific styles of response or support.

Table 2. Issues and support received.

Issues	Support theme	Approach
Transgender	Emotional support, for example, be yourself	Nondirective
Anxiety and panic attacks	Informational support	Directive
Self-harm	Emotional and informational	Directive
Bullying	Emotional support: not alone	Nondirective
Pregnancy related	Informational support	Directive

Discussion

Principal Findings

The study examined what the forum users discussed and how they sought support and found that forum users were provided with both informational and emotional support. This is consistent with previous research findings [15,26-28]. However, the findings from this large dataset reveal that this informational or emotional support can also be considered as coming from one of two approaches; directive or nondirective. The nondirective approach refers to young people providing others with either informational or emotional support by sharing their own experiences. The majority of responses were from young people in a similar situation, sharing practical advice or information on what works or worked for them, or what they have been recommended by health professionals. In light of previous research findings [25], through sharing similar experiences, the young forum users gained an understanding that they may not have received from their offline friends and family. The sharing of experiences also appears to provide empathy, the feeling of being less isolated, and that individuals are not alone in their situation; helping to provide some sense of normality and thus providing emotional support. The directive approach, in contrast, is associated with offering more practical advice. In using this approach, responders were able to help others with whom they may not share experiences but they still want to, and feel able to, offer support; adding a new dimension to peer support online.

The nondirective responses observed in the forum interactions might be considered in a similar vein to the therapeutic style advocated by person-centered therapists [41]. From this perspective, therapists are encouraged to be mindful of the client's frame of reference, and thus, be more tentative in making assumptions about a person's particular circumstances. Stereotypically, and we acknowledge the complexity inherent in such dynamics, responses from therapists might reflect back and summaries the words of those being helped, rather than explicitly direct the client to new ideas or ways of thinking. In all instances, therapeutic interventions would not be offered with the intention to steer the conversation to new territories but to communicate understanding and empathy. Here we note that the responses from the users in the forums varied greatly in style, but many might be construed in this nondirective way. Thus the respectful, caring tone of the responses, rather than the practical directive advice, can therefore be viewed as an important resource in such environments.

Considering the directive or nondirective form of support provides a novel approach to understanding how young people seek (posters) and provide (responders) support via an online forum based on their experiences. Posters tended to use more directive approaches when seeking support. However, even when directly requesting advice, posters often explained their personal situation to request advice in the first instance. What is most striking from the analysis is that many posters were not seeking support but instead were posting on the forum to offer what appears to be support to others on the forum. This could be linked to the disinhibition effect of the Internet [10] and the positive effects of disinhibition of mental health forums [11]. Offering support that has not been requested could be an avenue for young people to share their experiences on the site. This may provide those posters with the therapeutic benefits of writing about their difficulties [11,29], very much suggesting a dynamic approach to online support [22]. They may also share in the aim of potentially supporting others in similar positions. It would be interesting to understand this approach by young people in more depth, this perhaps being a feature of young people's use of online support as a less conventional approach.

The implications of the directional and nondirectional approach of forum usage could highlight to young people how their views and personal experiences may be used and helpful to other

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young people. Moderators of such online forums might want to consider the impact of postings that are more directive in nature, since they may not always be accurate and be based more on opinion than evidence or fact. Furthermore, if someone is asking for advice and the response they receive is reflection, then moderators may want to mediate so that the posters receive what they have requested. In terms of future research, it would be interesting to explore what people gain from the different response styles. It is interesting that certain issues primarily received a certain type of response, whether that be emotional or informational support and whether that comes from a directive or nondirective approach. Reasons for this would help researchers and health professionals understand forum use and health information seeking of young people and enable the development of future online services.

Findings revealed the young people using the forum were not limited to topic specific issues. It was also observed that different issues tended to receive different types of support and responses. This is particularly interesting and somewhat important, since much of the literature investigating the use of online forums focuses on issue or topic specific forums, such as self-harm [20,19] or depression [15]. Young people could discuss anything that concerned them, even discussing things that were not directly a health or mental health concern, such as music, films, and pets —a factor that perhaps reflects the holistic or humanistic position taken by Kooth. In these instances, music was openly discussed as being therapeutic, with the sharing of new music or favorite music with others helping to develop communities and provide what they considered to be uplifting music to others. In a similar vein, other topics were discussed and seemed to provide young people with a platform to talk to each other and build a community in a safe and friendly (moderated) environment. Jokes were often told, again presumably to build a fun community. This noncounseling discussion on the site supports previous research [26]; these discussions suggest a sense of community and friendship, aside from the problem specific supportive element of the forums, being developed on the forum and also the sense of wanting to share.

Interestingly, there is discussion of Internet and social media use, with security or privacy issues, the benefits of anonymity, as well as the ability and benefits of sharing with others online in a similar situation. Young people discussed the Internet more generally and social media such as Instagram and Facebook and how they used them to connect with others and offer each other advice on online safety. Supporting previous findings related to the affordances of the Internet benefiting young people seeking support online [5,13-15,31]. This may also potentially link to previous literature [27], suggesting that young people feel comfortable discussing issues outside of the topic areas not necessarily related to mental health issues.

Strengths and Limitations

Despite researchers growing interest in the area, much of the research has been conducted on an adult population. Research that has considered young people has tended to be conducted with university-based counseling sites [4,11,15] or sites set up specifically for certain conditions such as self-harm or depression [20-22], whereas this study is based on a large dataset of forum data from an established and active online counseling service aimed specifically at young people, allowing young people to discuss any issues relevant to them. A major strength of the study is that the study was conducted using a large dataset of posts and responses. These were posted over a 2-year period to an active and well-established online forum providing support for young people with emotional and mental health issues. This large set of forum data enabled the researchers to gain a deeper understanding of how young people used the forum; what they discussed, how they sought help, and how they provided peer-to-peer support on the forum. In particular, a major finding of the study is the novel approach of the support young people provided; either directional or nondirectional. This finding should be recognized as an important attribute of peer-to-peer support provided by young people using the forum.

There were many different emotional and mental health issues discussed. It is evident that despite the site having themed topics of discussion, what is discussed on the forum is not restricted or limited to these themes, and it is apparent that young people feel comfortable discussing issues outside of these areas on this forum. This suggests that the forum provides a safe environment for young people to disclose, supporting previous findings in the area [12]. Perhaps due to a reduction in social cues and the anonymous nature of online communication enables this safe environment [9].

Despite the strengths, a number of potential limitations and challenges should be acknowledged. First, the forum data did not allow for the researchers to take into account any demographic considerations such as age, gender, or location of the users of the forum. Demographic considerations would provide further insight into who uses the forum for support. This information may establish any demographic groups who do not use the site. This information could prove useful for service providers in accessing and potentially reaching a wider demographic or target hard to reach young people who may not be aware of the site. However, due to the anonymity of the site, it was not possible for this study to gain such information.

It could also be beneficial for researchers and service providers to know how young people use forums such as Kooth in conjunction with other services the site offers, such as one-to-one counseling, as well as how they use the site in conjunction with other counseling and health services, both online and offline. In essence, a deeper understanding is required into why the young people use this particular site and if they use other services for support.

It was notable that the responses and style of support varied greatly, with some posts reflecting content that might not always be construed as positive, or in some cases accurate. Such a dynamic proves a challenge to service providers, with the assessment of when to moderate or censor posts proving a major challenge. Future research may consider the impact of the multidimensional nature (informational-emotional and directive-nondirective) of responses to posts and how posters receive them.

Another limitation of the study is that the forum data does not give any real indication of how the responses are received and

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how helpful the responses are to young people. Further work is needed to explore the advice received and how the support provided is utilized. It is evident from the dataset that posts are online for a significant period of time, with young people able to continue to read and respond to these posts years after the initial posting. It would therefore be interesting to understand how these archived posts continue to help and support young people.

A further limitation is the limited generalizability of the findings. The findings from the study may be applied to other contexts of a similar online setting for young people. Indeed the findings may resonate with how young people approach online mental health services and health information more generally online. It should also be noted that the findings are based on the online forum service offered by Kooth and that this is just one of the services Kooth provide for young people seeking support with mental health and emotional issues. Due to the anonymity of the site, the extent of the needs of the young people using the forum is unknown to the researchers. Furthermore, it is not possible to identify where else young people gain further support either via Kooth or through other services.

It has been noted that online forums are viewed more positively when moderated [9,31]. Further research may consider the role of the moderator and how they recognize, and indeed manage, any such issues that might arise.

More research on the views of the young people who frequently and actively use online forums may help consider the potential downside to online forums. Previous research [21] suggests that active participation increases the likelihood of gaining benefits from being involved in online forums. Further understanding of participation level in online forums would also add light to how people use and potentially benefit from them, especially from young people who may be considered “lurkers” rather than active users of such forums.

This research indicates that the variety of support approaches may have different benefits to different people with a wide range of emotional or mental health needs. Further research might therefore consider these differences in the adoption of these approaches.

Conclusions

This study provides a unique insight into how young people seek and provide each other with online support for their emotional and mental health needs from a large dataset of online forum posts, adding to the developing body of research exploring the way young people interact in online forums. The research highlights the breadth of issues that young people discuss in online forums. Furthermore, it demonstrates how this medium can provide young people with a place to seek and provide emotional and informational support. In addition to this, it is interesting to observe that those using the site provide support in directive or nondirective ways, a factor that poses questions for those moderating such services. More research is clearly needed to examine the nuances of such interactions and community building processes.

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Conflicts of Interest

None declared.

Authors' Contributions

JP and TH were involved in the concept and design of the study. KU, JP, and TH made major contributions to data analysis. All authors made major contributions to the write-up and editing of the manuscript. All authors read and approved the final manuscript.

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Original Paper

Web-Based Cognitive Remediation Improves Supported Employment Outcomes in Severe Mental Illness: Randomized Controlled Trial

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Abstract

Background: Finding work is a top priority for most people; however, this goal remains out of reach for the majority of individuals with a severe mental illness (SMI) who remain on benefits or are unemployed. Supported employment (SE) programs aimed at returning people with a severe mental illness to work are successful; however, they still leave a significant number of people with severe mental illness unemployed. Cognitive deficits are commonly found in SMI and are a powerful predictor of poor outcome. Fortunately, these deficits are amenable to treatment with cognitive remediation therapy (CRT) that significantly improves cognition in SMI. CRT combined with SE significantly increases the likelihood of individuals with severe mental illness obtaining and staying in work. However, the availability of CRT is limited in many settings.

Objective: The aim of this study was to examine whether Web-based CRT combined with a SE program can improve the rate return to work of people with severe mental illness.

Methods: A total of 86 people with severe mental illness (mean age 39.6 years; male: n=55) who were unemployed and who had joined a SE program were randomized to either a Web-based CRT program (CogRem) or an Internet-based control condition (WebInfo). Primary outcome measured was hours worked over 6 months post treatment.

Results: At 6 months, those participants randomized to CogRem had worked significantly more hours (P=.01) and had earned significantly more money (P=.03) than those participants randomized to the WebInfo control condition. No change was observed in cognition.

Conclusions: This study corroborates other work that has found a synergistic effect of combining CRT with a SE program and extends this to the use of Web-based CRT. The lack of any improvement in cognition obscures the mechanism by which an improved wage outcome for participants randomized to the active treatment was achieved. However, the study substantially lowers the barrier to the deployment of CRT with other psychosocial interventions for severe mental illness.

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Trial Registration: Australian and New Zealand Clinical Trials Registry (ANZCTR) 12611000849998; http://www.anzctr.org.au/TrialSearch.aspx?searchTxt=12611000849998&isBasic=True (Archived by WebCite at http://www.webcitation.org/6sMKwpeos)

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KEYWORDS

severe mental disorders; supported employment; cognitive function; cognitive remediation; randomized controlled trial

Introduction

Functional recovery in people with a severe mental illness such as schizophrenia remains poor with high rates of dependence upon government benefits and significant difficulty with social isolation. An important index of a good recovery is a return to employment as this requires the individual to be able to combine motivation, cognitive performance, and the ability to relate to others. However, in the developed world few people with schizophrenia are employed. In the clinical antipsychotic trials of intervention effectiveness (CATIE) study, only 14.5% of subjects with schizophrenia had participated in competitive employment in the month before enrollment in the study [1]. In Europe, in a survey of the United Kingdom, France, and Germany by Marwaha and colleagues, only 7.6-11.8% of people with schizophrenia were supporting themselves entirely through work [2]. In Australia, only 22.4% of people with a psychotic disorder were in either part or full time employment, and this employment rate had not changed in a decade [3] despite paid employment being a priority for many [4]. This failure to return to competitive employment ensures continued poverty and marginalization for most people with a severe mental illness and shuts them out of important sources of socialization and integration with the rest of the community.

The reasons for such poor rates of employment are numerous and include the obvious effects of illness, especially negative symptoms [1,5] and the interruption to education and training caused by the onset of a psychotic illness during late adolescence and early adulthood [6,7]. However, one of the most significant contributors to poor outcome are the neurocognitive deficits of psychosis [1,8-10]. These deficits are broad based and severe [11], exist at the time of first presentation to mental health services [12], and persist [13]. Unfortunately existing pharmacological approaches fail to treat these deficits [14]. However, the development of effective treatments for cognitive deficits in psychosis variously known as cognitive remediation therapy (CRT) or cognitive training, suggests an alternate treatment approach to these problems [15,16]. Importantly, this translates into improved real life functioning more readily if CRT is combined with another psychosocial intervention [15,16]. One such intervention that has been shown to consistently improve return to employment in people with a severe mental illness is supported employment [17].

A number of trials have examined the combination of cognitive remediation with employment-based interventions [18-25]. Bell and colleagues combined CRT with a transitional employment program to significantly increase hours of work over 6 months [20]. In a second study over 24 months, individuals who received both CRT and a vocational intervention worked more hours and were more likely to stay in work than those who received the vocational intervention alone [19]. These gains were best in the participants with the lowest community functioning [25]. McGurk and colleagues also demonstrated that the addition of CRT to vocational programs significantly improved the likelihood of successful placement in and retention of employment for individuals with schizophrenia [18,21]. On the other hand, Au and colleagues [23] were unable to find an advantage for combining CRT with supported employment in Hong Kong in a trial notable for its high rate of job placement.

The extensive use of computer-based cognitive remediation in treatment raises the question of whether Internet-delivered cognitive remediation without the extensive use of skilled therapists is effective. This is a rapidly expanding part of Internet-delivered services; however, a recent review has cast doubt on provider's claims of effectiveness [26]. Nonetheless, the development of Internet-based CRT provides a means of delivering treatment in a way that enables a far larger number of people with cognitive difficulties to engage with it.

The aim of this study was to combine a supported employment (SE) program with Internet-based CRT in a randomized controlled trial (RCT) to test if this could improve the employment outcomes for people with a severe mental illness in frontline services.

Methods

Study Design

This study is an RCT of Internet-based cognitive remediation plus supported employment (CogRem) versus Internet-based information plus supported employment (WebInfo). In total, 89 participants were recruited from supported employments services situated in metropolitan and regional New South Wales, Australia. All participants who were unemployed and actively seeking work via a SE program (the Disability Employment Service [DES]) were invited to take part in the study. Participants were in the age range of 17-65 years, had English language skills adequate for understanding written instructions and completing assessments, and had a diagnosis of a severe mental illness (schizophrenia, schizophreniform disorder, schizoaffective disorder, bipolar disorder, or psychotic depression). Exclusion criteria were limited to having an intellectual disability or a diagnosis of substance dependence other than nicotine or caffeine. All sites were rated as to their compliance with the SE model using the Supported Employment Fidelity Scale [27].

Prospective participants were invited to take part in the study by their DES case manager. After reading a participant information sheet and agreeing to it, they logged on to a purpose

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built website and were asked to complete demographic and baseline measures. After the completion of those measures, they were randomized to one of two Internet-based programs and asked to log on twice weekly to that website either at home, their DES office, or at another rehabilitation support site. All participants had access to computers either at their DES provider or at a Clubhouse at a minimum. DES case managers were asked to encourage participants to continue to log on but were not expected to provide any other coaching or intervention. They were not blind to the allocation of the participant. The DES case managers recorded employment outcomes in detail as the performance on these outcomes form the basis of remuneration to the program by the federal government. This information was recorded for the 6 months after employment commences and was independently audited for accuracy by external government agencies.

Measures

Assessment of cognition was carried out before randomization and at 6 months using the WebNeuro, which is an Internet-based neuropsychological battery [28]. The cognitive domains tested included attention and concentration (continuing performance task—reaction time, omission, and commission error rates), working memory (digit span forward and trials correct), memory recognition (word list recognition and learning rate), information processing speed (verbal interference, choice reaction time, and switching of attention), response speed (motor tapping), and executive functioning (maze completion time and total errors). The battery takes 45 min to complete, and there are multiple forms for repeated assessment [29]. Scoring was conducted using automated software embedded in the program, and data were downloaded from the Brain Resource website.

DES staff collected information on hours worked, wages, number of jobs, and type of jobs at 6 months. This was required by the government agency funding the SE package. Other outcomes included paid work, voluntary work, or education. Function was also measured using the Role Functioning Scale [30], an observer rated scale with four domains: working productivity, independent living or self-care, immediate social network, and extended social network. This was also completed by the DES worker.

Symptomatology was measured using the Behavior and Symptom Identification Scale-24 (BASIS-24) [31], a self-rated scale measuring a broad range of psychopathology and substance use developed and validated for Web use. Function and quality of life was self-rated using the World Health Organization Quality of Life-BREF (WHOQOL-BREF), a 26-item rating scale [32]. These ratings were completed on the Web via the CogRem portal.

Intervention

Participants accessed all material via a purpose built website. This website was used to centralize all assessments, except for the cognitive testing that required a separate log-on to another website. Once randomized, participants were provided with password access to either the treatment (CogRem) or control group (WebInfo) and were sent an email with instructions. This information was also sent to the DES workers so they could assist participants if required. Participants in the CogRem group were requested to use 4 commercially available cognitive training packages—Lumosity, Brain HQ, MyBrainSolutions, and Scientific Brain Training Pro. Participants were not directed to any one exercise or website but suggested to sample and use as many as they liked. All access and costs for this were paid over a 4-month period. Access to BrainHQ was introduced after that product became available; access to Scientific Brain Training Pro ceased after the shutting down of that service. The control participants (WebInfo) were able to log on through the project portal to a large number of free news (eg, ABC News), information (weather and public transport planner), and entertainment (eg, YouTube and music) websites, none of which contained games used with cognitive remediation.

All participants were asked to log on through the study portal twice a week for a total of at least ten hours over a 4-month period. Adherence was monitored by the research team who also provided regular reminders to participants to log on via email. Time on the study website and choice of website was recorded; however, time on proprietary sites beyond the entry onto the study portal, that is, time on a particular game, could not be monitored.

Participants were welcomed into the study and contacted by both telephone and email to encourage them to continue in the study. Participants also received birthday and Christmas cards. There was no direct face-to-face contact with study staff; however, the participants continued to have regular visits with their SE worker. All participants received Aus $25 gift voucher following the completion of the 10-hour training and a further Aus $25 gift vouchers for the completion of the follow-up assessment measures at 6 and 12 months. DES workers and research team provided assistance to participants as required. All DES workers were given a brief orientation to the trial and were encouraged to refer their clients to the study.

Randomization

An independent statistician generated the randomization sequence using SPSS version 15 (IBM Corp). Patients were randomly allocated to either CogRem or WebInfo in blocks of 8 with a 1:1 allocation ratio. This method ensures that the treatment sample sizes were equal after every batch of 8 enrollments. The sequence generated was placed in order in sealed opaque envelopes by an independent person and were opened at the time of allocation by the research assistant. Allocation was in order of contact via the website and was concealed from the participants and their case workers who could only access the study via the website. The study coordinator had no prior knowledge of any participant at the time of allocation and was blind as to the allocation until the envelope was opened. Participants and DES workers were not blind to allocation nor was the research assistant coordinating the project.

Ethics

All participants in this study received written information about the project, and written consent was obtained. The study was approved by the University of Sydney Human Research Ethics Committee (project no. 2012/1350). The trial was registered

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with the Australian and New Zealand Clinical Trial Registry no: 12611000849998 before any participant recruitment.

Statistical Analysis

The sample size calculation (n=150) was based upon published effect sizes of combined cognitive remediation and psychosocial interventions [16]. This effect size was then significantly discounted by half to better reflect the Web-based delivery of the package. A dropout rate of one-third was factored into the final subject numbers [33]. Demographic characteristics were tested using *t*-tests and chi-square tests. The primary outcome for the study was wages earned. Secondary outcomes included number of hours worked, number of days worked, number of hours paid, and number of jobs. These outcomes were tested using nonparametric statistics due to the distribution of results. Secondary outcomes were corrected for multiple comparisons using a Bonferroni correction. Neuropsychological test results were compared using an analysis of variance (ANOVA) design. All statistics were performed using SPSS version 21.0.

Results

Participants

In total, 89 participants were enrolled into the study with 3 being excluded before randomization as they either did not have a psychotic disorder (n=2) or already had a job (n=1). Of the 86 participants who continued, 43 were randomized to each of the two experimental arms—CogRem or WebInfo (see Figure 1). The two groups were well balanced on gender, diagnosis, years of education, medication dose, psychopathology, and baseline functioning (see Table 1). Levels of symptomatology were consistent with other samples of community mental health participants [31]. However, the CogRem group was significantly older than the WebInfo group 42.3 years (standard deviation [SD] 11.0) versus 36.8 years (SD 10.7; df=83; *P*=.02).

Participants were recruited from 8 different sites. The number of participants from each site varied from 2 to 32 with the majority coming from 2 sites. Randomization remained satisfactory across all sites. Sites were assessed using the Supported Employment Fidelity Scale [27] and scored an average of 96.9 (SD 8.2) with a range from 84-107 on this scale, indicating fair to good adherence to the supported employment model.

Table 1. Demographics of participants at baseline.

Variable	CogRem (n=43)	WebInfo (n=43)	Difference
Gender: male, n (%)	25 (58)	30 (70)	*P*=.37[a]
Age (years), mean (SD[b])	42.3 (11)	36.8 (10.7)	*P*=.02
Diagnosis (n)			*P*=.53
Schizophrenia	28	22	
Schizoaffective	2	3	
Bipolar	11	16	
Other psychotic	2	2	
Education (n)			*P*=.56
≤ year 10	11	11	
Year 12	11	11	
Trade or other	11	14	
University	9	5	
CPZ[c] equivalent, mean (SD)	256 (287)	276 (342)	*P*=.79
BASIS-24[d] total score, mean (SD)	1.52 (0.66)	1.66 (0.79)	*P*=.56
Role Functioning Scale, mean (SD)	22.7 (3.7)	22.8 (3.5)	*P*=.91

[a]NS: not significant.

[b]SD: standard deviation.

[c]CPZ: chlorpromazine.

[d]BASIS-24: Behavior and Symptom Identification Scale-24.

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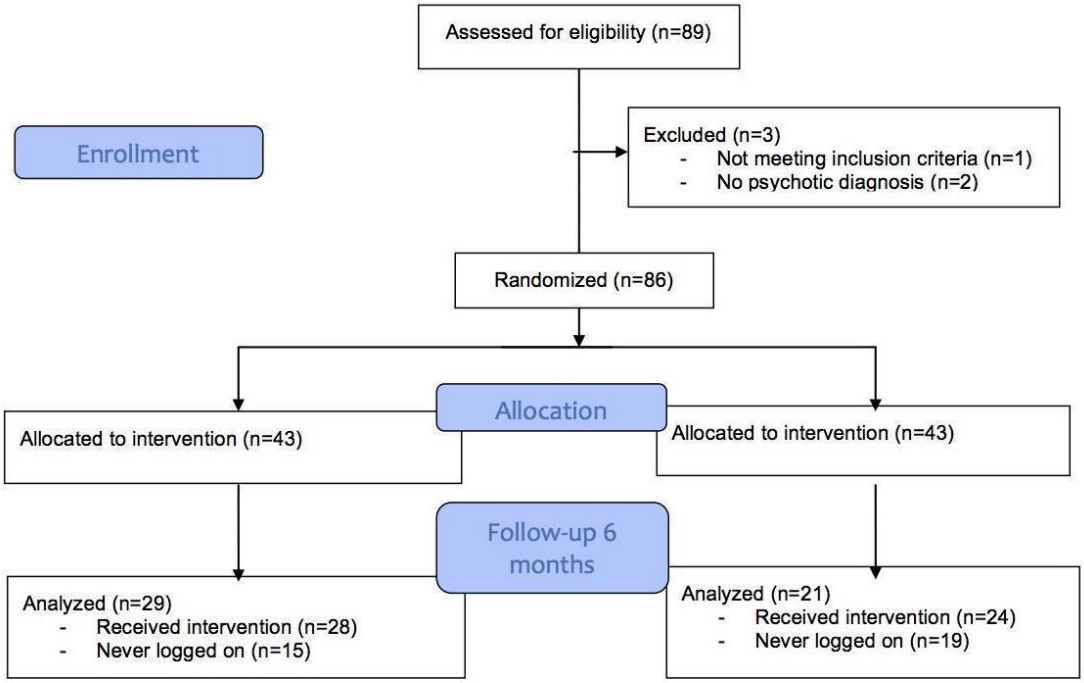
Figure 1. Consolidated Standards of Reporting Trials (CONSORT) diagram.



Participation and Engagement in Study

Dropout was high across the trial with only 49 subjects (57.0%, 49/86) being followed up at 6 months. This did not differ significantly between arms of the study. Subjects who dropped out usually never logged on to the website and were not exposed to either the CogRem (15/43, 35%) or to the control WebInfo (19/43; 44%) site. There was no significant difference in gender, age, diagnostic group, medication dose, or premorbid education between those who dropped out or continued in the trial. However, there was a significant difference on two subscales of the Role Functioning Scale with the participants who dropped out less likely to have a good immediate (t_{82}=3.37, *P*=.001) or extended (t_{82}=2.754, *P*=.007) social network. Those who did continue with the study were exposed to an equivalent amount of content from the study website (CogRem: median [Md]=5.5 hours, WebInfo: Md=6.9 hours; Mann Whitney *U*=331.5, *P*=.93). Those who remained in the study were engaged with their SE case managers seeing them a median of 25 times over the 6-month period.

Employment Outcomes

A total of 23 participants returned to some work during the 6-month follow-up, though for the majority it was infrequent. On the primary outcome for the study (see Table 2) of work place involvement, the CogRem group (Md=168, n=27) worked a greater number of hours than the WebInfo group (Md=50, n=19) (*U*=143.5, *P*=.01), more of which were paid (CogRem: Md=100, n=29; WebInfo: Md=0, n=21) (*U*=202.5, *P*=.04) and earned significantly more wages. Of wages earned, there was a significant difference between the groups with the CogRem group (Md=Aus $1950, n=29) earning significantly more money than the WebInfo group (Md=Aus $0, n=20) (*U*=189.5, *P*=.03). This pattern was repeated across measures and a greater number of paid hours. However, these two results were no longer significant after correction for multiple comparison; the latter two results referring to paid work as against paid and voluntary work or formal study. The two groups did not differ significantly in the number of paid jobs found over the 6 months (CogRem: Md=1, n=29; WebInfo: Md=0, n=20) or the number of days worked (CogRem: Md=51, n=24; WebInfo: Md=20, n=17). There were no significant differences between the two groups in regards to symptomatology or quality of life. There were no differences in relapse rates between the two groups.

Despite the significant differences in financial outcome, there were no significant change in neurocognition with the Internet-based cognitive remediation intervention in any of the cognitive domains between the two groups. There was no change psychopathology as measured on the BASIS-24 or on quality of life.

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Table 2. Results.

Variable	CogRem		WebInfo		Difference
	Average or Md[a]	SD[b] or range	Average or Md	SD or range	
No. contacts DES[c]	33	29	33	31	*P*=.99[d]
Hours on the Web[a]	5.5	0-21	6.9	0-19	*P*=.42
Hours worked[a]	180	0-1040	50	0-312	*P*=.01; *U*=143.5
No. days worked[a]	51	0-130	20	0-130	*P*=.17
No. of jobs	1	0-2	0	0-1	*P*=.27
Hours paid[a]	156	0-1040	50	0-312	*P*=.05; *U*=89.5
Total money earned[a]	Aus $1950 (US $1562)	Aus $0-31200 (US $0-24989)	0	Aus $0-6408 (US $0-5132)	*P*=.03; *U*=189.5
Role Functioning Scale	23.0	3.8	22.1	4.1	*P*=.41

[a]Md: median.

[b]SD: standard deviation.

[c]DES: Disability Employment Service.

[d]NS: not significant.

Discussion

Principal Findings

This trial supports the advantages of combining cognitive remediation therapy with supported employment in people with a severe mental illness who wish to return to work [18,21,24]. It extends this area of research by demonstrating that CRT could potentially be delivered via the Internet, considerably broadening the number of services that could provide combinations of CRT with supported employment. If this was replicated, it would decrease the dependence upon specially trained mental health professionals to deliver the therapy which has limited its provision to specialist services. This trial suggests that the range of settings in which CRT could be provided can be increased while maintaining at least some of the effectiveness of the therapy.

Why Did the Intervention Work?

The improvement in employment outcomes was found without significant changes being observed in cognition. Although other studies have observed changes in function with minimal or no neurocognitive improvement with CRT [34-37], the result begs the question of the mechanism of effect. Also, participants experienced relatively small doses of CRT. Whereas participants were asked to complete 10 hours on the Web, the median exposure was 5.5 hours. It is unclear what the necessary “dose” of CRT is, and it is possible that at least some of the benefits of CRT in engaging participants in thinking skills may be found after short courses of CRT. Wykes and colleagues did not find a significant effect for duration of treatment on function in their meta-analysis of CRT [15], yet found a moderate effect for CRT on functioning.

It might be argued that the Web-based intervention provided in this trial was not CRT and could not be expected to have the same effect as CRT on cognition. Certainly, the total period of exposure to the intervention and the intensity of exposure was low compared with other studies of CRT; however, the decision to choose commercially available educational cognitive exercises was based upon the Neuropsychological Educational Approach to Cognitive Remediation (NEAR) [38], a technique that has successfully integrated a broad range of software into CRT. As we were unable to access the detail of game choice and performance, we are unable to report on a more granular analysis of training, cognitive improvement, and functional outcome. This would be one of the targets of future work.

The lack of any significant change in cognition might be as a result of the Web-based neurocognitive measures used. These tests may not have the same sensitivity to change as observed in face-to-face testing nor have been performed in a consistent or rigorous fashion resulting in a considerable variation of results. Motivation to engage in neuropsychological testing without a trained administrator to encourage and assist a person is also suspect.

Participants did not show significant changes in their levels of psychopathology as measured by the BASIS-24. This is consistent with other studies that have seen few changes in psychopathology during treatment with CRT [15]. Little movement was seen in the scores elicited on the Role Functioning Scale. This may have been due to a reliance on DES case managers who had little familiarity with the use of such scales. Future work would be strengthened by face-to-face assessments by a researcher blind to participant allocation or the use of scales that did not require expert mental health worker input.

Was the Chosen Outcome Valid?

Hours in work, rather than change in neurocognition, was the primary outcome in this trial. There were three main reasons for this. First, return to open employment is a priority for people with a severe mental illness [39]. Employment has a real

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potential to help those individuals break through into the wider community and lift at least some people with a severe mental illness out of poverty. The amount of money earned has a clear and definite value. Second, the hours of work and amount of money earned by the person could be accurately determined. Participation in work is the basis for reimbursement by the Australian government to the SE program, and wages earned is a key performance indicator that is tightly measured and independently audited. Successful placement in work forms the basis of ongoing contracts for those services. Hence, they were likely to be the most accurately measured by non-mental health staff. Evidence such as pay slips were required to prove that individuals had returned to paid employment; hence, we are confident that the payments recorded accurately reflect what individuals earned. Finally, the participants were widely dispersed over a large geographical area and were being seen by supported employment workers with no research or specialist mental health skills. During planning for the study, it was thought impractical to train DES staff to be accurate and reliable raters of mental health measures, partly due to a lack of basic training in psychopathology and research method and partly in recognition of the high staff turnover in these positions. This also influenced the choice of Web-based measures of neurocognition and self-rated scales of psychopathology.

Limitations

The trial was significantly affected by operational issues in the supported employment provider which reduced recruitment. These difficulties amplified the lack of contact with the research team. DES staff and participants had little interaction with study staff beyond receiving emails and calls encouraging continued involvement in the study. This reliance on non-health or research staff may have been one of the factors responsible for the high dropout of participants from the program (43%). Importantly, subjects who dropped out did not differ from those who continued on gender, age, or premorbid education; however, they were already less socially integrated with family or their community. Other studies have suffered lower rates of dropout in the United States [18,19,40] or Hong Kong [23]; however, these studies had face-to-face input by mental health professionals. Studies of Web-based health interventions have observed similar rates of dropout [33].

No change was seen in the neurocognition test results. This may have been because of there was no change of scores with the CRT provided; however, it may also reflect poor motivation in those who interacted with the Web-based neurocognitive battery. The battery does appear to have adequate psychometric properties to detect any change [28]. A further possibility is that participants just simply did not interact with the training. Measurement of activity on the website is necessary before a better understanding of the mechanism of action of the treatments. This will be a target of future research.

The study was well controlled with no significant difference being observed between arms in level of education, study discontinuation, uptake of the CogRem website, or contact with a DES case manager. The active control successfully engaged participants randomized to it with no difference in overall hours spent in either arm of the study. Similarly, the intensity of DES case manager involvement was high in both arms of the study, underlining that differing levels of DES worker support was not the reason for the superiority of the CogRem intervention. The number of hours of DES worker contact also suggests that an active model of supported employment was being applied across sites. The arms did differ in the average age of participant; however, it was the WebInfo arm that was on average younger (36.8 years vs 42.3 years), biasing the study if anything to the active control arm of the study.

Conclusions

This study supports the value of combining psychosocial treatment such as Web-based CRT with supported employment services for people with a severe mental illness. Further work is planned to enhance Web-based neurocognitive CRT with social cognitive remediation as the immediate effects of social cognition upon functional outcome is possibly far greater than that of neurocognition [10,41].

Acknowledgments

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Conflicts of Interest

AWFH has received consultancy fees from Janssen Australia and Lundbeck Australia. He has been on an advisory board for Sumitomo Dainippon Pharma. He has received payments for educational sessions run for Janssen Australia, the Lundbeck Institute, and Servier Laboratories Australia. He has been an investigator on industry-sponsored trials by Janssen-Cilag Australia and Brain Resource Ltd.

Multimedia Appendix 1

CONSORT-EHEALTH checklist (v1.6.1).

[PDF File (Adobe PDF File), 13MB - mental_v4i3e30_app1.pdf]

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Abbreviations

ANOVA: analysis of variance
BASIS-24: Behavior and Symptom Identification Scale-24
CATIE: Clinical Antipsychotic Trials of Intervention Effectiveness
CRT: cognitive remediation therapy
DES: Disability Employment Service
NEAR: Neuropsychological Educational Approach to Cognitive Remediation
RCT: randomized controlled trial
SD: standard deviation
SE: Supported Employment
WHOQOL-BREF: World Health Organization Quality of Life-BREF

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Original Paper

A Validation Study of the Web Screening Questionnaire (WSQ) Compared With the Mini-International Neuropsychiatric Interview-Plus (MINI-Plus)

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Abstract

Background: There is a need for brief screening methods for psychiatric disorders in clinical practice. This study assesses the validity and accuracy of a brief self-report screening questionnaire, the Web Screening Questionnaire (WSQ), in detecting psychiatric disorders in a study group comprising the general population and psychiatric outpatients aged 18 years and older.

Objective: The aim of this study was to investigate whether the WSQ is an adequate test to screen for the presence of depressive and anxiety disorders in clinical practice.

Methods: Participants were 1292 adults (1117 subjects from the general population and 175 psychiatric outpatients), aged 18 to 65 years. The discriminant characteristics of the WSQ were examined in relation to the ("gold standard") Mini-International Neuropsychiatric Interview-Plus (MINI-Plus) disorders, by means of sensitivity, specificity, area under the curve (AUC), and positive and negative predictive values (PPVs, NPVs).

Results: The specificity of the WSQ to individually detect depressive disorders, anxiety disorders, and alcohol abuse or dependence ranged from 0.89 to 0.97 for most disorders, with the exception of post-traumatic stress disorder (0.52) and specific phobia (0.73). The sensitivity values ranged from 0.67 to 1.00, with the exception of depressive disorder (0.56) and alcohol abuse or dependence (0.56). Given the low prevalence of separate disorders in the general population sample, NPVs were extremely high across disorders (≥0.97), whereas PPVs were of poor strength (range 0.02-0.33).

Conclusions: In this study group, the WSQ was a relatively good screening tool to identify individuals without a depressive or anxiety disorder, as it accurately identified those unlikely to suffer from these disorders (except for post-traumatic stress disorders and specific phobias). However, in case of a positive WSQ screening result, further diagnostic procedures are required.

(JMIR Ment Health 2017;4(3):e35) doi:10.2196/mental.5453

KEYWORDS

depressive disorders; anxiety disorders; surveys and questionnaires; diagnostic, brief; clinical practice

Introduction

Structured diagnostic interviews such as the Composite International Diagnostic Interview (CIDI) [1] and the Structured Clinical Interview for DSM-III-R (SCID) [2] are considered gold standards in research, used to diagnose psychiatric disorders in a standardized way [1,3,4]. However, they are less suitable for clinical practice because their administration is time

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consuming, and they can only be administered by well-trained interviewers [5]. The Mini-International Neuropsychiatric Interview-Plus (MINI-Plus) [6] is a much shorter diagnostic interview with diagnostic properties similar to the CIDI [6,7]. However, the MINI-Plus also requires trained interviewers and takes up to 30 min to complete, making it costly for routine use in clinical practice. Therefore, because these interviews are often impractical to be used as a screener for routine use, a reliable, valid, and briefly self-rating screening questionnaire is desired. The Web Screening Questionnaire (WSQ) [8] was developed to quickly screen for common psychiatric disorders (ie, anxiety or depressive disorders and alcohol abuse or dependence). This Internet-based, self-report screening questionnaire consists of only 15 items and requires less than 5 min to complete. The WSQ has good to excellent validity for social phobia, panic disorder with agoraphobia, agoraphobia (without panic disorder), obsessive compulsive disorder (OCD), and alcohol abuse or dependence (sensitivity ranges from 0.72-1.00; and specificity from 0.63-0.80) [8]. Slightly more modest psychometric properties were reported for depressive disorder, generalized anxiety disorder (GAD), post-traumatic stress disorder (PTSD), specific phobia, and panic disorder (without agoraphobia), that is, sensitivity 0.80 to 0.93; specificity 0.44 to 0.51 [8]. These data reflect the validation of the WSQ compared with CIDI diagnoses ascertained in the general population with 6-month prevalence rates of the Diagnostic and Statistical Manual, 4th edition-Text Revision (DSM-IV-TR) diagnoses [9]. As the WSQ screens for current symptoms [8], it is relevant to test the WSQ against current DSM-IV diagnoses.

This study examines the validity and accuracy of the WSQ as a screener against 1-month prevalence MINI-Plus disorders covered by the WSQ. The study group mainly comprised a general population sample recruited from primary care registrations. To increase the prevalence of psychiatric disorders, we enriched this general population sample with a smaller sample of psychiatric outpatients to form one large study group.

Methods

Sample

For this study, to ensure statistical power of the analyses, participants from a general population study and participants from a pragmatic randomized controlled trial (RCT) conducted in clinical practice were combined into one large study group.

The 1302 participants from the general population were recruited (from November 2009 to January 2011) from the administration of eight university-affiliated general practices in the vicinity of Leiden, the Netherlands. In the Netherlands, since nearly 100% of the population is registered with a general practitioner (GP), the primary care sample is equivalent to a general population sample [10,11]. To form a nonpatient control group, representative of a population referred for suspected (but not necessarily diagnosed with) mood, anxiety and/or somatoform disorders, four exclusion criteria were applied by Schulte-van Maaren and colleagues (2013) [12]: (1) treatment in a secondary psychiatric care center in the last 6 months for psychiatric problems and/or dependence on alcohol or drugs; (2) hearing impairment or limited cognitive abilities such as aphasia, severe dyslexia, or dementia; (3) illiteracy or insufficient mastery of the Dutch language; and (4) suffering from a potentially lethal disorder. The initial study was designed to generate reference values in primary care for questionnaires used in the assessment of psychopathology. Details of this study by Schulte-van Maaren and colleagues (2013) are described elsewhere [12]. This study focuses on the main aspects relevant for the current research question.

The general population sample derived from the study of Schulte-van Maaren et al (2013) [12] was enriched with a sample of 182 secondary care outpatients who were originally recruited for a pragmatic RCT and in whom the WSQ and the MINI-Plus were assessed at baseline. This RCT is published in Meuldijk and colleagues (2012) [13]. The trial was conducted (from March 2010 to December 2012) at five outpatient mental health clinics in and around Leiden of Rivierduinen (RD), a secondary Regional Mental Health Provider (RHMP) in the province of South-Holland, the Netherlands. Eligible participants were patients aged 18-65 years, referred to the mental health clinics by their GP for the treatment of a current mild to moderate anxiety and/or depressive disorder including depressive disorder, dysthymia, panic disorder (with or without agoraphobia), social phobia, specific phobia, GAD, OCD, and PTSD. Exclusion criteria were (1) suicidal or homicidal risk; (2) delusions, hallucinations, bipolar, or psychotic disorder; (3) severe social dysfunction; and/or (4) insufficient knowledge of the Dutch language.

In both subsamples, the assessment included (among others) the MINI-Plus and the WSQ. Of the initial general population sample of 1302 participants, 185 had incomplete WSQ data, leaving 1117 participants for inclusion in the present analysis. Of the outpatient sample of 182 patients, 6 had incomplete WSQ data and 1 MINI-Plus interview was incomplete, resulting in 175 outpatients. Thus, the (combined) study group for this study consisted of (1117+175) 1292 participants.

The study protocol for both samples was approved by the medical ethical committee of the Leiden University Medical Center.

Web Screening Questionnaire (WSQ)

The WSQ (see Multimedia Appendix 1) is a 15-item, self-report instrument that screens for depressive disorder, GAD, panic disorder with or without agoraphobia, social phobia, specific phobia, OCD, PTSD, agoraphobia, suicidality, and alcohol abuse or dependence [8]. The RCT of Meuldijk and colleagues excluded participants with a moderate to high suicidality risk and/or suicidal ideation [13]. Therefore, in this study, the WSQ item that assesses the risk of suicide or self-harm was not included in the analysis. The WSQ is based on the screening questionnaire of Marks and colleagues [14]. Compared with the 6-months CIDI diagnoses, in the general population, the WSQ has moderate to good screening properties (sensitivity 0.72 to 1.00; specificity 0.44 to 0.80) [8]. Depression, panic disorder with agoraphobia, and alcohol dependence were each assessed by two items, whereas the other disorders were assessed by single items. The same WSQ cut-off scores were applied as used in the study by Donker and colleagues (2006) [8].

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Mini-International Neuropsychiatric Interview-Plus (MINI-Plus)

The MINI-Plus 5.0.0, Dutch version, was used as the "gold standard" reference [6]. The MINI-Plus is a structured and standardized diagnostic interview used to determine the most common psychiatric disorders according to axis I DSM-IV-TR [9] and the International Classification of Diseases and Related Health Problems (ICD-10) [6].

For this study, we used the diagnoses of (1) mood disorders (depression and dysthymia), (2) anxiety disorders (panic disorder with or without agoraphobia, agoraphobia, social phobia, specific phobia, GAD, PTSD [type I or single trauma], and OCD), and (3) alcohol abuse or dependence. The MINI-Plus has good psychometric properties and is widely used to support diagnostics in psychiatry. The MINI-Plus was conducted by trained research nurses. As the WSQ screens for current diagnoses, only the 1-month MINI-Plus was used.

Statistical Analyses

The discriminant function of the WSQ was assessed for each of the MINI-Plus Axis 1 DSM-IV-TR disorders for which it screens, using sensitivity, specificity, receiver operating characteristics (ROC) curve (area under the curve [AUC]) [15], and positive and negative predictive values (PPVs, NPVs). Specificity was calculated as the proportion of patients who did not have the MINI-plus diagnosis and who had a negative WSQ screen. Sensitivity was determined as the proportion of patients with a MINI-Plus psychiatric diagnosis who had a positive WSQ screen for the same disorder. The AUC, (interpreted as the probability that a randomly selected clinical case will score higher on the test than a noncase), is not sensitive to prevalence and is proposed to correct this problem [16]; it can range from 0.50 (worthless test) to 1.00 (perfect test). Following Agresti (2002) [17], we considered the AUC to be of excellent evidence of concordance if ≥0.90, good evidence of concordance if between 0.80 and 0.90, acceptable although only average if between 0.70 and 0.80, and poor if <0.70. The PPV was calculated as the percentage of participants with a positive test on the WSQ who actually had the disorder according to the MINI-Plus diagnosis, whereas the NPV was calculated as the percentage of participants with a negative test that did not have the disorder according to the MINI-Plus. As the PPV and the NPV strongly depend on the prevalence of the disorder, we calculated these indices on the general population sample only, without the enrichment; otherwise, the results would be artificially inflated. Furthermore, WSQ cut-off scores were applied as originally recommended by Donker et al 2006 [8] and slightly adapted to fit within routine outcome monitoring (ROM), a monitoring system for psychiatric patient care [18]. All analyses were conducted using IBM SPSS version 20.0 for Windows.

Results

Demographics and Prevalence of Diagnostic and Statistical Manual, 4th Edition-Text Revision (DSM-IV-TR) Diagnoses

Characteristics of the two subsamples are presented in Table 1. In the total study group, the mean age was 39.6 years (range 18-65, standard deviation [SD]=12.6), and 60.53% (782/1292) of the participants were female. Most participants were of Dutch origin (1223/1292; 94.66%) and had completed a higher level of education (972/1292; 75.23%). At baseline, 77.32% of the participants (999/1292) were employed, and 66.18% (855/1292) were married. In the total group, 79 participants (6.11%) met the DSM-IV-TR MINI-Plus criteria for a current (ie, within the past month) depressive (with or without anxiety) disorder. Of the total group, 139 participants (10.76%) met the criteria for an anxiety with or without a depressive disorder; these participants were diagnosed according to the common subtypes of anxiety as indicated in Table 2. In addition, 55 participants (4.26%) met the criteria for current alcohol abuse or dependence disorder. The majority of the study group (934/1292, 72.29%) did not pass the threshold for a current MINI-Plus diagnosis. It is recognized that the two study groups are not the same. The study population contains selected subgroups of particular interest; the difference in clinical and demographic characteristics within these subgroups contributes to define the target population.

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Table 1. Baseline sociodemographic and clinical characteristics of the two subsamples and the total study group (n=1292). The MINI International Neuropsychiatric Interview-Plus (MINI-Plus) 5.0.0 was used to collect diagnostic information. Participants can have more than one diagnosis.

Characteristics	General population sample (n=1117)	Outpatient sample (n=175)	Total study sample (n=1292)
Baseline sociodemographic[a] characteristics			
Age (years), mean (SD[b])	40.04 (12.53)	36.67 (12.40)	39.6 (12.56)
Gender, n (%)			
Female	712 (63.74)	70 (40.0)	782 (60.53)
Ethnical background[c] , n (%)			
Dutch	1116 (99.91)	160 (91.4)	1223 (94.66)
Other	53 (4.74)	10 (5.7)	63 (4.88)
Educational status[d] , n (%)			
Lower education	250 (22.38)	64 (36.6)	314 (24.30)
Higher education	866 (77.53)	106 (60.6)	972 (75.23)
Employment status, n (%)			
Employed	914 (81.83)	85 (48.6)	999 (77.32)
Unemployed or retired	202 (18.08)	85 (48.6)	287 (22.21)
Marital status, n (%)			
Married or cohabitating	766 (68.58)	89 (50.9)	855 (66.18)
Clinical characteristics or MINI[e] -Plus Diagnosis[f] , n (%)			
Depressive (with or without anxiety) disorder	12 (1.07)	67 (38.3)	79 (6.11)
Anxiety (with or without depressive) disorder	60 (5.37)	79 (45.1)	139 (10.76)
Panic disorder (without agoraphobia)	4 (0.36)	24 (13.7)	28 (2.17)
Agoraphobia	27 (2.42)	37 (21.1)	64 (4.95)
Panic disorder with agoraphobia	2 (0.18)	18 (10.3)	20 (1.55
Social phobia	10 (0.09)	9 (5.1)	19 (1.47)
Specific phobia	9 (0.81)	3 (1.7)	12 (0.93)
Generalized anxiety disorder	13 (1.16)	22 (12.6)	35 (2.71)
Posttraumatic stress disorder	5 (0.45)	14 (8.0)	19 (1.47)
Obsessive compulsive disorder	6 (0.54)	3 (1.7)	9 (0.70)
Alcohol abuse or dependence	51 (4.57)	4 (2.3)	55 (4.26)
No current DSM-IV-TR[g] diagnosis[h]	902 (80.75)	32 (18.3)	934 (72.29)

[a]Demographic data; ethnic background, educational status, and employment status are missing for 6 participants (1 participant from the general population sample, and 5 outpatients).

[b]SD: standard deviation.

[c]Dutch ethnic background was assumed when the participant was born in the Netherlands.

[d]Lower education=having completed elementary school, lower general primary education, or no education at all; higher education=more than lower education (includes university).

[e]MINI: Mini-International Neuropsychiatric Interview.

[f]Clinical characteristics or diagnosis were missing for 1 participant.

[g]DSM-IV-TR: Diagnostic and Statistical Manual of Mental Disorders, 4th edition-Text Revision.

[h]Denotes participants who did not pass the threshold for having a current Axis- I DSM-IV-TR diagnosis according to the MINI-Plus interview.

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Table 2. Agreement between the Mini-International Neuropsychiatric Interview (MINI)-Plus and the Web Screening Questionnaire (WSQ) for individual disorders in the total sample (n=1292). Numbers in the table reflect the use of each screening subscale to detect any diagnosis rather than only the diagnosis associated with the subscale. WSQ cut-off scores were derived from the original cut-offs recommended by Donker et al (2009) [8]. WSQ cut-off scores: depression: Q1≥5 and Q2=1; panic disorder: Q4≥1; agoraphobia Q5=1; panic disorder with agoraphobia Q4≥1 and Q5=1; social phobia: Q8=1 and Q9=1; specific phobia: Q6 or Q7=1; generalized anxiety disorder (GAD): Q3≥2; post-traumatic stress disorder (PTSD): Q10=1 or Q11=1; obsessive compulsive disorder (OCD): Q12≥1; and alcohol abuse or dependence: Q13≥2 and Q14≥3.

DSM-IV-TR[a] diagnosis	MINI[b] prevalence (%)	WSQ[c] prevalence (%)	True positive	False positive	False negative	True negative	Specificity (95% CI)	Sensitivity (95% CI)	AUC[d] (95% CI)
Depressive disorder	79 (6.11)	115 (8.90)	46	69	33	1144	0.94 (0.93-0.96)	0.58 (0.47-0.69)	0.83 (0.68-0.98)
Panic disorder	28 (2.16)	170 (13.16)	28	142	0	1122	0.89 (0.87-0.90)	1.00 (0.88-1.00)	0.98 (0.96-1.00)
Agoraphobia	64 (4.95)	111 (8.59)	52	59	12	1169	0.95 (0.94-0.96)	0.81 (0.70-0.90)	0.80 (0.69-0.91)
Panic disorder with agoraphobia	20 (1.55)	61 (4.72)	18	43	2	1229	0.97 (0.96-0.98)	0.90 (0.68-0.99)	0.99 (0.98-1.00)
Social phobia	19 (1.47)	101 (7.82)	15	86	4	1187	0.93 (0.92-0.95)	0.79 (0.54-0.94)	0.95 (0.92-0.99)
Specific phobia	12 (0.93)	363 (28.10)	12	351	0	929	0.73 (0.70-0.75)	1.00 (0.74-1.00)	0.93 (0.89-0.97)
Generalized anxiety disorder	35 (2.71)	145 (11.22)	23	122	12	1135	0.90 (0.89-0.92)	0.66 (0.48-0.81)	0.89 (0.79-0.99)
Post-traumatic stress disorder	19 (1.47)	621 (48.07)	15	606	4	667	0.52 (0.50-0.55)	0.79 (0.54-0.94)	0.86 (0.74-0.98)
Obsessive compulsive disorder	9 (0.69)	120 (9.3)	6	114	3	1169	0.91 (0.89-0.92)	0.67 (0.30-0.93)	0.82 (0.59-1.00)
Alcohol abuse or dependence	55 (4.26)	121 (9.37)	31	90	24	1147	0.93 (0.91-0.94)	0.56 (0.42-0.70)	0.82 (0.75-0.88)

[a]DSM- IV-TR: Diagnostic and Statistical Manual of Mental Disorders, 4th edition-Text Revision.

[b]MINI: Mini International Neuropsychiatric Interview; MINI-Plus 5.0.0.

[c]WSQ: Web Screening Questionnaire.

[d]AUC: area under the curve.

Concordance Between Mini-International Neuropsychiatry Interview (MINI)-Plus and Web Screening Questionnaire (WSQ)

The concordance between each diagnosis classified according to the DSM-IV-TR with the MINI-Plus and the WSQ questionnaire is presented in Table 2. Specificity was high (range 0.89-0.97) for most individual disorders, with the exception of specific phobia (0.73) and PTSD (0.52). Sensitivity was substantial to high (0.67 to 1.00) for the majority of disorders. The exceptions were depressive disorder (0.58) and alcohol abuse or dependence (0.56). All AUC values were good to excellent (≥0.82) for the individual disorders. The best discriminating subscale was panic disorder with agoraphobia (AUC=0.99), followed by panic disorder (AUC=0.98) and social phobia (AUC=0.95). Figure 1 presents the discriminative power of each subscale of the WSQ. Data on PPCs and NPVs are given in Table 3. These indices were calculated for the general population subsample only because of the strong relation to the prevalence of the disorders. Despite generally strong discriminative power, the PPV was of poor strength ranging from 0.01 (PTSD) to 0.33 (agoraphobia); the NPVs were uniformly high (≥0.97) for all scales.

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Figure 1. Distribution of the MINI-Plus diagnosis for the corresponding Web Screening Questionaire (WSQ) subscales in the study sample (N = 1292) MINI-Plus=The MINI International Neuropsychiatric Interview-Plus 5.0.0. WSQ=Web Screening Questionnaire. WSQ cut-off scores were derived from the original cut-offs recommended by Donker and colleagues (2009) [8]. WSQ cut-off scores: depression: Q1≥5 and Q2=1; panic disorder: Q4 ≥1; agoraphobia: Q5=1; panic disorder with agoraphobia Q4≥1 and Q5=1; social phobia: Q8=1 and Q9=1; specific phobia: Q6 or Q7=1; generalized anxiety disorder (GAD): Q3≥2; post-traumatic stress disorder (PTSD): Q10=1 or Q11=1; obsessive compulsive disorder (OCD): Q12≥1; and alcohol abuse or dependence : Q13≥2 & Q14≥3. MINI-Plus: The Mini-International Neuropsychiatric Interview-Plus 5.0.0. WSQ: Web Screening Questionnaire.

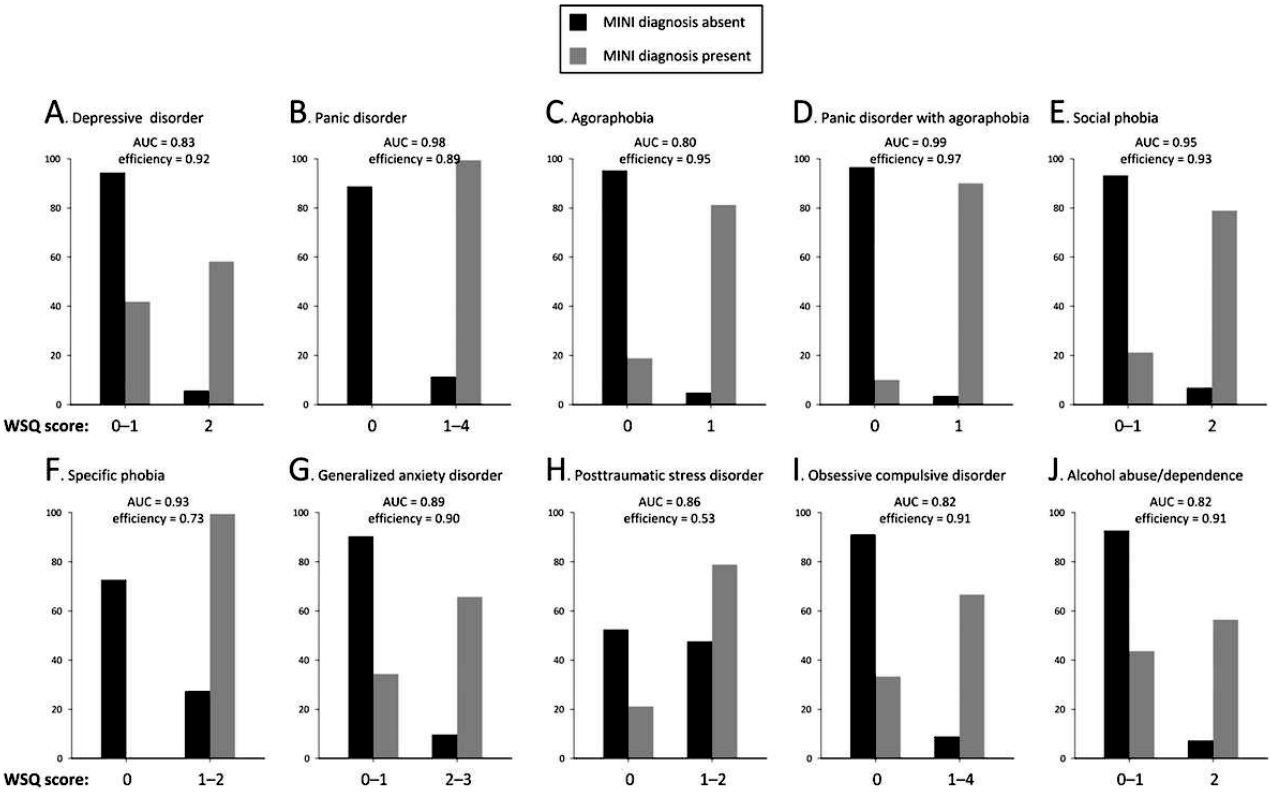

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Table 3. Predictive value of the Web Screening Questionnaire (WSQ) for individual disorders according to the Mini-International Neuropsychiatry Interview (MINI)-Plus in the general population subsample (n=1117). Numbers in the table reflect the use of each screening subscale to detect any diagnosis rather than only the diagnosis associated with the subscale. WSQ cut-off scores were derived from the original cut-offs recommended by Donker et al (2009) [8]. WSQ cut-off scores: depression: Q1≥5 and Q2=1; panic disorder: Q4≥1; agoraphobia: Q5=1; panic disorder with agoraphobia Q4≥1 and Q5=1; social phobia: Q8=1 and Q9=1; specific phobia: Q6 or Q7=1; generalized anxiety disorder (GAD): Q3≥2; post-traumatic stress disorder (PTSD): Q10=1 or Q11=1; obsessive compulsive disorder (OCD): Q12≥1; and alcohol abuse or dependence: Q13≥2 and Q14≥3.

DSM-IV-TR[a] diagnosis	MINI[b] prevalence (%)	WSQ[c] prevalence (%)	True positive	False positive	False negative	True negative	PPV[d] (95% CI)	NPV[e] (95% CI)
Depressive disorder	12 (1.107	28 (2.51)	6	22	6	1083	0.21 (0.08-0.41)	0.99 (0.99-1.00)
Panic disorder	4 (0.36)	64 (5.73)	4	60	0	1053	0.06 (0.02-0.15)	1.00 (0.99-1.00)
Agoraphobia	27 (2.42)	52 (4.66)	17	35	10	1055	0.33 (0.20-0.47)	0.99 (0.98-1.00)
Panic disorder with agoraphobia	2 (0.18)	11 (0.98)	2	9	0	1106	0.18 (0.02-0.52)	1.00 (0.99-1.00)
Social phobia	9 (0.81)	47 (4.21)	7	40	3	1067	0.15 (0.06-0.28)	1.00 (0.99-1.00)
Specific phobia	9 (0.81)	281 (25.16)	9	272	0	836	0.03 (0.01-0.06)	1.00 (0.99-1.00)
Generalized anxiety disorder	13 (1.16)	46 (4.12)	8	38	5	1066	0.17 (0.08-0.31)	1.00 (0.99-1.00)
Post-traumatic stress disorder	5 (0.45)	511 (45.75)	5	506	0	606	0.01 (0.03-0.02)	1.00 (0.99-1.00)
Obsessive compulsive disorder	6 (0.54)	55 (4.92)	4	51	2	1060	0.07 (0.02-0.18)	1.00 (0.99-1.00)
Alcohol abuse or dependence	51 (4.57)	110 (9.85)	28	82	23	984	0.25 (0.18-0.35)	0.98 (0.97-0.99)

[a]DSM-IV-TR: Diagnostic and Statistical Manual of Mental Disorders, 4th edition-Text Revision.

[b]MINI: Mini International Neuropsychiatric Interview; MINI-Plus 5.0.0.

[c]WSQ: Web Screening Questionnaire.

[d]PPV: positive predictive value.

[e]NPV: negative predictive value.

Discussion

Principal Findings

This study evaluated the feasibility of the WSQ to screen for DSM-IV-TR diagnoses of depressive disorder, anxiety disorders, and alcohol abuse or dependence. Overall, the WSQ was relatively successful in discriminating between individuals with and without a MINI-Plus diagnosis. However, if the WSQ tests positive for a psychiatric disorder, further examination is warranted because of the poor PPVs. Thus, most patients who tested positively, did not receive a MINI-Plus diagnosis.

The adequate strength of the findings regarding sensitivity, specificity, and AUC values suggest that the WSQ has some desirable screening characteristics. Its high sensitivity suggests that it may help to confirm the absence of most of these psychiatric diagnoses, that is, ruling out the disorders. However, the exceptions are depressive disorder, specific phobia, PTSD, and alcohol abuse or dependence, for which the agreement in ruling out these psychiatric disorders was lower. In the general population subsample, the NPVs were high, but the PPVs were relatively low compared with the MINI-Plus results. Although the PPVs and NPVs are not intrinsic to the test, they are directly related to the prevalence of the disease in the population. Assuming all other factors remain constant, PPV increases with increasing prevalence, and NPV decreases with an increase in prevalence.

Together with the results reported by Donker and colleagues [8] who found AUCs of 0.65 to 0.83 in their validation of the WSQ against DSM-IV-TR diagnoses with the CIDI in the general population, the present results indicate that the WSQ has potential as a screener, ruling out the presence of a disorder.

Our findings are in line with other validation studies comparing brief screening tools with longer ones and also showing the feasibility of these short screening instruments. This applies, for example, to the Psychiatric Diagnostic Screening Questionnaire (PDSQ) in outpatients [19,20] and the Mental Health Inventory 5 (MHI-5) and the Anxiety and Depression Detector (ADD) for primary care populations [21-23].

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Strengths and Limitations

A strength of this study is the large number of participants included. Another strength is that our MINI-Plus data allowed to determine the concordance of the WSQ with the last 1-month DSM-IV-TR diagnoses, providing an accurate measure of the current (or very recent) prevalence of this mental disorder. In contrast, Donker and colleagues (2009) [8] used 6-month prevalence rates, which implies that some disorders could have receded during the past 5 months.

A limitation of this study is that all the GP practices included were affiliated with a university hospital. Because such practices tend to have more focus on research and training than nonaffiliated practices, this may have introduced bias in the study group population. Moreover, the study group was mainly compiled from participants included in an earlier general population study [12]; these participants did not have psychiatric treatment for 6 months before recruitment and did not report dependence on alcohol or other drugs. Although we made considerable effort to compensate for this potential source of bias in recruitment by adding a psychiatric outpatient subsample [13], the prevalence of psychiatric disorders in our general population subsample was substantially lower than expected from population-based surveys in the Netherlands [24,25]. Therefore, it is likely that we probably included an overly healthy study group, thereby limiting the generalizability of these results to the general population or other patient samples. Therefore, the present results need to be confirmed in other study populations. As a result, the NPV estimates may have been too high and the PPV too low. Our findings with regard to the predictive value must be considered extreme, given the very low prevalence of disorders in the present sample. In addition, as the number of participants with certain conditions was small, this yielded less precise effect estimates, which should be taken into account when interpreting these results. Predictive values from one study should not be transferred to another setting with a different prevalence of the disease in the population. However, our estimates of the sensitivity, specificity, and AUC are not affected by this limitation. Moreover, reconsidering the diagnostic criteria and the screening items used for the individual WSQ items could contribute to a higher accuracy of detecting disorders and higher positive and predictive values.

A final limitation is that our sample was restricted to Dutch-speaking individuals able to write (illiterate or non-Dutch speaking persons were excluded); this may also limit the generalizability of our results, especially across different immigrant groups. In addition, future research could investigate the impact of demographic factors on our study results. Although it is generally assumed that structured diagnostic interviews (ie, the MINI-Plus and SCID) are the "gold standards" for the assessment of diagnoses in psychiatric research, these standards have their limitations. One advantage for reproducibility is that it is fully clear what standardized procedures had been followed. However, the notion that mental disorders (eg, depression and anxiety) are entities that can be diagnosed remains debatable, despite the apparent clinical value of such diagnoses.

Conclusions

The WSQ is a short questionnaire to screen for depression, GAD, panic disorder with or without agoraphobia, social phobia, specific phobia, OCD, PTSD, and alcohol abuse or dependence. In has proven useful in the general population to screen for the 6-months prevalence for these disorders, compared with the CIDI as gold standard [8]. This study yielded similar results, with the 1-month prevalence of these disorders in the MINI-Plus in a general practice population, combined with psychiatric outpatients. Taken together, exploring the agreement between both instruments, or findings, indicates that the WSQ can (potentially) be used as a brief and less costly screening tool for depressive or anxiety disorders (except for PTSD and specific phobia). The WSQ seems a promising tool with a two-step diagnostic approach, for example, in primary care. It could assist health care providers in screening patients before consultation. Patients who screen positive should undergo more extensive diagnostic procedures, whereas a negative screen indicates that it is highly unlikely that further evaluation would be useful. With such an approach, diagnostic accuracy might be increased and costly diagnostic procedures limited or avoided.

However, this study had several limitations which should be considered when interpreting and generalizing our finding to other groups. For example, participant recruitment was not standard, and recruitment barriers could not be completely eliminated. Also, in our study group, the prevalence of psychiatric disorders was lower than expected. Moreover, concern still exists about the usefulness of the WSQ in its current form; some revision of the scale may be required to improve its psychometric properties. Future research exploring the feasibility of the WSQ for assessing mental health in general practice might be a further step in the economization and optimization of mental health care.

Acknowledgments

This is a collaborative study between Rivierduinen (RD) and the department of Psychiatry of the Leiden University Medical Center (LUMC) and is funded entirely by RD.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Web Screening Questionnaire (WSQ).

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[PDF File (Adobe PDF File), 111KB - mental_v4i3e35_app1.pdf]

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Abbreviations

ADD: anxiety and depression detector
AUC: area under the curve
CIDI: Composite International Diagnostic Interview
DSM-IV-TR: Diagnostic and Statistical Manual of Mental Disorders, 4th edition-Text Revision
GP: general practitioner
ICD-10: The International Classification of Diseases and Related Health Problems
GAD: generalized anxiety disorder
LUMC: Leiden University Medical Center
MEC: Medical Ethical Committee
MHI-5: Mental Health Inventory-5
MHC: mental health clinics
MINI-Plus: Mini-International Neuropsychiatric Interview-Plus
NPV: negative predictive values
OCD: obsessive compulsive disorder
PPV: positive predictive values
PDSQ: Psychiatric Diagnostic Screening Questionnaire
PTSD: post-traumatic stress disorder
RCT: randomized controlled trial
RD: Rivierduinen
RHMP: regional mental health provider
ROC: receiver operating characteristic
ROM: routine outcome monitoring
WSQ: Web Screening Questionnaire

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Original Paper

A Smartphone App for Adolescents With Sleep Disturbance: Development of the Sleep Ninja

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Abstract

Background: Sleep disturbances are common in young people and have consequences for academic, social, emotional, and behavioral development. The most effective treatment is cognitive behavioral therapy for insomnia (CBT-I), with evidence suggesting that it is efficacious even when delivered digitally.

Objective: There are no commercially available digitally delivered CBT-I programs for use by young people. The aim of this project was to develop a smartphone app that delivers CBT-I to young people to improve sleep.

Methods: To inform the development of the app, young people (N=21) aged between 12 and 16 years attended one of the 3 focus groups (each with 4-10 participants). These focus groups were conducted at different stages of the development process such that the process could be iterative. Participants were asked the reasons why they might use an app to help them sleep, the kinds of features or functions that they would like to see in such an app, and any concerns they may have in using the app. Data were analyzed using a thematic analysis approach. Of the issues discussed by the participants, the researchers selected themes associated with content, functionality, and accessibility and user experience to examine, as these were most informative for the app design process.

Results: In terms of content, young people were interested in receiving information about recommended sleep guidelines and personalized information for their age group. They reported that keeping a sleep diary was acceptable, but they should be able to complete it flexibly, in their own time. They reported mixed views about the use of the phone's accelerometer. Young people felt that the functionality of the app should include elements of game playing if they were to remain engaged with the app. Flexibility of use and personalized features were also desirable, and there were mixed views about the schedule of notifications and reminders. Participants reported that for the app to be accessible and usable, it should be from a trusted developer, have engaging aesthetics, have a layout that is easy to navigate, not rely on Internet coverage, and preferably be free. Participants felt that being able to conceal the purpose of the app from peers was an advantage and were willing to provide personal information to use the app if the purpose and use of that information was made clear. Overall, participants endorsed the use of the app for sleep problems among their age group and reported motivation to use it.

Conclusions: The Sleep Ninja is a fully-automated app that delivers CBT-I to young people, incorporating the features and information that young people reported they would expect from this app. A pilot study testing the feasibility, acceptability, and efficacy of the Sleep Ninja is now underway.

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KEYWORDS

insomnia; sleep; adolescence; depression; cognitive behavioral therapy; smartphone

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Introduction

Some researchers have suggested that sleep problems are epidemic among young people, with approximately 30% of adolescents reporting at least some level of sleep difficulty, and 10% to 40% of high school youth indicating sleep deprivation [1,2]. At the clinical end of the spectrum, insomnia is the most common sleep disorder, with prevalence rates of approximately 4% in youth [2]. Insomnia is categorized by chronic and persistent difficulty initiating sleep, maintaining sleep, or waking up too early and is associated with functional impairment [3].

Sleep disturbance experienced by young people has profound consequences across academic, social, emotional, and behavioral domains [4]. In terms of education, sleep quality, lower levels of sleepiness, and longer sleep duration are each independently associated with improved academic performance [5]. Sleep problems also have an adverse impact on behavior, with studies consistently showing that poor sleep negatively influences interpersonal relationships [6] and is associated with increased risky behaviors [7]. Poor sleep also has a marked impact on mental health generally and specifically on depression and suicidality. Longitudinal evidence has accumulated suggesting that sleep disturbance is an independent risk factor for the onset of depression [8-13]. For example, in a large community-based longitudinal study, adolescents who met clinical criteria for insomnia were between 1.5 and 3 times more likely to develop depression in the future (up to 7 years later) and up to 6.5 times more likely to attempt suicide [14]. Accordingly, sleep disturbance can seriously derail psychological, social, and vocational pathways into adulthood.

The most effective treatments for insomnia are behavioral treatments such as cognitive behavioral therapy for insomnia (CBT-I), which has consistently been found to reduce symptoms of insomnia to a greater extent than pharmacotherapy [15]. CBT-I is the first-line treatment for adult insomnia [16] and typically involves a combination of strategies, including psychoeducation, sleep restriction, stimulus control, cognitive therapy, and sleep hygiene and is usually delivered over the course of 6 to 12 weeks. A meta-analysis reported that the effect of CBT-I on sleep indices such as Sleep Onset Latency, Total Sleep Time, and Sleep Efficiency ranged from medium to large (0.67-1.09; [17]). Importantly, this approach has also been validated in adolescents [18].

Over the past decade, researchers have increasingly investigated digitally delivered CBT-I (dCBT-I) and have reported comparable effect sizes to face-to-face formats [19]. Several recent studies have directly compared dCBT-I with group and individual face-to-face formats. Results from these investigations converge on the finding that individual face-to-face CBT-I is associated with larger effect sizes than other formats, although there is no difference between group-delivered and dCBT-I, with these programs yielding conventionally large effect sizes [18,20,21]. Most of the existing research has investigated Web-based CBT-I programs, although encouragingly, a recent randomized controlled trial evaluated a fully automated CBT-I app in adults compared with a waitlist and found large effect sizes on sleep outcomes [22].

Although several digital programs are available for sleep disturbances in adults [23,24], to our knowledge, there is only one Web-based program that has been tested for use by young people [18]. This program involves 6 weeks of Web-based sessions, during which users receive individualized feedback and recommendations by a qualified sleep therapist, in addition to accessing core CBT-I components (eg, psychoeducation, stimulus control, sleep restriction, cognitive therapy, and relaxation). However, this program is not commercially available for use and requires substantial clinician input, thus limiting the accessibility of the program. The lack of automated digital programs available for use by young people is particularly surprising, given that delivering treatment digitally may have particular appeal to young people who have a preference for management of their own symptoms and problems, without the input of health professionals [25].

The aim of this study was therefore to design and develop an automated smartphone app for use by young people to improve their sleep. The scope of the app was broadened to target not only insomnia but also mild to moderate levels of sleep disturbance because insomnia is progressive and intervening early may prevent escalation to clinical levels. Using a participatory design approach, adolescents contributed their views via focus group discussions that informed the design and development process. There has been increasing recognition that involving users in the development of health information systems increases technology adoption, user satisfaction, as well as trust and ease of use of specific programs [26]. Currently, adherence rates to technology-mediated treatment are low at just 52%, suggesting that there is considerable room for improvement [27]. Using a participatory design approach may improve eventual adherence and was selected to align with best practice guidelines in the development of mental health smartphone apps [28]. According to these guidelines, understanding the needs of the end user is paramount to the eventual uptake of the app and should be systematically addressed during the development and design phases. Therefore, adoption of a participatory design aligns with these recommendations. The decision to employ focus groups was made because young people are generally comfortable and familiar with the process of discussing issues in small groups [29].

Methods

Design

This qualitative study involved 3 focus groups. Focus groups, rather than interviews or surveys, were selected for their specific ability to identify group norms [30], to foster interaction between participants and generate new ideas [31], as well as their capacity to encourage participation by group members who might otherwise feel that they do not have much to contribute [32]. Three focus groups, each with 4 to 10 participants, were held at different stages of the design and development process such that the process could be iterative. The first focus group was held before the commencement of the project for feedback on the concept, the second was conducted after the concept had been established, and the final group was held when a prototype

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was available to maximize the capacity for feedback at each stage of the design process. Participants attended only one of the 3 groups.

Participants and Recruitment

A convenience sample of young people aged 12 to 16 years was recruited via Web-based channels, including the Black Dog Institute Web page, Facebook, and Twitter. Study flyers were also placed in community areas such as libraries and doctors' waiting rooms. Potential participants responded to advertisements asking young people to participate in a focus group about the development of a smartphone app to improve their sleep. To be eligible to participate, respondents needed to be aged between 12 and 16 years, fluent in English, able to travel to Randwick for focus groups, own a smartphone, and have a parent willing to provide consent. Participants were not required to be experiencing current sleep disturbance because the aim of the focus groups was to elicit a wide variety of perspectives from those with significant sleep problems through to those without. However, one might assume that this study was likely to appeal to people for whom sleep is a significant concern, making it likely that the sample would include participants at the clinical end of the spectrum. This sampling approach was chosen to ensure that the app appealed to a range of young people with varying levels of sleep difficulty. Interested participants contacted the research team via phone or email to confirm eligibility and their availability to attend a face-to-face focus group at the Black Dog Institute in Randwick. Written consent forms from a parent or guardian were emailed to researchers before the focus group session. After consent had been provided, focus groups were conducted when at least four participants had signed up.

Procedure

Focus groups were held at the Black Dog Institute and conducted by the research lead (AWS) who has a background in clinical psychology (PhD/MPsychol) and extensive experience in facilitating interviews and focus groups. No relationship between the research lead and participants was established before the focus group. A graphic designer involved in the development of the sleep app also attended the focus groups as an observer but did not contribute to the discussion. Each group session was held in a quiet meeting room and lasted approximately 90 min. The focus groups were conducted using a semistructured format, with questions generated to address areas of interest as informed by commonly identified risks and ethical considerations in app development, which include functionality, privacy issues, and usability [33]. The facilitator asked general questions about app content, before providing an overview of core content areas. Focus group participants provided their views about a range of candidate content areas such as the establishment of regular sleep-wake cycles and the introduction of a pre-bedtime routine. The questions were piloted by the research team before conducting the groups. Questions were open ended, with specific prompts being used as necessary (see Multimedia Appendix 1 for sample questions). The same question outline was used in all 3 groups. The only difference was that a prototype was presented to all the participants in the third focus group toward the end of the session, and they were therefore able to provide additional specific feedback on user experience components (eg, look and feel and age appropriateness). Focus groups were audiotaped for later transcription. Participants completed a set of 3 paper-based questionnaires (see below) at the end of the focus group discussion. They were reimbursed with a Aus $30 gift voucher for their time. All procedures received ethical approval from the University of New South Wales Human Research Ethics Committee (HC15422).

Measures

Demographics

Participants were asked to provide information about age, gender, school year, main language spoken at home, and an estimate of time spent on their phone each day.

Insomnia Severity Index

The Insomnia Severity Index (ISI; [34]) is a 7-item self-report questionnaire based on the Diagnostic and Statistical Manual of Mental Disorders, fourth edition criterion for insomnia [35]. It assesses perceived symptoms and consequences of insomnia as well as how concerning these difficulties are. Each item is rated on a scale of 0 to 4, with total ISI scores ranging from 0 to 28. The ISI has the following cutoff points: 0 to 7 for no clinically significant symptoms, 8 to 14 for subthreshold insomnia, 15 to 21 for clinical insomnia of moderate severity, and 22 to 28 for severe clinical insomnia [36]. The ISI has been widely used among adolescent samples, with internal consistency of .83, and 2-week test-retest reliability of .79 [37].

Kessler 10 Psychological Distress Scale

The Kessler 10 Psychological Distress Scale (K10; [38]) is a 10-item scale that assesses levels of general psychological distress. Total K10 scores of 1 to 15 indicate low, 16 to 21 indicate moderate, 22 to 29 indicate high, and 30 to 50 indicate very high psychological distress [39]. The K10 has high internal consistency (.93) and good discriminant validity in population-based samples [40]. Additionally, the sensitivity of the K10 measure at both ends of the scale lends it to use among community, nonclinical samples [41].

Data Analysis

Digital recordings were transcribed verbatim by a research assistant. In line with thematic analysis guidelines [42], coding was conducted by 2 primary coders (AWS and LJ) using a data-driven approach. Two independent coders reviewed the transcripts; one of the coders was already familiar with the data on account of conducting the focus groups (AWS), whereas the other listened to recordings and closely reviewed transcripts (LJ).

Thematic analysis was selected to analyze the data because of its flexibility [43] and rigor [44]. Thematic analysis is well-suited to this study because it allows for the identification, interpretation, and reporting of patterns within the data [45] while simultaneously recognizing the reflexive role of the researcher in presenting the data [46]. Data from the 3 focus groups were exported into Microsoft Excel. Both coders were experienced in conducting focus groups and interviews. A qualitative analyst (AF) oversaw the data analytic approach.

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Initial coding was conducted by 2 coders on the same single transcript, each blind to each other's codes, to generate an initial first-stage coding framework. These initial codes were discussed and refined until both coders were in agreement about the coding framework. The senior qualitative analyst then reviewed this coding framework before it was applied to the remaining 2 transcripts and reapplied to the initial transcript upon which it was based. Codes were compared between the 2 coders, and discrepancies were resolved to create detailed code descriptions that could be applied consistently to the text. Constant comparison was used to further refine the codes and generate higher-order explanatory thematic groupings in the data. This final coding framework was then applied to all 3 transcripts to test the validity and appropriateness of identified themes. The consolidated criteria for reporting qualitative research checklist was used to guide the reporting of results [47].

Results

Participant Characteristics

A total of 21 young people (age range: 12-16 years, mean age: 14 years; 71% (15/21) female) participated in the 3 focus groups (see Table 1 for details on participant characteristics). No participants withdrew or dropped out after the study commenced. A total of 90% (15/21) nominated English as the language spoken most at home. On average, participants estimated that they spent 3.5 hours per day on their phones (range: 30 min-9 hours). Total scores on the ISI ranged from 0 to 19, with considerable variability in severity—55% of the participants had no clinically significant symptoms, 25% of participants reported moderately severe insomnia, and 20% reported subthreshold insomnia. Scores on the K10 ranged from 11 to 37, with 33% of the participants reporting low levels of psychological distress, 33% reporting moderate levels of psychological distress, and 10% and 24% describing high and very high levels of psychological distress, respectively. Scores on the ISI and K10 were positively correlated, r=.76, P<.01.

Table 1. Participant characteristics.

Participants (N=21)	Mean (standard deviation)	Range
Gender (female), n (%)	15 (71)	-
Age, in years	14.10 (1.26)	12-16 years
School year	8.76 (5.65)	6-10
Language mostly spoken at home (English), n (%)	19 (90)	-
Time spent on phone per day (hours)	3.56 (2.72)	0.50-9
ISI[a]score	8.71 (5.65)	0-19
K10[b]score	20.95 (8.05)	11-37

[a]ISI: Insomnia Severity Index.

[b]K10: Kessler 10 Psychological Distress Scale.

Thematic Analysis Results

The thematic analysis generated 3 distinct themes, which guided the development of the Sleep Ninja app. These included (1) content; (2) functionality; and (3) accessibility and user experience. An additional 5 themes were identified, which were broader in scope and related to current behavioral patterns and attitudes rather than to the development of the sleep app specifically. These included (1) current obstacles to healthy sleep; (2) current sleep strategies; (3) motivation to change sleep habits; (4) general phone usage habits; and (5) attitudes toward apps for health and sleep. Each of these themes emerged from all 3 groups, with the addition of specific feedback on aspects of the prototype presented in the focus group 3. All themes are listed in Table 2 with subcodes and illustrative quotes listed for each theme. Given the objective of the study, the detailed reporting of results and discussion will be limited to the 3 themes that directly relate to the development of the sleep app.

Content

Content refers to the psychoeducational material contained within the app and the information collected about users' actual sleeping patterns.

Sleep Information

Adolescents expressed interest in the number of hours of sleep that are recommended for people their age. Many wanted help setting their body clock and being able to get to sleep earlier, whereas others were less receptive to the idea of being reminded to maintain consistent sleep/wake times, particularly over the weekend. There was also an interest in obtaining information about sleep in general, including why we sleep, what happens to the brain during sleep, what the stages of sleep are, and why we dream. A majority of adolescents liked the idea of including a large database of sleep tips that varied in themes ranging from relaxation strategies to factual information about the benefits of quality sleep. Participants agreed that the user should be free to enter and exit the sleep information as they wish.

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Sleep Diary

There were mixed opinions about completing a daily sleep diary, but most adolescents thought that filling in a sleep diary was acceptable. Some adolescents preferred the idea of completing the sleep diary first thing in the morning, whereas others indicated a preference to complete the diary later in the day or as a way to fill "dead time" such as when on the bus or train to school. One issue that arose was that some young people were concerned that their recollections of sleep and wake times would not be very accurate. On the whole, adolescents were positive about having a sleep record and being able to look back on it as a way to track progress.

Functionality

Functionality refers to the range of operations and capabilities of the app that define the characteristics of the app.

Gamification

Gamification is the application of typical elements of game playing in nongaming systems to improve user experience and engagement [48]. The concept of making the app a game where the user has to "level-up" was universally endorsed. Young people liked the idea of using a belt system within the Sleep Ninja concept as a way to distinguish the different levels. The "belt system" refers to the idea that users begin with a beginner level "white belt" and progress through the levels of increasing difficulty until they become an advanced-level "black belt" in sleep. Having a series of goals that need to be attained before moving to the next level was considered a positive feature of the Sleep Ninja, and adolescents reported that it would enhance their ongoing engagement with the app:

> *It keeps you using the app while otherwise some people may use it for a day and then forget about it.*

Flexibility

Participants indicated that the app should be delivered flexibly. For example, one young person suggested that the user should be able to complete the content components (training sessions) in small chunks rather than all in one go. Others suggested that being given the choice to do shortened versions of each training session as opposed to the regular length training session would add appeal:

> *...you could have a short training session or a long one, so there's the option.*

However, a majority of adolescents then agreed that one standard length training sessions for everyone would be superior because if there were short options they didn't think they would be motivated to do the longer version.

Personalization

Several participants thought the app would be more appealing if it could be personalized. For example, one young person commented:

> *Sometimes when people have apps like this and it's helping them to do with something in their life, they like it to feel like it's connected to you so maybe something like "Hi [name]" or something related to you would be good?*

Other young people felt that the app would be strengthened by having the information tailored to the user and their specific sleep issue.

Reminders and Notifications

Participants expressed mixed opinions about reminders and notifications. Although several young people discussed switching off notifications and ignoring reminders because they "stuff up my phone," in the context of a sleep app, many thought reminders and notifications were acceptable:

> *If it were important and only up to 2 a day asking "Have you filled in your data yet?" I'd do it - it's not annoying or anything.*

A commonly expressed opinion was that reminders and notifications from a sleep app would be helpful:

> *If you're getting notifications and they're definitely going to help you...it would be good.*

On the whole, young people indicated that reminders and notifications needed to be delivered at times that were suitable to the individual and that up to 2 per day would be acceptable.

Accelerometer

A number of participants expressed interest in using the phone's inbuilt accelerometer to track their sleep. However, some participants were concerned about having to keep the phone under their pillow at night for a variety of reasons, which included it being uncomfortable, not being allowed to keep their phones in their room overnight, and concerns about radiation and the health implications. At least six participants did not have these concerns. Interest in the accelerometer was contingent on users being able to receive feedback from the app about their sleep.

Extra Features

Adolescents provided a "wish list" of features they would like to see included in the sleep app. These included calming music/and or stories to read; a meditation recording; an inbuilt function that disables communication at a certain time to remove ability to use social media; a hotline or Web-based portal to discuss sleep problems and strategies with an expert; personal stories of sleep strategies that have worked for other people; an option to have the text read aloud to you; a chatroom to share advice with other users; tangible rewards for improving sleep habits; and a dream diary/notes section.

Accessibility and User Experience

As suggested by the code label, acceptability and user experience relates to attitudes, emotions, and experience of users interacting with the app.

Trust

Participants indicated that trusting the source of an app before downloading it was important. Whereas most participants endorsed the Black Dog Institute to be a trustworthy organization, there was the perception that same-aged peers would be unlikely to recognize the brand. Young people agreed that they often relied on the look of the logo to make decisions about how trustworthy the app is ("It just has to have a good logo."). Developers who have made more than a single app or

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that have user reviews were considered more trustworthy. Participants did not report evaluating the credentials of the developer to assess trust issues nor did they raise scientific quality or validity as important factors in determining trust.

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Table 2. Themes, subthemes, and illustrative quotes for each theme that emerged in the thematic analysis.

Theme	Subtheme	Examples
Content	Sleep information	"A sleep calculator. So, depending on age and things, when you should go to bed or when you should wake up."
		"It would have lots of different information and ideas and strategies."
		"It could have fun sort of facts like if it says you get this amount of sleep, it improves your actual mood, your awareness, your reflexes."
	Sleep diary	"I would do it 5 times a week it's just at the weekend because you don't really know when you wake up."
		"...cause with the tracking, I might not do it as soon as I wake up but maybe once I leave the house when I'm like on the school bus."
Functionality	Gamification	"I think it's good that you can unlock levels...it encourages you to use the app."
		"That's good for young people as young people want to play games."
	Flexibility	"You could have a short training session or a long one."
		"I'm not that keen on the long and short version idea, I think it would be better to say, there are this many questions in the session and it will take approximately this amount of time and when you have the time you sit down and do that."
	Personalization	"...different types of information for people with different sleeping problems -
		something like "Hi [name]" or something related to you."
	Reminders and notifications	"If it were important...asking "Have you filled in your data yet?" I'd do it, it's not annoying."
		"An option that we can swipe across and snooze it so that you can set it again later."
		"Notifications I just ignore in general."
	Accelerometer	"A lot of parents make you sleep with your phones outside of your bedrooms so they wouldn't want you to sleep with your phone under your pillow."
		"I would actually be really interested...so you can tell what helped you sleep."
	Extra features	"A social media thing, so you could...post a message asking for help."
		"...kind of like Siri, so you would ask her like, questions about your sleeping, and she would give you a list of options or something."
Accessibility and user experience	Trust	"There's a lot of dodgy app makers but if it's some trustworthy - like you guys [Black Dog Institute], then I would [trust it]."
		"The logo is really important."
	Privacy	"I feel secure, I like the password."
		"I think the "Sleep Ninja" is really good because you can say it's a game."
	Data security and confidentiality	"I usually put in fake details."
		"Sometimes I don't like, trust the app. Coz I could do my own thing and they could steal my identity, for all I know."
	Data usage and Internet coverage	"If I'm gonna download an app that requires a lot (of data) I'll wait awhile."
		"I don't really use Internet that much. I restrict my apps."
	Cost	"Okay um 50/50 an app costing something is not necessarily going to turn you off."
		"I'm just happy to tolerate some ads and stay with the free version."
	Age-appropriateness	"I think it's good for people our age group...it's very simple to use."
	Look and feel	"It just has to have a good logo."
		"Cartoons are good because they're just kind of easy to recognize."
		"...it needs to have a good layout and easy to navigate."
	Predicted likelihood of using Sleep Ninja	"I would definitely download it and I would do it for a couple of days but I don't know if I'd get sick of it."

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Theme	Subtheme	Examples
Obstacles to sleep	Technology use	"When you're using Instagram or Facebook you're kinda going quickly so if you're in that mindset before going to sleep you can't really relax completely."
	Cognitive and emotional factors	"Sometimes I overthink and then I can't get to sleep because I'm overthinking."
		"...if I'm not getting to sleep, I start stressing that I can't get to sleep because I worry that the next day I'm going to be tired and I keep on thinking about things and I worry."
	Environmental factors	"...even if the door is slightly open and there is a little bit of light coming in, it's also disrupting. And if I'm sleeping in a spot that's not my usual bed."
	School commitments	"...with group assignments we often have to do all-nighters and things."
General phone habits		"I always carry my phone with me."
		"I would feel like half empty [if I forgot my phone]. Coz, I would be thinking the whole time like, has someone messaged me?"
		"I'm not allowed to sleep with my phone in my room but I hide it."
Bedtime habits		"I sometimes put my phone on aeroplane mode right before I go to bed."
		"I usually do something that doesn't help me go to sleep. I will go through my Twitter timeline and my YouTube feed...does keep me awake for a long time."
Attitudes toward apps for health		"If there was something you had a problem with, you would want to go see someone but if it was something you were more curious about...like, I wonder if doing this affects me, you would get an app."
		"I reckon if I did have a sleeping problem, I would be interested."
Motivation for changing sleep habits		"I would do it, if, in the long term it would affect me in a positive way."
		"I sleep well, well...not well, but I don't really care about how I sleep, like I'm not a really bad sleeper but I don't really mind."

Privacy

Participants discussed the idea of concealing the true purpose of the app from their peers. They indicated that a password or lock on the app would be a positive feature. A suggested strategy to enhance privacy was to use an innocuous name for the app:

> *...with the design for the app, someone said something earlier about feeling self-conscious about it so I think [calling it] the "Sleep Ninja" is really good because you can say it's a game.*

Data Security and Confidentiality

Participants raised general confidentiality concerns that they have with apps. Willingness to provide personal information was largely contingent on whether they could understand the reason for needing to sign in and/or provide personal information. Participants did not raise any issues or concerns with data security or storage.

Data Usage and Internet Coverage

Participants discussed different phone data plans and reported a range of levels of concern with the data usage from no concern ("I've got heaps of data.") to a lot of concern ("You don't wanna use your 3G."). Many participants reported downloading apps that run without Internet coverage.

Cost

Some participants had previously paid for apps, whereas others would rather tolerate ads and use only apps that are free. There were mixed opinions on whether they would pay for apps, and those who would, mainly said that they would pay for games or Spotify, and some indicated it would be their parents who would pay for an app.

Age-Appropriateness

The second and third focus groups were shown images of the app, which were rated favorably ("They're easy to understand, they're pretty clear."). Participants generally felt that the images were age-appropriate and felt that the gamified component (see System Design section below) of the app was considered particularly relevant to their age group.

Look and Feel

The aesthetic aspect of the app generated a lot of discussion and was important to all participants. Common preferences were that the app had a simple logo and short name and that these factors contributed toward the impression that the app would be of a good quality. The Sleep Ninja images were generally viewed positively, however, some participants saw them as being too detailed and felt that these could be improved by minimizing the shading and relying just on outlines and block colors.

Predicted Likelihood of Using Sleep Ninja

There were mixed ratings of likelihood to use the Sleep Ninja, ranging from 2 to 9 out of a possible 10. Some participants expressed disinterest because of healthy sleep habits already or not prioritizing changes to their sleep patterns. Other good sleepers did not agree and indicated that they would use it. Whereas most participants thought that they were more likely than not to download the app, the motivation to continue using the app was more commonly questioned:

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I would definitely download it and I would do it for a couple of days but I don't know if I'd get sick of it

System Design

The information raised in the focus group discussions informed a number of key changes made in the Sleep Ninja app:

Content

Specific sleep information requested by young people (eg, sleep stages, reasons for sleeping, and what happens to the brain during sleep) was built into the app in an "Information Section." A database of "Sleep Tips" was also incorporated into the app. As requested by young people, both of these content areas were optional and could be entered and exited at any time by the user. With respect to the sleep diary, the app now includes prompts for the user to complete it first thing in the morning, because young people indicated that they may forget. However, in line with the importance of flexibility expressed by participants, the prompt can be dismissed, and users can complete the diary at any time of the day. Users are also able to access their own past sleep diary data as a way to monitor their progress.

Functionality

The positive consensus about the gamification of the app led to the confirmation of the belt system concept, by which participants could "level up." To align with young people's preferences in terms of flexibility and consistency, the app comprises standard lessons that do not vary in length from user to user, but users can complete as little or as much of each lesson as they wish. Upon reentering the app, the users can then pick up exactly where they left off. Although the app is not personalized to the user in terms of specific details such as their name, the chat-bot structure allows it to be responsive to the needs and interests of the user by asking questions about what they would like to know more about and what issues they are experiencing, and it can also tailor recommendations about sleep times and efficiency goals based on the data inputted by the user. Focus group participants felt that reminders and notifications would be helpful but had to be delivered at suitable times and should not be too frequent. Therefore, notifications are delivered first thing in the morning when the user has indicated they would like to get up and 1 hour before the recommended bedtime. These notifications are configurable and can be "snoozed" should the user be unable to respond immediately. An option to turn off notifications at any time was also built into the design. The accelerometer function has been added as an optional feature; however, given the concerns expressed by young people about keeping their phone close to them while they sleep, this is not a core component of the app. Finally, most of the extra features suggested by young people were beyond the scope of the app because they either did not accord with the best practice guidelines for the treatment of sleep problems (eg, a dream diary), they were impractical (eg, tangible rewards for implementing sleep strategies), or contradicted privacy issues that young people brought up (eg, sharing stories in a chatroom of users). However, in response to requests from young people about a strategy they could use while trying to fall asleep, the inclusion of a meditation recording was incorporated into the app. Although not a core part of all CBT-I programs, the use of relaxation and meditation strategies have been incorporated into some standardized programs (eg, [18]). The need for young people to be able to reach an expert led to the inclusion of a "Get Help Now" function with a direct link to an existing Australian 24-hour crisis helpline.

Accessibility and User Experience

Some participants expressed that trusting the source of an app was important, so to address this, information about the app developers with a link to the organization's website was included in the "Frequently Asked Questions" section. The app was designed to look like a game, based on participant feedback regarding privacy and discretion. The potential for a passcode has been built in, but given that no sensitive personal data are stored in the app, the use of this feature will be determined by user feedback at a later stage. Similarly, given that no sensitive data are collected and stored by the app, there is no need for users to provide personal information, which was a concern for young people. Participants reported a preference for apps that do not require a significant amount of data or continuous Internet coverage. Therefore, the download and use of the Sleep Ninja app is not contingent on an Internet connection, with data uploads to occur only when the device is connected to a Wi-Fi network. There will be no cost to access the app while it undergoes testing. Should it be effective, every effort will be made to keep the app free, but this will depend on the continued cost of making it publicly available. No changes were made to the content to make it more age-appropriate, as the participants agreed that it was suitable for their age-group. The look and feel of the app was simplified based on focus group discussions, with unnecessary detail being removed.

Combining this information garnered from the focus groups, with several core strategies of CBT-I, the Sleep Ninja was created. The structure of the app includes 6 training sessions (lessons), a sleep tracking function, recommended bedtimes based on sleep guidelines, reminders to start the wind-down routine each night, a series of sleep tips, and general information about sleep. The home screen has 3 options: Train, Track, or More (see Figure 1). The Train tab is where users complete the training sessions, each of which covers a core strategy that is delivered through a chat-bot format where the sleep ninja essentially acts as a sleep coach. The core strategies include psychoeducation (training 1), stimulus control (training 2), daytime behavioral activation to improve tiredness at night and sleep hygiene (training 3), identifying and planning for high-risk situations (training 4), cognitive therapy (training 5), and a final review session (training 6). As requested by the participants, the user interacts with the app through the forced choice chat-bot format, so information can be personalized to what they want to know about, without the need to type. Users level up and reach their next "belt" by completing one training session and tracking their sleep for 3 nights (out of a 7-night period).

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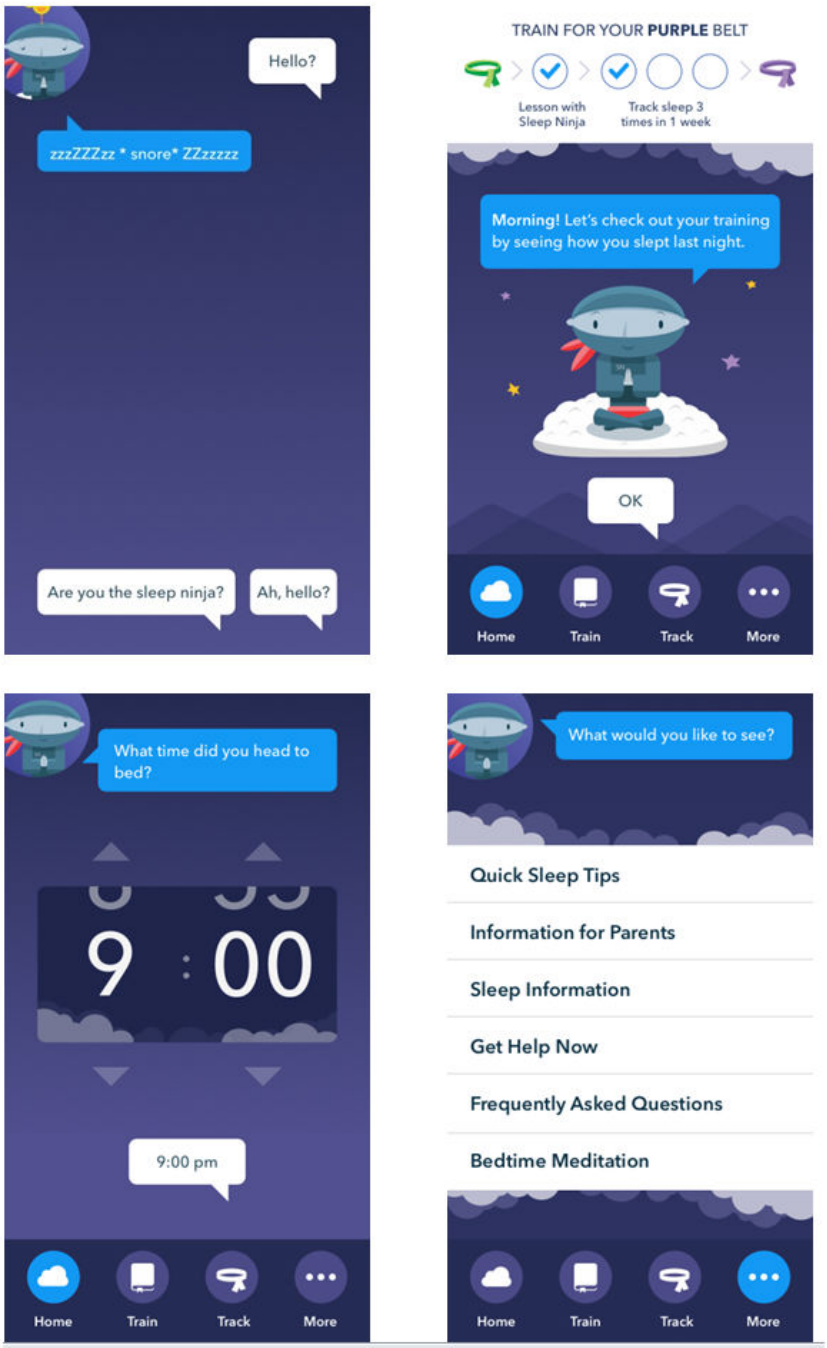
Figure 1. Top-left panel shows Sleep Ninja chat-bot format for training sessions with forced choice options for user at the bottom of the screen; Top-right panel shows home screen where the user can choose to train or track their sleep. An index of what the user needs to do to "level-up" to the next belt is shown at the top of the screen; Bottom-left panel shows an example of completing the sleep diary; Bottom-right panel shows options in the "More" section.



The Track option allows the user to enter data about how they slept last night, and set a wake-up time for tomorrow. This provides the information necessary for the ninja to prompt the user to start their wind-down period an hour before bedtime. Users receive a report at each level about their progress, and when they complete all 6 levels, they become a "black belt" in sleep. The More section contains over 40 different sleep tips, general sleep information and frequently asked questions, details of crisis helplines, a link to email parents information about the app, and a bedtime relaxation exercise. The app is not designed to be used at night, but a relaxation recording was included based on what young people wanted, and so that there was something practical they could use in the moment should they be trying to fall asleep.

Discussion

Principal Findings

This study outlines the involvement of young people in the development and design of a smartphone app, the Sleep Ninja,

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which is a CBT-I based program to help adolescents with their sleep. The adolescents who participated in this study declared a strong interest in the app concept, and most reported that they would be willing to use the app if experiencing poor sleep. However, the likelihood of participants' use of the app was found to be influenced by the sleep content included in the app, its functionality, and user-experience characteristics. Participants made a number of recommendations for how the app could be improved, which included a section outlining the scientific basis for the need to sleep, the ability to enter and exit the app flexibly, tailoring of information to meet the needs of the specific user, limiting reminders to 2 per day, adding a "Get Help Now" function, and the simplification of the app layout and color palette. Participants who saw the prototype were able to provide specific guidance regarding the look and feel including the colour scheme. Most notably, across the focus groups, the young people indicated a preference for gamification, which is not surprising, given the adoption of gaming strategies in other health apps (eg, [49,50]) and the general popularity of games in this age group [51]. These recommendations were accepted in that the app is now delivered in a gamified format with a leveling-up component.

The sample of young people who participated in this study was spaced across the full spectrum of insomnia and psychological distress, with scores from normative levels to the clinical range. This suggests that multiple viewpoints and perspectives in terms of sleep difficulty and psychological distress were provided in the focus group process. The finding that 45% of participants reported at least some clinically notable level of sleep disturbance is commensurate with prevalence estimates in this age group [1,2], as were estimates of psychological distress [52]. The significant correlation between sleep disturbance and psychological functioning in this sample provides evidence of the link between poor sleep and adverse psychological outcomes. The variability in scores and comparability to prevalence estimates confirm that this was a representative and appropriate sample to consult with for the development and design of the Sleep Ninja app.

Even though CBT-I is the gold standard treatment for sleep difficulties, it is not always easily accessible to young people. Adolescents are unlikely to seek professional help for their sleep problems and report a preference for self-reliance methods [53]. The introduction of a smartphone app for the management of sleep disturbance is in line with the preferences of young people, as it is an automated, self-directed tool. A potential concern associated with a low-intensity fully automated app is that some users may require additional support but may not follow up with support services. This aligns with previous work indicating that clinician support for the use of the app can be helpful, particularly in clinical groups [54]. However in this study, users are continually provided feedback while using the app and encouraged to seek help from their doctor or a trusted adult if their symptoms do not improve. This advice, coupled with the easy access to crisis helpline numbers embedded in the app, encourages help-seeking behavior among users who require additional support.

The context in which the app will be delivered and adopted by users will require careful consideration. For example, participants indicated that they seldom search for things off the app store and are likely to get suggestions from friends and families. One possibility is to introduce the app within the school setting such that teachers and school counselors can recommend it for use to young people and their families to treat sleep disturbance, with the possibility of ongoing monitoring. This will also help to mitigate any risks associated with young people failing to seek additional help when they need to. However, before this issue is addressed, the next step in this phase of work is to empirically test the feasibility, acceptability, and efficacy of the app. A pilot trial to address these issues is now underway in Australia (#ACTRN12617000141347).

Limitations

Several limitations to this study warrant mention. First, focus group participants ranged across the continuum in terms of their level of sleep disturbance. Although this had the advantage of incorporating a range of opinions because of the diversity in the sample, it is unclear whether some groups (eg, those with clinical levels of insomnia) are more likely to respond better than others to the app or would perceive certain app features as more crucial than others. This will need to be verified in the next phase of testing. Moreover, the sample size of the study was relatively limited, and focus group methodology is associated with bias in terms of those who volunteer to participate. Although both these factors potentially limit the generalizability of the findings, diversity in the sample in terms of how they were recruited and their level of sleep disturbance in part mitigate this issue. The second limitation is that the focus groups were conducted across different phases of the development process in order to be iterative. This meant that there were fewer participants who contributed to each specific stage of development. However, the semistructured approach taken to conduct the focus groups elicited participants' own views and opinions in general, before specific features or functions associated with the app were presented. As the amount of detail presented about the app was a function of the development stage, the groups did not respond to exactly the same material. Although this is a limitation of the study, it nonetheless allowed for feedback at different points of development, which was deemed important so that the process could be iterative.

Key strengths of this study include the participatory design approach, the automated nature of the intervention, the ability to use the Sleep Ninja on both the iPhone and Android operating systems, and the fact that the Sleep Ninja can be readily scaled to reach large numbers of young people. Although the app has been developed in Australia, there is no reason why it is not suitable for broader use (although it would require crisis helpline information to be adapted).

Conclusions

Sleep disturbance during adolescence at both a subthreshold and clinical level has tremendous impact on broad areas of functioning across social, educational, behavioral, and emotional domains. With up to 40% of young people affected by sleep issues [1,2], establishing healthy sleep patterns early in life among this group has great potential to change a lifelong trajectory toward poorer academic performance, behavioral

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problems, and the onset of mental illness. Information from both the broader literature and the focus groups we report here specifically suggests that not only is there a need for such an app but also that young people are willing and open to adopt its use. Although several digital programs based on CBT-I exist (eg, SHUTi and Sleepio), these have not been designed specifically with young people in mind. Such programs tend to be text-heavy, include content that may not be suitable for adolescents, and can be expensive, making them less appealing and inappropriate for a younger age group. Incorporating elements that have been tailored specifically on the expressed needs of young people, as is the case for Sleep Ninja, is more likely to keep them engaged with the program and will be more suitable than existing adult programs.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Focus group sample questions.

[PDF File (Adobe PDF File), 31KB - mental_v4i3e28_app1.pdf]

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Abbreviations

CBT-I: cognitive behavioral therapy for insomnia
dCBT-I: digitally delivered cognitive behavioral therapy for insomnia
ISI: Insomnia Severity Index
K10: Kessler Psychological Distress Scale

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Editorial / Patient Perspective

Patient-Driven Innovation for Mobile Mental Health Technology: Case Report of Symptom Tracking in Schizophrenia

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Abstract

This patient perspective piece presents an important case at the intersection of mobile health technology, mental health, and innovation. The potential of digital technologies to advance mental health is well known, although the challenges are being increasingly recognized. Making mobile health work for mental health will require broad collaborations. We already know that those who experience mental illness are excited by the potential technology, with many actively engaged in research, fundraising, advocacy, and entrepreneurial ventures. But we don't always hear their voice as often as others. There is a clear advantage for their voice to be heard: so we can all learn from their experiences at the direct intersection of mental health and technology innovation. The case is cowritten with an individual with schizophrenia, who openly shares his name and personal experience with mental health technology in order to educate and inspire others. This paper is the first in JMIR Mental Health's patient perspective series, and we welcome future contributions from those with lived experience.

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KEYWORDS

schizophrenia; mobile health technology; smartphone; mhealth; serious mental illness; apps

Introduction

This patient perspective piece presents an important case at the intersection of mobile health technology, mental health, and innovation. The potential for digital technologies to advance mental health is well known [1], although the challenges are being increasingly recognized [2]. Making mobile health work for mental health will require broad collaborations. We already know that those who experience mental illness are excited by the potential technology, with many actively engaged in research, fundraising, advocacy, and entrepreneurial ventures. But we do not always hear their voices as often as others. There is a clear advantage for their voices to be heard: we can all learn from their experiences at the direct intersection of mental health and technology innovation. This case is co-written with an individual with schizophrenia, who openly shares his name and personal experience with mental health technology in order to educate and inspire others. This paper is the first in JMIR Mental Health's patient perspective series. We welcome future contributions from those with lived experience.

Brief Case

Spencer Roux is a 28-year-old man who was diagnosed with schizophrenia approximately four years ago in 2013. In 2016, he was doing well and working 40 hours per week at his full-time job. However, in the fall of that year he began to notice that symptoms of auditory hallucinations were becoming more frequent. His psychiatrist recommended a change in his antipsychotic medication; however, before agreeing, Spencer wanted to be able to quantify the effects of this new medication.

In order to understand what effect the medication changes would have on his auditory hallucinations, he began theorizing how to track his symptoms. The primary question he sought to answer

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was, would higher doses of medication directly correspond to decreased symptoms of schizophrenia, in particular, hallucinations? To answer his question, he needed data to measure the number of hallucinations experienced per day during the time he was changing his medication. Spencer explained his plan to his psychiatrist and began looking for an easy way to count the number of hallucinations he was having per day.

He first investigated whether smartphone apps could serve as a tally counter, where each time he had a hallucination he could press the screen and log the event. But he quickly found that it was not convenient to use an app because unlocking his smartphone, opening the app, and pushing the digital on-screen counter was cumbersome and often impractical in many social settings. Searching for a better solution, he opted to use an actual tally counter to track his symptoms directly. Because he wanted to be able to access and store his data easily, mechanical tally counters did not match his needs. Instead he researched and purchased a smart tally counter, a digital device that, with the push of a button, wirelessly transmitted the current count to an online portal where he could later access it. While there are numerous digital tally counters available, Spencer selected one after seeing it in use at a local retail establishment and testing it there himself. This digital tally counter was convenient to use as it was easy to access, did not require frequent battery charging, and offered easy access to automatically time-stamped data which could be analyzed later.

After buying this tally counter, he and his psychiatrist began the planned medication change. Over the course of the next four months, every time he had an auditory hallucination, Spencer simply recorded the instance with a press of a button with the digital counter. Below are the results for the first month. Spencer was able to access his own data whenever he wished and began to create graphs of his results, shown in Figures 1 and 2. These figures directly reflect Spencer's efforts and were made in Excel (Microsoft Corp).

Spencer found the results to be exciting and informative. He shared them at each appointment with his psychiatrist and together they used the data to make shared and informed treatment decisions. As shown in Figure 2, Spencer noted that there was a correlation between higher doses of medication and fewer symptoms. Although he began this tally count monitoring with the hope that the lowest dose, or even no medication, would prove effective, the data seemed to tell a different story. While this was not the result Spencer was hoping for, having conducted his own experiment gave him confidence in the results and made him comfortable to remain on the dose that he and his psychiatrist agreed upon.

From the experience, Spencer learned it was possible not only to track and quantify his own mental health experience, but also that such data could be useful for assessing the effectiveness of treatment. The fact that the tally counter tracked the time of each button press allowed Spencer to gain insight into times of the day that were more triggering and to identify weekly fluctuations in symptoms.

Figure 1. Cumulative sum and temporal distribution of auditory hallucinations (colored pink) on one particular day as recorded by button presses on the tally counter.

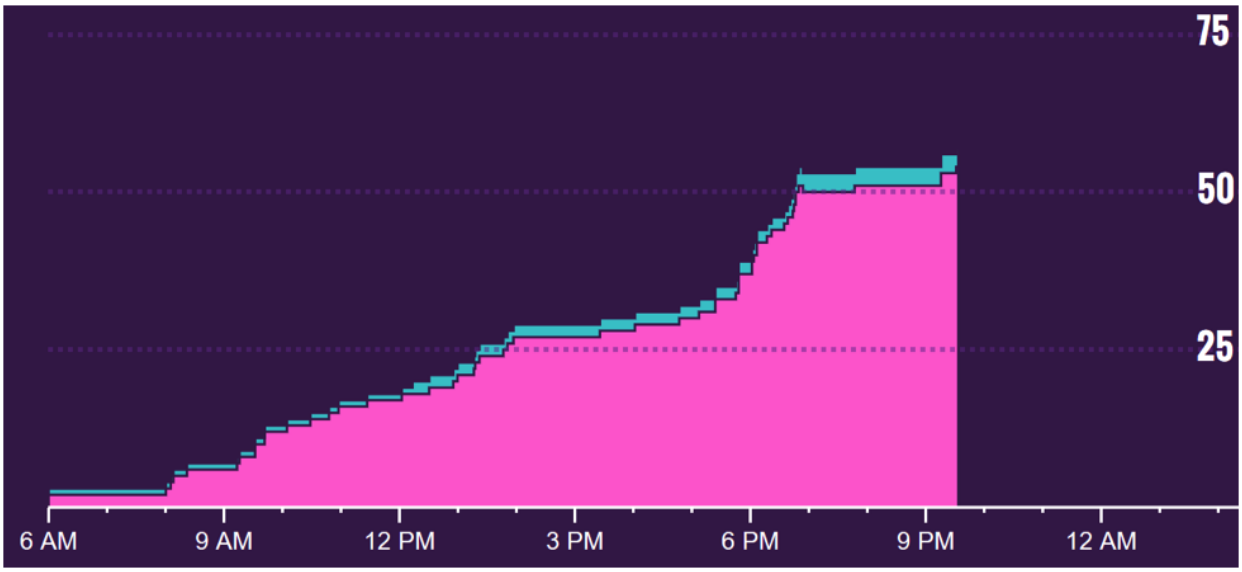

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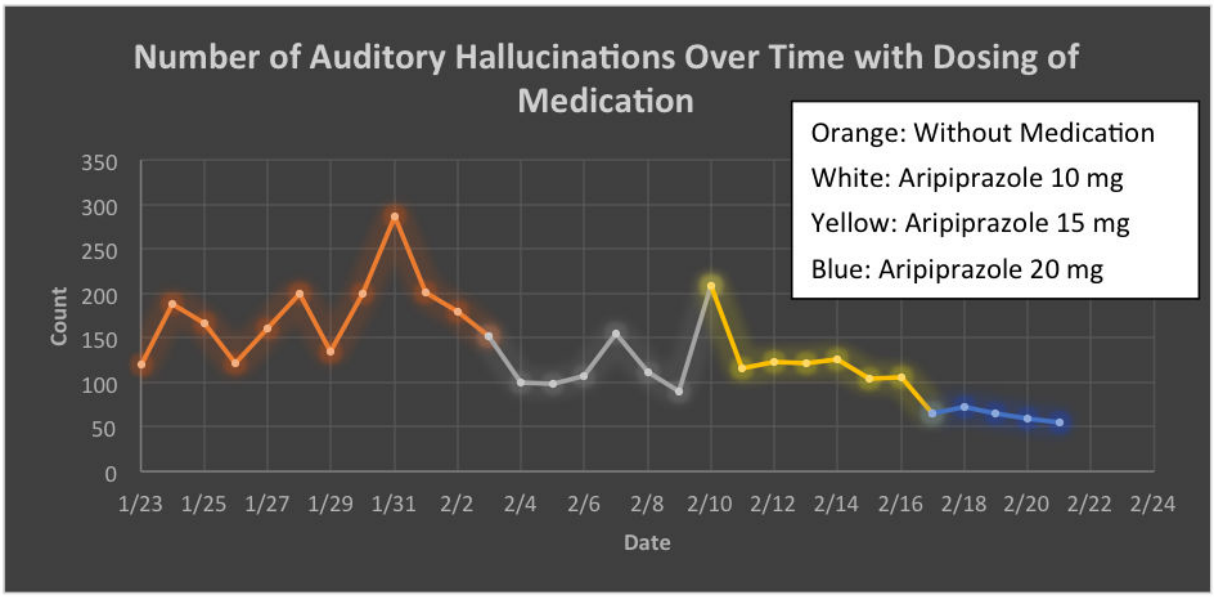
Figure 2. Daily frequency of auditory hallucinations as recorded by the tally counter across time and different doses of medications.



Brief Discussion

Spencer's case is important in advancing recognition of innovation by those with lived experience of schizophrenia, challenging common notions of digital technology use for mental health and highlighting an important use case of mobile technology in mental health. While this is a single case so it is impossible to generalize to others, the lessons are useful for the entire field. Spencer's case is notable for the combination of high engagement, strong interest in technology, and ability to accurately interpret symptoms and, thus, is not applicable to all patients. However, the broad themes of this case are of direct relevance to the entire field.

Creating technology solutions for those with the lived experience of schizophrenia must start with individuals like Spencer. While there has been much attention to the efforts of those with diabetes to use innovative wireless glucose tracking through the Nightscout project [3], there has been less attention to innovations for schizophrenia. When discussing the role of digital technologies for schizophrenia, many still question whether such technologies may worsen delusions or paranoia despite substantial evidence to the contrary [4,5]. Instead we need to be asking how we can learn from the experiences and innovations of those with schizophrenia to co-create digital solutions that are useful and impactful.

Spencer's case also underscores how diverse digital solutions for mental health can be. There is increasing evidence that smartphone apps can be effective monitoring tools for mental health, in part because they are practical given that they are often within reach at all times [6]. But as Spencer's case shows, sometimes a smartphone app is not the solution. There is also growing excitement about the potential of big data in mental health and using smartphones and sensors to gather tremendous amounts of data from those with mental illness, in order to uncover new insights [7]. Passive data, sensor data gathered without active user engagement (e.g., step count collected automatically by a fitness tracker versus active button presses on a tally counter), is an accelerating area of health research now. But as Spencer's case shows, sometimes collecting the right data is more important than collecting a lot of data. Sometimes active data, in the form of hundreds of button presses, is the right answer over passive data. This is not to say that smartphone apps, big data, and passive data are not important for mental health but rather that, in Spencer's case, there was a different technology solution that worked well. Given that passive data solutions require minimal engagement, they are likely to become an important tool for many, although active data solutions should not be overlooked.

Finally, this case serves as a good example of how technology can successfully integrate with clinical care and of how innovative ideas can be created. Spencer did not approach his journey by wondering how he could use a tally counter to improve his mental health. Rather he began with a focused, relevant, and actionable question of how changes in medication dosage were impacting his symptoms. Starting with a question and need, he explored how technology could provide him the necessary data. This question and need guided him to the right technology solution and fueled him with the motivation. Also of note, Spencer worked directly with his psychiatrist, and the technology was used to augment an existing treatment relationship with clinically actionable data and not to disrupt or challenge his care.

Spencer's case represents the unique experiences and journey of a single individual with schizophrenia. What worked well for him may not work well for others as may be the case with many n of 1 and single-case experiments. But the message that those with schizophrenia are innovators in mobile health technology is applicable to all and one that we must increasingly recognize and learn from. Spencer's solution reminds us that while big data, passive data, and smartphone apps are current areas of rapid growth for mental health technology, what really

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matters is what really works. Spencer built a solution that worked for him and created an impactful change in his mental health. Future iterations of Spencer's solution may include a wearable device, although for now his current solution is working well. As we continue to learn more from the leadership and innovation of those with mental illness, the future for digital technology in mental health will be even brighter.

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Conflicts of Interest

None declared.

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