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Original Paper

Developmental Assets of Adolescents and Young Adults With Chronic Illness and Comorbid Depression: Qualitative Study Using YouTube

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Abstract

Background: Developmental assets provide a framework for optimizing development among adolescents but have not been studied in adolescents with chronic illness and comorbid depression, which is a group at risk for poor health outcomes. YouTube postings provide valuable insights to understand this understudied population.

Objective: This study aims to explore asset development from the perspectives of adolescents and young adults (AYAs) with chronic illness and comorbid depression.

Methods: YouTube was searched using 12 chronic illnesses (eg, diabetes) coupled with “depression” as keywords. Videos were included if they were uploaded by AYAs aged between 11 and 29 years and discussed living with chronic illness and depression during adolescence. Video transcripts were coded deductively for 40 internal and external assets that constitute the Developmental Assets Framework. Categories not captured by deductive coding were identified using conventional content analysis. Categories and their respective assets were labeled as being discussed either negatively or positively.

Results: In total, 31 videos from 16 AYAs met the inclusion criteria. A total of 7 asset categories, support, constructive use of time, boundaries and expectations (external assets), identity, commitment to learning, positive values, and social competence (internal assets), reflecting 25 (13 internal; 12 external) assets, were discussed. Internal assets, particularly relating to identity, were commonly discussed by AYAs either in a negative way or fluctuated between positive and negative perspectives.

Conclusions: In this sample of AYAs with chronic illness and comorbid depression, internal assets were commonly discussed in a negative way. Future research is needed to better understand how assets develop and if the Developmental Assets Framework adequately represents the experiences of this population.

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KEYWORDS

adolescent development; chronic disease; depression; developmental assets; positive youth development; YouTube

Introduction

Background

The Positive Youth Development (PYD) theory has become a principal driver of national initiatives supporting the growth and development of youth [1], supporting a comprehensive approach to helping adolescents build on their strengths, rather than identifying and addressing their weaknesses. The Developmental Assets Framework provides a standard framework for conceptualizing the PYD theory, detailing a research-grounded set of 40 protective factors or developmental assets that build on one another to foster positive development [2]. In this framework, assets are categorized as either external, referring to the support and opportunities provided by a youth's community (eg, family support), or internal, encompassing the commitments and values that youth build themselves through engaging in these opportunities and relationships (eg, academic motivation). Longitudinal studies have demonstrated that having a greater number of assets is associated with a number of positive academic, psychosocial, and behavioral outcomes, including a decreased risk of depression [3-6]. These outcomes have been well established among demographically diverse, healthy populations [2].

Up to 30% of adolescents live with a chronic illness [7], broadly defined as a long-term condition requiring ongoing care and management. Recent evidence suggests that developmental assets have a protective effect on mental health, including among adolescents with chronic illness [8-10], offering potential strategies to mitigate this population's increased risk for depression [11,12]. However, as PYD is prevention oriented, applying a PYD lens to adolescents with chronic illness and comorbid depression is rarely undertaken. This represents a significant gap given that depressive symptoms can exacerbate chronic illness-related symptoms and worsen health outcomes [13,14]. An increased understanding of how adolescents with chronic illness and comorbid depression build assets is needed to inform care strategies to mitigate depressive symptoms in this population.

Objectives

YouTube, a public video sharing site with more than 100 million active users, of which, 81% are aged between 15 and 25 years [15], can serve as a valuable secondary source of qualitative data [16-18]. Both registered and nonregistered users can post and consume an array of videos, including those discussing personal experiences. As adolescents with chronic illness and comorbid depression are often difficult to recruit for participation in research, YouTube may serve as an important avenue for gaining an understanding of their viewpoints. This qualitative study aims to explore asset development from the perspectives of adolescents and young adults (AYAs) who lived with chronic illness and comorbid depression during adolescence using videos from YouTube.

Methods

Design

This qualitative descriptive study used YouTube videos uploaded by AYAs with chronic illness and comorbid depression. The goal of qualitative description research is to provide rich accounts about a phenomenon that is not well understood, which can often serve to inform health care strategies by learning from those who experience the phenomenon under investigation [19]. This is accomplished by gathering the "surface of the data and events," as described directly by individuals without a high degree of interpretation [20].

YouTube Video Search and Selection

Eligibility Criteria

We included vlogs (ie, blog-style videos where individuals speak directly to the camera) if the individuals (1) were AYAs aged between 11 and 29 years who discussed experiences during adolescence; (2) indicated having a long-term, noncommunicable physical illness that requires ongoing self-management (ie, diabetes, cystic fibrosis, inflammatory bowel disease, rheumatoid arthritis, sickle cell disease, systemic lupus erythematosus, Lyme disease, mast cell activation syndrome); (3) disclosed having current depression in either the title, description, or content of their video; and (4) shared experiences related to assets in the context of living with chronic illness and depression (eg, discussion on peer relationships). We excluded videos that (1) were not created by an AYA (eg, formal interviews, educational videos); (2) did not indicate age; and (3) were outside the scope of the research question. All videos uploaded since the inception of YouTube in 2005 were considered. One investigator (KZ) screened videos by title, thumbnail, and description and viewed any relevant videos in full to determine whether eligibility criteria were met. Video searches were conducted in June 2019 and repeated in September 2019 and January 2020 to ensure the identification of all relevant videos.

As YouTube users often upload multiple videos over time, we conducted a second search to identify supplementary videos from our selected participants to enrich our understanding of their experiences. Consistent with the process and criteria used to screen primary videos, we went to each AYA's YouTube profile and screened these additional videos by title, thumbnail, and description to assess whether content could be relevant. Supplemental videos deemed relevant on the initial screen were then viewed in full and included if they met all eligibility criteria. Although any video from the same individual can add valuable insight into their lived experiences, we excluded supplemental videos that added no new and relevant information to the first video to keep our scope focused, given our inability to use a traditional interview guide.

Search Terms

We employed separate searches for each chronic illness that met the eligibility criteria. As the YouTube search engine is programmed to identify videos with exact or related search terms, we searched YouTube by pairing the names of each

chronic illness of interest with the term *depression* (eg, *diabetes and depression*). We also conducted a broader search using the terms *chronic illness* and *depression* to identify videos that may have not been identified through the specific search terms listed above.

Transcription

We downloaded the video transcripts directly from YouTube. We indicated the upload date and time of each video and merged multiple videos from the same individual into one transcript. One investigator (KZ) then watched all videos multiple times to clean transcripts and to create fieldnotes (descriptions of nonverbal behaviors and appearance). We extracted descriptive information on each AYA's age, sex, chronic illness type, and whether the conversation reflected past or current experiences from each video. We also documented the number of views, likes, and dislikes the videos obtained, as these measures can be indicators of how popular a video is and whether viewers agree or disagree with the content being shared. We uploaded all transcripts to NVivo qualitative data analysis software to manage the qualitative data.

Data Analysis

We analyzed transcripts using both directed and inductive content analysis [21]. For our deductive approach, we used a priori categories from the Developmental Assets Framework. This framework defines 8 broad categories, in which internal assets are categorized into individual strengths that reflect an adolescent's (1) commitment to learning, (2) positive values, (3) social competence, and (4) positive identity, and external assets are categorized into environmental factors that provide youth with (5) support, (6) empowerment, (7) boundaries and expectations, and (8) constructive use of time. These 8 categories encompass 40 total individual assets that have been identified as fostering positive development among adolescents.

A total of 3 investigators (KZ, AS, and JB) independently coded the first 4 transcripts by labeling segments reflecting the 8 defined asset categories. We further coded passages to label the specific asset and characterized its discussion as positive or negative. These 3 investigators then met to reconcile the discrepancies and created an initial definition of the asset constructs. Using this initial template as a guide, one investigator (KZ) then independently coded the remaining transcripts, meeting weekly to review coding and obtain consensus. We iteratively updated this codebook throughout the coding process, compiling direct quotes from each transcript and grouping them by asset category and specific asset. We then created a template that allowed for side-by-side comparisons of assets used both positively and negatively in the discussion. This allowed for comparisons across transcripts and for the same AYA. Using this template, we then constructed a heat map to visualize the assets most commonly discussed and to identify where heavy fluctuations occurred between positive and negative discussions.

Through an iterative process, we also analyzed transcripts inductively to allow for the emergence of additional categories that did not fall under defined categories of the framework, but still provided context on youth development. Given that an interview guide was not used, we used the following a priori

questions as guidance for this additional analysis, specifically assessing whether (1) AYAs discussed additional factors relating to the broad categories of the Developmental Assets Framework but not directly encompassed by the 40 specific assets listed; (2) whether AYAs mentioned additional types of activities, feelings, or behaviors that may impact their development; and (3) whether these new, emerging codes could potentially fall into the framework, and if not, what related context they arose from. We maintained an updated codebook of emerging codes and categories and their definitions, as determined by consensus. These categories were also marked to indicate whether the discussion was positive or negative. During weekly meetings, the 3 coders worked together to review inductive coding. Concurrent to the analysis of videos, we monitored for data saturation, the point at which no new information was learned. Typically, data saturation signals the end of data collection; however, with secondary analyses, only a finite number of data points (in this case, videos) are available without the option of returning to the field to continue data collection.

Measures to Ensure the Trustworthiness of Qualitative Findings

We employed measures to enhance the trustworthiness of our findings [22]. To enhance confirmability (ie, the neutrality of interpretations) and dependability (ie, consistency of findings), we created a codebook, saturation table, and maintained a comprehensive audit trail by outlining each step of the decision-making process used for data collection, coding, and analysis. Bias was further reduced by multiple investigators with multidisciplinary expertise (ie, psychology and nursing), a form of investigator triangulation. Credibility was enhanced via weekly debriefings and immersion in the data, a form of prolonged engagement. To enhance transferability (ie, applicability of findings to like populations), we collected descriptive information about the YouTube community and videos.

Ethics

The Institutional Review Board of Columbia University Medical Center designated this study as exempt from institutional review board review. We obtained a waiver of consent for the AYAs who uploaded the videos. Although YouTube is a public platform, we took measures to ensure the anonymity of the AYAs who uploaded videos by deidentifying all data. In addition, we searched quotes from each individual using Google and confirmed that the selected videos could not be identified by searching exact quotes that we extracted from the transcripts.

Results

Video Search Results and Descriptive Characteristics

Figure 1 depicts a flow diagram of the video selection process. Of the 862 primary videos screened, most were excluded for being (1) an educational health video, (2) uploaded by an individual outside the targeted age range, and (3) a clip from the news or a television show. Videos from 16 AYAs met all eligibility criteria (n=31 videos; range: 1-3 videos per person). A total of 15 primary videos were identified during the first search and one during the third search. Each of the 16 AYAs

included in the initial search had uploaded anywhere from 1 to 528 total videos to their profiles. Of these supplementary videos, 15 (13 selected after the first search; 2 selected after the second

search) met the eligibility criteria and added new information to the primary videos, resulting in 31 videos describing the experiences of 16 AYAs.

Figure 1. A flow diagram summarizing the YouTube video search selection.

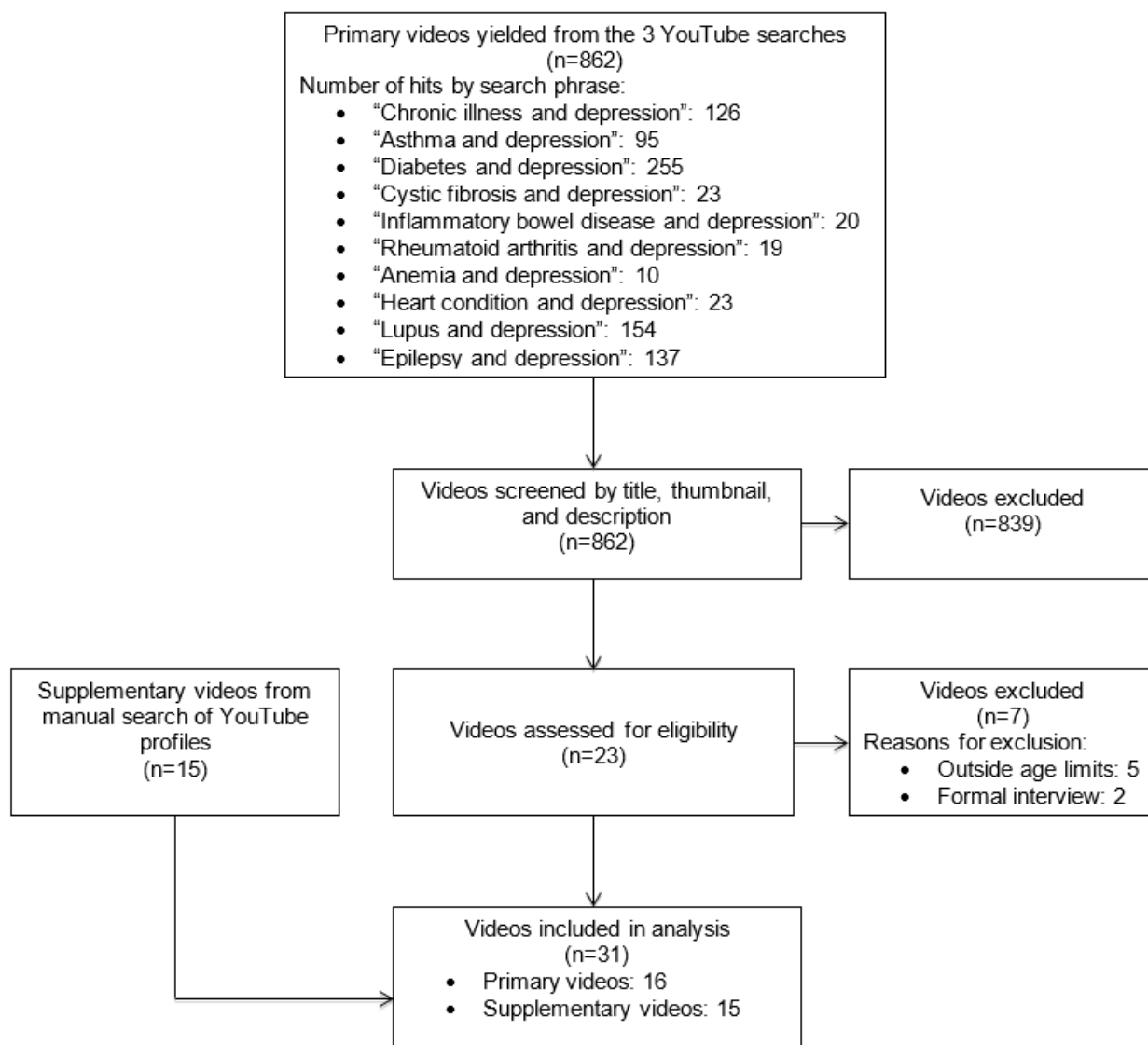


Table 1 summarizes the characteristics of the sample. AYAs were aged between 18 and 27 years during video recording. Most were female, reported type 1 diabetes, and had been diagnosed with their illness between the ages of 3 and 19 years. Collectively, the videos had obtained over 13,606 views, 1104 likes, and 12 dislikes. Overall, AYAs uploaded videos between

November 5, 2013, and March 29, 2019, ranging in length from 3:13 min to 30:35 min. In total, 10 AYAs had more than 1 video included in our analysis. Videos from the same individual were mostly uploaded within the same month, with the exception of videos from 3 individuals that were uploaded across a 2- to 8-month time frame.

Table 1. Descriptive characteristics of the sample.

ID	Chronic illness	Sex	Age (years) ^a	Age of illness diagnosis (years)	Videos, n	Length of videos (mm:ss)	Total views, n	Total likes, n	Total dislikes, n
1	Type 1 diabetes	Male	22	19	1	8:57	972	29	1
2	Type 1 diabetes	Male	24	3	1	9:29	183	2	2
3	Type 1 diabetes	Female	22	15	1	13:22	2166	116	1
4	Type 1 diabetes	Female	20	12	1	8:26	152	1	0
5	Type 1 diabetes	Female	22	NR ^b	2	22:45	104	0	0
6	Type 1 diabetes	Male	21	18	3	28:00	617	54	0
7	Cystic fibrosis	Female	22	NR	2	20:49	482	5	4
8	Colitis	Male	22	10	2	25:56	415	2	0
9	Colitis	Female	27	17	2	16:26	353	11	0
10	Crohn disease	Female	22	14	1	30:35	312	6	0
11	RA ^c	Female	21	16	3	17:30	1309	77	1
12	SCD ^d	Female	22	NR	1	9:05	35	1	0
13	SLE ^e	Female	25	14	3	15:59	4772	609	2
14	MCAS ^f	Female	24	16	3	28:30	77	10	0
15	Lyme disease	Female	18	15	3	25:07	1087	38	0
16	IBS ^g	Female	22	19	2	26:59	570	53	1

^aAge is documented as reported in the most recently uploaded video.

^bNR: not reported.

^cRA: rheumatoid arthritis.

^dSCD: sickle cell disease.

^eSLE: systemic lupus erythematosus.

^fMCAS: mast cell activation syndrome.

^gIBS: inflammatory bowel syndrome.

Developmental Assets Identified by Deductive Coding

Table 2 provides definitions of all framework categories and their respective assets [2]; assets discussed in the videos are marked with an asterisk.

Figure 2 displays the heat map depicting the frequency and direction in which categories and assets are discussed. All but one category on the framework (empowerment) was discussed, reflecting 25 of the 40 assets.

Table 2. Developmental Assets Framework categories and asset definitionsa.

Category and definition	Asset and definition
Internal assets	
Positive identity	
Having high self-esteem, autonomy, holding life purpose, and optimism about the future	<ul style="list-style-type: none"> • Personal power: feels he or she has control over “things that happen to me”^b • Self-esteem: reports having a high self-esteem^b • Positive view of personal future: optimistic about her or his personal future^b • Sense of purpose: reports, “my life has a purpose”^b
Positive values	
Willingness to help others, be honest, and demonstrate respect for others, and give to the community	<ul style="list-style-type: none"> • Caring: places high value on helping other people^b • Honesty: tells the truth even when it is not easy^b • Responsibility: accepts and takes personal responsibility^b • Restraint: places importance on not being sexually active or using alcohol or drugs^b • Equality and social justice: promotes equality and reducing hunger and poverty • Integrity: acts on convictions and stands up for her or his beliefs
Commitment to learning	
Appreciation of school and learning, reflected in ability to complete homework, be curious, and attend school	<ul style="list-style-type: none"> • Achievement motivation: motivated to do well in school^b • School Engagement: actively engaged in learning^b • Homework: 1+ hours of homework done every school day • Bonding to school: cares about her or his school • Reading for pleasure: reads for pleasure 3+ hours per week
Social competence	
Ability to express feelings, maintain peer relationships, say no to risky behaviors, and find positive ways to deal with hardships	<ul style="list-style-type: none"> • Interpersonal competence: has empathy, sensitivity, and friendship skills^b • Planning and decision making: knows how to plan ahead and make choices^b • Resistance skills: can resist negative peer pressure and dangerous situations^b • Cultural competence: comfortable with different cultural, racial, ethnic backgrounds • Peaceful conflict resolution: seeks to resolve conflict nonviolently
External assets	
Support	
Caring adult role models within an adolescent’s life, which may include parents, adults, teachers, and neighbors	<ul style="list-style-type: none"> • Family support: received high levels of love and support from family life^b • Other adult relationships: receives support from 3 or more nonparent adults^b • Positive family communication: willing to seek advice and counsel from parents^b • Caring school climate: school provides a caring, encouraging environment^b • Caring neighborhood: experiences caring neighbors • Parent involvement in schooling: parents actively help young person succeed in school
Constructive use of time	
Extracurricular activities	<ul style="list-style-type: none"> • Time at home: out with friends “with nothing special to do” 2 or fewer nights per week^b • Youth programs: spends 3+ hours per week in sports, clubs, organizations in school, community^b • Religious community: spends 1+ hour per week in activities in religious institution^b • Creative activities: spends 3+ hours per week in lessons or practicing music, theater, other arts^b
Boundaries and expectations	

Category and definition	Asset and definition
Expectations set at home, school, or in the neighborhood that teach adolescents responsible behavior	<ul style="list-style-type: none"> Positive peer influence: best friends model responsible behavior^b School boundaries: school provides clear rules and consequences^b Family boundaries: family has clear rules and monitors the young person's whereabouts^b Adult role models: parents and other adults are modeling positive, responsible behavior^b Neighborhood boundaries: neighbors responsibly monitor young people's behavior High expectations: both parents and teachers encourage the young person to do well

Empowerment

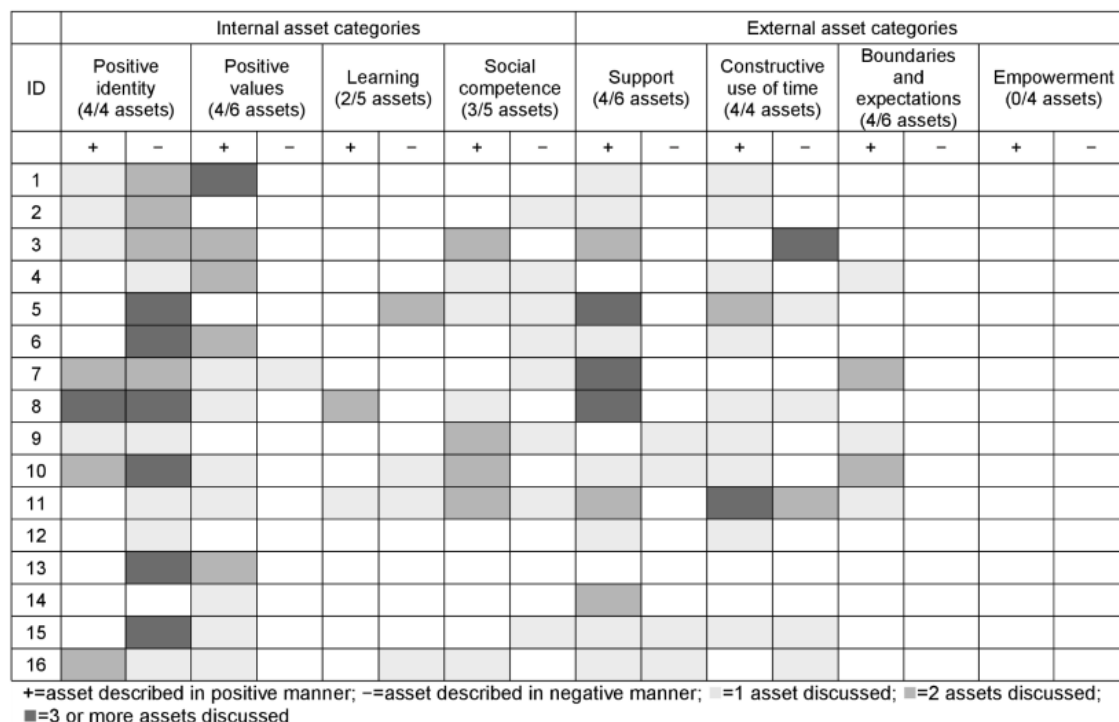
Climate at home or at school that allows youth to feel safe, valued, and appreciated

- Community values youth: perceives that adults in the community value youth
- Youth as resources: given useful roles in the community
- Service to others: serves in the community 1+ hours per week
- Safety: feels safe at home, school, and in the neighborhood

^aThe 40 Developmental Assets was used with permission from Search Institute. Copyright 1997, 2006 Search Institute, Minneapolis, MN.

^bAsset reflected in YouTube videos.

Figure 2. A heat map depicting the density of assets discussed within categories by each individual.



Internal Assets

Positive Identity

All assets in this category were reflected across videos. Overall, the discussion about identity was more negative than positive. However, several AYAs described personal power and view of the future in both positive and negative ways. For example, one individual spoke about moments where his condition left him feeling powerless:

Diabetes for me, I thought that was the end of it. I thought I couldn't touch sugar. I couldn't touch any kind of drinks. I couldn't eat much food. I couldn't do anything...I thought, right, I'm effectively a broken

toy now, so why would you want to be with me? [ID 1, male, age 22, type 1 diabetes]

Later on, he expressed feeling more in control of his disease:

Knowing you can control your diabetes is giving me the strength, and it should give you the strength to say that if you can master this, and keep control of this, you can pretty much do anything.

Another individual spoke about previously viewing his future negatively due to his illness:

I went through a long two months of just...really just depression. My life was not going anywhere. [ID 8, male, age 22, colitis]

However, he noted that more recently he had developed a more positive outlook:

Now I don't take anything for granted, you know, and everything that I receive, everything that goes well, I'm extremely grateful for.

Discussion on self-esteem was mostly negative, with several AYAs expressing struggles with self-confidence manifesting from visible side effects from their medication or symptoms:

My body wasn't reacting very well to the insulin, so I started losing my hair, and as a teenage girl, hair and like body image, self-image is like really important...And when I looked into the mirror I saw someone who was sickly. [ID 3, female, age 22, type 1 diabetes]

Several questioned their sense of purpose in living with an illness:

But the one thing that did stick with me was the question that I had during that time in my life, and it was 'What's the point of my life? What's the point of living?' [ID 15, female, age 18, Lyme disease]

Positive Values

All but two assets were reflected in the discussions. In contrast to the negative discussions around identity, almost all AYAs described the asset of caring in a positive way, encouraging their viewers to reach out to them for help:

If you need help, comment here. If you need advice, or anything...Anything that you want to talk to me about, just leave me an inbox message, or a personal message, or a comment below, and we'll help you out for sure. [ID 4, female, age 20, type 1 diabetes]

Except for one individual who admitted lying to hide self-harming behaviors from family, many pledged honesty in speaking to their viewers and the people around them:

I want to be transparent. I want you guys to truly see what I go through and not just, you know, my edited videos, but the ones that I just feel like saying what's on my mind." [ID 13, female, age 25, systemic lupus erythematosus]

A few AYAs also discussed assets of restraint and responsibility, such as restraining from drugs and alcohol and responsibility for managing their illness:

I feel lucky and happy that I've been able to kind of kick depression right in the arse and say no, you're not taking over my life because the way I look at diabetes is it's not a disability, it's a responsibility. [ID 1, male, age 22, type 1 diabetes]

Commitment to Learning

In total, 2 assets in this category, school engagement and achievement motivation, were discussed. A few individuals emphasized the importance of school and their future careers:

Um, you know, going to college, starting my career...I- I can't just take a year off, I can't do that. Um . . . especially in today's world with how the job

market is, with how competitive everything is. I can't do that. [ID 8, male, age 22, colitis]

Conversely, others admitted that their conditions made them lose any desire to show up to class or complete school-related work:

And for the past few weeks, my depression has been pretty bad. I've not wanted to get out of bed. I've not wanted to do my college work. [ID 5, female, age 22, type 1 diabetes]

Social Competence

AYAs discussed 3 assets within this category. Most AYAs positively described interpersonal competence through discussing their relationships with friends:

I would just talk to them, and I was friends with- my best friend has diabetes, had diabetes, and is still my best friend. [ID 4, female, age 20, type 1 diabetes]

However, a few expressed struggling with interpersonal competence, such as one individual who had difficulty relating to others with diabetes:

I know a lot of people that have been diagnosed at a younger...uh at older ages like 10, 15, 11...And, I don't really know how to communicate with them about it, because so many of them, it's like, it's this life-changing thing. And to me, it's just...it's there because I've always dealt with it as long as I can really remember, you know? And, I mean yeah it sucks. [ID 2, male, age 24, type 1 diabetes]

Several AYAs positively expressed their ability to plan and make decisions for their illness; however, one fluctuated between positive and negative discussions, voicing how she used to dwell on her depression:

But in asking all those questions about my depression and where is this coming from, I wasn't actually looking into the future of actually making it better. [ID 9, female, age 27, colitis]

Later, she explained how one positive decision to implement a better diet and care regimen had propelled her into a better lifestyle:

And that's the only reason I'm sitting here today, is because of that one little decision I made years ago.

A few AYAs also spoke about their inability to resist engaging in behaviors that they knew worsened their condition:

Because I'm binge-eating and- and like, I don't know how to deal with food. I never did. Like it's- I don't know what to say right now. [ID 6, male, age 21, type 1 diabetes]

External Assets

Support

Support was most commonly discussed across AYAs, with 4 of the 6 assets described. Almost all voiced the value of family support and other adult relationships, including health care providers:

Luckily, I've got a great doctor and a great support system behind me with my family and I feel like I can get through this and everything's gonna be okay. [ID 14, female, age 24, mast cell activation syndrome]

Although support was mainly positive, some spoke negatively about their relationships with adults other than family, often due to skepticism from health care providers:

I was also dealing with not being believed by the medical community. [ID 15, female, age 18, Lyme disease]

Another individual also described positive family communication, explaining how conversations with her father helped her deal with depression:

I came up to my room and my dad was lying on my bed and he asked me very specific questions about very specific things that I had been doing. And why, and what I was using, and what he could do to help. [ID 7, female, age 22, cystic fibrosis]

Constructive Use of Time

All assets in this category were discussed, though not as frequently as other assets. Discussion around constructive use of time varied, with a few AYAs fluctuating between positive and negative discussions about time at home. One individual explained how when her condition worsened, it impacted her ability to engage in activities:

I didn't want to eat. I didn't want to hang out with friends. I didn't really want to talk. And I just really didn't want to socialize. [ID 11, female, age 21, rheumatoid arthritis]

She also noted that when her symptoms lessened, she was able to enjoy activities again:

Once my RA symptoms actually started to lessen and the flares were way down, I started to do things that I enjoyed. I started to hang out with my friends...basically, just started to try enjoying my last year of college.

Others briefly touched upon the assets of youth programs, creative activities, and the religious community:

I know you can't see my wall, but I'm looking at it, and I have gotten into anime. It is phenomenal. I'm being more creative, I made a launcher for my room. I've got into art. [ID 5, female, age 22, type 1 diabetes]

Conversely, a few lacked involvement in activities due to their illness:

I stopped doing things that made me happy, like writing for example. I was so into like creative writing, making stories, I had those fan fictions sometimes, just little things like that. And that was something I did to make myself happy. And also dancing, and just pretty much anything that I did before, I just stopped doing because I just didn't feel like myself anymore. [ID 3, female, age 22, type 1 diabetes]

Boundaries and Expectations

Although sparsely reflected, 4 assets within this category were discussed solely in positive light. For example, one individual discussed the asset, positive peer influence, by explaining how a friend to whom she reported her suicidal ideation had saved her:

Because, if you have that one person, they will be your saving grace, just like that one person was for me. And I'm so thankful for her. I'm so thankful she said something even though it was embarrassing and scary...I would not be where I am today without that stepping stone. [ID 7, female, age 22, cystic fibrosis]

Additional Categories Identified Through Inductive Coding

A total of 6 categories relevant to the broad categories of the framework but not encompassed by any of the specific asset definitions were also identified. We reached data saturation for all 6 categories early in the analysis, identifying no new categories after the second video. All categories were discussed by at least 3 individuals, with others (eg, learning about condition, sense of belonging, coping, caring online community) discussed by several.

Learning About Conditions

Several AYAs described their motivation to learn more about their illness and depression, including better ways to manage it:

I studied neuroscience to get a better handle on what was going on with my own body and also understand what was going on with, you know, the realm of chronic illness and mental illness and all of that stuff. [ID 14, female, age 24, mast cell activation syndrome]

Sense of Belonging

Many discussed feelings of belonging to others who were in similar situations:

I found an amazing community of people who are like-minded, just like me, and that's...really incredible for me. [ID 10, female, age 22, Crohn's disease]

Conversely, others voiced feeling alone due to their illness:

And I feel lonely. Mentally, we can feel lonely in a room full of people, in a concert, anywhere. It's a mind state. [ID 6, male, age 21, type 1 diabetes]

Coping

Almost all AYAs shared experiences of when they were able to cope positively or negatively with their illness and depression, with several fluctuations between the two. For example, one individual explained her previous battle with contemplating suicide as an escape from her illness:

Like, having chronic illness is...it ruins your whole life. And it makes you want to die. I mean, I can't tell you how many times in high school I contemplated suicide because I was so sick. [ID 10, female, age 24, mast cell activation syndrome]

She later spoke about how she had found healthier ways to cope more recently:

And in college, I really just started getting a hold of myself, and my stress level, and my anxiety. So that helped a lot too.

Caring Online Community

Almost all AYA expressed receiving strong support from the online community, especially on YouTube:

RA [Rheumatoid Arthritis] community that I came across on Instagram and YouTube, and just being close with you guys have really helped, because I have been able to see how y'all handle RA and just actually have a group of people that I am close with and understand everything that I am going through. [ID 11, female, age 21, rheumatoid arthritis]

Feeling Normal

One individual expressed coming to terms that her illness was a normal part of her life:

People can't tell unless you know my face like, you would think I'm normal. Like, I am normal, but God...um...It's draining. It's honestly draining. But I've come to it, like I've come to it in a light that it's going to be normal, it's going to be my life now. [ID 16, female, age 22, inflammatory bowel disease]

Others voiced feeling *out of the norm* due to their illness:

I have suffered with depression, anxiety, uh...all sorts of minor issues...with sort of...myself, uh, feeling, you know, out of the norm. [ID 2, male, age 24, type 1 diabetes]

Jobs

A few AYA also specified holding a job in their spare time:

Everything was going great! I was in a job, I was back on track, you know, I went to regular meetings, I felt on top of the world. [ID 1, male, age 22, type 1 diabetes]

There were also a few individuals who disengaged from their job due to their illness:

Um, I went through another huge depressive episode when I- I lost my job...I was severely depressed.

Discussion

Principal Findings

Deductive findings provide important information as to the extent that adolescents with chronic illness and comorbid depression discuss developmental assets. Discussion of internal assets was more frequent than that of external assets. AYAs discussed assets from both a positive and negative perspective, demonstrating that asset development is not always a linear path forward. This was most evident for 2 internal asset categories (positive identity and social competence) and 1 external category (constructive use of time). Almost all AYAs in this sample discussed identity in a negative light, with some individuals

fluctuating between positive and negative discussion, which often paralleled changes in reported illness and depression severity. It is important for professionals who work with adolescents to recognize that illness and depression may delay or dictate their ability to develop internal assets.

Contrary to identity, discussions regarding values were mostly positive. These AYAs emphasized helping viewers like them and pledged honesty about their experiences in their YouTube videos. Although this was a self-selected sample of AYAs who willingly uploaded videos on the web, this highlights the utility of using YouTube to identify individuals ready to discuss sensitive topics. As shown in 2 recent reviews, health education resources on YouTube have been examined quite extensively [23,24]; however, few studies have used this platform to explore experiences shared by those affected by health conditions [16,18,25]. As AYAs with chronic illness and comorbid depression are a difficult population to recruit, this study demonstrated the value of listening to their narratives on YouTube.

The Developmental Assets Framework builds on developmental theory of the bidirectional interaction of an adolescent's internal capacity with their environment, suggesting that, at least in part, external assets (representing their environment) foster the development of internal assets [2]. Optimal development is most likely to occur when adolescents and their contexts are self-organized, with each reinforcing positive development of the other. In this sample, most individuals discussed their external assets, notably support, in a positive way; however, for the most part, this was not true for several internal assets. Most AYAs noted that their support systems helped them overcome difficult times, but their struggles with identity were ongoing, suggesting disequilibrium in their development that is likely associated with their illness and depression. In this case, their internal identity struggles may account for withdrawal from external assets, such as those in constructive use of time, with feelings of lack of power over their illness and many other areas of their lives. This may also explain the lack of reflection on empowerment opportunities in external assets.

Implications for Clinical Practice

Monitoring assets relating to identity can be challenging given that they are expressed at the discretion of an adolescent. However, the narrative across AYAs revealed identifiable patterns of behavior that may serve as indicators of identity struggle. For example, individuals indicated withdrawing from activities that they were previously involved in, avoiding their friends, or disengaging from school, even if learning was important to them. These periods of withdrawal were expressed in conjunction with negative identity related to a depressive episode. As such, assets related to positive identity may need focused support (and opportunities to experience being empowered) when adolescents with chronic illness and comorbid depression experience depressive symptoms. Ongoing monitoring of not only an adolescent's overall asset profile but also the types of assets exhibited in the context of the adolescent's current condition and how they change can serve as an important avenue to provide higher quality of care for this population.

Implications for Theory

The additional categories identified from the inductive analysis were more unique to adolescents with chronic illness. These findings may inform extensions of the Developmental Assets Framework tailored to the specific needs of this population while also aligning with broader PYD indicators. Another relationship to explore is the extent to which the current asset framework is associated with positive change in these potential assets related to understanding and coping with illness. An adolescent's motivation to learn about their condition, sense of belonging, feeling normal, and coping may all be, at least in part, results of a strong base of other assets.

The fluctuation in discussions of assets between positive and negative is consistent with developmental theory. Human development is not a straight trajectory of positive growth toward adulthood, and development does not proceed from one step to the next and never *look back*. Rather, development is an iterative process in which persons interact with their contexts [1]. Some incidents may set them back, whereas other incidents may propel them forward. Thus, it is no surprise that many of these AYAs shifted their perspectives as they processed and integrated new experiences.

Related to internal assets, several individuals expressed a commitment to learning, but more in the context of learning about their respective health conditions and ways to manage them. In addition, having an illness appeared to be an additional factor that AYAs had to normalize and integrate into their identity. Consistent with our previous work [26], these additional categories reflect some of the common steps of understanding one's illness, normalizing illness, overcoming limitations, and embracing responsibility that adolescents take in accepting their chronic illness. In addition, learning how to cope is a fundamental aspect of dealing with chronic illness during adolescence [27]. Much like discussions around assets within the framework, our findings illustrate that this sample fluctuated between positive and negative coping styles in relation to their depressive symptoms. Related to external assets, almost all AYAs expressed ways in which the YouTube community served as a strong form of support. Although it has been suggested that social media negatively impacts the mental health of adolescents [28], it is important to recognize the benefits that such platforms can offer. In addition, all of the videos we included obtained either no or very few dislikes and several videos had garnered tens to hundreds of likes, providing some indication that the content being shared was relatable or agreeable to the viewers on this platform. The Developmental Assets Framework does not specifically address the online community as a potential external resource for young people, a significant gap in the framework generally but particularly for this and other populations that find some of their most supportive communities

on the web. Future research can focus on understanding developmental assets that are unique to the needs of those with chronic illness and comorbid depression.

Limitations

Although this study sought to understand asset development among adolescents with chronic illness and comorbid depression, this sample may not be generalizable to non-YouTube users. It is plausible that those who were willing to share experiences may have presented a curated version of themselves that does not accurately depict their experience. In addition, the data were limited to what the individuals within the videos decided to discuss from their experiences. Despite the inclusion of multiple videos from the same individuals, these videos were mostly uploaded within the same month; therefore, we were unable to obtain a detailed sense of the temporal changes associated with asset development. Although 7 of the 8 categories on the Developmental Assets Framework were reflected, empowerment was not. It is possible that we could have heard discussion on the empowerment category if we had the option to sample more AYAs. Therefore, more research to explore asset development in this category is warranted. Relatedly, we were unable to gather information on the treatment, duration, or age at diagnosis of depression based on the content available. Furthermore, as individuals self-reported their diagnosis of chronic illness and depression, verification from either medical records or a health professional was not possible. As YouTube is used globally, there may also have been additional videos in other languages that were not included, limiting our ability to consider cultural generalizability. Finally, this qualitative study could not offer insight into whether and how the assets that were articulated by AYAs were related to positive outcomes such as coping with the illness, maintaining treatment protocols, and other well-being indicators.

Conclusions

This study explored developmental assets from the perspectives of AYAs who lived with chronic illness and comorbid depression during adolescence using videos on YouTube. This sample discussed certain assets in both positive and negative ways. In addition, internal assets appeared to be more difficult to develop for these AYAs, despite external support from family, friends, and care providers. Additional categories highlight unique ways in which assets may apply to adolescents with chronic illness and comorbid depression (eg, learning about illness, support from health care providers). The findings of this study highlight the value of YouTube not only as a source of data but also as a support modality for AYAs who upload videos. More research is needed to understand how to better monitor and reinforce asset development among adolescents with chronic illness and comorbid depression.

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Conflicts of Interest

None declared.

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Abbreviations

AYA: adolescent and young adult

PYD: positive youth development

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Original Paper

Impact of a Web-Based Psychiatric Assessment on the Mental Health and Well-Being of Individuals Presenting With Depressive Symptoms: Longitudinal Observational Study

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Abstract

Background: Web-based assessments of mental health concerns hold great potential for earlier, more cost-effective, and more accurate diagnoses of psychiatric conditions than that achieved with traditional interview-based methods.

Objective: The aim of this study was to assess the impact of a comprehensive web-based mental health assessment on the mental health and well-being of over 2000 individuals presenting with symptoms of depression.

Methods: Individuals presenting with depressive symptoms completed a web-based assessment that screened for mood and other psychiatric conditions. After completing the assessment, the study participants received a report containing their assessment results along with personalized psychoeducation. After 6 and 12 months, participants were asked to rate the usefulness of the web-based assessment on different mental health-related outcomes and to self-report on their recent help-seeking behavior, diagnoses, medication, and lifestyle changes. In addition, general mental well-being was assessed at baseline and both follow-ups using the Warwick-Edinburgh Mental Well-being Scale (WEMWBS).

Results: Data from all participants who completed either the 6-month or the 12-month follow-up (N=2064) were analyzed. The majority of study participants rated the study as useful for their subjective mental well-being. This included talking more openly (1314/1939, 67.77%) and understanding one's mental health problems better (1083/1939, 55.85%). Although most participants (1477/1939, 76.17%) found their assessment results useful, only a small proportion (302/2064, 14.63%) subsequently discussed them with a mental health professional, leading to only a small number of study participants receiving a new diagnosis (110/2064, 5.33%). Among those who were reviewed, new mood disorder diagnoses were predicted by the digital algorithm with high sensitivity (above 70%), and nearly half of the participants with new diagnoses also had a corresponding change in medication. Furthermore, participants' subjective well-being significantly improved over 12 months (baseline WEMWBS score: mean 35.24, SD 8.11; 12-month WEMWBS score: mean 41.19, SD 10.59). Significant positive predictors of follow-up subjective well-being included talking more openly, exercising more, and having been reviewed by a psychiatrist.

Conclusions: Our results suggest that completing a web-based mental health assessment and receiving personalized psychoeducation are associated with subjective mental health improvements, facilitated by increased self-awareness and subsequent use of self-help interventions. Integrating web-based mental health assessments within primary and/or secondary care services could benefit patients further and expedite earlier diagnosis and effective treatment.

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KEYWORDS

online assessment; mental health; e-health; digital diagnosis; mood disorders; bipolar disorder; major depressive disorder

Introduction

Background

Mood disorders are psychiatric conditions in which disturbances in a person's mood are associated with a diverse range of functional impairments [1,2], psychiatric and physical comorbidities [3-5], and increased mortality [6,7]. It is estimated that between 300 and 400 million people worldwide are affected from a mood disorder [8,9]. The most devastating mood disorders are major depressive disorder (MDD) and bipolar disorder (BD), which affect around 6% and 1% of the world's population, respectively [1,2], and consistently rank among the leading causes of disability worldwide. In particular, MDD is considered the second or third largest contributor to the global burden of disease [8,9] and is expected to rank first by 2030 [1]. The resulting economic costs of mood and comorbid disorders are significant, with a recent estimate of the cost associated with loss of productivity because of depressive and anxiety disorders amounting to US \$1.13 trillion every year [10].

The high socioeconomic burden of mood disorders is, in part, a consequence of the difficulty in early diagnosis and treatment of these conditions, resulting in chronic and sometimes lifelong illness. A major cause of delayed diagnosis is that many psychiatric patients are affected in silence and never seek help [11]. Moreover, mood disorders are frequently misdiagnosed because of highly overlapping clinical symptom profiles with other disorders. In particular, BD is frequently (in 40% of cases) misdiagnosed as MDD because of patients seeking help mainly when experiencing a depressive episode [12], with an average 8- to 10-year delay before obtaining a correct diagnosis [13]. A key factor underlying inappropriate diagnosis of mental health concerns is the restricted access to mental health services starting from primary care [14], with low availability of mental health professionals and short consultation times being the norm. There is a clear need for earlier and more accessible psychiatric assessments to reduce the need for high clinician availability.

A particularly promising innovation in this area comprises digital diagnostic tools, in the form of web-based or smartphone apps, which offer increased user accessibility, cost efficiency, and data collection capacity [15]. Most of the efforts in this area have focused on digitalizing existing psychiatric questionnaires [16]. Such apps can add convenience to an approach that is trusted by clinicians and have been shown to collect equivalent data to other questionnaire delivery modes [17]. However, most existing mental health questionnaires are limited in scope, usually focusing on a single disorder and/or a narrow range of symptoms. A more comprehensive approach includes structured interviews [18,19], which implement state-of-the-art diagnostic methodologies in an adaptive questionnaire format and are capable of supporting differential diagnosis. However, these assessments also require time-consuming face-to-face assessments by trained health care professionals. A potential solution to this problem is to incorporate the comprehensive

diagnostic and adaptive format of structured interviews into self-report instruments. These lend themselves well to digitalization, and combining extensive mental health data collection with the pattern-detection power of machine learning algorithms could help achieve more accurate diagnosis.

Despite the potential for fast, cost-effective, and accurate diagnosis, the benefit of web-based psychiatric assessments on users' mental health remains unclear. First, a clear link between completing a web-based assessment and improved clinical outcomes, such as help seeking, diagnosis, and treatment, has not been established. Although there has been evidence that receiving web-based assessment results can promote help-seeking attitudes and behaviors [20-22], one study found the opposite effect in people with social anxiety symptoms [23]. Moreover, only a few studies have explored the effects of web-based assessments on other outcomes, such as changes in awareness and self-help behaviors [24]. Finally, it is unclear which aspects of a web-based assessment are most helpful for users, as there is evidence that users might not engage with the additional information and resources that often accompany an assessment result [25]. Therefore, an examination of the impact of a web-based assessment in a large population is desirable.

Objectives

This study aimed to address the following primary question: Does completing a web-based assessment have the ability to improve participants' perceived mental health and well-being? To answer this question, we used data from over 2000 participants in the Delta Study, a single-arm study that aimed to improve the diagnosis of mood disorders through comprehensive screening for mood and comorbid disorders combined with the development of diagnostic algorithms [26]. We analyzed a variety of baseline and follow-up self-reported measures, ranging from usefulness ratings of the assessment for different mental health-related outcomes to clinical outcomes and well-being scores measured on a psychometric scale. We were interested in examining whether completing the assessment would be perceived as having mental health benefits, through increased awareness and changes in behavior, and whether this would translate into an impact on clinical outcomes, such as a change in diagnosis and/or medication. We also aimed to examine which aspects of the assessment were perceived as most beneficial and to assess the association between perceived effects on mental health and changes in well-being.

Methods

Study Participants

Data used in this analysis were collected as part of the Delta Study (previously known as the Delta Trial, Figure 1), conducted by the Cambridge Centre for Neuropsychiatric Research at the University of Cambridge between April 2018 and February 2020. Over 5000 participants were recruited online through (1) Facebook advertisements and posts, (2) the laboratory website, and (3) emails to participants from previous studies who had

given consent to be recontacted. The inclusion criteria were age between 18 and 45 years; UK residency; and a score of 5 or greater on the Patient Health Questionnaire-9 [27], corresponding to at least *mild depression*. Participants who were pregnant or breastfeeding or who self-reported current suicidal thoughts or behavior were excluded. This resulted in 3232 participants completing the baseline mental health assessment. Of these, participants who replied to either the 6- or the 12-month follow-up were included in the analysis (2064/3232, 63.86%). Baseline demographic data (Table 1) showed that

participants were mostly female (1505/2064, 72.92%) and employed (1169/2064, 56.64%) and had poor self-rated mental health (1402/2064, 67.93%) and at least one previous psychiatric diagnosis (1534/2064, 74.32%), with similar proportions at both follow-ups. A comparison between follow-up respondents and nonrespondents revealed mostly nonsignificant differences in demographics, with the exception that nonrespondents were significantly younger, had less education, and were more likely to rate their mental health as poor or good (Table S1 in Multimedia Appendix 1).

Figure 1. Outline of the Delta Study. Participants displaying depressive symptoms completed a web-based psychiatric assessment on the Delta Study website. The questionnaire asked about demographics, medical history, substance use, and personality, and screened for mood and other comorbid disorders using an adaptive, nonlinear question flow. Upon questionnaire completion, participants were sent a brief report containing their results, personalized psychoeducation, and a list of relevant sources of help (1-3 in the middle panel). Participants could also access a list of self-help tips and existing mental health apps (4-5 in the middle panel) on the Delta Study website. After 6 and 12 months, participants were asked to complete a brief web-based follow-up questionnaire. BD: bipolar disorder, MDD: major depressive disorder, MH: mental health, PHQ-9: Patient Health Questionnaire-9.

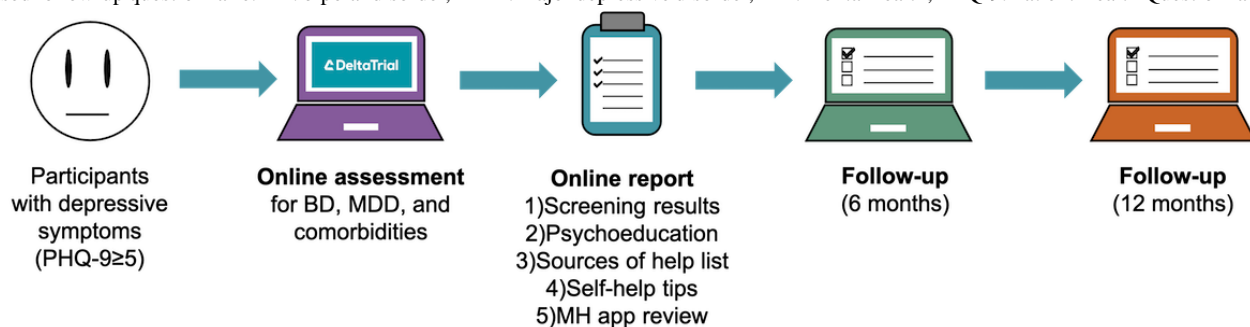


Table 1. Demographic, physical, and mental health characteristics of Delta Study participants at follow-ups (N=2064).

Characteristic	Total (N=2064)	6 months (n=1779)	12 months (n=1542)
Demographic characteristics			
Age (years), mean (SD)	28.97 (7.49)	29.08 (7.49)	29.3 (7.55)
BMI, mean (SD)	28.46 (7.69)	28.54 (7.68)	28.64 (7.78)
Sex, n (%)			
Male	559 (27.08)	490 (27.54)	440 (28.53)
Female	1505 (72.92)	1289 (72.46)	1102 (71.47)
Education, n (%)			
GCSE ^a or lower ^b	381 (18.46)	327 (18.38)	278 (18.03)
Advanced level ^b	610 (29.55)	534 (30.02)	443 (28.73)
Undergraduate	726 (35.17)	616 (34.63)	553 (35.86)
Postgraduate	347 (16.81)	302 (16.98)	268 (17.38)
Employment, n (%)			
Employed	1169 (56.64)	1021 (57.39)	874 (56.68)
Self-employed	113 (5.47)	90 (5.06)	80 (5.19)
Student	449 (21.75)	388 (21.81)	325 (21.08)
Unemployed	314 (15.21)	265 (14.90)	249 (16.15)
Physical health			
Physical illness, n (%)			
Thyroid disease	100 (4.84)	86 (4.83)	76 (4.93)
Multiple sclerosis	5 (0.24)	4 (0.22)	5 (0.32)
Diabetes	45 (2.18)	39 (2.19)	39 (2.53)
Cardiovascular disease or stroke	13 (0.63)	12 (0.67)	10 (0.65)
Chronic bowel problems	195 (9.45)	168 (9.44)	145 (9.40)
Chronic pain (current)	474 (22.97)	404 (22.71)	359 (23.28)
Migraine (moderate-severe)	402 (19.48)	346 (19.45)	297 (19.26)
Blood-borne illnesses	15 (0.73)	13 (0.73)	8 (0.52)
Self-rated physical health, n (%)			
Poor	666 (32.27)	570 (32.04)	496 (32.17)
Fair	773 (37.45)	655 (36.82)	584 (37.87)
Good	626 (30.28)	554 (31.14)	462 (29.96)
Mental health			
Psychiatric diagnoses, n (%)			
Any diagnosis	1534 (74.32)	1328 (74.59)	1154 (74.84)
Major depressive disorder	1441 (69.82)	1244 (69.93)	1092 (70.82)
Bipolar disorder	153 (7.41)	133 (7.48)	113 (7.33)
Generalized anxiety disorder	889 (43.56)	763 (42.89)	676 (43.84)
Social anxiety	381 (18.46)	318 (17.88)	289 (18.74)
Panic disorder	210 (10.17)	168 (9.44)	155 (10.05)
Borderline personality disorder	187 (9.06)	167 (9.39)	135 (8.75)
Obsessive compulsive disorder	149 (7.22)	120 (6.75)	106 (6.87)
An eating disorder	164 (7.95)	141 (7.93)	111 (7.20)

Characteristic	Total (N=2064)	6 months (n=1779)	12 months (n=1542)
Schizophrenia	4 (0.19)	3 (0.17)	3 (0.19)
Self-rated mental health, n (%)			
Poor	1402 (67.93)	1197 (67.28)	1025 (66.47)
Fair	554 (26.84)	485 (27.26)	433 (28.08)
Good	108 (5.23)	97 (5.45)	84 (5.45)

^aGCSE: General Certificate of Secondary Education.

^bThe General Certificate of Secondary Education and the Advanced level are academic qualifications taken by students enrolled in secondary education in the United Kingdom. These are taken after 11 and 13 years of education (upon school leaving), respectively.

Baseline Web-Based Mental Health Assessment

Upon enrolment in the study, participants completed the baseline web-based assessment. This contained 635 questions organized into 6 sessions focusing on (1) demographic information, mental well-being, and diagnostic history; (2) manic and hypomanic symptoms; (3) depressive symptoms; (4) personality traits; (5) history of medication, treatment, and substance use; and (6) other psychiatric symptoms. Questions in the psychiatric screening sessions (2, 3, and 6) were based on existing questionnaires for mood disorders, drawing from the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) [28]; the International Classification of Diseases and Related Health Problems, Tenth Revision [29]; and other previously developed questionnaires and scales [18,30-37]. Psychiatrist and service user input also informed the design and phrasing of the questions. Mental well-being was quantified using the Warwick-Edinburgh Mental Well-being Scale (WEMWBS) [38]. Personality profiling was based on the Big Five framework [39]. The assessment had an adaptive structure, meaning that participants were only asked to answer relevant questions, based on their previous answers. The longest possible chain of questions totaled 382 questions.

Participant Results Report

Following the completion of the baseline assessment, participants were sent a brief nondiagnostic results report through email (middle panel of Figure 1). This suggested the most likely mood and comorbid disorders computed from their answers by an algorithm incorporating DSM-5-like logic. The report also contained tailored psychoeducation about the relevant disorders and a list of sources of help. To complement this information, the Delta Study website additionally contained a list of self-help tips and a review of mental health-related mobile apps that participants could use.

Follow-Up Participation and Questionnaire

After 6 and 12 months, participants were sent emails inviting them to complete a short online follow-up questionnaire. This asked whether they had sought professional help and whether and how their diagnosis and medication had changed over the previous 6 months. It also reassessed mental well-being using the WEMWBS. A total of 1779 participants completed the 6-month follow-up (1779/3232, 55.04%), 1542 completed the 12-month follow-up (1542/3232, 47.71%), and 1257 completed both (1257/3232, 38.89%).

Usefulness Questionnaire

At the end of each follow-up questionnaire, participants were asked whether they wished to answer a further short set of questions. These asked them to rate the usefulness of participating in the Delta Study for different aspects of their mental health: (1) talking more openly, (2) understanding their mental health problems better, (3) being more proactive about help-seeking, (4) getting the right diagnosis, (5) communicating better with mental health professionals, and (6) getting more effective medication. In addition, they were asked to mark which aspects of the Delta Study online assessment (middle panel of Figure 1) they found useful in a multiple-choice question. In total, 1939 completed at least one of the usefulness questionnaires (1939/3232, 59.99%). A total of 1646 completed the 6-month questionnaire (1646/3232, 50.93%), 1398 completed the 12-month questionnaire (1398/3232, 43.25%), and 1105 completed both (1105/3232, 34.19%).

Data Processing and Analysis

All data processing and analysis were performed in R version 3.5.1, and all plots were made using the R package ggplot2 version 3.2.1. Where possible, the 6- and 12-month follow-up responses were combined into one single *follow-up* variable, by either averaging (for Likert-type variables, such as the usefulness ratings), using *or* Boolean logic (for binary variables, such as help-seeking), or imputing missing values with values from the previous time point (for categorical variables, such as diagnosis). Details on data coding and preprocessing can be found in Multimedia Appendix 1.

Self-Reported Usefulness

All participants who responded to the usefulness questionnaire at the end of either follow-up session were included (n=1939). Two types of ratings were assessed: (1) the usefulness of the online assessment for different mental health aspects and (2) the usefulness of different aspects of the Delta Study (middle panel of Figure 1). Usefulness ratings, which were initially coded on 5-point Likert scales, with 1 being not useful at all and 5 being extremely useful, were converted into binary variables, by setting a usefulness threshold of 4. This was done to avoid biases arising because of different interpretations of the midpoint [40].

Professional Help-Seeking Behavior

The following questions were asked: (1) Has the participation in the Delta Study encouraged people to seek professional help? (2) Have participants sought professional help to review their

assessment results? To answer the former question, the number and proportion of participants who sought professional help were computed for before and after the baseline assessment, respectively. To answer the latter question, the number and proportion of participants who sought help after the baseline assessment and also discussed their results report with a professional were computed.

Changes in Diagnosis and Medication

The following questions were asked: (1) How many participants received a new mood diagnosis? (2) With what sensitivity were newly received mood diagnoses predicted by the Delta Study diagnostic algorithm (ie, what percentage of the new mood diagnoses matched the Delta Study assessment results)? (3) How appropriate was the medication change for the newly diagnosed participants? Two categories of participants were of primary interest: those who gained a BD diagnosis (*new BD*) and those without a previous mood disorder diagnosis who received an MDD diagnosis (*new MDD*). Baseline and follow-up diagnoses were self-reported in the respective assessments. The assessment results were computed using a DSM-5-style algorithm that used the clinical symptom profiles to output a diagnostic label. This was presented as a nondiagnostic mood result in the report participants received, to clarify its distinction from a clinical diagnosis. This result was either BD, MDD, or neither. Medication was divided into 3 classes: antidepressants, antipsychotics (including mood stabilizers such as lithium), and anxiolytics. Diagnosis and medication numbers were summarized for the whole population and subpopulations of interest. McNemar tests were used to test whether the proportion of prescriptions from each class was the same before and after baseline; for medication changes in the new BD and new MDD groups, McNemar exact tests were used because of the small sample sizes.

Changes in Mental Well-Being

WEMWBS total scores were computed by summing up the scores from each of the 14 questions of the scale. Paired *t* tests were used to assess whether the mean difference in well-being between each consecutive time point was 0. Linear regression was used to identify significant predictors of 6-month follow-up total scores among predefined outcomes described in the sections Self-Reported Usefulness, Professional Help-Seeking Behavior, and Changes in Diagnosis and Medication above. The baseline score was also added as a predictor, to account for the regression to the mean effect. Only participants who completed both follow-up questionnaires, including the usefulness questions, were included in the analysis (*n*=1105).

Results

Self-Reported Usefulness

The majority of participants reported that the online assessment was useful for talking more openly (1314/1939, 67.77%) and understanding one's mental health problems better (1083/1939, 55.85%; see Figure S1, left panel, in [Multimedia Appendix 1](#)). Fewer participants deemed the assessment useful for encouraging them to be more proactive about help seeking (910/1939, 46.93%) and for improving clinical outcomes, that

is, obtaining the correct diagnosis (652/1939, 33.63%), better communication with professionals (368/1939, 18.98%), and getting more effective medication (258/1939, 13.31%). Among the specific features of the online assessment, the assessment results and personalized psychoeducation had the highest usefulness ratings (1477/1939, 76.17%, and 1267/1939, 65.34% of respondents found them useful, respectively; Figure S2, right panel, in [Multimedia Appendix 1](#)). Meanwhile, other aspects, such as the list of self-help tips and the list of sources of help, were rated lower and were only deemed useful by a minority of respondents (less than 40%).

Professional Help-Seeking Behavior

Approximately the same number of people sought help before (1316/2064, 63.76%) and after the online assessment (1294/2064, 62.69%). Around half (1019/2064, 49.37%) of all the participants sought help both before and after the baseline assessment, and approximately equal numbers of participants initiated (275/2064, 13.32%), or discontinued clinical contact after the baseline assessment (297/2064, 14.39%), respectively. Among all the 1295 participants who sought clinical help after the assessment, only 302 (23.32%) discussed their report with a mental health care professional. The percentage of participants who discussed their report with a professional was higher among participants who first sought clinical support after the assessment (92/275, 33.45%) as compared with participants who had sought help before (210/1019, 20.60%; Table S2 in [Multimedia Appendix 1](#)).

Changes in Diagnosis and Medication

Of the 1295 participants who sought clinical help within the year after the study, 110 (8.49%) received a new diagnosis of either BD (*n*=45) or MDD (*n*=55), with the total number of patients diagnosed with BD increasing by 15.7% (24/153) and the total number of patients with MDD decreasing by 7.07% (92/1301; Figure S2 in [Multimedia Appendix 1](#)). In line with this, there was a significant increase ($P<.001$, McNemar test) in the prescription of antipsychotic or mood-stabilizing medication from baseline (*n*=161) to follow-up (*n*=219). In contrast, the prescription of antidepressant and anxiolytic medication did not change significantly (Table S3 in [Multimedia Appendix 1](#)).

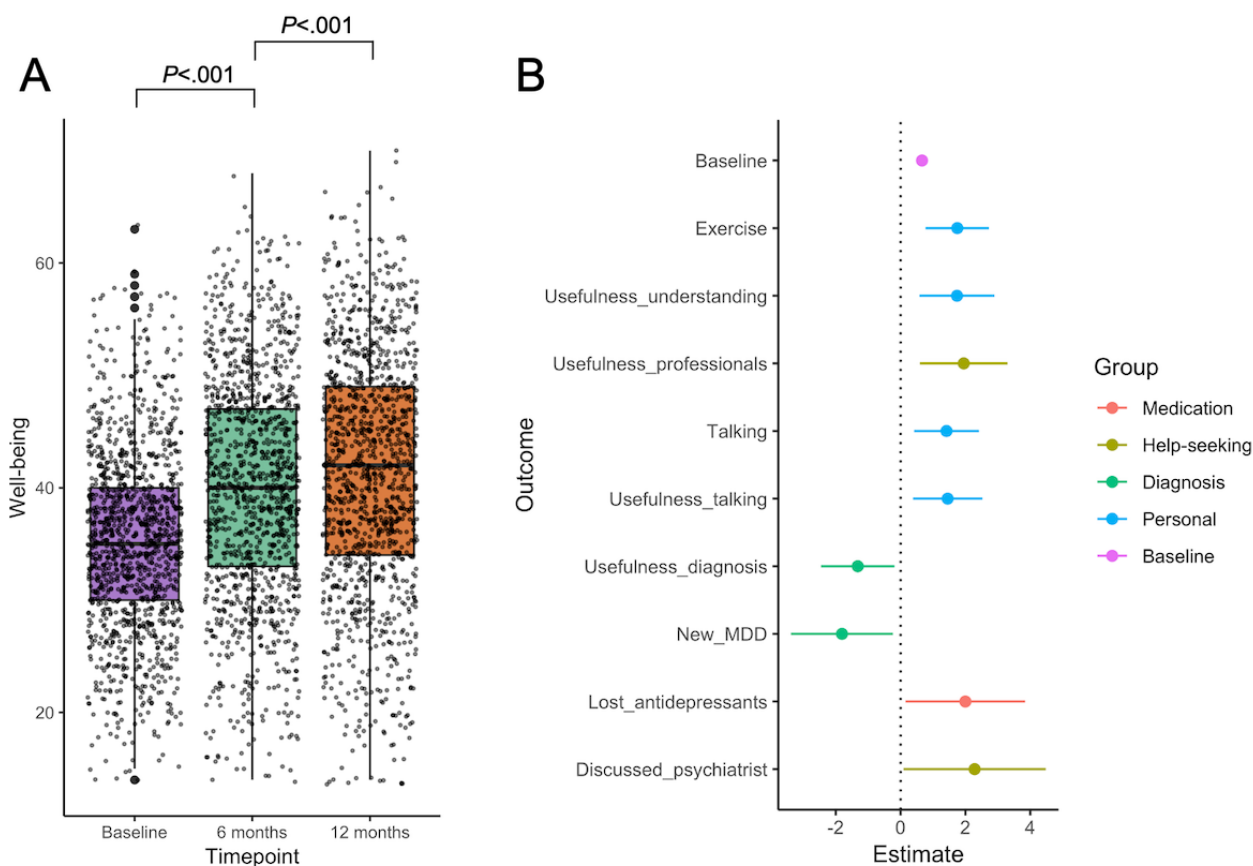
The algorithm predicted new BD diagnoses with 76% sensitivity and new MDD diagnoses with 73% sensitivity (Figure S3 in [Multimedia Appendix 1](#)). In addition, the new diagnoses led to changes in medication for the majority of participants. As expected, the number of participants from the new BD group taking antipsychotics or mood stabilizers increased from baseline (*n*=7) to follow-up (*n*=28), and the number of participants from the new MDD group taking antidepressants increased from baseline (*n*=5) to follow-up (*n*=32, Table S4 in [Multimedia Appendix 1](#)). Both of these changes were significant ($P<.001$, McNemar exact test). In total, 46.4% (51/110) of the participants who received a new diagnosis also received new, clinically appropriate medication (23 new antipsychotic prescriptions in the new BD group and 28 new antidepressant prescriptions in the new MDD group).

Change in Mental Well-Being

At the population level, mental well-being significantly improved on average over the course of the 12 months, by 4.75 WEMWBS points between the baseline and 6-month assessments ($P<.001$; $t_{1256}=19.52$, paired t test) and a further 1.20 points between the 6- and 12-month assessments ($P<.001$; $t_{1256}=4.56$, paired t test; [Figure 2](#), left panel, and Table S5 in [Multimedia Appendix 1](#)). In the regression analysis, we found 10 significant predictors of change in the WEMWBS score, 8 of which had positive coefficient estimates ([Figure 2](#), right

panel, and Table S6 in [Multimedia Appendix 1](#)). The predictor with the lowest P value was the baseline total WEMWBS score ($P<.001$), followed by 2 behavioral changes (talking more about mental health and exercising more) and the 2 highest usefulness ratings (talking more openly and understanding one's mental health problems better). The other 3 significant predictors were discontinuing antidepressant medication (associated with depression remission) and 2 outcomes related to professional contact (discussing the results report with a psychiatrist and the self-reported usefulness of the study toward better communication with clinical professionals).

Figure 2. Longitudinal mental wellbeing of Delta Study participants. (A) Distribution of Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS) scores at all three time points for all participants who completed both the 6- and 12-month follow-up. P values were calculated using paired t tests. (B) Significant predictors of 6-month WEMWBS scores. Dot-and-whisker plot shows regression coefficient estimates and their 95% confidence intervals. The colors correspond to 5 outcome groups: blue for all personal outcomes; orange, yellow, and green for each clinical outcome (medication, help-seeking, and diagnosis, respectively); and purple for baseline. MDD: major depressive disorder.



Discussion

Principal Findings

In this study, we aimed to evaluate the impact of a comprehensive online psychiatric assessment on mental health among participants presenting with symptoms of depression. We showed that completing the online mental health assessment was perceived to have a positive impact on participants' mental health and well-being. On the basis of self-reported usefulness ratings, this impact was primarily associated with receiving the assessment report, along with personalized psychoeducation. The key benefits of the assessment were that participants became more understanding, talked more openly, and became more proactive about seeking help for their mental health concerns.

Moreover, participants' well-being increased on average over time, and people who adopted lifestyle changes and those who thought the assessment was useful for improving their awareness and behavior were more likely to experience an increase in well-being after 6 months.

Improved well-being at the follow-up was also associated with psychiatrist contact and higher self-reported usefulness for communicating with medical professionals. Overall, approximately the same number of participants sought mental health support before and after the online assessment. Only a small proportion of participants discussed their assessment results with a mental health professional; however, participants who had not sought help before were more likely to do so. Finally, for the majority of participants who subsequently

received a new mood disorder diagnosis, the diagnosis matched the results from the online assessment. In addition, nearly half of these newly diagnosed participants also received clinically appropriate treatment.

Overall, the findings of this study can be broadly grouped into *personal* outcomes, which participants could initiate themselves (such as mental health awareness, self-help, and help-seeking attitude), and *clinical* outcomes, which require access to mental health services (such as clinical contact, receiving the right diagnosis, and receiving effective treatment). The self-reported data clearly showed that taking the assessment had a greater impact on personal outcomes. This was further supported by the well-being regression results, in which 4 of the 7 significant positive predictors of well-being (excluding the baseline score) were related to personal factors. This underlines the benefit of online mental health assessments for promoting mental health, even in the absence of clinical help.

It is important to consider through which mechanisms online mental health assessments can improve mental health. According to the participants in the Delta Study, the results and psychoeducation were the most useful aspects of the assessment. The latter is an established means of increasing awareness, and online psychoeducation has previously been shown to increase help-seeking attitudes [41]. However, we did not fully anticipate the effect, as because of ethical considerations, the report had to be kept very brief and, therefore, did not provide detailed information. We also found the low usefulness ratings for the list of self-help tips surprising, given the conceptual overlap with the highly rated personalized psychoeducation. It appears that by providing a diagnostic label and personalized psychoeducation alone, an online psychiatric assessment can exert a positive effect on the mental health of help seekers.

Two of the positive significant predictors of well-being were related to help-seeking, suggesting that contact with health care professionals positively contributes to patient well-being. However, restricted access to mental health care services, a reality across the world (including the United Kingdom [42]), is a major limiting factor. Importantly, this assessment seemed to motivate people to be more proactive about seeking help, in line with previous reports [20]; however, it appears that many help seekers were not able to access clinical support. This was not unexpected, as the study was not integrated within a mental health triage and treatment framework. Future efforts in deploying online mental health assessments and studies investigating their effects should be focused not only on increasing diagnostic accuracy but also on securing access to clinical support.

Although the impact of the Delta Study on diagnostic outcomes was limited, new mood disorder diagnoses were predicted with more than 70% sensitivity. However, the algorithm employed during the study was preliminary, allowing us to provide a screening result and a brief personalized report to each participant. Since the completion of the Delta Study, we have been able to improve the accuracy of the diagnostic algorithm. Moreover, we developed new machine learning algorithms that were validated against a structured clinical interview. Specifically, highly accurate algorithms have recently been

developed for identifying patients with BD who were initially misdiagnosed as MDD [43] and for the differential diagnosis of clinical depression and low mood [44,45]. These recent results have highlighted the tremendous potential of combining the digital collection of psychiatric data with powerful machine learning techniques for informing clinical decision making in the evaluation of psychiatric disorders. Building upon this study, Censeo—a modified and improved version of the Delta Study online mental health assessment—has been developed, which will be tested within primary care settings in the United Kingdom from early 2021.

Finally, as an online mental health assessment is not a psychological intervention, we did not expect a substantial impact on participants' well-being. Nonetheless, the well-being improvement of 6 WEMWBS points over 12 months is comparable with the average effect size of different psychological interventions [46]. It is important to note, however, that the Delta Study was a single-arm study and there was, therefore, no control group with which we could compare. As such, we cannot be sure that the change in well-being is directly linked to the online assessment, especially given the fact that the average WEMWBS baseline score of our participants was around 35, which is lower than the average of 50 for representative studies in the literature [38]. More comprehensive and controlled research is required to investigate the impact of online mental health assessments on well-being.

Strengths and Limitations

To our knowledge, this study is the largest study involving an online mental health assessment of BD to date [47,48]. Targeted online recruitment methods facilitated the recruitment of traditionally hard-to-reach participants. Online delivery also meant that the sample size was large ($n > 2000$) and the follow-up response rate was good (more than 60%), allowing a well-powered detection of changes in behavioral and clinical outcomes.

On the downside, the recruitment strategy employed also meant that the population might differ from patients recruited within specific health care settings. First, people with suicidal ideation, despite being most in need of a timely assessment, were excluded from the study for ethical reasons, as we had no means to provide crisis support. Second, although the preliminary algorithm used to classify participants had good sensitivity (more than 70%), it tended to overdiagnose both BD and MDD and thus suffered from low specificity (65.33% for new BD and 30.78% for new MDD diagnoses). Third, for assessing the perceived impact, we relied on self-reported usefulness ratings, which are prone to response biases [49]. Fourth, as mentioned before, the lack of a control group limits the strength of the causal interpretation of the subjective improvement in well-being. Finally, although the demographic comparison of respondents and nonrespondents showed only minor differences in demographics and self-reported health outcomes, we cannot exclude the possibility that our sample was affected by differential attrition.

Conclusions

We provide evidence that completing an online mental health assessment and receiving personalized assessment results and psychoeducation are associated with a perceived positive impact on mental health and well-being. More precisely, our results suggest a high perceived impact on personal, self-initiated

outcomes, such as awareness and self-help; however, the effect on clinical outcomes such as access to clinical support and treatment is lower. Therefore, we recommend that online mental health assessments should be integrated within existing mental health triage and treatment pathways, such that assessment results are reviewed by clinical professionals, allowing for the initiation of effective interventions.

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Authors' Contributions

SB and DC conceived the study and conceptualized and supervised the development of the online mental health assessment. SB, DC, GB, TO, JD, SH, L Farrag, L Friend, and EB were involved in the design of the study. GB, TO, and PE collected the online mental health assessment data. GB developed the diagnostic algorithm. DM processed and analyzed the data and produced the figures, with input from SB, JT, NM, and GB. DM drafted the manuscript, with contributions from SB, NM, and JT. All authors were involved in reviewing the final version of the manuscript. PE provided computer support. L Farrag provided regulatory advice.

Conflicts of Interest

SB is the Director of Psynova Neurotech Ltd and Psyomics Ltd. SB, DC, GB, L Farrag, and EB have financial interests in Psyomics Ltd. SB, PE, and TO have received payments from the University of Cambridge for licensing data from the Delta Study.

Multimedia Appendix 1

Data processing methods and supplementary tables and figures.

[DOCX File, 1875 KB - [mental_v8i2e23813_app1.docx](#)]

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Abbreviations

BD: bipolar disorder

DSM-5: Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition

MDD: major depressive disorder

WEMWBS: Warwick-Edinburgh Mental Well-being Scale

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Original Paper

Predictors, Outcomes, and Statistical Solutions of Missing Cases in Web-Based Psychotherapy: Methodological Replication and Elaboration Study

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Abstract

Background: Missing cases present a challenge to our ability to evaluate the effects of web-based psychotherapy trials. As missing cases are often lost to follow-up, less is known about their characteristics, their likely clinical outcomes, or the likely effect of the treatment being trialed.

Objective: The aim of this study is to explore the characteristics of missing cases, their likely treatment outcomes, and the ability of different statistical models to approximate missing posttreatment data.

Methods: A sample of internet-delivered cognitive behavioral therapy participants in routine care (n=6701, with 36.26% missing cases at posttreatment) was used to identify predictors of dropping out of treatment and predictors that moderated clinical outcomes, such as symptoms of psychological distress, anxiety, and depression. These variables were then incorporated into a range of statistical models that approximated replacement outcomes for missing cases, and the results were compared using sensitivity and cross-validation analyses.

Results: Treatment adherence, as measured by the rate of progress of an individual through the treatment modules, and higher pretreatment symptom scores were identified as the dominant predictors of missing cases probability (Nagelkerke $R^2=60.8\%$) and the rate of symptom change. Low treatment adherence, in particular, was associated with increased odds of presenting as missing cases during posttreatment assessment (eg, odds ratio 161.1:1) and, at the same time, attenuated the rate of symptom change across anxiety (up to 28% of the total symptom with 48% reduction effect), depression (up to 41% of the total with 48% symptom reduction effect), and psychological distress symptom outcomes (up to 52% of the total with 37% symptom reduction effect) at the end of the 8-week window. Reflecting this pattern of results, statistical replacement methods that overlooked the features of treatment adherence and baseline severity underestimated missing case symptom outcomes by as much as 39% at posttreatment.

Conclusions: The treatment outcomes of the cases that were missing at posttreatment were distinct from those of the remaining observed sample. Thus, overlooking the features of missing cases is likely to result in an inaccurate estimate of the effect of treatment.

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KEYWORDS

psychotherapy; treatment adherence and compliance; missing data; treatment evaluation; statistical bias

Introduction

Background

The ability to evaluate the effect of psychotherapy often depends on the measurement of outcomes before-and-after an intervention. However, many participants are unable to complete measurement questionnaires and become missing cases, thus threatening the validity of conclusions drawn from trials. Missing cases are frequently reported in psychotherapy trials [1,2] and pose a risk to the validity of the evidence base for some treatments [3,4]. Overlooking the causes and outcomes of missing cases can lead to systematic measurement bias and misrepresentation of treatment outcomes and, therefore, risks compromising the validity of clinical research [5,6]. For this reason, careful analysis of the effect of missing cases is now considered an important part of the process of measuring and reporting clinical evidence [3].

Although the importance of handling missing cases is well understood [3,7], accounting for the outcomes of missing cases is a challenging task, as researchers can never verify whether the replacement values they generate accurately captured patient outcomes. Thus, researchers must rely on statistical approximation and the assumption that any replacement outcomes are suitable [8].

A key requirement for handling missing data is to ensure that the outcomes of missing cases are represented within statistical analyses [8]; typically, this involves using a statistical solution that generates replacement values for missing cases [5,8,9]. Researchers rely on statistical methods that explore the characteristics of missing cases to determine whether a statistical solution is suitable for missing cases and whether these features could also be associated with distinct clinical outcomes. This is typically achieved through analyses that identify variables that predict both the probability that participants will become missing cases and the clinical outcome of such missing cases [4,8,10]. Identifying such variables enables researchers to generate replacement scores that are likely to capture the outcomes of treatment for missing cases [7,10]. For example, if older age is associated with a decreased probability of becoming a missing case and an increased rate of symptom change, a statistical model that can adjust for participants' age will be considered to create replacement outcomes that are more accurate and representative of the effects of treatment than models that overlook age. In statistical terms, variables that predict both the likelihood of becoming a missing case and the outcome of missing cases are known as mechanisms of nonignorable missing cases [6,10,11].

Although statistical models that incorporate replacement values for missing cases have been in use for decades [7,8,12], relatively few published studies have reported the characteristics of missing cases in psychotherapy trials or research that identified nonignorable mechanisms of noncompletion that might influence the reported outcomes [2,13]. This gap in methodological research may result from (1) the limited

knowledge about missing cases and the patient features that may generalize across clinical trials [2] and (2) the scarcity of large and comparable treatment samples that are statistically powered to explore nonignorable mechanisms of noncompletion.

Preliminary evidence from trials of internet-delivered cognitive behavioral therapy (iCBT) suggests that common patient variables, such as treatment completion and baseline depressive symptom severity, were the main predictors of both the likelihood of patients dropping out of treatment and moderating the clinical effect [2,4]. These findings suggested that (1) the symptom outcomes of missing cases were not comparable with the patients that provided their data following treatment and (2) missing cases can be characterized through key features that shape the likelihood of a case to present as missing during posttreatment assessment. In particular, minimal treatment adherence, as measured by the partial progress of an individual through the treatment modules, was associated with increased odds of presenting as a missing case during posttreatment assessment (eg, odds ratio 70.6, 95% CI 34.5 to 145.1) and a lower rate of symptom change (eg, 21% for low treatment adherence vs 49% for high adherence) [4]. Without accounting for these variables, web-based psychotherapy researchers risk overlooking a systematic pattern of worse treatment outcomes for missing cases and generating estimates of treatment effects that are unrealistically optimistic. However, the evidence from this study regarding the effect of missing cases in internet-delivered psychotherapy is limited to a single study that focused on symptoms of depression using data from a highly controlled clinical trial with high participant retention (87%) [4]. Replicating this study in an additional therapeutic context and within additional clinical outcomes is needed before conclusions can be drawn regarding the characteristics and effect of missing cases in internet-delivered psychotherapy and the appropriate statistical methods for handling missing cases.

Objectives

The main aim of this study is to examine the characteristics and possible clinical outcomes of missing cases in a large sample in routine care and compare different statistical methods for estimating those outcomes. This study examined the outcomes of a large sample of patients enrolled in treatment courses provided by an established digital mental health service (DMHS) offering internet psychotherapy based on cognitive behavior therapy (n=6701), in which the patients were administered validated self-report questionnaires to measure symptoms of depression, anxiety, and psychological distress at baseline, at intervals during treatment, and at follow-up. It was hypothesized that (1) lower treatment completion and increased baseline depressive symptoms would predict both increased likelihood of noncompletion and higher symptoms of depression posttreatment and that (2) statistical models that account for these features will result in higher posttreatment symptom replacement scores compared with the statistical models that assume missing cases occur as a random event.

Methods

The Sample

This study examined the outcome of routine care provided by Australian National DMHS, the MindSpot Clinic [14]. All participants provided consent for their deidentified data to be used in evaluation and quality improvement activities. Approval for this research was provided by the Macquarie University Human Research Ethics Committee. Further information about the sample, the course content and delivery protocols, and the outcomes of the iCBT can be found in a study by Titov et al [15]. The standardized nature of clinical engagement and treatment delivery in iCBT reduces the likelihood that differences in outcomes are because of different approaches of therapists.

The 6701 participants who commenced treatment during a 30-month period completed self-report symptom scales and

provided other information pretreatment and completed symptom scales midtreatment (surveyed at Week 4), posttreatment (Week 8), and at follow-up (Week 20).

In this study, emphasis was on the prediction of posttreatment symptom outcomes, where posttreatment was considered the main time point for evaluating the effects of treatment [15]. From the participants who initiated treatment, 63.7% (4271/6701) of the sample provided data posttreatment, with 36% (2430/6701) considered to be missing cases as individuals who did not comply with weekly email and telephone prompts to complete a posttreatment evaluation assessment. For cross-replication analysis, the sample was randomly allocated into 5 subgroups, each with more than 1340 participants pretreatment and more than 840 completed measurements posttreatment. Tables 1 and 2 collate the demographic information of the samples, including chi-square values, to confirm adequate randomization.

Table 1. Randomization of cross-validation samples and participant characteristics (N=6701).

Sample	Available sample at pretreatment, n (%)	Available sample at posttreatment, n (%)	Randomization test	
			Chi-square (df)	P value
Total sample	6701 (100)	4271 (64)	0.01 (4)	.99
Replication sample 1	1341 (20.01)	842 (62.79)	N/A ^a	N/A
Replication sample 2	1340 (20.00)	846 (63.13)	N/A	N/A
Replication sample 3	1340 (20.00)	843 (62.91)	N/A	N/A
Replication sample 4	1340 (20.00)	846 (63.13)	N/A	N/A
Replication sample 5	1340 (20.00)	848 (63.28)	N/A	N/A

^aN/A: not applicable (redundant parameter).

Table 2. Sample demographics.

Variable	Value	Randomization test	
		Chi-square (df)	P value
Age (years), mean (SD)	37.57 (10.9)	3.8 (1)	.44
Completed 1/5 modules, n (%)	513 (7.66)	7.5 (4)	.96
Completed 2/5 modules, n (%)	715 (10.67)	N/A ^a	N/A
Completed 3/5 modules, n (%)	718 (10.71)	N/A	N/A
Completed 4/5 modules, n (%)	653 (9.74)	N/A	N/A
Completed 5/5 modules, n (%)	4102 (61.21)	N/A	N/A
In a relationship, n (%)	4458 (66.53)	0.6 (1)	.97
Employment (employed), n (%)	4908 (73.24)	0.8 (1)	.94
Education (tertiary), n (%)	3239 (48.34)	4.0 (1)	.41
Gender (female), n (%)	4866 (48.34)	6.8 (1)	.15
Comorbidity (GAD-7 ^b ≤8 and PHQ-9 ^c ≤10), n (%)	3437 (51.29)	3.0 (1)	.56

^aN/A: not applicable (redundant parameter).

^bGAD-7: generalized anxiety disorder-7 item scale.

^cPHQ-9: patient health questionnaire-9.

Intervention

The participants enrolled in the Wellbeing Course [15], a 5-lesson course delivered over 8 weeks to patients experiencing depression and anxiety. The lessons covered (1) the cognitive behavioral model and symptom identification, (2) thought monitoring and challenging, (3) de-arousal strategies and pleasant activity scheduling, (4) graduated exposure, and (5) relapse prevention. Additional material included downloaded lesson summaries, patient stories, and a range of resources, for example, improved sleep, problem solving, and communication. Each of the lessons provided homework assignments to assist participants in learning and applying the skills described in the lessons to their everyday lives.

Measures

The primary outcome measures for this study were standardized symptom scales for anxiety, depression, and psychological distress.

Patient Health Questionnaire-9

Patient Health Questionnaire-9 (PHQ-9) is a 9-item measure of depressive symptoms. Total scores range from 0 to 27 with higher scores indicating more severe depressive symptoms. PHQ-9 has demonstrated excellent reliability and validity in previous studies [16,17] and high internal reliability (Cronbach $\alpha=.848$) and stability over time (assessment to pretreatment intraclass correlation=.72) within this sample.

Generalized Anxiety Disorder Scale-7 Item

Generalized Anxiety Disorder Scale-7 Item (GAD-7) is a 7-item measure of generalized anxiety. Total scores range from 0 to

21, with higher scores indicating more severe symptoms of anxiety. GAD-7 has shown excellent reliability and validity in previous studies [17,18] and high internal reliability (Cronbach $\alpha=.85$) and stability over time (assessment to pretreatment intraclass correlation=.74) within this sample.

Kessler 10 Item

Kessler 10 Item (K-10) is a widely used 10-item measure of psychological distress. The scale has demonstrated adequate reliability and validity in previous studies [17,19] and within this sample (Cronbach $\alpha=.83$; intraclass correlation=.71). Total scores range from 10 to 50 with higher scores indicating greater levels of psychological distress. The 10 to 50 score range was converted into a 0 to 40 range within the analysis of longitudinal symptom change.

The following measures were also included as possible independent variables or predictors that might predict clinical trajectory through treatment and noncompletion.

Comorbidity

Individuals were considered to have comorbidity if they demonstrated scores of both anxiety and depression above predetermined clinical thresholds (GAD-7 ≥ 8 and PHQ-9 10 at baseline [17]).

Demographic Measures

This included age (in years at the start of treatment), gender, relationship status, pretreatment symptom scores, pretreatment anxiety scores, and educational attainment (Tables 3 and 4).

Table 3. Univariate missing cases probability models of the total sample (N=6701).

Variable considered	Variable test <i>P</i> value	Time* predictor odds ratio (95% CI)	Variance explained (<i>R</i> ²)	RR ^a % missing, odds ratio (95% CI)	Model sensitivity (true positive, %)	Model specificity (true negative, %)	Overall model accuracy, %	AUROC (95% CI) ^b
Sample average	<.001	0.566 (.539 to .595)	N/A ^c	36 (35 to 37)	N/A	N/A	N/A	N/A
Demographic								
Age (% per year)	<.001	0.967 (.963 to .972)	3.80	−1 (−1.1 to −1.1)	62.60	53.00	56.50	0.603 (0.589 to 0.617)
Gender								
Female	.003	1.188 (1.06 to 1.330)	0.20	37 (36 to 39)	74.80	28.60	45.30	0.517 (0.503 to 0.531)
Male	N/A	N/A	N/A	33 (31 to 35)	N/A	N/A	N/A	N/A
Employment status								
At least some employment	.62	0.972 (.868 to 1.088)	0.00	36 (35 to 37)	73.10	26.90	56.80	0.503 (0.488 to 0.517)
Otherwise	N/A	N/A	N/A	37 (34 to 39)	N/A	N/A	N/A	N/A
Relationship status								
In a relationship	0.01	0.876 (.789 to .974)	0.10	35 (34 to 37)	67.80	64.80	56.80	0.515 (0.500 to 0.529)
Otherwise	N/A	N/A	N/A	38 (36 to 40)	N/A	N/A	N/A	N/A
Education level								
Tertiary education	<.001	0.736 (.665 to .813)	0.70	32 (31 to 34)	56.50	51.30	53.10	0.538 (0.524 to 0.553)
Otherwise	N/A	N/A	N/A	40 (38 to 41)	N/A	N/A	N/A	N/A
Initial severity								
Baseline anxiety symptoms (% per GAD-7 ^d point)	<.001	1.024 (1.014 to 1.034)	0.50	0.7 (0.7 to 0.72)	53.10	54.80	51.00	0.535 (0.521 to 0.549)
Baseline depression symptoms (% per PHQ-9 ^e point)	<.001	1.037 (1.028 to 1.046)	1.40	1.4 (1.4 to 1.44)	56.10	53.10	55.00	0.562 (0.548 to 0.576)
Baseline psychological distress (% per K-10 ^f point)	<.001	1.033 (1.026 to 1.040)	1.90	1.1 (1.1 to 1.08)	54.80	55.50	55.00	0.571 (0.557 to 0.585)
Comorbidity at baseline: (PHQ-9 ≥10 and GAD-7 ≥8)	<.001	0.718 (0.649 to 0.793)	0.90	40 (38 to 42)	N/A	N/A	N/A	0.541 (0.556 to 0.527)
None	N/A	N/A	N/A	32 (31 to 34)	N/A	N/A	N/A	N/A
Treatment completion								
Completed all modules	<.001	N/A	60.30	10 (9 to 11)	86.60	83.60	85.50	0.881 (0.872 to 0.891)
Completed (4 of 5)	N/A	9.104 (7.565 to 10.956)	N/A	49 (45 to 53)	N/A	N/A	N/A	N/A
Completed (3 of 5)	N/A	33.715 (27.454 to 41.403)	N/A	78 (75 to 81)	N/A	N/A	N/A	N/A
Completed (2 of 5)	N/A	106.01 (79.5 to 141.36)	N/A	92 (90 to 94)	N/A	N/A	N/A	N/A
Completed (1 of 5)	N/A	162.104 (109.23 to 240.572)	N/A	95 (92 to 96)	N/A	N/A	N/A	N/A

^aRRI: relative risk increment.

^bAUROC: area under receiver-operator characteristics.

^cN/A: not applicable (redundant parameter).

^dGAD-7: Generalized Anxiety Disorder Scale-7.

^ePHQ-9: Patient Health Questionnaire-9.

^fK-10: Kessler 10-Item Scale.

Table 4. Univariate missing cases probability replication models across the five random cross validation samples (N=6701).

Variable considered	Probability estimate of missing values at posttreatment in replication subsamples (95% CI)				
	RRI ^a Rep ^b 1 (n=1341)	RRI Rep 2 (n=1340)	RRI Rep 3 (n=1340)	RRI Rep 4 (n=1340)	RRI Rep 5 (n=1340)
Sample average	36 (34 to 39)	36 (34 to 39)	36 (34 to 39)	36 (34 to 39)	36 (34 to 39)
Demographic					
Age (% per year)	-1.1 (-1.5 to -0.7)	-1.1 (-1.5 to -0.7)	-1.1 (-1.5 to -0.7)	-1.1 (-1.5 to -0.7)	-1.4 (-1.8 to -1)
Gender					
Female	37 (34 to 41)	36 (34 to 40)	38 (35 to 41)	37 (34 to 40)	37 (34 to 40)
Male	33 (29 to 38)	35 (31 to 41)	31 (27 to 36)	34 (29 to 39)	33 (28 to 38)
Employment status					
At least some employment	36 (33 to 39)	35 (32 to 38)	37 (34 to 40)	36 (33 to 39)	36 (34 to 40)
Otherwise	37 (32 to 42)	40 (35 to 45)	35 (31 to 40)	36 (32 to 42)	35 (30 to 40)
Relationship status					
In a relationship	35 (32 to 38)	34 (31 to 37)	37 (34 to 40)	35 (32 to 38)	35 (32 to 38)
Otherwise	38 (33 to 42)	41 (36 to 45)	35 (30 to 39)	39 (35 to 44)	38 (34 to 43)
Education level					
Tertiary education	32 (29 to 36)	31 (27 to 34)	35 (31 to 39)	32 (28 to 35)	33 (30 to 37)
Otherwise	40 (36 to 44)	41 (37 to 45)	37 (34 to 41)	40 (37 to 44)	39 (36 to 43)
Initial severity					
Baseline anxiety symptoms (% per GAD-7 ^c point)	1.1 (0.3 to 1.9)	0.7 (-0.1 to 1.5)	1.4 (0.6 to 2.2)	0.4 (-0.4 to 1.2)	0.7 (-0.1 to 1.5)
Baseline depression symptoms (% per PHQ-9 ^d point)	1.4 (0.7 to 2.1)	1.4 (0.7 to 2.1)	1.1 (0.4 to 1.8)	1.4 (0.7 to 2.2)	1.4 (0.7 to 2.1)
Baseline psychological distress (% per K-10 ^e point)	1.1 (0.5 to 1.6)	1.1 (0.5 to 1.6)	1.4 (0.9 to 2)	1.1 (0.5 to 1.6)	1.1 (0.5 to 1.6)
Comorbidity at baseline: (PHQ-9 ≥10 and GAD-7 ≥8)	40 (36 to 44)	40 (36 to 44)	41 (37 to 44)	40 (36 to 44)	40 (36 to 43)
No comorbidity	33 (29 to 36)	33 (29 to 36)	32 (28 to 35)	32 (29 to 36)	33 (30 to 37)
Treatment completion					
Completed all modules	9 (7 to 11)	9 (8 to 12)	11 (9 to 13)	10 (8 to 12)	9 (7 to 11)
Completed (4 of 5)	57 (48 to 66)	47 (39 to 55)	48 (39 to 56)	51 (42 to 59)	45 (36 to 53)
Completed (3 of 5)	77 (70 to 83)	82 (75 to 88)	72 (64 to 79)	79 (72 to 85)	81 (73 to 86)
Completed (2 of 5)	90 (84 to 94)	91 (85 to 95)	91 (86 to 95)	95 (90 to 98)	93 (87 to 96)
Completed (1 of 5)	95 (88 to 98)	96 (90 to 99)	95 (89 to 98)	94 (87 to 97)	93 (86 to 96)

^aRRI: relative risk increment.

^bRep: randomized subsample for cross-validation purposes.

^cGAD-7: Generalized Anxiety Disorder Scale-7.

^dPHQ-9: Patient Health Questionnaire-9.

^eK-10: Kessler 10-Item Scale.

Treatment Completion

Treatment completion was measured by the progression of participants through the 5 modules of the course, consistent with definitions of treatment progression and adherence in eHealth interventions [20]. Completion was measured by (1) logging in to the assigned secured website and (2) accessing the lesson modules, either being online, when the duration of participation could be recorded, or by downloading the lessons.

Analytical Plan

Identifying Predictors of Missing Cases and the Rate of Clinical Change

The characteristics of missing cases and the estimates of their likely outcomes were examined in 3 steps. All analyses were conducted using SPSS (IBM Corporation) version 25 and a dedicated R software package [21] for longitudinal power [22].

Missing Cases Probability

The first step aimed to identify the relative importance of variables that examined the probability of becoming a missing case. Testing and modeling of the probability of missing cases followed the variable selection strategy outlined by Harrell [23] for logistic regression modeling. In this strategy, potential moderating predictors were tested through separate (univariate) logistic regression models, with the missing case status of the patient at posttreatment as the binary dependent variable. Subsequently, a stepwise variable selection analysis was used to identify factors included in the multivariate model, including treatment completion; baseline depression score; baseline anxiety score; and demographic variables, such as gender, age, employment status, educational attainment, and relationship status. Variables that increased the probability of becoming a missing case were retained in the final model of predictors of missing cases probability. Additional forward and backward model building techniques were also employed to replicate the findings of the stepwise variable selection analysis. Each possible predictor of missing cases was assessed for statistical significance at a more conservative P value of .01. In addition, the ability of each predictor to account for the probability variance of missing cases likelihood was represented with the Nagelkerke R-squared values, which illustrates the predictive contribution of each variable and the variance it can account for in comparison with a model with no predictors [24]. The potential of each variable to differentiate between missing and nonmissing cases was evaluated with sensitivity (prediction of true positives; noncompletion), specificity (prediction of true negatives; observed), and the overall rate of prediction accuracy statistics such as receiver-operator characteristics.

Moderators of Clinical Change

Longitudinal statistical models were also employed to test the influence of baseline and treatment variables on the rate of symptom change. Together, these models sought to identify variables that jointly predicted missing cases and the rate of symptom change, where a significant result on both outcomes would imply a mechanism of missing cases. Longitudinal predictors of symptom change were examined using generalized estimating equation models, such as generalized estimating

equations (GEEs) [25] that included a time covariate, each of the predictors as a main effect, and a time by predictor interaction. In these models, the coefficient of change between pre- and posttreatment (β_{time}) represents the average rate of pre-post symptom change (longitudinal change from baseline) after accounting for within-subject variance (repeated individual scores over time). The moderation of symptom change following treatment was tested by examining the time by covariate interaction (eg, $\beta_{\text{time} \times \text{Gender}}$). All models included a gamma scale, an unstructured pattern of within-subject correlation matrix, and a log link function to account for positive skewness and the proportional pattern of symptom change from baseline [26]. These models were also tested with the overall sample and retested within each of the 5 subsamples. The purpose of cross-replication sought to test whether characteristics of certain missing cases could be observed reliably within cross-validation subsamples.

Power Analyses

A power analysis was conducted for both the GEE longitudinal models of symptom change, and the binary logistic regression models of missing cases probability at posttreatment [27]. To estimate power, these analyses used the observed statistical parameters from pilot GEE models, such as the rate of change over time, the variance of symptom scores at each time point, and within-subject correlation. This information was then used to determine the minimal differences in the rate of longitudinal change (moderation of longitudinal change) that could be refuted as false negatives [22]. The pilot data used to determine the overall rate of change were replication sample 1 ($n=1341$), and the differences from the overall rate of symptom change, or missing cases likelihood, were calculated as the relative difference ($\exp\beta$) from the overall rate of change. These power analyses determine whether nonsignificant tests of symptom change variance, or missing cases probability, are genuine nonsignificant results or whether certain nonsignificant results could be masked by the size of the sample. Separate power estimates were created for the GEE models of symptom change and the binary logistic regression models of missing cases probability. All analyses also specified the probability of power at 80% and a probability of Type I error of .05. The resulting power estimates are further described in the Results section.

Comparison of Different Missing Cases Outcome Approximation Models

Approximated missing cases replacement scores were generated using several types of stratified longitudinal models and evaluated side by side. Models differed from one another by the inclusion of different covariates and a covariate by a time interaction term. For example, by including covariates such as gender and a time-by-gender interaction term, the prediction of replacement outcome scores for missing cases is considered to approximate the corresponding clinical outcomes of that individual as a male or a female. The inclusion of different covariates in the models is thought to test different assumptions about why patients were missing and lead to the adjusted prediction of their likely outcomes [5,8]. In statistical terms, the conditional adjustment of missing cases outcomes by different variables is often referred to as the replacement of

missing cases under a conditional missing at random assumption (MAR) [5,8].

In contrast to the adjusted models, models assumed that posttreatment missingness occurred as a completely random event. In these models, the probability of missingness was assumed to be without any systematic characteristics and was unrelated to the patient's outcome [5,8]. These models included no individual patient covariates, other than the time coefficient, and were labeled as missing completely at random (MCAR). Under such MCAR models, the average replacement of missing cases would reflect the average outcome of the remaining sample of completers, given that missing cases are not assumed to be unique from their completer peers.

Missing cases were also replaced through statistical methods such as multiple imputations and a predictive longitudinal mixed model, which included random slopes and random intercepts [9]. The replacement outcomes from such models were used to compare the estimation of missing cases replacement across different types of statistical methods. This addition intended to establish that the impact from the phenomena of nonignorable missing case mechanisms would be observed despite different statistical techniques. Finally, the results using nonstatistical methods for missing cases replacement, such as the last observation carried forward (LOCF) method and baseline observation carried forward (BOCF) method were compared.

To gauge the accuracy and impact associated with the different replacement models, adjusted models (MAR) were compared and interpreted as either overestimating, underestimating, or being equivalent to models that overlook the features of missing cases (MCAR models). Specifically, if the mean CI from an adjusted model was within the mean CI of an unadjusted model, evidence of statistical equivalence was concluded [28]. If the CI of the mean replacement scores was outside the mean of the scores from unadjusted models cases, the models were considered to approximate distinct (statistically significant) symptom outcomes.

Results

Predictors of Missing Cases and the Rate of Clinical Change

Results from the logistic regression models and testing for predictors of missing cases at posttreatment are presented in Table 3.

The binary models indicated that increased psychological distress (Wald $\chi^2_{1,6701}=70.1$; $P<.001$), increased baseline depressive symptoms (Wald $\chi^2_{1,6701}=152.4$; $P<.001$), decreased treatment completion (Wald $\chi^2_{4,6701}=2247.4$; $P<.001$), and decreased age (Wald $\chi^2_{1,6701}=183.1$; $P<.001$) were significant predictors of missing cases. Together, these variables predicted 60.8% of the variance observed out of the total probability variance for becoming missing at posttreatment (Nagelkerke $R^2=60.80\%$). Predictors of missing cases included relationship status, educational attainment, and comorbidity. However, these

variables accounted for a substantially lower explained variance ($R^2<.005$) and were associated with predictive accuracy that was close to random or around 50% overall accuracy.

The effect of increased baseline severity demonstrated that for every additional PHQ-9 point at baseline, the probability of a participant becoming a missing case at posttreatment increased by 2% or 0.7% as a measure of relative risk (eg, 0.7% of 36%). Similarly, the effect of a 1-point increase in psychological distress at baseline, as measured by K-10, increased the odds of an individual becoming missing by 1.6% or 0.56% as a measure of relative risk.

The age of the participant was associated with a reduced probability of presenting as a missing case, with each additional year of age reducing the odds of becoming a missing case by 3.3% or 1.2% as a measure of relative risk. However, treatment completion, which is the number of lessons completed during treatment, was the dominant predictor of missing cases and accounted for 60.3% of the total 60.8% probability variance of missing cases. The disparity among different rates of treatment completion demonstrated that only 9.80% of participants who completed the entire program did not complete the posttreatment assessment, whereas more than 95% of those who completed only one lesson were missing cases posttreatment.

An interaction between the severity of depressive symptoms at baseline and treatment completion was found to be nonsignificant (Wald $\chi^2_{1,6701 \text{ Treatment completion} * \text{Baseline symptoms}}=2.2$, $P=.71$), as was the age by treatment completion interaction (Wald $\chi^2_{1,6701 \text{ Age} * \chi^2_{\text{Treatment completion}}}=4.9$, $P=.30$). These nonsignificant interactions imply that baseline symptom severity, age, and treatment completion were distinct predictors of missing cases probability and were independently impacting missingness (eg, additive effects that are not conditional on one another).

Table 4 provides estimates of different missing cases predictors and the replication of these results within each of the 5 subsamples.

Power Analyses of Missing Cases Probability Models

Post hoc power analyses of the missing cases models illustrated that the 5 replication subsamples were powered to refute false-negative effects that were as little as 10% of the overall sample probability of missing cases. For example, sample 1 ($n=1341$) was powered to refute false-negative predictors that moderated the probability rate of missing cases by 3.6% or more (10% of the 36% who did not complete the posttreatment assessment). Refuting nonsignificant tests of predictors that were smaller than 3.6% required a sample larger than the sample available (1341). The power to refute nonsignificant results can be illustrated with the test of the gender predictor in Table 5, where missing cases of males were estimated as 33% and that of females at 37%. The difference between males and females was not statistically significant, and the sample in this study was large enough to refute this difference as a genuine nonsignificant (true negative) result, with a power of at least 80%.

Table 5. Longitudinal estimates of average anxiety (generalized anxiety disorder-7) symptom moderation.^a

Characteristic	Moderation of the rate of GAD-7 ^b (anxiety) symptom change		
	<i>P</i> value	Time*Predictor interaction coefficient (exp ^c [β]) for symptom change	Symptom change rate (95% CI)
Sample average	<.001	0.519	48 (47 to 49)
Demographic			
Age (% per year)	.62	0.999	−0.1 (−0.3 to 0.2)
Gender			
Female	.29	0.975	48 (47 to 50)
Male	N/A ^d	N/A	47 (45 to 49)
Employment status			
At least some employment	.046	0.952	49 (47 to 50)
Otherwise	N/A	N/A	46 (44 to 49)
Relationship status			
In a relationship	<.001	0.887	50 (49 to 52)
Otherwise	N/A	N/A	44 (41 to 46)
Education level			
Tertiary education	.46	0.984	48 (47 to 50)
Otherwise	N/A	N/A	48 (46 to 49)
Initial severity			
Baseline anxiety symptoms (% per GAD-7 point)	<.001	0.976	−2.4 (−2.9 to −2)
Baseline depression symptoms (% per PHQ-9 ^e point)	.62	1.001	0.1 (−0.3 to 0.5)
Baseline psychological distress (% per K-10 ^f point)	.30	1.002	0.2 (−0.1 to 0.5)
Comorbidity at baseline: (PHQ-9 ≥10 and GAD-7 ≥8)	.09	0.963	49 (47 to 50)
No comorbidity	N/A	N/A	47 (45 to 49)
Treatment completion			
Completed all modules	<.001	N/A	49 (48 to 51)
Completed (4 of 5)	N/A	0.82	43 (38 to 48)
Completed (3 of 5)	N/A	0.699	35 (28 to 42)
Completed (2 of 5)	N/A	0.694	38 (27 to 49)
Completed (1 of 5)	N/A	0.686	40 (27 to 53)

^aAll estimated cases were derived from generalized estimating equations models and their marginal means.

^bGAD-7: Generalized Anxiety Disorder Scale-7.

^cexp: exponentiated.

^dN/A: not applicable (redundant parameter).

^ePHQ-9: Patient Health Questionnaire-9.

^fK-10: Kessler 10-Item Scale.

Predictors of the Rate of Clinical Improvement

Variables that moderated the rate of symptom improvement were also tested to determine whether similar variables identified to predict missingness also moderated the rate of symptom change over time. The coefficient statistics in [Tables 6 and 7](#)

illustrate the symptom change moderation, associated with each independent variable, for each of the 3 symptom outcomes, with the results presented with separate tables for depressive symptoms ([Table 6](#)), anxiety symptoms ([Table 5](#)), and psychological distress symptoms ([Table 7](#)).

Table 6. Longitudinal estimates of average depressive (Patient Health Questionnaire-9) symptom moderation.^a

Characteristic	Moderation of the rate of PHQ-9 ^b (depressive) symptom change		
	<i>P</i> value	Time*Predictor interaction coefficient (exp ^c [β]) for symptom change	Symptom change rate (95% CI)
Sample average	<.001	0.521	48 (47 to 49)
Demographic			
Age (% per year)	.12	0.998	−0.2 (−0.4 to 0)
Gender			
Female	.18	0.967	48 (47 to 50)
Male	N/A ^d	N/A	47 (44 to 49)
Employment status			
At least some employment	.02	0.946	49 (47 to 50)
Otherwise	N/A	N/A	46 (43 to 48)
Relationship status			
In a relationship	<.001	0.893	50 (48 to 52)
Otherwise	N/A	N/A	44 (42 to 46)
Education level			
Tertiary education	.82	0.995	48 (46 to 50)
Otherwise	N/A	N/A	48 (46 to 50)
Initial severity			
Baseline anxiety symptoms (% per GAD-7 ^e point)	<.001	1.003	0.3 (−0.1 to 0.7)
Baseline depression symptoms (% per PHQ-9 point)	<.001	0.988	−1.2 (−1.6 to −0.9)
Baseline psychological distress (% per K-10 ^f point)	<.001	1.003	0.3 (0 to 0.6)
Comorbidity at baseline: (PHQ-9 ≥10 and GAD-7 ≥8)	.006	1.051	36 (34 to 37)
No comorbidity	N/A	N/A	39 (37 to 41)
Treatment completion			
Completed all lesson modules	<.001	N/A	49 (48 to 51)
Completed (4 of 5)	N/A	0.874	42 (37 to 47)
Completed (3 of 5)	N/A	0.779	35 (28 to 42)
Completed (2 of 5)	N/A	0.75	33 (20 to 45)
Completed (1 of 5)	N/A	0.711	29 (13 to 45)

^aAll estimated cases were derived from generalized estimating equations models and their marginal means.^bPHQ-9: Patient Health Questionnaire-9.^cexp: exponentiated.^dN/A: not applicable (redundant parameter).^eGAD-7: Generalized Anxiety Disorder Scale-7.^fK-10: Kessler 10-Item Scale.

Table 7. Longitudinal estimates of average psychological distress (Kessler-10) symptom moderation.^a

Characteristic	Moderation of the rate of K-10 ^b (psychological distress) symptom change		
	P value	Time*Predictor interaction coefficient (exp ^c [β]) for symptom change	Symptom change rate (95% CI)
Sample average	<.001	0.63	37 (36 to 38)
Demographic			
Age (% per year)	.64	1	0 (–0.2 to 0.1)
Gender			
Female	.29	0.975	48 (47 to 50)
Male	N/A ^d	N/A	47 (45 to 49)
Employment status			
At least some employment	.01	0.946	38 (36 to 40)
Otherwise	N/A	N/A	34 (32 to 37)
Relationship status			
In a relationship	<.001	0.892	39 (38 to 41)
Otherwise	N/A	N/A	32 (30 to 35)
Education level			
Tertiary education	.79	1.005	37 (35 to 39)
Otherwise	N/A	N/A	37 (35 to 39)
Initial severity			
Baseline anxiety symptoms (% per GAD-7 ^e point)	.01	1.005	0.5 (0.1 to 0.8)
Baseline depression symptoms (% per PHQ-9 ^f point)	<.01	1.005	0.5 (0.2 to 0.8)
Baseline psychological distress (% per K-10 point)	<.001	0.994	–0.6 (–0.9 to –0.4)
Comorbidity at baseline: (PHQ-9 ≥10 and GAD-7 ≥8)	.08	0.962	49 (47 to 50)
No comorbidity	N/A	N/A	47 (45 to 49)
Treatment completion			
Completed all modules	<.001	N/A	38 (37 to 39)
Completed (4 of 5)	N/A	0.881	34 (29 to 39)
Completed (3 of 5)	N/A	0.77	27 (19 to 34)
Completed (2 of 5)	N/A	0.763	30 (19 to 41)
Completed (1 of 5)	N/A	0.644	18 (2 to 34)

^aAll estimated cases were derived from generalized estimating equations models and their marginal means.

^bK-10: Kessler 10-Item Scale.

^cexp: exponentiated.

^dN/A: not applicable (redundant parameter).

^eGAD-7: Generalized Anxiety Disorder Scale-7.

^fPHQ-9: Patient Health Questionnaire-9.

Table 6 shows that posttreatment depressive symptoms were moderated by treatment completion, all 3 baseline symptom levels, and relationship status; all presenting with significant predictor by time interactions. Thus, increases in baseline symptom severity, increased treatment completion, and relationship status significantly increased the rate of depressive symptom improvement in therapy.

Significant predictors of the rate of change in anxiety symptoms were similarly identified. Specifically, increased baseline anxiety

symptoms, increased treatment completion, and the relationship status in treatment seemed to increase the rate of symptom change. The results of the anxiety moderators are presented in Table 5.

Analyses exploring moderators of general psychological distress (K-10) yielded the same pattern, with the results presented in Table 7, showing treatment completion, baseline severity, and relationship status to significantly moderate changes in psychological distress.

Power Analyses of Symptom Change Rate Models

Post hoc power analyses of the GEE symptom change models demonstrated that each of the 5 replication subsamples was adequately powered to determine which variables were nonsignificant if they moderated the rate of symptom change by as little as 12% of the total depression symptom change effect (5.7% of 48%). Within the anxiety symptom change models, the sample was powered to refute nonsignificant predictors that moderated 12% of the total reduction of anxiety symptom reduction (5.7% of 48%) and 13% of the total psychological distress symptom reduction (4.4% of 37%). Refuting predictor effects that were smaller than 5.7% (PHQ-9 and GAD-7) and 4.4% (K-10) required a sample that was larger than the 842 participants available in each of the subsamples.

Identified Mechanisms of Nonignorable Missing Cases

The predictors of treatment completion, baseline symptoms, and, to a lesser extent, relationship status demonstrated an

association with both the likelihood of missing data at posttreatment and the rate of symptom change over time. These results confirm that treatment completion and, to a lesser extent, baseline symptoms were not significantly associated with noncompletion.

The association of treatment completion and baseline symptoms with both clinical improvement and risk of presenting as missing cases are illustrated in Figure 1 (missing cases probability at posttreatment and symptom change, associated with program completion) and Figure 2 (missing cases and symptom change trends associated with depressive symptom baseline severity and depressive symptom outcomes). These figures illustrate how the probability of missing cases is likely to increase for those individuals who also experience higher depressive symptoms at the end of the treatment period (8 weeks), as a result of low treatment completion (Figure 1) and increased baseline symptoms (Figure 2).

Figure 1. Probability for observing cases at posttreatment (inverse probability of missing cases) and treatment outcome trends associated with treatment completion; 95% CI is drawn around each effect in dotted lines. PHQ-9: Patient Health Questionnaire-9.

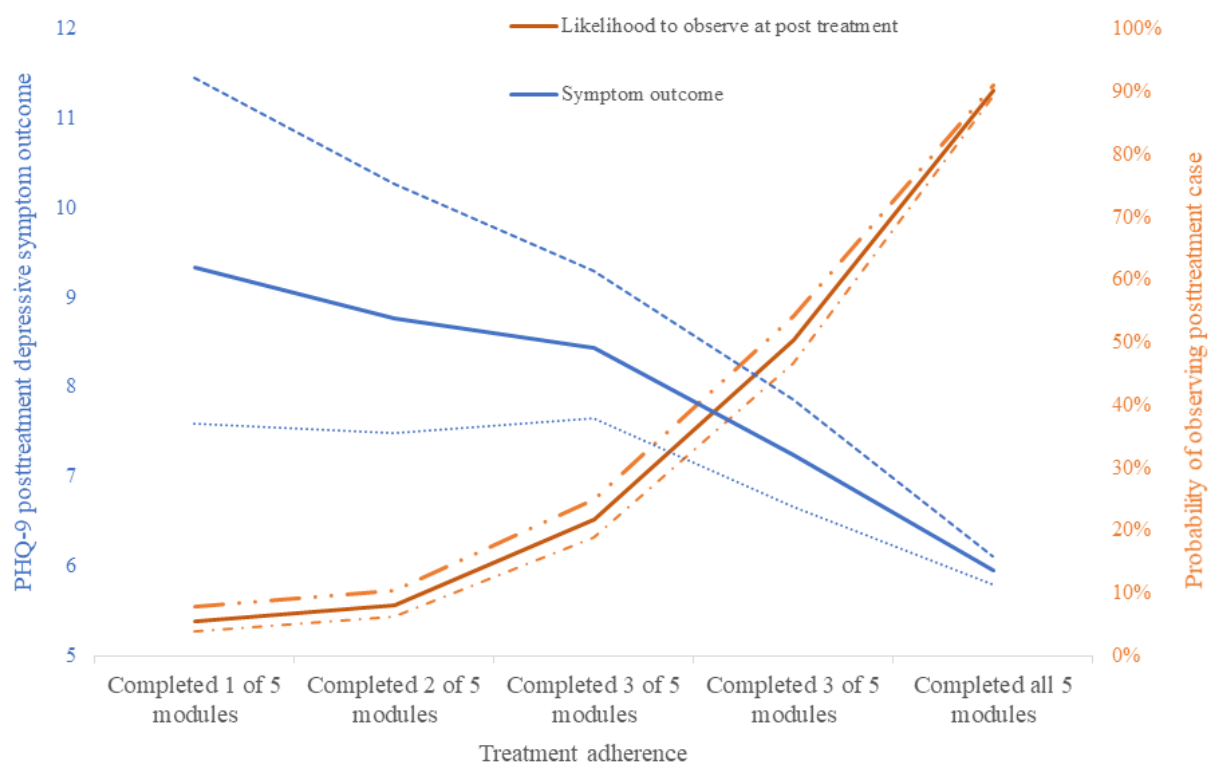
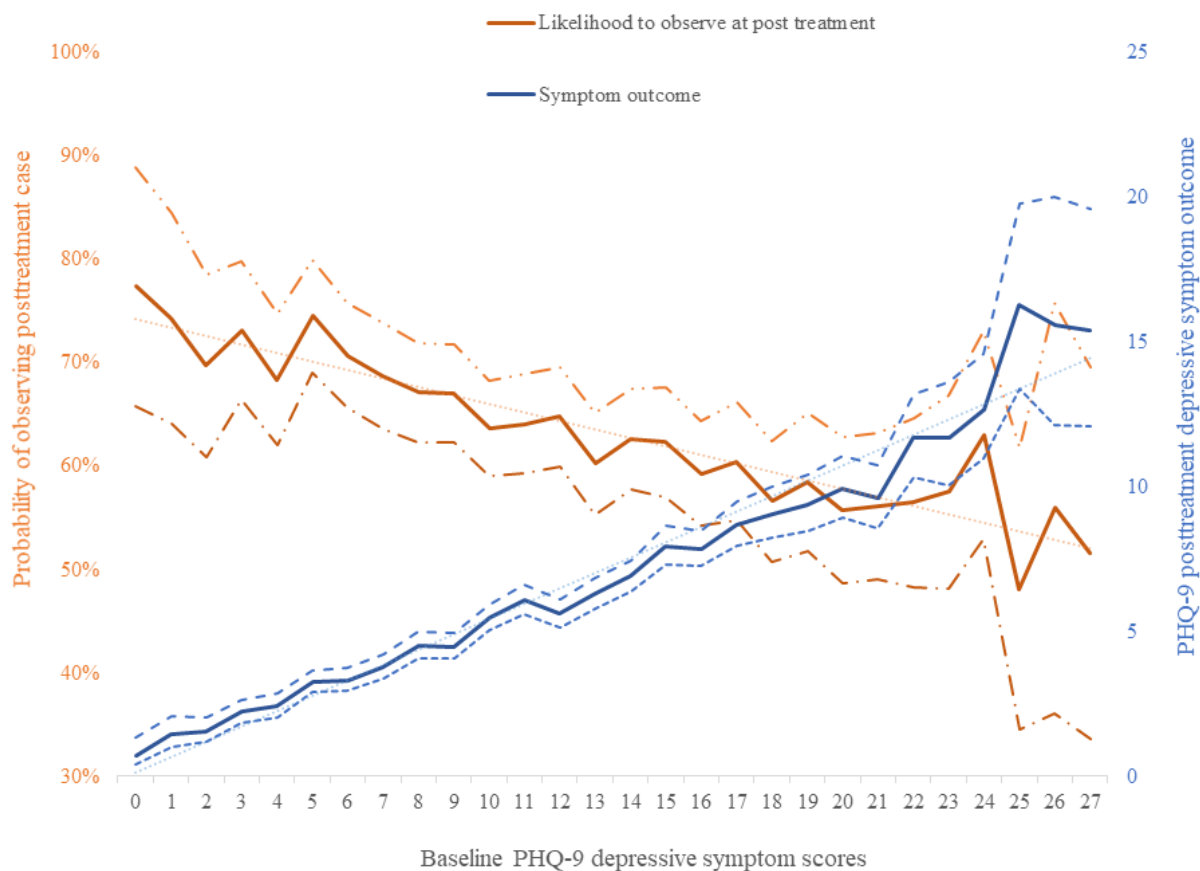


Figure 2. Probability for observing cases at posttreatment (inverse probability of missing cases) and treatment outcomes trends associated with depressive symptoms baseline severity; 95% CI is drawn around each effect in dotted lines. PHQ-9: Patient Health Questionnaire-9.



Comparison of Replacement Outcomes From Different Statistical Models

In this step, the statistical approximation of replacement symptom outcomes was compared between 3 different statistical models: (1) models that adjust for the predictors that form missing cases mechanisms (eg, treatment completion), (2) models that adjust only for time (Completer's analysis), and (3)

models that adjust for predictors that are not considered to be a cause of missing cases (eg, gender, age, education). These models differ from one another by the inclusion of different covariates that adjust the projected outcomes of missing cases. Tables 8 to 10 present the approximated mean PHQ-9, GAD-7, and K-10 scores and the CIs for the replacement scores for the various models.

Table 8. Predicted Patient Health Questionnaire-9 outcomes generated with different replacement models—compared with average posttreatment model estimate (missing completely at random).

Model estimation type considered	Mean predicted posttreatment score (95% CI)	Relative to the completer case analysis (MCAR; 95% CI)	The conclusion drawn about the replacement approach
Pretreatment symptom scores from posttreatment missing cases	13.09 (12.8-13.34)	N/A ^a	N/A
Outcomes from (MCAR ^b) completer case analysis	6.3 (6.2-6.5)	N/A	N/A
Models adjusted for predictors that do not form missing cases mechanisms			
(MAR ^c) Age	6.3 (6.3-6.3)	1 (1-1)	Equivalent to MCAR
(MAR) Gender	6.3 (6.3-6.3)	0 (0-0)	Equivalent to MCAR
(MAR) Employment status	6.3 (6.3-6.3)	0 (0-1)	Equivalent to MCAR
(MAR) Relationship status	6.3 (6.3-6.4)	1 (0-1)	Equivalent to MCAR
(MAR) Education level	6.3 (6.3-6.4)	1 (1-1)	Equivalent to MCAR
Models adjusted for predictors that form nonignorable missing cases mechanisms (missingness and PHQ-9^d outcome moderators)			
(MAR) Baseline anxiety symptoms (GAD-7 ^e)	6.5 (6.4-6.6)	3 (2-4)	Significant scores above MCAR
(MAR) Baseline depressive symptoms (PHQ-9)	6.9 (6.8-7.1)	10 (8-12)	Significant scores above MCAR
(MAR) Baseline psychological distress (K-10 ^f)	6.9 (6.8-7)	10 (8-12)	Significant scores above MCAR
(MAR) Comorbidity (PHQ-9 ≥10 and GAD-7 ≥8)	6.6 (6.5-6.6)	4 (3-6)	Significant scores above MCAR
(MAR) Treatment adherence	8.1 (8.1-8.2)	29 (29-30)	Significant scores above MCAR
(MAR) Treatment completion and baseline symptoms	8.8 (8.6-8.9)	39 (36-42)	Significant scores above MCAR
Adjusted models from alternative statistical methods (missingness and PHQ-9 outcome moderators)			
Mixed linear model (MLM)—slopes and intercepts (adjusting for PHQ-9 baseline)	7.4 (7.2-7.6)	18 (14-21)	Significant scores above MCAR
Multiple imputation (MI) pooling—adjusted for PHQ-9 baseline	7.6 (7.2-8)	21 (14-27)	Significant scores above MCAR
Mixed linear model (MLM)—treatment completion, slopes, and intercepts	8.4 (8.2-8.6)	33 (30-37)	Significant scores above MCAR
Multiple imputation (MI) pooling—treatment completion and baseline symptoms	8.8 (8.4-9.2)	40 (33-46)	Significant scores above MCAR
Last observation carried forward (LOCF)	10.4 (10.2-10.7)	65 (62-69)	Significant scores above MCAR
Baseline observation carried forward (BOCF)	13.1 (12.8-13.3)	108 (104-112)	Significant scores above MCAR

^aN/A: not applicable (redundant parameter).^bMCAR: missing completely at random.^cMAR: missing at random.^dPHQ-9: Patient Health Questionnaire-9.^eGAD-7: Generalized Anxiety Disorder Scale-7.^fK-10: Kessler 10-Item Scale.

Table 9. Predicted Kessler-10 outcomes generated with different replacement models—compared with average posttreatment model estimate (missing completely at random).

Model estimation type considered	Mean predicted posttreatment score (95% CI)	Relative to Completer's treatment effect (MCAR; ^a 95% CI)	The conclusion drawn about the replacement approach
Pretreatment symptom scores from posttreatment missing cases	19.44 (19.1-19.8)	N/A ^b	N/A
Outcomes from (MCAR) Completer's analysis	11.4 (11.1, 11.6)	N/A	N/A
Models adjusted for predictors that do not form missing cases mechanisms			
(MAR) ^c Age	11.4 (11.4-11.4)	1 (1-1)	Equivalent to MCAR
(MAR) Gender	11.3 (11.3-11.4)	0 (0-0)	Equivalent to MCAR
(MAR) Employment status	11.3 (11.3-11.4)	0 (0-0)	Equivalent to MCAR
(MAR) Relationship status	11.4 (11.4-11.4)	1 (0-1)	Equivalent to MCAR
(MAR) Education level	11.4 (11.4-11.4)	0 (0-1)	Equivalent to MCAR
Models adjusted for predictors that form nonignorable missing cases mechanisms (missingness and K-10^d outcome moderators)			
(MAR) Baseline anxiety symptoms (GAD-7 ^e)	12.4 (12.2-12.7)	10 (8-12)	Significant scores above MCAR
(MAR) Baseline depressive symptoms (PHQ-9 ^f)	12.2 (12-12.4)	7 (6-9)	Significant scores above MCAR
(MAR) Baseline psychological distress (K-10)	11.7 (11.5-11.8)	3 (2-4)	Significant scores above MCAR
(MAR) Comorbidity (PHQ-9≥10 and GAD-7≥8)	11.8 (11.6-11.9)	4 (3-5)	Significant scores above MCAR
(MAR) Treatment completion	13.7 (13.7-13.8)	21 (21-22)	Significant scores above MCAR
(MAR) Treatment completion and baseline symptoms	14.6 (14.3-14.9)	29 (26-31)	Significant scores above MCAR
Adjusted models from alternative statistical methods (missingness and K-10 outcome moderators)			
Mixed linear model (MLM)—slopes and intercepts (adjusting for K-10 baseline)	12.7 (12.5-12.9)	11 (10-13)	Significant scores above MCAR
Multiple imputation (MI) pooling—adjusting for K-10 baseline	12.1 (11.9-12.4)	6 (4-9)	Significant scores above MCAR
Mixed linear model (MLM)—treatment completion, slopes, and intercepts	14 (13.8-14.2)	23 (21-25)	Significant scores above MCAR
Multiple imputation (MI) pooling—treatment completion and baseline symptoms	14.1 (13.3-14.9)	24 (17-31)	Significant scores above MCAR
Last observation carried forward (LOCF)	17.8 (17.5-18.2)	56 (54-59)	Significant scores above MCAR
Baseline observation carried forward (BOCF)	19.4 (19.1-19.8)	71 (68-74)	Significant scores above MCAR

^aMCAR: missing completely at random.^bN/A: not applicable (redundant parameter).^cMAR: missing at random.^dK-10: Kessler 10-Item Scale.^eGAD-7: generalized anxiety disorder scale-7.^fPHQ-9: patient health questionnaire-9.

Table 10. Predicted generalized anxiety disorder scale-7 outcomes generated with different replacement models—compared with average posttreatment model estimate (missing completely at random).

Model estimation type considered	Mean predicted posttreatment score (95% CI)	Relative to Completer's only (MCAR; 95% CI)	The conclusion drawn about the replacement approach
Pretreatment symptom scores from posttreatment missing cases	11.45 (11.2-11.7)	N/A ^a	N/A
Posttreatment outcomes from (MCAR ^b) Completer's analysis	5.7 (5.6-5.8)	N/A	N/A
Models adjusted for predictors that do not form missing cases mechanisms			
(MAR ^c) Age	5.8 (5.8-5.8)	2 (1, 2)	Equivalent to MCAR
(MAR) Gender	5.7 (5.7-5.7)	0 (0-0)	Equivalent to MCAR
(MAR) Employment status	5.7 (5.7-5.7)	0 (0-0)	Equivalent to MCAR
(MAR) Relationship status	5.7 (5.7-5.7)	0 (0-1)	Equivalent to MCAR
(MAR) Education level	5.7 (5.7-5.7)	1 (1-1)	Equivalent to MCAR
Models adjusted for predictors that form nonignorable missing cases mechanisms (missingness and GAD-7^d outcome moderators)			
(MAR) Baseline anxiety symptoms (GAD-7)	6 (5.9-6.1)	5 (3-7)	Significant scores above MCAR
(MAR) Baseline depressive symptoms (PHQ-9 ^e)	6 (5.9-6.1)	6 (4-7)	Significant scores above MCAR
(MAR) Baseline psychological distress (K-10 ^f)	6.1 (6-6.2)	7 (6-9)	Significant scores above MCAR
(MAR) Comorbidity (PHQ-9≥10 and GAD-7≥8)	5.9 (5.8-6)	4 (3-5)	Significant scores above MCAR
(MAR) Treatment completion	6.8 (6.8-6.8)	19 (19-20)	Significant scores above MCAR
(MAR) Treatment completion and baseline symptoms	7.1 (6.9-7.2)	24 (22-27)	Significant scores above MCAR
Adjusted models from alternative statistical methods (missingness and GAD-7 outcomes)			
Mixed linear model (MLM)—slopes and intercepts (adjusting for GAD-7 baseline)	6.3 (6.2-6.5)	11 (9-14)	Significant scores above MCAR
Multiple imputation (MI) pooling—adjusted for GAD-7 baseline	6.8 (6.5, 7.1)	20 (14-25)	Significant scores above MCAR
Mixed linear model (MLM)—treatment completion, slopes, and intercepts	7 (6.8, 7.1)	23 (20-25)	Significant scores above MCAR
Multiple imputation (MI) pooling—treatment completion and baseline symptoms	7.3 (7, 7.6)	28 (23-34)	Significant scores above MCAR
Last observation carried forward (LOCF)	9.1 (8.8-9.3)	60 (56-63)	Significant scores above MCAR
Baseline observation carried forward (BOCF)	11.5 (11.2-11.7)	102 (98-105)	Significant scores above MCAR

^aN/A: not applicable (redundant parameter).^bMCAR: missing completely at random.^cMAR: missing at random.^dGAD-7: Generalized Anxiety Disorder Scale-7.^ePHQ-9: Patient Health Questionnaire-9.^fK-10: Kessler 10-Item Scale.

Tables 8 to 10 demonstrate that the statistical models that adjust their estimates of missing cases outcome according to the prominent characteristics of missing cases resulted in the prediction of increased symptom outcomes and a more restrained estimation of the treatment effect. For example, missing cases

replacement models that account for the rate of treatment completion resulted in PHQ-9 estimates that were 29% higher than the outcomes from the Completer's analysis (Table 8). Similarly, missing cases replacement models that adjusted for both baseline and treatment completion resulted in outcomes

that were 39% higher than the average treatment effect. In contrast, the application of models that adjust missing cases replacement scores by covariates that *only* predict missing cases (eg, age) or the rate of symptom change (eg, relationship status) did not result in missing cases symptom estimates that were different than average (nonadjusted MCAR models).

The influence of nonignorable mechanisms of missing cases is repeated in Table 9 (GAD-7) and Table 10 (K-10). Accounting for the role of low treatment completion in missing cases increased the projected symptom scores for missing cases by 20%. When the role of baseline symptom severity was also included in the replacement procedure, the predicted missing cases outcomes increased to nearly 30% above the average symptom outcome scores. In contrast, models that adjust their predicted outcome by variables that do not jointly predict missing cases and symptom change have resulted in outcomes that were very close to those of the completers.

A comparison between the GEE replacement estimation, multiple imputation, and mixed model-based replacement also demonstrates that the effect of treatment completion could be reliably observed across different statistical techniques. For example, the multiple imputations and mixed model replacement methods that accounted for a measure of treatment completion (stratified) all resulted in higher and comparable symptom replacement outcomes across GEE and multiple imputation and mixed models methods and across all symptom outcomes: depression (PHQ-9), anxiety (GAD-7), and psychological distress (K-10).

Finally, LOCF and BOCF replacement methodologies were compared with the other outcomes. Tables 8 to 10 show that using BOCF and LOCF methodologies, replacement scores for missing cases were higher when compared with the statistical approximation of outcomes for completers.

Discussion

Principal Findings

The aim of this study is to better understand the characteristics of missing cases and compare methods for estimating the symptom outcomes of missing cases in psychotherapy. The results of the study identified the following variables: (1) treatment adherence rate, defined as the rate of module progression through a treatment protocol and (2) the severity of symptom scores before treatment as variables that moderated both the probability for a case to present as missing during posttreatment assessment and the rate of symptom reduction. Low treatment adherence in particular dominantly predicted both the odds ratio of a case to present as missing during a posttreatment evaluation (162.1:1), and at the same time, low adherence dulled the rate of symptom reduction effect by up to 29%, 41%, and 52% for anxiety, depression, and psychological distress symptoms, respectively. These results are congruent with preliminary research [4] and suggest that the effect of missing cases is fundamental for the measurement process of clinical evidence and is of vital importance to anyone interested in a complete and unbiased account of the efficacy of psychological treatment.

With regard to the hypotheses stated, the first hypothesis that treatment completion and the severity of symptoms at baseline would predict both the likelihood of missing cases and symptom outcomes was supported. Treatment completion accounted for most of the missing case probability variance at posttreatment ($R^2 < 60\%$). More than 95% of participants who completed all of the intervention provided symptom data posttreatment compared with the 5% of those who completed a single module. Consistent with previous research in psychotherapy, treatment completion also moderated the rate of symptom improvement for depression, anxiety, and distress, suggesting a positive dose-response relationship in the efficacy of iCBT [29,30]. Specifically, individuals who completed more of the treatment modules demonstrated up to double the rate of symptom change for psychological distress, depression, and anxiety within the same period of 8 weeks.

The identification of the association between treatment completion, noncompletion, and clinical outcomes as related concepts in a very large sample and with multiple outcomes confirms findings from earlier studies of factors associated with outcomes in psychotherapy [1,29,30]. However, in comparison, few studies of psychotherapy outcomes have examined the relationship between these variables, and instead, treatment completion, reasons for dropping out of treatment, and clinical outcomes have been defined as distinct outcomes [20] and explored as parallel outcomes in meta-analyses of noncompletion [2] or in studies of predictors of noncompletion [13].

The findings of this study are also consistent with those of previous studies [4], which suggested that noncompleters were likely to have significantly worse treatment outcomes that would be overlooked without adjusting for the rate of treatment completion and the severity of symptoms of a patient at baseline. The comparison of statistical techniques demonstrated the effect of these variables on the replacement outcomes, regardless of the statistical technique employed. For this reason, it is recommended that to produce accurate and representative replacement estimates for missing cases, researchers should account for the relationship between treatment completion, the probability of completion, and the rate of improvement of symptoms.

The key recommendation arising from these findings concerns the measurement and evaluation of treatment outcomes in both clinical trials and routine care. At present, missing case patterns are mostly overlooked [9] despite being common and comprising a substantial portion of samples examined in psychotherapy research [1]. To date, there has been comparatively little research attempting to examine the suitability of different statistical methods to handle missing cases.

The second aim of this study is to explore the suitability of different statistical solutions to replace the outcomes of missing cases and identify methodological opportunities for psychotherapy researchers. From the range of patient characteristics, 2 types of models were identified: (1) models that included the key nonignorable mechanisms of treatment completion and (2) models that included alternative less dominant predictors, such as age, gender, and education. For

example, the analyses of psychotherapy patient characteristics demonstrated that higher psychological distress symptoms at baseline, higher depressive symptoms at baseline, or relatively younger age, also predicted the increased probability of noncompletion. This study found that age, gender, and baseline symptoms are limited in their ability to account for the variance in missing cases ($R^2 < 5\%$) or account for the outcomes of missing cases. In contrast, treatment completion far outweighed other competing explanations for missing cases. In this manner, the study results supported the second hypothesis postulating that models that adjust for treatment completion and baseline severity would be more representative of the outcomes of missing cases.

In technical statistical terms, the joint association of the treatment adherence variable with missingness probability and the rate of symptom change is considered to demonstrate a nonignorable mechanism of missing cases. Simply put, the results show that missing cases do not occur as a random event and that missing cases outcomes do not compare with the remaining sample. This study, together with previous research [4], demonstrated that the inclusion of a single key treatment adherence covariate is enough to substantially improve the prediction and replacement of missing cases outcomes. Such findings support the proposed recommendation to use treatment completion as a key mechanism of missing cases and as an adjustment variable in the process of approximating missing cases outcomes [5,31].

Limitations and Future Directions

The findings must be considered in light of several key limitations. First, the demonstration of missing cases, their characteristics and outcomes, and the suitability of replacing missing cases through adjusted models can only be considered preliminary and, at this time, relevant to iCBT [15]. Given that missing cases estimates vary between treatments [2,9], it is possible that the patterns, predictors, and outcomes of missing cases also vary between treatment models. Although this sample employed extensive cross-validation efforts, the trajectories of missing cases identified in this sample should be considered preliminary and experimental. Replication of these findings using different treatments could affirm the generalizability of early treatment completion as a key mechanism of missing cases and the importance of treatment completion for clinical improvement in psychotherapy. Specifically, additional and more detailed replications of the findings across different clinical contexts, such as trials with differing outcome measurement methodologies (eg, self-reported vs clinical diagnosis [32]), differing levels of treatment intensity [30], and differing timelines within study methodology [33], are needed to further verify the validity of treatment adherence as a mechanism that shapes the prediction of missing cases outcomes in psychotherapy research.

Second, this study was unable to examine other variables influencing the trajectories of missing cases or test all of the theoretical causes of missing cases, for example, the effect of interaction between a participant and an individual therapist despite the regimented nature of iCBT or the intervention of external events affecting participation. Other possible variables include the presence of major depression [32,34], perception of treatment credibility [35], or motivation [13] that can also affect treatment completion and the trajectory of participants in psychotherapy. Future studies may consider a more direct or more sophisticated measurement of participant engagement, such as motivation and time spent engaged with treatment, and even directed follow-up surveying to explore why patients dropped out of treatment and lapse out of the assessment protocol.

In addition, although not a limitation of this study, it is important to note that the ability to use statistical replacement models adjusted by treatment completion and baseline symptoms may not be realistic in studies involving small samples [27], where many psychotherapy trials involve samples less than 50 patients and do not have the statistical power to confirm the associations found in this study. In smaller studies, LOCF for cases that do not complete treatment (eg, less than 80% adherence) could be combined with the replacement values from unadjusted models for cases who complete treatment in full (MCAR). Such an approach could result in a less statistically demanding procedure that balances overly conservative LOCF statistics with overly liberal unadjusted model approximation [1].

In conclusion, this study aimed to explore the characteristics of missing cases, the possible clinical outcomes of missing cases in internet-delivered psychotherapy, and the suitability of different strategies for accounting for the outcomes of missing cases in psychotherapy trials. The findings of this study suggest that (1) missing cases are associated with lower treatment completion, (2) the clinical trajectories of missing cases are not likely to be similar to the average participant, and (3) overlooking the nonignorable mechanisms of missing cases is likely to result in erroneous replacement of missing cases outcomes and inflated estimates of treatment effects. The findings suggest that researchers need to consider how they account for the outcomes of missing cases in psychotherapy trials where nonignorable missing cases mechanisms are likely to occur. Accounting for missing cases in this manner provides a more realistic estimate of treatment effects in the *real world*, as it is expected that some participants will drop out. In this manner, more complete and realistic estimates that account for the outcomes of missing cases can contribute toward more realistic psychotherapy evaluation and outcome modeling.

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Conflicts of Interest

None declared.

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Abbreviations

BOCF: baseline observation carried forward
DMHS: digital mental health service
exp: exponentiated coefficient
GAD-7: Generalized Anxiety Disorder Scale-7
iCBT: internet-delivered cognitive behavior therapy
K-10: Kessler 10-Item Scale
LOCF: last observation carried forward
MAR: missing at random
MCAR: missing completely at random
PHQ-9: Patient Health Questionnaire-9

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Original Paper

Blending Cognitive Analytic Therapy With a Digital Support Tool: Mixed Methods Study Involving a User-Centered Design of a Prototype App

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Abstract

Background: Patients can struggle to make good use of psychotherapy owing to deficits in awareness, and digital technologies that support awareness are at a premium. Currently, when patients participate in cognitive analytic therapy (CAT), the technology supporting relational awareness work involves completion of paper-based worksheets as between-session tasks.

Objective: We aimed to design, with therapists and patients, a prototype digital mobile app. This was to help patients better engage in the “recognition” phase of the CAT treatment model by providing an unobtrusive means for practicing relational awareness with dynamic feedback on progress.

Methods: A national online survey was conducted with CAT therapists (n=50) to determine readiness for adoption of a mobile app in clinical practice and to identify core content, functionality, and potential barriers to adoption. A prototype mobile app based on data and existing paper-based worksheets was built. Initial face-to-face user testing of the prototype system was completed with three therapists and three CAT expatients.

Results: Among the therapists surveyed, 72% (36/50) reported not currently using any digital tools during CAT. However, the potential value of a mobile app to support patient awareness was widely endorsed. Areas of therapist concern were data security, data governance, and equality of access. These concerns were mirrored during subsequent user testing by CAT therapists. Expatients generated additional user specifications on the design, functionality, and usability of the app. Results from both streams were integrated to produce five key changes for the reiteration of the app.

Conclusions: The user-centered design process has enabled a prototype CAT-App to be developed to enhance the relational awareness work of CAT. This means that patients can now practice relational awareness in a much more unobtrusive manner and with ongoing dynamic feedback of progress. Testing the acceptability and feasibility of this technological innovation in clinical practice is the next stage in the research process, which has since been conducted and has been submitted. The important challenges of data protection and governance must be navigated in order to ensure implementation and adoption if the CAT-App is found to be acceptable and clinically effective.

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KEYWORDS

cognitive analytic therapy; digital app; relational awareness; user-centered design; acceptability; user testing

Introduction

Cognitive Analytic Therapy

Cognitive analytic therapy (CAT) is a brief, relational, and integrative psychotherapy most often offered in secondary care services in 16- or 24-session formats to patients with complex psychological needs. It can also be delivered in an eight-session version for less complex problems in primary care [1]. Rather than relying on a treatment protocol that therapists follow on a session-by-session basis, CAT has been described as a “humanized and skilled” psychotherapy [2], requiring a relatively high level of training and supervision to practice competently. The competences for CAT delivery are well-specified [3,4], where CAT therapists implement a three-phase approach in terms of reformulation, recognition, and revision. However, within this framework, therapists exercise judgement, draw on a range of techniques, and adapt the delivery and the methods used to be responsive to the needs and limitations of each patient [5].

The reformulation phase of CAT is supported through early production of narrative and diagrammatic reformulations based on the procedural sequence object relation model [6]. The therapist and client negotiate a shared understanding of target problems and the target problem procedures. These target problem procedures are ways in which the client relates to himself or herself (self-to-self reciprocal roles and associated procedural sequences) and to others (self-to-other and other-to-self reciprocal roles and associated procedural sequences), including the therapist. Crucially, roles and sequences are linked through narrative and diagrammatic reformulations to early developmental traumatic or neglectful experiences and their repetition in adult life through the action of procedural memory [7]. Once the reformulation is agreed, the recognition phase helps the client become aware of the ways these patterns operate in everyday life. The recognition phase tries therefore to build relational awareness of the manner in which the patient relates to himself or herself and others (and vice versa), including the therapist. The revision phase of CAT is the “change work” phase of the model and supports patients in changing roles and sequences, working within the individual’s zone of proximal development [5].

The recognition phase of CAT is therefore an integral part of the change process. Because reciprocal roles and associated procedures are enacted automatically, revision (ie, change) requires new awareness of them. CAT therapists therefore try to support patients in building better relational awareness of when they are about to enact, are currently enacting, or have just enacted a problematic role or procedure with themselves or others. The main aim of the recognition phase of CAT is that the patient builds awareness through being able to occupy the “observing eye” position. Indeed, an observing eye is often drawn on sequential diagrammatic reformulations in order to remind patients to occupy this position. This position has much in common with the “self-as-context” process of acceptance

and commitment therapy [8]. There is evidence that outcome in CAT is heavily dependent on the patient being able to occupy the “observing eye” position, as from this position of awareness, change is then possible [9].

Currently, the self-monitoring tools that support within- and between-session relational awareness practices are wholly paper based. These consist of two types of worksheets. The first between-session tool enables the patient to make observations in daily life of key interpersonal events and resulting thoughts, emotions, and actions, which link to their problem procedures. This written diary record is brought to the session for review and analysis. The second within-session tool lists the patient’s target problems and associated target problem procedures in a standardized format. The patient rates the manner in which awareness is improving, static, or deteriorating and whether revision is improving, static, or deteriorating. In clinical practice, however, patients have repeatedly reported to the authors (SK, GP, and JV) that diary keeping of this very personal kind is inconvenient, physically clunky, or potentially embarrassing, especially when observed by others. The development and use of a digital tool suitable for a smartphone or tablet could provide privacy, ease, and convenience, so that patients can practice relational awareness.

Digital Technology and Mental Health

The value of digital technology to increase access, availability, and innovation in mental health care is high on national and global research and policy agendas [10-14]. Digital tools, such as mobile phones, tablets, laptops, and wearable devices, are ubiquitous in modern life. For some patients, the greater convenience, accessibility, and availability afforded by digital health technology have been found to outweigh the advantages of face-to-face contact with health professionals [15]. However, evidence suggests that for digital mental health to be as effective as traditional face-to-face delivery of care, a blended/augmented or guided approach with some real-time personal support is preferable to using digital tools in isolation from human contact [16]. The value of such a blended approach was highlighted in a recent James Lind Alliance Priority Setting exercise on digital mental health by patients and clinicians [11]. Mobile technologies, such as smartphones and mobile apps, have been suggested to be superior treatment delivery platforms, because they allow constant access to treatment materials [17].

CAT and Digital Support

Currently, there are no digital apps that are influenced by or support the practice of CAT. CAT principles have been applied to a six-session guided self-help intervention, which has been feasibility tested for use in the United Kingdom Increasing Access to Psychological Therapies (IAPT) services with good outcomes [18]. This demonstrates that it is possible to translate the model into other easily accessible formats. While it may be possible to develop a computer-based self-help program based on CAT principles, the therapy itself is intrinsically personally delivered, since the relationship between the therapist and the patient is itself a central focus of procedural recognition and

revision. The purpose of this project was therefore different. We aimed to support blended patient engagement in the recognition phase of CAT, rather than develop computerized delivery of CAT.

There are clearly identifiable aspects of the model that could be better supported through the development of a mobile app, such as easy access to narrative and sequential diagrammatic reformulations; monitoring of mood, target problems, and target problem procedure methods for logging and evaluating the effectiveness of a change strategy; and storing the “goodbye letters” from both patients and therapists that are a distinctive aspect of how endings are negotiated with the model. There are therefore potential benefits of an app to augment therapy by making the process more accessible both between sessions or after the therapy has finished, by increasing the ways in which a patient can hold the therapy in mind outside the therapy room (ie, an internalization process) [19] and make use of the treatment model [20]. There is evidence of reduced interpersonal problems during the follow-up from CAT [21], and therefore, an app may be particularly important in terms of supporting the durability of relational change through ongoing relational awareness.

The notion of taking a relational awareness approach is novel in terms of digital health care, as the plethora of cognitive-behavioral therapy (CBT) apps tend to focus on symptom monitoring, and associated thinking and behavior change [17]. Unlike many “off-the-shelf” CBT or therapy support apps, it is essential that any CAT app be customized to each individual user owing to the often highly idiosyncratic and person-specific approach of the model [5]. The content of the app should therefore be created through collaboration between both the therapist and patient and should mirror the content of the sessions and the phased approach of CAT. To summarize, the aim of this research was to design and develop a prototype digital app to support patients accessing CAT, particularly to support the out-of-session relational awareness tasks of the recognition phase of the therapy.

Methods

Design

A user-centered design approach was adopted as this was in line with the Medical Research Council (MRC) guidelines [22], suggesting process evaluation and feasibility testing before moving onto effectiveness testing. A working group of CAT experts, psychologists, and an app developer collaborated to conduct a mixed methods study with the following stages: stage 1, collaborative design of the core clinical content of the system in order to develop an initial prototype app (online questionnaire survey for therapists); stage 2, scoping out functional and nonfunctional/operational requirements for the system, including interface features and visual appearance, and addressing issues of acceptability and usability (CAT therapist and expatient user testing); stage 3, technical development and refinement, making it ready for feasibility testing (technical development).

Stage 1: Clinical Content

In stage 1, a bespoke questionnaire survey was developed and conducted in Qualtrics (Qualtrics). The sample for the online survey was recruited via an advertisement in “Reformulation,” the house journal of the Association for Cognitive Analytic Therapy (ACAT). Any CAT therapist reading the journal could access the online survey via a link provided. The survey ran from September 20, 2016, to October 20, 2016. Information sheets and informed consent forms were included at the start of the online survey. The survey contained a mix of closed and open items relating to current eHealth usage in practice, components of CAT that should form an aspect of app content, and suggestions for names for the app. Closed items asked respondents to identify the importance of suggested clinical content in the app on a 5-point Likert scale, ranging from “not at all important” (1) to “very important” (5). Open items asked for suggestions for key features and allowed respondents to share concerns and considerations for a digital CAT tool. The clinical content items were initially developed in a consensus meeting with CAT therapists on the team (SK, GP, and JV). Through the survey, we could identify which contents a larger sample of therapists felt were vital to ensure theoretical fidelity of the intervention.

Stage 2: User Testing

In stage 2, informal one-to-one user testing was used with co-operative evaluation methods. Specifically, a cognitive walk-through method was used where users verbalize their thinking as they navigate the app [23] in order to gather data for the design of the prototype app. Co-operative evaluation methods attempt to get users to see themselves as “collaborators” in the development of health technology and any associated evaluation. The aim of this was to identify ways to make the app more intuitive for future users. The cognitive walk through allows the researchers/designers to assess the usability of the system and assign causes to usability problems early in the design process. We chose one-to-one testing over focus group methods, as clients may wish to use their own experiences and symptoms to work through the app in testing and such discussions may not arise in a group setting. CAT therapists and expatients for the user testing were recruited through an organization that provides CAT in the independent sector on a not-for-profit basis (Catalyse Sheffield Psychotherapy Practice). Eligible therapist participants were required to have completed CAT practitioner (2-year training) or CAT psychotherapy (4-year training) training and have a current caseload of CAT patients. Eligible service user participants were required to have recently undertaken and completed a full course of one-to-one 16- or 24-session CAT, regardless of the outcome. Patients who recently completed the course were selected as opposed to active patients for the following two reasons: (1) not interfere with the therapeutic process with this early stage research and (2) have the full experience of CAT where the end stages are particularly salient for procedural revision. Patient participants were required to be nominated by therapists in order for them to be selected for recruitment. The research was advertised internally to therapists via email, and therapists were asked to identify any former clients who they felt might be suitable for the research. Potential patient participants were contacted initially by the

therapist and were asked to email the researcher (KE) to express interest and receive an information sheet and consent form via email. We had no participant numbers in mind, and we aimed to recruit a small sample of both users in order to explore a range of issues and identify any consensus problems with the first prototype version.

User testing occurred face to face either at The University of Sheffield or at the Catalyse Sheffield offices. During user testing, the participants (therapists and expatients) were shown a prototype version of the app and asked to work through the stages and processes of the app. During user testing, participants were encouraged to “think aloud” during their engagement with the app, so that thoughts and feelings could be recorded (ie, cognitive walk through). The testing lasted for as long as was needed to work through the app; however, we estimated that this would take no longer than an hour based on our previous user testing. The user testing was audio recorded in order to track how users navigated the features of the app and the internal commentary that occurred. When service users worked through the app and entered data relating to the nature of their condition, they were reminded that all data were confidentially stored and destroyed once the testing was complete. They were also free to use hypothetical problems rather than their own, and these were provided if preferred. User testing of the basic prototype app (based on findings from the questionnaire research) began in January 2017.

Stage 3: Technical Development

The following two prototype apps were created: a therapist web application and a patient mobile app. The therapist application is a web-based tool allowing therapists to create profiles for patients by updating information about the client’s target problems and target problem procedures. This can potentially include images and videos that the client may find useful in their therapy. Once a patient is set up on this system, the therapist’s web application will allocate a personal identification number (PIN) to allow the patient to access the mobile app. The current web application is hosted on a Sheffield Hallam University server. Data are stored on a Google Firebase Cloud service [24]. Data are fully anonymized via the PIN process.

The mobile app is designed for patients to use on their mobile phone or tablet as an “app.” The app is accessed via a PIN allocated through the set-up procedure undertaken by the therapist in the web application outlined above. Once patients have access to the app, they can review and rate the current recognition and revision (0-100 scale from ineffective recognition/revision to effective recognition/revision) of their personalized target problems and target problem procedures, see their personal narrative and diagrammatic personal reformulations, and provide a current mood rating. Patients rated their mood on a slider scale (0-10 points) in terms of sad/happy, anxious/calm, and excited/bored (reverse scored). Mood items reflected the pleasure (valence) and arousal (activation) dimensions of the core affect [25]. Feedback on current and all previous attempts at the recognition and revision of target problems, target problem procedures, and mood were presented as progress graphs. Therefore, the app contains a combination of ideographic content that is highly personalized

and a nomothetic measurement for standardized clinical outcome measurement and research purposes.

These data are stored anonymously in the same Google Firebase Cloud accessed by the therapist web application.

The patient app has been accepted as an app on both the Apple iOS and Google Android App stores. Both versions of the app were built with the Ionic hybrid framework [26].

Data Analysis

Data from the stage 1 therapist survey were extracted, and descriptive statistics were calculated to identify the most important clinical features of the app. Any clinical features that were reported as “extremely important” or “very important” by over 50% of the sample were included in the prototype. Audio recordings from the stage 2 user testing conducted by KE were transcribed, and a thematic analysis was conducted by KE to identify key user requirements to feed into the app development. Analysis was not iterative but summative. Data saturation was not sought. We were looking to identify primary areas of concern with respect to functionality and usability in a short span of time to improve the next iteration of the app for follow-on feasibility testing. All themes were brought to a consensus team meeting along with transcriptions for discussion and validation across the team.

Ethical approval for the research was obtained from The University of Sheffield (no: 011086 and 011553).

Results

Stage 1: Clinical Content

Sixty-four CAT therapists accessed the survey, of which 62 provided consent to participate. Twelve did not complete the survey with consent, leaving a final sample size of 50 participants. The majority (n=36, 72%) of respondents reported not using any eHealth approaches in their current clinical practice. The 14 (28%) respondents who did use some eHealth support reported integrating a range of apps for different purposes. The most commonly recommended apps were those that support mindfulness and meditation, such as Headspace (n=6), Moodnotes (n=1), Moodshift (n=1), Buddify (n=1), and those that encourage connections with others/peer support, such as Big White Wall (n=1) and Silent Secret (n=1). Only one respondent mentioned recommending an app to monitor mood via the Patient Health Questionnaire (PHQ)-9 [27]. Although one respondent did not use any apps during CAT therapy, the respondent mentioned the following:

...several of my private patients use their phones for diary keeping which they find helpful. Likewise, they take pictures of maps to take with them and look at in between sessions. I often use my iPad camera and phone, to snap maps sketched out on a white board which I can then either transfer onto paper or print out and delete. I have noticed there is a sense of being able to own a piece of the fluid experience within the session.

Table 1 presents the features that were felt to be most important in a potential app to support CAT. The following features were

rated as extremely important: “A place to store the *map* (ie, the sequential diagrammatic reformulation), so it can be accessed by clients on their phone” (21/50, 42%) and “A list of personal exits developed in the therapy” (22/50, 44%). Moreover, the following were rated as very important: “Ability to write a short

reminder/diary of events (ie, enactments, etc) during the week, so they can be better discussed during therapy sessions;” “Rating for recognition of target problem procedures;” “Rating of revision of target problem procedures;” and “Rating of the severity of the person’s target problems” (Table 1).

Table 1. Clinical features for inclusion in the app.

Item	Importance (N=50), n (%)				
	Not at all important	Slightly important	Moderately important	Very important	Extremely important
A list of personal exits developed in the therapy	1 (2%)	1 (2%)	7 (14%)	19 (38%)	22 (44%)
A place to store the <i>map</i> , so it can be accessed by clients on their phone	2 (4%)	4 (8%)	6 (12%)	17 (34%)	21 (42%)
Ability to write a short reminder/diary of events (ie, enactments, etc) during the week, so they can be better discussed during therapy sessions	2 (4%)	0 (0%)	12 (24%)	23 (46%)	13 (26%)
Rating for recognition of target problem procedures	1 (2%)	6 (12%)	12 (24%)	21 (42%)	10 (20%)
Rating of revision of target problem procedures	1 (2%)	7 (14%)	12 (24%)	20 (40%)	10 (20%)
A place to store the goodbye letter, so that it can be accessed by clients on their phone	3 (6%)	10 (20%)	12 (24%)	18 (36%)	7 (14%)
A place to store the reformulation letter, so that it can be accessed by clients on their phone	3 (6%)	9 (18%)	16 (32%)	15 (30%)	7 (14%)
Rating of the severity of the person’s target problems	2 (4%)	13 (26%)	16 (32%)	14 (28%)	5 (10%)
Session list/countdown to total number of sessions attended	3 (6%)	6 (12%)	22 (44%)	16 (32%)	3 (6%)
Alarms and reminders for therapy	3 (6%)	9 (18%)	24 (48%)	10 (20%)	4 (8%)

When asked what other *features* should be included other than those listed in Table 1, six CAT therapists indicated that an interactive version of the sequential diagrammatic reformulation (ie, the *map* of patient’s reciprocal roles, self-states, and procedures) could be useful for patients to track their progress and update with exits in real time as they progress. In addition, six CAT therapists recommended the use of reminders, prompts, or alarms that patients could set for themselves on the app to remind them to complete the between-session recognition work. The option to use other creative visual tools in the app to support progress and change was highlighted by three CAT therapists. A glossary of key terms used during CAT was highlighted as potentially useful, in addition to links to crisis support, additional CAT resources, and literature. A storage area for recording personalized “exits” (ie, new ways of relating to others or self) being useful in supporting and implementing successful change strategies was noted by two CAT therapists.

These recommendations were logged but not incorporated into the prototype for initial design work, as they were not integral to the therapeutic process and the inclusion of an interactive map, for instance, represents a larger technical challenge than

is needed in this initial design phase (data available on request to the corresponding author).

Respondents were asked if there were any other *issues for consideration* when developing digital technology to support CAT, and the issues of data protection and confidentiality were crucial and key concerns for all respondents in the survey. The need for the app to be accessible to all was another core requirement identified in the questionnaire feedback (n=9), in relation to cost, ease of use, and accessibility for clients with learning disabilities and visual impairments.

Stage 2: User Testing

The two applications (therapist web application and patient mobile app) were user tested with a small sample of three therapists. All therapists were female. Two were clinical psychologists, and one was a counselling psychologist. All were experienced CAT therapists and supervisors. Three expatients took part in the testing. Two were female, and one was male. The CAT therapists viewed both applications (ID1, self-reported novice; ID2, expert; ID3, proficient user of technology), and expatients used the patient app (all self-reported proficient users

of technology), working through it on their own and thinking aloud as they did so for between 30 and 60 minutes.

Therapist Feedback

Two main themes emerged during therapist user testing, including data protection and fidelity to the intervention process. Two therapists stressed the need for clear and early information on data protection and data sharing for patients on first viewing of the patient app. The following comments were made:

This needs to feature a pretherapy agreement on first use of the app (or something similar) for data protection and storage information. You wouldn't need to access this again. [ID3]

I had assumed this would have a high level of security. You need to think carefully about this. We need to know where the data are being stored and need to have an agreement around it between the app provider, therapist, organization, and client. Does the app provider host the data? Does the clinical organization have responsibility for the data? Clients will need to know who is looking after their data and what is happening to it. [ID2]

You will need a statement on the app which refers to the following: I keep records in accordance with my professional body's guidelines and the data protection legislation. These records are kept confidentially and securely, with a personal record number. Records are kept for 7 years. [ID3]

The dangers of not fully considering data protection were highlighted. One therapist made the following comment:

I used (NAMED APP) with a client, and after it shut down, she had no idea where all the data are now. [ID2]

When testing the therapist web application, the need for it to be secure and separate to any client access was stressed as important for data protection and privacy.

There needs to be separate areas, one for administrative tasks for the therapist and one collaborative work space for the client that the therapist can also access. It's important to be able to access clients via a home page search function and drop down menu option – this function should be password protected, and if in the same room as a client, they should only be able to see their data – not a list of people – even if nicknames are used. [ID3]

All therapists interviewed stated that they felt the app should more accurately reflect the way in which target problem procedures are developed and shared with patients. They commented as follows:

I found it easy to use but it needs to reflect TPP. [ID1]

It needs to reflect TPP. It's too prescriptive and doesn't allow for individualized ways of working. I got frustrated very quickly and not happy with the layout. Too complicated. When working with a client a lot of work is sketchy to begin with – create a map and refine as sessions progress. This app allows for

one map. You would need to be able to upload newer versions as you progress and archive older ones. [ID2]

I wondered why it doesn't reflect TPP. You need to work from CAT documents and build on it. If the app does less than what you can access face to face and on paper, then no one will use it. You need to have target – pattern – leading onto recognition, revisions, and progress toward the target problem listed (for clients, and as a consequence, the therapist). [ID3]

With respect to the patient app, all three therapists felt the mood tracker function should be personalized. They commented as follows:

Patients need to be able to personalize the emotions within this. This part needs more work. Patients need more options. [ID1]

This needs to be more creative. Photos or emoji's, that would make it easier for people with learning difficulties and younger users. [ID2]

This needs to be more creative and personalized, but we need to be able to aggregate data! You can't aggregate photos, for example, so it still needs to be temporal scale of some kind. [ID3]

In this prototype, the “exit” list for clients to refer to was labeled “to do list,” which caused confusion. The following comments were made:

I like this function, an area to keep working on, this needs to be a flexible space where patients can add resources as they go and it should link to the map. [ID1]

To do lists? What's this exits? I like this. Could it link to a bank of tools that clients draw on? [ID2]

All therapists felt that a digital support tool was a good idea. However, therapist two raised a concern that the app felt a little paternalistic and, as it stood, represented more of a research tool than a therapy app. Therapist three also emphasized considering patients' expectations when they use it and mirrored therapist two's thoughts on clarifying why data are being held and what will be done with the data.

Expatient Feedback

The themes identified by past patients were (1) usability and personalization, (2) lack of concern with privacy, and (3) convenience of a digital tool.

None of the users found the flow of content intuitive. All three suggested a drop down menu at the top of the app, so that they would not need to backtrack through stages. The following comments were made:

This (the navigation system) needs to be at the top left like most other apps. I don't want to click back each time to get out of targets. [ID1]

You need to make it easier to move about the app. It's a bit clunky at the moment, moving about though the sections. It needs to flow better. [ID2]

The design and colors of the app were not thought to be particularly appealing; however, no users found them abrasive or off putting. All three users stressed the need for the app to be personalizable. The following comments were made:

Hmmmm the colors are a bit dull, but then again, I'm not using this as a game or anything. I don't mind it and the leaf design wouldn't stand out on my homescreen as a medical/mental health app. [ID1]

It could be good to personalize this. Like, have a profile, that you can create a character for. Change some settings like the colors, or something. [ID3]

The patients were less concerned about data protection and privacy than were the therapists.

I don't really think about the T's & C's to be honest. You get them on all apps now. They all need you to agree or you can't use them. So I just scroll and accept. [ID2]

All expatients were positive about the app as an addition to the paper processes in sessions, as this allowed for convenient tracking and reporting in the moment and sharing with their therapist. The following comments were made:

I think it's a great idea. I wish I'd had it for my sessions. The paper was a pain when I was out and about. I could use this on the bus or if I was in a meeting and I felt myself slipping into a bad pattern of behavior. It would be better to make a note of that as it happened rather than at the end of the day. [ID2]

Sometimes I forget what's happened in the week. I could use this to show my therapist in the session, like an overview. [ID3]

Based on the user testing, the following five key user requirements were identified for the next iteration of the app that will be advanced for feasibility testing (will be reported in a follow-on paper) and assessment against UK National Health Services Digital Assessment Questions:

1. An early page is required for General Data Protection Regulations (GDPR) compliance, so that clients understand how their data will be processed and used, and can provide explicit consent for the therapist to have access to the data and the use of anonymized data for research purposes.
2. The whole client list will be hidden when one client is selected (on the therapist's system).
3. There should be a place for the target problem procedure to be included, and the flow should be my target problem and my target problem procedure (actually called the target pattern description), followed by recognition rating and revision rating.
4. The mood scale (although disliked in terms of wording) needs to remain as presented owing to being a validated tool in CAT therapy and of added value for research purposes.
5. The "to do list" should be changed to "my exit list."

Discussion

Principal Findings

We demonstrated that it is possible to design a relational awareness support tool for CAT clients that can be accessed on mobile phones and tablets. There was support for the development of the app from 50 CAT therapists who completed the online questionnaire. The results from the questionnaire showed that digital adoption in CAT practice is in its infancy and that any tool created would, rightly so, need to adhere to strict standards in GDPR. The therapist user testing also highlighted the need for strict GDPR in order to secure buy in and adoption from therapists and their host organizations. It is essential for any therapy support app to meet high data security standards, although expatients were less concerned about data security than therapists. This may have been the result of them being frequent users of a range of mobile apps and younger in age than the therapists; therefore, they had experience of accepting the terms and conditions of apps related to data sharing and storage. Conversely, they may simply not be aware of the potential for breaches in privacy with sensitive information. Assessing the final release version of the app against the UK National Health Service Digital Assessment Questions will ensure that all data security and regulatory issues are addressed. Three expatients of CAT found some functionality issues with the app and provided useful feedback that will improve the intuitiveness of the tool.

Limitations

This early design work to develop a prototype app has been conducted using a medium-sized survey and a small cohort of mostly proficient users of technology for user testing. The results may not necessarily be replicated in a larger more diverse sample. However, for the purpose of designing an initial prototype for acceptability, adherence, and feasibility testing and for having a tool to assess against the National Health Service Digital Assessment Questions, the sample allowed us to develop content and highlighted key functionality issues for refinement of the app. This sample size is not uncommon in early prototyping research. Jakob Neilson is a world leader in the field of web and mobile app usability. His studies have shown that usability testing can be effectively carried out with a sample size as low as five [28,29]. This is because of the inverse exponential relationship between problems found and number of testers. Beyond five users, little new insight is gained, with 15 suggested as the number to remove 100% of usability issues. With a simple input app, such as the CAT-App, a sample size of six was deemed adequate for the identification of usability issues.

A simple yet effective user test is often overlooked when digital apps are developed, but is an essential element in creating mobile apps in mental health that meet global standards [10]. Owing to resource and time restraints, we were unable to explore and address all suggestions from the user testing, in particular, the value of an interactive map or more creative approaches to engaging patients in therapy. In this early work, we were keen to ensure that content did not interfere with fidelity to an evidence-based clinical intervention. Additional development

and adaptation are things we will look to explore in future development of the app.

Comparisons With Other Studies

The app enables the personal narrative and sequential diagrammatic reformulation of the patient to be preloaded and therefore enables each patient to be aware of his/her unique relational issues and the factors driving such issues. This is quite different from some of the more generic CBT apps. This creates new opportunities for clients to engage more fully in the self-awareness tasks of their therapy, without the inconvenience of referring back to paper diagrams, letters, and rating sheets. There is evidence that change in CAT is built on this foundation of self-awareness [9]. Therefore, the CAT-App aims to enable the patient to build an “observing self” and, from this position, change relational responding. These real-time self-awareness tasks can then be analyzed during therapy sessions by the client opening the app. The act of self-monitoring itself fosters important skills in reflective function. The patient-owned record also saves therapists’ time in maintaining records of their patients’ awareness and progress with changing problematic relationship patterns. This also saves in-session time as the client has already rated (possibly on numerous occasions out of the session, as opposed to just once in the session) the effectiveness of recognition and revision efforts. The graphical longitudinal feedback also enables clients to take more of a metaperspective on their progress with target problems and target problem procedures.

The CAT-App connects with and informs CAT treatment sessions, rather than being a stand-alone tool (as is the case with many CBT apps). The tool was also designed to map onto the phases of therapy, and it is therefore grounded in theory. The CAT-App is not a form of treatment, but rather a scaffold for effective treatment engagement in the relational recognition component of the approach in either 1:1 or group CAT therapy. This type of blended therapy is distinct from online or e-therapy, where the therapist and client communicate solely via messaging, video link, email, or phone. Blending face-to-face

therapy with various technology-based interventions is now very common, but the mix varies. It ranges from minimal therapist support when following an online program to online or email support during primarily face-to-face therapy. The development of an app for mobile use specifically designed as an adjunctive tool to enhance a particular therapeutic method is innovative, although web-based programs have been developed, for example, in acceptance and commitment therapy [30]. Patients are prone to drop out of therapy when it is not meeting their needs, and this is, like deterioration in mental health during therapy, rightly seen as a negative outcome and one where therapists have a major ameliorating impact [31]. The app has potential for reducing drop out via an increase in engagement, particularly in the middle phase of treatment.

Conclusions

Despite its technical complexity, patients found the CAT-App easy to use and therapists found it easy to configure. The data collected, when stripped of all personal identifiers, have great potential for research. The app removes the practical difficulties of releasing therapists and funding researchers to prepare and submit patient data, which are ubiquitous in practice-based research. Once informed consent has been obtained through the app, data collection and transfer are automated.

By introducing an adjunctive tool, there is a possibility that a well-tested therapy with known outcomes can be altered in ways that have unintended consequences, such as a negative impact on therapeutic alliance. In designing the app with therapists and former CAT clients, we sought to minimize these risks. Follow-on acceptability, adherence, and feasibility testing has been conducted, and the findings have been submitted for publication. Additional accessibility issues identified by therapists, including the need to make the app appropriate for patients with learning differences and visual impairment, will be addressed once funding is secured. Further research is clearly needed to test the impact of the app on clinical outcomes and will establish the best way to blend the app with CAT practice and specify the therapist competences required when using it.

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Authors' Contributions

KE: conceptualization, investigation, data collection, data analysis, and writing (original draft and editing); SK: conceptualization, resources, data analysis, and writing (contribution to original draft, review, and editing); MC: software design and data curation; AM: conceptualization; JV: conceptualization; GP: conceptualization and writing (contribution to original draft, review, and editing).

Conflicts of Interest

GP is an executive director of Catalyse CAT Ltd, a not-for-profit company that will market the app to accredited cognitive analytic therapists, but no personal financial advantage is conferred. The other authors have no conflicts to declare.

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Abbreviations

CAT: cognitive analytic therapy

CBT: cognitive-behavioral therapy

GDPR: General Data Protection Regulations

PIN: personal identification number

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Review

Evidence on Technology-Based Psychological Interventions in Diagnosed Depression: Systematic Review

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Abstract

Background: Evidence on technology-based psychological interventions (TBIs) for the treatment of depression is rapidly growing and covers a broad scope of research. Despite extensive research in this field, guideline recommendations are still limited to the general effectiveness of TBIs.

Objective: This study aims to structure evidence on TBIs by considering different application areas (eg, TBIs for acute treatment and their implementation in health care, such as stand-alone interventions) and treatment characteristics (eg, therapeutic rationale of TBIs) to provide a comprehensive evidence base and to identify research gaps in TBIs for diagnosed depression. Moreover, the reporting of negative events in the included studies is investigated in this review to enable subsequent safety assessment of the TBIs.

Methods: Randomized controlled trials on adults diagnosed with unipolar depression receiving any kind of psychotherapeutic treatment, which was at least partly delivered by a technical medium, were eligible for inclusion in our preregistered systematic review. We searched for trials in CENTRAL (Cochrane Central Register of Controlled Trials; until August 2020), MEDLINE, PsycINFO, PSYINDEX, CINAHL; until the end of January 2018), clinical trial registers, and sources of gray literature (until the end of January 2019). Study selection and data extraction were conducted by 2 review authors independently.

Results: Database searches resulted in 15,546 records, of which 241 publications were included, representing 83 completed studies and 60 studies awaiting classification (ie, preregistered studies, study protocols). Almost all completed studies (78/83, 94%) addressed the acute treatment phase, being largely either implemented as stand-alone interventions (66/83, 80%) or blended treatment approaches (12/83, 14%). Studies on TBIs for aftercare (4/83, 5%) and for bridging waiting periods (1/83, 1%) were scarce. Most TBI study arms (n=107) were guided (59/107, 55.1%), delivered via the internet (80/107, 74.8%), and based on cognitive behavioral treatment approaches (88/107, 79.4%). Almost all studies (77/83, 93%) reported information on negative events, considering dropouts from treatment as a negative event. However, reports on negative events were heterogeneous and largely unsystematic.

Conclusions: Research has given little attention to studies evaluating TBIs for aftercare and for bridging waiting periods in people with depression, even though TBIs are seen as highly promising in these application areas; thus, high quality studies are urgently needed. In addition, the variety of therapeutic rationales on TBIs has barely been represented by identified studies hindering the consideration of patient preferences when planning treatment. Finally, future studies should use specific guidelines to systematically assess and report negative events.

Trial Registration: International Prospective Register of Systematic Reviews (PROSPERO) CRD42016050413; https://www.crd.york.ac.uk/prospero/display_record.php?ID=CRD42016050413.

International Registered Report Identifier (IRRID): RR2-10.1136/bmjopen-2018-028042

KEYWORDS

internet; telephone; psychotherapy; depression; depressive disorder; systematic review; mobile phone

Introduction

Depression is a common [1] and debilitating mental disorder for both affected individuals and society. It is often accompanied by psychosocial difficulties [2], increased mortality [3], concurrent psychological [4] and/or somatic disorders [5], and high societal costs [6]. There are many effective treatment options for people with unipolar depression, especially psychotherapeutic (eg, cognitive behavioral therapy [CBT], interpersonal therapy) and pharmacological treatments [1,7]. Despite the high prevalence, burden, and the presence of many effective treatment options, depression is still underrecognized [8] and undertreated [9]. For example, in Germany—with a comparatively well-developed mental health care system—only 54% of people with a lifetime diagnosis of major depression and 62% with dysthymia report lifetime service use, indicating barriers and gaps in the health care system [10]. Technology-based psychological interventions (TBIs) are one option to address barriers (eg, long waiting periods before starting a treatment) and gaps (eg, providing psychotherapeutic treatment in rural areas) in the context of mental health care [11]. We defined TBIs as psychotherapeutic or psychological interventions being (at least partly) delivered by technical mediums and tailored to the treatment of depression (eg, guided or unguided web-based self-help programs, telephone therapy, or the combination of onsite therapy and web-based self-help; see study protocol by Köhnen et al [12] for details).

TBIs cover a heterogeneous group of treatments, differing in various aspects, as described by Ebert et al [13]: technical aspects (ie, the application of different technologies such as email or telephone), the amount of human support (eg, TBIs with or without human support, using either synchronous or asynchronous communication), theoretical background (ie, TBIs can be based on different therapeutic rationales), and application areas (eg, TBIs can be provided in different clinical phases of depression management).

In the last decade, research on TBIs has grown rapidly [14], resulting in many randomized controlled trials (RCTs) on people with depression [15-17] as well as systematic reviews [18-20]. Despite extensive research efforts in the field of TBIs for depression treatment, there are still neglected issues, which we aim to address in our systematic review.

First, there is no systematic review that structures available evidence on TBIs regarding different clinical phases of depression management (considering waiting periods, acute treatment, and aftercare) and their implementation in health care (stand-alone intervention, blended care, and stepped and/or collaborative care). Thus, little is known about the effectiveness and acceptance of TBIs concerning their specific application area (eg, as stand-alone interventions for acute depression treatment), as the majority of systematic reviews focus on the assessment of a specific TBI in general, such as computerized

CBT (cCBT) for depression [18]. Thus, current guideline recommendations are still limited to the general effectiveness of cCBT [1,7]. Given the large heterogeneity of TBIs, it is of great relevance—especially when deciding on the implementation of TBIs for health care systems—to determine the differential indication of TBIs considering structural (eg, different clinical phases of depression management), interventional (eg, technical medium of intervention delivery), and person-related (eg, symptom severity) determinants. This is the only way to answer what kind of TBIs are effective, accepted, and safe for whom under specific circumstances. Therefore, we aim to build and structure a comprehensive evidence base.

Second, to date, there is only one systematic review evaluating internet- and mobile-based interventions in people with formally diagnosed depression [19]. However, the vast majority of synthesizing research in this field includes studies based on cutoff scores of depression rating scales (ie, focusing on depressive symptoms) rather than focusing on studies using a formal diagnostic process (ie, focusing on depressive disorders), which is in turn required to initiate treatment (and not only prevention) in the mental health care system. In addition, high-quality evidence (RCTs) in clinical samples is the preferred source of evidence for the development and updating of clinical treatment guidelines, such as the German [1] and the United Kingdom [7] guidelines for depression.

Third, there is little research considering different types of negative events with regard to TBIs [21]. Although there are 2 meta-analyses assessing the safety of TBIs, both studies focused only on depressive symptom deterioration in guided [22] and self-administered [23] internet-based therapy. However, other types of negative events, such as treatment dropout, serious adverse events, nonresponse, or unwanted events (eg, frustration caused by technical problems) may occur during the course of internet-based therapy, which is relevant for safety assessment. In addition, depressive symptom deterioration was only assessed for a specific subsample of TBIs; deterioration regarding other delivery modes, such as telephone therapy, is still unknown. However, a comprehensive safety assessment is indispensable for reliable guideline recommendations, patient education, and individual treatment recommendations. By capturing whether (considering different types of) negative events are reported in the included studies, we aim to prestructure evidence for subsequent safety assessments on TBIs.

We chose the methodology of a systematic review to structure a broad and rapidly growing research field. First, the systematic review should provide an overview considering published and unpublished evidence—including gray literature—in the field of TBIs for the treatment of depression. Second, by considering relevant aspects of TBIs as defined by Ebert et al [13], we aim to structure available evidence to build a comprehensive evidence base for a subsequent, more differentiated assessment

of effectiveness, acceptance, and safety on TBIs and to identify research gaps.

In summary, our main aim is to structure available evidence on TBIs for the treatment of diagnosed depression, addressing the following research questions:

- How much high-quality evidence (ie, RCTs) on TBIs in the treatment of diagnosed depression is available?
- How is the evidence on TBIs distributed regarding general study characteristics (eg, year of publication)?
- How is the evidence on TBIs distributed regarding treatment characteristics (investigated TBI programs, technologies for intervention delivery, degree and purpose of guidance, qualification of people providing guidance, intervention duration, and therapeutic rationale) and application areas (different clinical phases of depression management and their implementation in mental health care)?
- Are negative events reported in studies of TBIs for the treatment of diagnosed depression and what kind of negative events are addressed (eg, symptom deterioration, nonresponse)?

Methods

This study was preregistered (PROSPERO registration number CRD42016050413), and a study protocol was published a priori [12]. This review is in accordance with the standards of the Cochrane Collaboration [24] (eg, preregistration, study protocol, systematic literature search considering gray literature, risk of bias assessment, statistical methods of data syntheses) and reported in line with the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) statement [25].

Inclusion and Exclusion Criteria

We included studies if (1) the whole sample ($\geq 80\%$) consisted of people (aged ≥ 18 years) diagnosed with unipolar depression (assessed by a formal classification system or by conducting a diagnostic interview) with any comorbidities and in any clinical phase of depression management, (2) the intervention was at least partly delivered through technical devices (eg, smartphones, computers, telephones), (3) the intervention was based on an explicit psychotherapeutic theory, and (4) the study was conducted as a (cluster) RCT.

We excluded studies if (1) participants were solely diagnosed by applying cutoff scores on depression scales or when they had a depressive episode in the course of a bipolar disorder; (2) concurrent conditions (either somatic or mental) were the main focus of the intervention; and (3) the intervention provided solely psychoeducational content, patient decision aids, depression management tools, or focused only on drug adherence.

The study protocol by Köhnen et al [12] provides more details on definitions and eligibility criteria.

Search Strategy

We searched the following key databases: CENTRAL (Cochrane Central Register of Controlled Trials), MEDLINE, PsycINFO, PSYINDEX, and CINAHL; see the study protocol by Köhnen et al [12] for the search strategies. The search was not limited

by date, language, or publication status. We further searched clinical trial registers (ClinicalTrials.gov, International Clinical Trial Registry Platform, German Clinical Trial Register) and sources of gray literature (Open Grey, Trip Database, ProQuest Dissertations & Theses Abstract and Indexing, and [specialized registers of] ISI Web of Science). Finally, we contacted all the first authors of the included studies for additional information on (un)published trials and supplementary information or the status of ongoing studies (preregistered trials and study protocols).

Selection Procedure

In total, 2 reviewers (MK and SL) independently screened the first 100 records for inclusion. As the interrater reliability for this sample was found to be high (98%), only one reviewer (MK) screened the remaining records in the course of the title or abstract screening. However, a second reviewer (SL) assessed publications labeled as *unclear*. Selected full-text publications were subsequently assessed for inclusion by 2 independent reviewers (MK and MD). Discrepancies were resolved by discussion with a third reviewer (SL).

Data Extraction

We developed and piloted a standardized data extraction sheet containing characteristics of interest (see study protocol by Köhnen et al [12] for further information on extracted data). The data extraction sheet comprised information regarding general study information (eg, authors), methodological characteristics (including the risk of bias assessment), sample characteristics (eg, age), treatment characteristics, application areas, sample size and study flow, and primary (posttreatment scores of depression and treatment dropout rates) and secondary (eg, remission rates, quality of life) outcome data.

Essential characteristics were either judged (risk of bias assessment [24], rating of included trials on the efficacy-effectiveness spectrum [26]) or extracted (primary and secondary outcomes) independently by 2 reviewers (MK and MD or TS or Eileen Wehmann). Half of the included studies were extracted completely by 2 independent reviewers; in the other half, further characteristics (eg, therapeutic rationale of TBIs) were extracted by one reviewer (MK). Disagreements were resolved by discussion or by consulting a further reviewer (SL). As the aim was to structure evidence for TBIs, not all extracted data will be reported in this publication.

The risk of bias assessment was evaluated using the criteria described in the Cochrane Handbook for Systematic Reviews of Interventions [24] (including the domains: random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective outcome reporting, and other bias). In line with a previous operationalization [27], we specified the domain *other bias* using the following 3 categories: insufficient treatment adherence, allegiance bias, and attention bias.

Data Extraction: Classification of Negative Events

We applied the recommended definition of negative effects from the *consensus statement on defining and measuring negative effects of internet interventions* [21] to describe if

negative effects are reported in included studies. We waived using the term *effect* in this context, as it implies a causal relationship between treatment and harmful outcome; thus, we used the term *event* implying that a harmful outcome has occurred during or after treatment, independent of whether it was caused by it [24].

According to this, negative events comprise the following categories:

- Deterioration: worsening of target symptoms in the course of treatment measured by validated target symptom scales [21].
- Adverse events: any types of adverse events occurring during or after treatment, including physical symptoms (eg, headache); psychological symptoms (eg, depressed mood); and psychosocial, legal, and economic consequences (eg, conflicts with the partner) [27].
- Severe adverse events: any type of adverse events leading to serious consequences, such as death, mortal danger, hospitalization, or disability [28].
- Novel symptoms: novel symptoms describe the emergence of new psychological symptoms (other than the symptoms addressed in treatment), independent of whether novel symptoms are associated with treatment [21].
- Dropout from treatment.
- Nonresponse.
- Unwanted events: any type of events that are experienced as negative by patients in the course of the treatment, independently of whether unwanted events are associated with the treatment being used. In addition, unwanted events are not necessarily related to the treatment outcome, such as technical issues causing frustration or social stigma [21].

Data Analysis

We structured the included studies according to application areas: clinical phases of depression management consisted of waiting periods, acute treatment, and aftercare. Within different phases of depression management, TBIs can be distinguished concerning their implementation in mental health care. They can be delivered as stand-alone interventions (TBIs replacing face-to-face [F2F] therapy), as blended treatments (combining TBIs and F2F therapies), or as part of stepped (TBIs are used as low threshold, initial treatment options for people with a

mild-to-moderate depressive disorder) and/or collaborative care models (TBIs may be provided alongside different treatment components, such as a TBI is offered in addition to a monitoring care manager, general practitioners' care, and the provision of an online discussion forum). In addition, treatment characteristics were used to structure the available evidence. We used descriptive statistics (eg, frequencies, measures of central tendency, measures of variability) for quantitative analysis using Microsoft Excel 2013 (Microsoft).

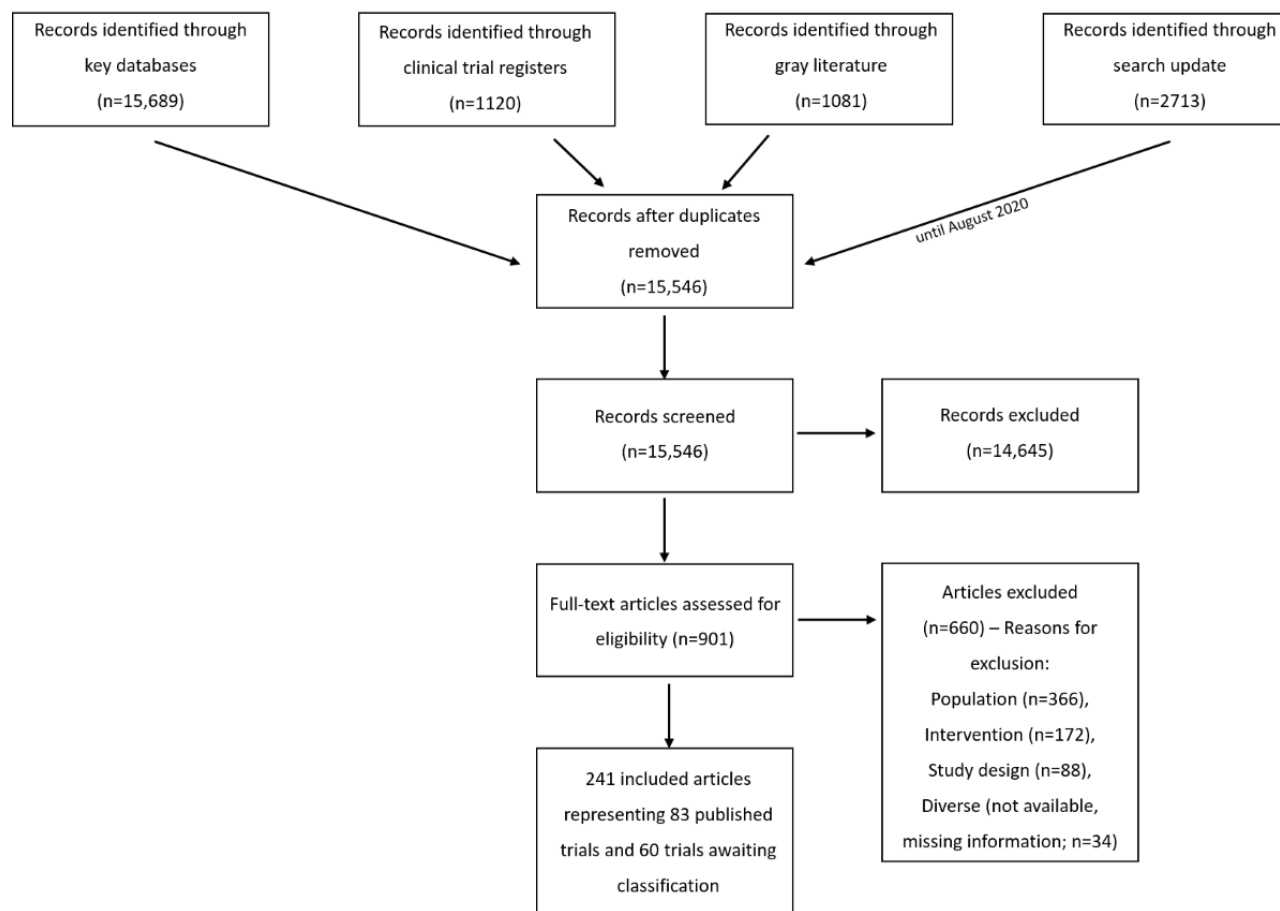
Patient Involvement

We actively involved patients and their relatives in the process of conducting our systematic review by means of 2 workshops (see study protocol by Köhnen et al [12] for details). The first workshop provided general information on systematic reviews and TBIs, and we collected the most relevant outcome domains concerning TBIs from a patient or relative perspective. The second workshop provided study findings and discussed the results of reporting practices concerning these patient-relevant outcomes.

Results

Search Results

Electronic searches yielded 20,613 records. After deduplication, 15,546 records were screened by title or abstract. In total, 901 full-text articles were assessed for eligibility. Not fulfilling the population criteria was the major reason (366/901, 40.6%) for exclusion, as many studies included their participants by applying cutoff scores on depression rating scales, rather than including participants on the basis of a formal diagnostic process (eg, clinical interview). Other reasons for exclusion were not fulfilling intervention (172/901, 19.1%) and study design (88/901, 9.8%) criteria. The remaining studies (34/901, 4.0%) were excluded for diverse reasons: publications were unavailable or relevant study information was missing (eg, distribution of diagnoses across the sample) and also not retrievable by contacting corresponding authors. Overall, we included 241 publications representing 143 trials (83 published trials and 60 trials awaiting classification) covering all clinical phases of depression management. Figure 1 provides a detailed study flow.

Figure 1. Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flowchart.

General Study Characteristics

Overall, the identified studies ($N=83$) included 14,080 participants, ranging from 14 to 1089 per study. The mean age of the participants was 44.9 (SD 12.1) years, and two-thirds were female (67%; see [Multimedia Appendix 1](#) for details [15-17,29-108]).

Most included trials had a trial registration (58/83, 70%), and approximately one-fourth (22/83, 27%) of the included trials

had an accompanying study protocol ([Table 1](#)). The most common source of risk of bias was nonblinding of participants and personnel (as blinding is barely possible in psychotherapy research), selective reporting, and other bias (especially because of insufficient treatment adherence; see [Multimedia Appendix 2](#) for details).

Studies on TBIs for depression were published from 1990 to the date of our search update in August 2020 ([Table 2](#)). The geographical region and country of trials are shown in [Table 3](#).

Table 1. General study characteristics ($N=83$).

Variables	Studies, n (%)
Registration of studies and publication of study protocols	
Trials with study registration	58 (70)
With study protocol	21 (25)
Without study protocol	37 (45)
Trials without study registration	25 (29)
With study protocol	1 (1)
Without study protocol	24 (28)
Number of study arms in included trials	
2	64 (77)
3	16 (19)
≥4	3 (4)

Table 2. Publications on TBIs for depression per decade (N=83).

Decade	Studies, n (%)
1990 to 1999	2 (2)
2000 to 2009	4 (5)
2010 to 2019	69 (83)
2020 (end of August)	8 (10)

Table 3. Trials by geographical region (N=83).

Geographical region	Studies, n (%)
Europe	44 (53)
North America	23 (28)
Australia	9 (11)
Asia	7 (8)

Treatment Characteristics

Investigated TBI Programs

Overall, 26 specific TBI programs were evaluated in the included studies; 18 of these programs were evaluated by 1 study, and 8 were evaluated by more than 1 study. However, approximately half of the studies (40/83, 48%) did not provide a name for the applied TBI program ([Multimedia Appendix 3 \[15-17,29-109\]](#)).

Technologies for Intervention Delivery

We identified 107 arms (from 189 arms) in the included studies that applied TBIs. Most TBIs (78%) were delivered by one technical medium (eg, internet or telephone), whereas 22% of TBIs applied more than one technical medium (eg, internet and telephone). Most TBIs were delivered via the internet (54%), followed by telephone (11%), offline computer programs (7%), videoconferencing tools (3%), and mobile phones delivering text messages (2%; see [Multimedia Appendix 4](#) for details).

Purpose of Guidance

The purpose of guidance in TBIs was heterogeneous ([Multimedia Appendix 3](#)).

To structure the guidance in TBIs, we summarized the reported purposes of guidance to categories and identified 5 functions of guidance: (1) informative function (eg, answering queries related to technical issues or treatment), (2) monitoring function (eg, symptom monitoring), (3) adherence-facilitating or motivational function (eg, encouragement to continue with intervention), (4) feedback function (eg, providing feedback for homework), and (5) therapeutic function (eg, goal setting).

Most guided TBIs fulfilled more than one function addressing different needs of participants.

Degree of Guidance in TBIs

We rated the degree of guidance in TBIs according to the framework of Newman et al [109], consisting of 4 categories, as follows: self-administered therapy, predominantly self-help, minimal-contact therapy, and predominantly therapist-administered intervention.

Trials applying blended treatments were classified in an extra category because these trials provide F2F guidance (eg, by psychotherapists). The included trials applied TBI arms that were either unguided (20/107, 18.7%), guided (59/107, 55.1%; combination of predominantly self-help, 46/107, 43.0%, and minimal contact therapy, 13/107, 12.1%), therapist-delivered (14/107, 13.1%), or blended treatments (14/107, 13.1%).

Qualifications of People Providing Guidance

The qualification of people who provided guidance on TBIs and who delivered treatment via TBIs ranged from lay supporters (technicians, research assistants, etc; 8/71, 11%) to clinicians with experience in the treatment of people with mental illness (trained psychotherapists, 6/71, 8% as well as psychiatrists, 1/71, 1%). Most people providing guidance and delivered treatment via TBIs had a background in psychology (36/71, 51%).

Interventions' Duration

Interventions' duration of identified TBIs ranged from 1 to 52 weeks, with most interventions lasting between 6 and 12 weeks (median treatment length of 8.5 weeks). Interventions of 8-week duration were the most frequent (26/107, 24.3%) in the included studies.

Therapeutic Rationale of TBIs

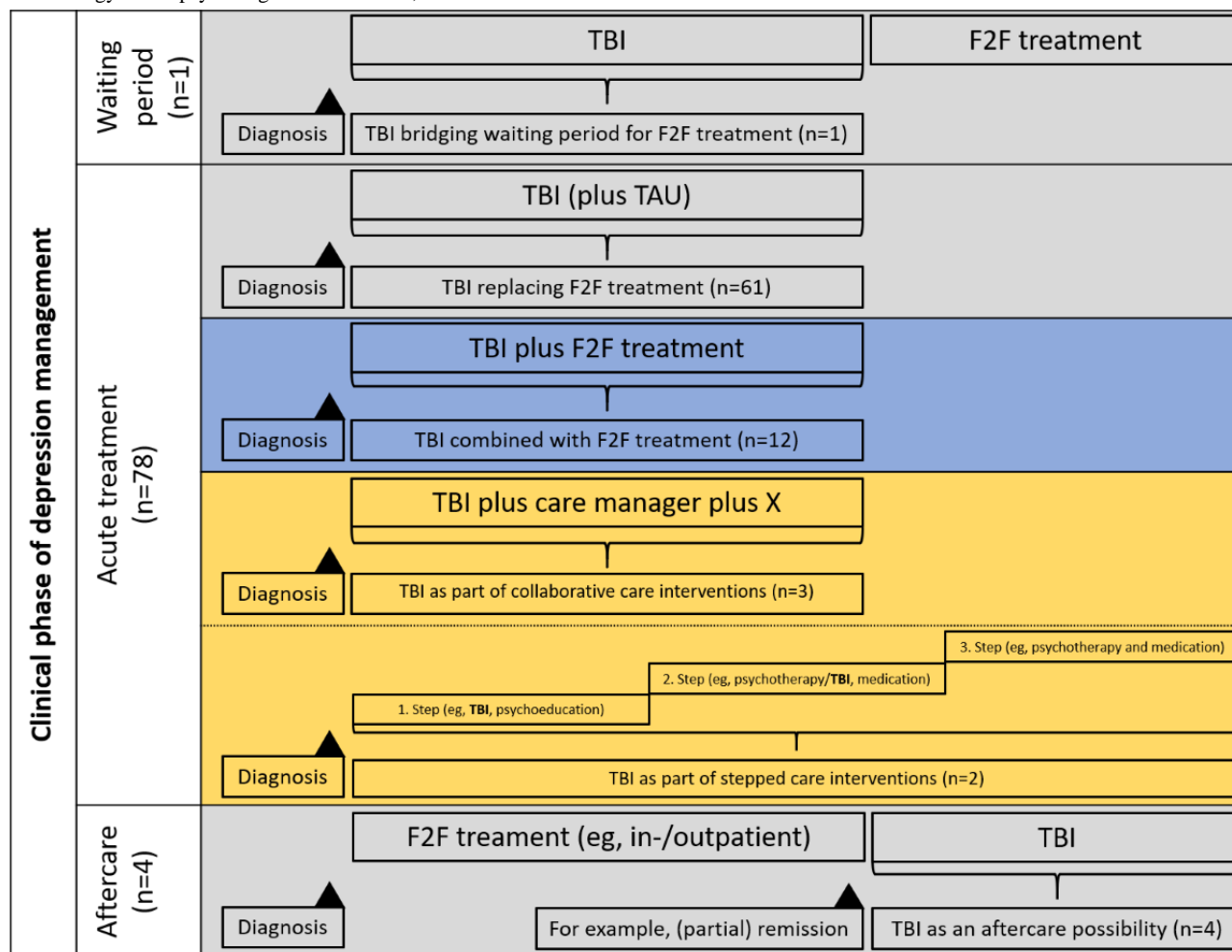
Overall, we identified 15 different therapeutic rationales for TBIs, ranging from mindfulness to psychodynamic therapy. Most TBIs were based on cognitive behavioral treatment approaches (79%; [Multimedia Appendix 5](#)).

Application Areas of TBIs

Concerning the clinical phase of depression management, almost all trials were related to the acute treatment of people with acute depression (94%), followed by trials addressing the aftercare of people with depression (5%), and one trial that applied a TBI as a tool for bridging waiting periods (1%). Regarding the implementation of mental health care, most TBIs were delivered as a (enhanced) stand-alone intervention (80%), followed by blended treatment approaches (14%), and 5 studies (6%)

delivered TBIs as part of a collaborative (4%) or stepped (2%) care interventions (Figure 2).

Figure 2. Distribution of studies (N=83) on application areas. Color highlighting of cells indicates format of implementation of TBIs: grey = (enhanced) stand-alone intervention; blue = blended treatment approach; yellow = TBI as part of collaborative/stepped care interventions. TAU: treatment as usual; TBI: technology-based psychological intervention; F2F: face-to-face.



We applied a rather broad definition for blended treatments, since we included all studies that provided any type of F2F treatment tailored to depression (eg, psychotherapy, medication, depression specific GP care) in addition to TBIs irrespective of the study's definition/label. In contrast, trials concurrently providing treatment as usual in addition to TBIs were considered as enhanced stand-alone interventions, if treatment as usual consisted of a systematically offered generic treatments (eg, general GP care for all participants) that was not specifically tailored to depression.

Report of Negative Events

Most studies (70/83, 84%) reported dropout rates. However, reporting on dropouts is heterogeneous, as studies differed in their definitions on dropouts: there were studies reporting dropouts from treatment (or treatment completion rates; 38/83, 46%), whereas other studies applied other definitions of dropouts, for instance, treatment completers as defined by authors or withdrawals from the study (32/83, 39%), and approximately 16% (13/83) of included studies did not report any extractable dropouts (Table 4; see Multimedia Appendix 6 [15-17,29-108] for an overview on negative events). On average, the included trials reported on 1.67 (SD 1.06; range 0-5) categories of negative events (out of 7 potential categories).

Table 4. Report of negative events in included studies (N=83).

Report of negative events	Studies, n (%)
Dropout	70 (84)
Deterioration	21 (25)
Adverse events	18 (22)
Nonresponse	16 (19)
Severe adverse events	14 (17)
Novel Symptoms	0 (0)
Unwanted Events	0 (0)

Discussion

Principal Findings

The aim of our study was to structure available evidence on TBIs for the treatment of diagnosed depression to build a comprehensive evidence base and to identify research gaps.

Application Areas

As shown in [Figure 2](#), the vast majority (94%) of the included studies focused on the acute treatment phase. Significantly less evidence was available for TBIs in aftercare (5%) and for TBIs bridging waiting periods (1%), indicating research gaps despite extensive discussions on their usefulness in these clinical phases of depression management. For example, TBIs for bridging waiting periods may help to establish early symptom reduction [11] or to counteract symptom manifestation, which may prevent aggravation, recurrence, and the experience of a persistent course for people on waiting lists for treatment. Furthermore, TBIs may prepare for F2F treatments by providing, for example, psychoeducational information on depression (eg, symptoms) [11] so that there is subsequently more time for working on therapeutic content (eg, behavioral activation). TBIs in aftercare are seen as (potentially) useful tools providing an aftercare possibility attached to inpatient treatment with lower barriers (eg, waiting periods) compared with traditional aftercare approaches [110]. In view of the fact that we have identified only a few studies for aftercare [16,29-31] and one for bridging waiting periods [32], the question arises whether firm conclusions about the effectiveness and acceptance of these clinical phases can be made on the basis of the available evidence. This is also supported by looking at the level of synthesizing research, as only 2 reviews [111,112], which dealt with one of these phases, could be identified. However, even if these reviews were based on broader inclusion criteria (eg, the presence of a [former] depressive disorder was not required), they could identify only a few—quite heterogeneous—studies and could not draw firm conclusions about effectiveness and acceptance in these clinical phases of depression care [111,112]. Given the unconvincing evidence base and the probable potential of TBIs to overcome treatment barriers for aftercare and in bridging waiting periods, it is of great relevance to conduct research on TBIs in these specific clinical phases of depression management, at best pragmatic large-scale RCTs with people having diagnosed depression, so that a comprehensive assessment, also decisive for guideline recommendations, is possible in the future.

In addition, most studies implemented TBIs either as (enhanced) stand-alone interventions (80%) or as blended treatment approaches (14%) in the acute treatment phase of depression treatment, indicating a comprehensive evidence base useful for further analyses on the differential indication for this clinical phase of depression management. There is little evidence on TBIs as part of collaborative (4%) or stepped (2%) care interventions in our review ([Figure 2](#)), which may be traced back to the fact that studies were only considered if the results were differentially reported for the technology-based treatment component.

Stepped care approaches incorporating TBIs are recommended by the German [1] and the United Kingdom [7] guidelines for improving depression care. In addition, stepped care approaches are seen as promising options to up-scale (depression) treatment options being concurrently more cost-effective compared with other approaches, especially when TBIs are integrated. Thus, care within stepped care models is initially offered as a low-threshold (and low-cost) intervention with constant symptom monitoring. When patients do not respond to an intervention, they will be stepped up receiving more intensive interventions. However, to the best of our knowledge, there is no meta-analysis on the effectiveness of stepped care approaches with TBIs, indicating that a sufficient evidence base is missing. In contrast, traditional stepped care approaches without TBIs have been found to be effective for treating depression [113]. Thus, not surprisingly, we only identified 2 studies [33,34] offering TBIs (internet-based CBT) as a low-threshold intervention in the course of a stepped care approach. To assess the usefulness of specific TBIs within stepped care approaches, we need studies testing different treatment options comparatively at different levels of the stepped care approach (for instance, first step: watchful waiting vs iCBT (internet-based CBT) vs bibliotherapy; second step: F2F psychotherapy vs telephone psychotherapy). In addition, studies would be useful for assessing both the whole stepped care approach depending on whether a TBI component was implemented (eg, [non]provision of iCBT as a low-threshold first-step intervention) and the benefit of these components within the stepped care approach (eg, pre-post gains, stepping-up rates, step-specific adherence rates).

In summary, there is evidence on the acute treatment phase of depression, and there are promising approaches to improve mental health care for people with depression by using TBIs. However, there are only a few studies investigating TBIs outside

of acute treatment and applying innovative treatment approaches, which is why we call for (1) more research in previously less-considered clinical phases of depression management (aftercare, waiting periods) and (2) more studies investigating stepped care approaches with different TBI components.

Treatment Characteristics

We found that most TBIs were based on cognitive behavioral treatment approaches (79%), especially CBT (65%), and that other guideline-recommended treatment rationales for F2F depression treatment, such as psychodynamic treatments, are barely researched in TBIs of diagnosed depression. This may be because of the fact that psychodynamic-oriented therapists have a more negative attitude toward internet interventions compared with other therapists [114]. In addition, there is an ongoing debate in the psychodynamic community—at least in German-speaking countries—concerning whether an adequate therapeutic alliance, which is emphasized being a central treatment component, can be established in treatments outside of the F2F setting, as, for example, certain cues (visual and/or auditory) are missing [115]. However, recent reviews suggest that establishing a sustainable therapeutic alliance may be possible when treatment is delivered by different technical mediums [116,117]. Another reason cognitive behavioral rationales are particularly suitable may be because of their more manualized content [118]. Content intended for F2F treatment may be easier transferred to other settings and, for example, made available via web-based programs.

Owing to the lack of studies investigating other approaches recommended by guidelines, we call for more studies on TBIs considering a broader variety of treatment approaches. This would allow for more differentiated guideline recommendations, as they are currently limited to the effectiveness of cCBT [1,7]. In addition, patient preferences regarding TBIs could be considered when treatment is planned because preferences (CBT vs psychodynamic therapy) seem to have predictive value for treatment outcome in internet-delivered interventions [119] and significantly affect outcomes in regular treatment of mental disorders [120].

Report of Negative Events

Considering the report of negative events in included studies, we found that apart from dropouts, other negative events such as deterioration, nonresponse, and (severe) adverse events were reported in a few studies (range 17%-25%) or not at all (unwanted events and novel symptoms). Although dropouts were reported by most studies (84%), there were reported quite heterogeneously, as only 46% of all studies reported dropouts from treatment (or completion rates), which is an important indicator for treatment adherence in TBIs. For example, it is well known that unguided TBIs produce significantly more dropouts than guided TBIs [18]. Dropout rates (as an indicator for treatment adherence and therefore also for safety) have to be considered when comparing other treatment characteristics (eg, video vs telephone). Moreover, 39% of studies reported other kinds of dropouts (eg, withdrawals from study, treatment completers, as defined by the authors). This kind of dropouts

is less meaningful, as the link to treatment adherence or safety is less clear.

Although adverse events have been reported in 22% of studies, many studies have reported adverse events unsystematically. For instance, by stating that no adverse events have been noted for any study participants, which did not specify the method of capturing adverse events as well as the definition of adverse events in included trials. It was not clear if participants were asked about the occurrence of adverse events during or after treatment. On the other hand, there were trials systematically assessing adverse events, for instance, by mapping them to different symptom domains (eg, somatically and psychologically) and specifying time points for the assessment. In total, the method on how and when adverse events were captured remained unclear in most included studies, which may contribute to an underestimation of the occurrence of adverse events because it is more likely to report such events when specifically asked for it in comparison to spontaneous reports [121,122].

Our findings on the report of negative events are in line with a previous systematic review, which also noted that adverse events were heterogeneous and insufficiently reported in RCTs on people with a persistent depressive disorder, especially in psychotherapeutic studies, where the report of adverse events was largely neglected [123]. However, in our review, when all categories of negative events were considered, almost all studies reported at least some information on negative events (93%); nonetheless, the reporting between studies on certain categories (eg, dropouts) was inconsistent. This inconsistency may be explained by the fact that included trials considered more generic reporting guidelines (eg, Consolidated Standards of Reporting Trials [CONSORT]), rather than considering specific guidelines or guideline extensions (eg, CONSORT Extensions [for harms]), as they are rarely endorsed by high-impact journals [124], which may also influence authors' use [125].

Given the great heterogeneity in the reporting of negative events in included studies, we suggest the use of specific guidelines or guideline extensions to future trialists, such as the CONSORT extensions for harms [126], which may help make the report more precise and homogeneous, by for instance clarifying how information concerning negative events was collected.

Strengths and Limitations

Our review was conducted in line with the Cochrane guidelines, reported following PRISMA guidelines [25], and studies were selected according to prespecified criteria [12], reflecting high methodological standards. However, we deviated from the study protocol by waiving an additional forward and backward reference search because our systematic literature search was already very comprehensive.

Despite strict eligibility criteria (eg, diagnosed depression), the focus of our review is still broad because all TBIs were considered irrespective of application areas and certain treatment characteristics. Following a broad focus resulted in large heterogeneity of the included studies, which is probably challenging for subsequent meta-analyses. It may be possible that certain questions regarding the differential indication are

unsuitable for evidence synthesis because of large heterogeneity (eg, differences in intervention duration) or because there are not enough studies available (eg, evidence for TBIs bridging waiting periods [n=1]).

We conducted a highly sensitive literature search considering key databases, databases of gray literature, and clinical trial registries, without limiting the literature search to language. Nonetheless, we may have missed trials published in languages other than English because databases containing primarily English records may fail to find trials published in other languages even when language restrictions were avoided [127].

Conclusions

Overall, the results indicated that there is a proper evidence base for TBIs in the acute treatment phase being either implemented

as stand-alone or blended treatments. However, the evidence base of TBIs in aftercare or for bridging waiting periods was found to be hardly convincing. Moreover, most TBIs were theoretically based on cognitive behavioral treatment rationales. Thus, a (broader) evidence base including TBIs based on other therapeutic rationales is still missing.

Concerning the report of negative events in studies evaluating TBIs, it was found that some information on negative events was reported in almost all studies, but the report was quite inconsistent between studies.

Despite the unequal distribution of evidence concerning differing clinical phases of depression management and treatment characteristics, we compiled a comprehensive evidence base to subsequently assess the effectiveness, safety, and acceptance of TBIs.

Acknowledgments

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Conflicts of Interest

HB received consultancy fees, reimbursement of congress attendance, and travel costs as well as payments for lectures from psychotherapy and psychiatry associations as well as psychotherapy training institutes in the context of e-mental health topics. He has been the beneficiary of study support (third-party funding) from several public funding organizations. HB and MH participated in the current revision of the German S3 national clinical practice guideline on the treatment of adults with unipolar depression. MH and LK participated in the 2015 revision of the German S3 national clinical practice guideline on the treatment of adults with unipolar depression. MH and SL are licensed psychotherapists. SL is additionally employed at the institute for psychotherapy at the University Medical Center Hamburg-Eppendorf, which provides psychotherapist training in CBT. MK and MD are psychotherapists in training (CBT). TS is a psychotherapist in training (psychodynamic therapy).

Multimedia Appendix 1

Study characteristics.

[PDF File (Adobe PDF File), 307 KB - [mental_v8i2e21700_app1.pdf](#)]

Multimedia Appendix 2

Risk of bias assessment.

[PDF File (Adobe PDF File), 74 KB - [mental_v8i2e21700_app2.pdf](#)]

Multimedia Appendix 3

Treatment characteristics of technology-based psychological interventions.

[PDF File (Adobe PDF File), 322 KB - [mental_v8i2e21700_app3.pdf](#)]

Multimedia Appendix 4

Technologies for intervention delivery.

[PDF File (Adobe PDF File), 126 KB - [mental_v8i2e21700_app4.pdf](#)]

Multimedia Appendix 5

Therapeutic rationales of technology-based psychological interventions.

[PDF File (Adobe PDF File), 128 KB - [mental_v8i2e21700_app5.pdf](#)]

Multimedia Appendix 6

Report of negative events.

[PDF File (Adobe PDF File), 195 KB - [mental_v8i2e21700_app6.pdf](#)]

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Abbreviations

CBT: cognitive behavioral therapy

cCBT: computerized cognitive behavioral therapy

CENTRAL: Cochrane Central Register of Controlled Trials

CONSORT: Consolidated Standards of Reporting Trials

F2F: face-to-face

iCBT: internet-based CBT

PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses

RCT: randomized controlled trial

TBI: technology-based psychological intervention

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Review

Suitability of Text-Based Communications for the Delivery of Psychological Therapeutic Services to Rural and Remote Communities: Scoping Review

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Abstract

Background: People living in rural and remote areas have poorer access to mental health services than those living in cities. They are also less likely to seek help because of self-stigma and entrenched stoic beliefs about help seeking as a sign of weakness. E-mental health services can span great distances to reach those in need and offer a degree of privacy and anonymity exceeding that of traditional face-to-face counseling and open up possibilities for identifying at-risk individuals for targeted intervention.

Objective: This scoping review maps the research that has explored text-based e-mental health counseling services and studies that have used language use patterns to predict mental health status. In doing so, one of the aims was to determine whether text-based counseling services have the potential to circumvent the barriers faced by clients in rural and remote communities using technology and whether text-based communications, in particular, can be used to identify individuals at risk of psychological distress or self-harm.

Methods: We conducted a comprehensive electronic literature search of PsycINFO, PubMed, ERIC, and Web of Science databases for articles published in English through November 2020.

Results: Of the 9134 articles screened, 70 met the eligibility criteria and were included in the review. There is preliminary evidence to suggest that text-based, real-time communication with a qualified therapist is an effective form of e-mental health service delivery, particularly for individuals concerned with stigma and confidentiality. There is also converging evidence that text-based communications that have been analyzed using computational linguistic techniques can be used to accurately predict progress during treatment and identify individuals at risk of serious mental health conditions and suicide.

Conclusions: This review reveals a clear need for intensified research into the extent to which text-based counseling (and predictive models using modern computational linguistics tools) may help deliver mental health treatments to underserved groups such as regional communities, identify at-risk individuals for targeted intervention, and predict progress during treatment. Such approaches have implications for policy development to improve intervention accessibility in at-risk and underserved populations.

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KEYWORDS

mental health services; text messaging; counseling; mobile health; natural language processing

Introduction

Defining E-Mental Health Services

E-mental health is an umbrella term used to describe services delivered via online, mobile, or phone-based platforms to diagnose, treat, or prevent mental health conditions, such as depression, anxiety, and substance abuse. This burgeoning field includes websites offering static information and resources such as Headspace and Beyond Blue [1,2], peer support services such as 7 Cups [3], interactive counseling services via telephone such as Kids Help Line [4], videoconferencing, email, and text-based chat (eg, SMS). With numerous approaches to e-mental health, some services use several modes of delivery (eg, Mental Health Online offers therapy via email, chat, and video). Technology has evolved rapidly, and the number of e-mental health services is growing, but without a rigorous evaluation of service delivery, much remains unknown.

Context and Scope for the Review

E-mental health services can potentially fill an important service gap in the context of improving mental health outcomes for communities outside major cities. In Australia, these account for 28% of the population (over 7 million people) [5]. Living in rural and remote communities is associated with poorer health outcomes, including mental illness. As remoteness increases, the prevalence of mental illness and the incidence of self-harm and suicide also increase [6]. Suicide rates are 40% higher in rural areas than in cities, and double in remote areas, whereas suicide rates in regional and rural areas are increasing faster than in capital cities [7]. Farmers are at an increased risk of suicide compared with other occupations in rural and remote communities [8-10]. People living in rural areas generally have poorer access to health services than those living in cities for several reasons. First, fewer mental health professionals work in rural and remote areas [11], rendering access to mental health services more difficult owing to time requirements, distance, and limited service capacity. Public transport is often not viable in low-density rural areas, which is particularly problematic in Australia [12]. Second, stigma toward mental health issues becomes a help-seeking barrier in smaller communities, because of fears of compromised confidentiality and being the topic of community gossip [13]. This may be more pronounced for males, for whom self-stigma and entrenched stoic beliefs about help seeking as a sign of weakness can delay psychological counseling or prevent engagement with mental health services altogether [13,14]. Per capita needs for mental health services in rural and remote areas are at least as great as in cities; therefore, these barriers to mental health service delivery are a cause for concern. Through this lens of concern, we approach our review.

With the proliferation of smartphones, mental health services can use technology to circumvent barriers and span great distances to reach individuals. E-mental health initiatives can potentially make a valuable contribution to service delivery in rural areas, although more research is needed [15]. Two aspects of text-based counseling services are especially likely to appeal to people living in rural and remote communities. First, the potentially anonymous nature of text-based interactions with

therapists will appeal to individuals who are concerned with stigma and are reluctant to engage with face-to-face services. Second, text-based counseling allows clients to interact in real time with a qualified therapist at a time convenient for them, without the need to take time off work. Encouragingly, there is evidence that clients who have accessed e-mental health services show comparable outcomes to those in traditional face-to-face counseling services, as described previously [16].

Objectives

This scoping review maps the research that has explored text-based e-mental health counseling services and studies that have used language use patterns to predict mental health status. Our search considered publications in both peer-reviewed and gray literature to capture existing and emerging research within the field. In addition to providing an overview of the literature, this review aims to identify priorities for future research. As will become clear, text-based communications lend themselves to predictive analyses more readily and on a larger scale than spoken communication.

Methods

Overview

We performed a scoping review following the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-analyses) Extension for Scoping Reviews checklist (Multimedia Appendix 1). A scoping review protocol was created to guide the process and is available from the corresponding author upon request.

Eligibility Criteria

It was decided that relatively broad inclusion criteria would be used to consider all publications with reference to the relevant mental health conditions (ie, depression, suicidal ideation, and anxiety), online counseling, and linguistic indicators for psychological conditions. All publication types were available for selection (journal articles, conference proceedings, reports, and unpublished theses). Therefore, studies were included if they (1) involved an intervention that occurred in real time, (2) were text-based, and (3) involved a qualified human clinician.

Publications were also considered for inclusion if they were related to mental health or counseling more generally if they had a text-based component. In addition, studies were included if they examined whether text patterns could be used to predict mental health status. Only articles written in English were included in this study.

Our scope is limited to the literature that examined e-mental health approaches involving text-based, real-time communication with a qualified human therapist and the predictive power of language use patterns. Within the eHealth sector, SMS text messaging and email are increasingly used for mental health care [17], medication adherence [18], treatment compliance [19], aftercare support [20], and reminders and supportive messages between face-to-face visits [21,22]. Encouragingly, virtual interventions incorporating scheduled messages or emails to support client participation have shown reductions in symptoms of depression, anxiety, and stress

[21,23-25]. However, text-based technologies or the provision of mental health services by virtual agents or artificial intelligence algorithms cannot capture the dynamic back-and-forth communication exchanges of interest here and are not covered in the review. Therefore, studies that fell into the above categories were excluded.

Information Sources

Articles were identified by searching through the following databases: PsycINFO, PubMed, ERIC, and Web of Science.

Search Strategy

A literature search was conducted in July 2019 and updated in November 2020. The following search terms were used: (“therap*” OR “counsel*” OR “intervention” OR “depress*” OR “suicid*” OR “anxiety”) AND (“internet” OR “text” OR “linguistic” OR “word use” OR “natural language processing”). The search strategy was modified according to the different databases. The databases were searched from inception to November 24, 2020. As a final step, the reference lists contained within selected publications were searched for other relevant publications.

Selection of Sources of Evidence

Screening is a two-step process. AD removed duplicates and screened titles and abstracts to determine relevance to the topics of mental health and text-based counseling. These publications were then read in full to determine their relevance to the research question. CLC and MA checked the excluded studies and confirmed that the exclusion criteria were applied correctly.

Data Charting Process

We created a standardized template to extract relevant data from the included studies, such as publication type, journal name, reference to text-based e-mental health (or its variants) in the article title, reference to psychological conditions in the publication title, country of focus of the research, geographic location of data collection (urban, rural, etc), sample size of individual groups, and the gender composition of the sample. Data were extracted by AD, DE, and CLC and cross-checked by MA to ensure correctness and completeness.

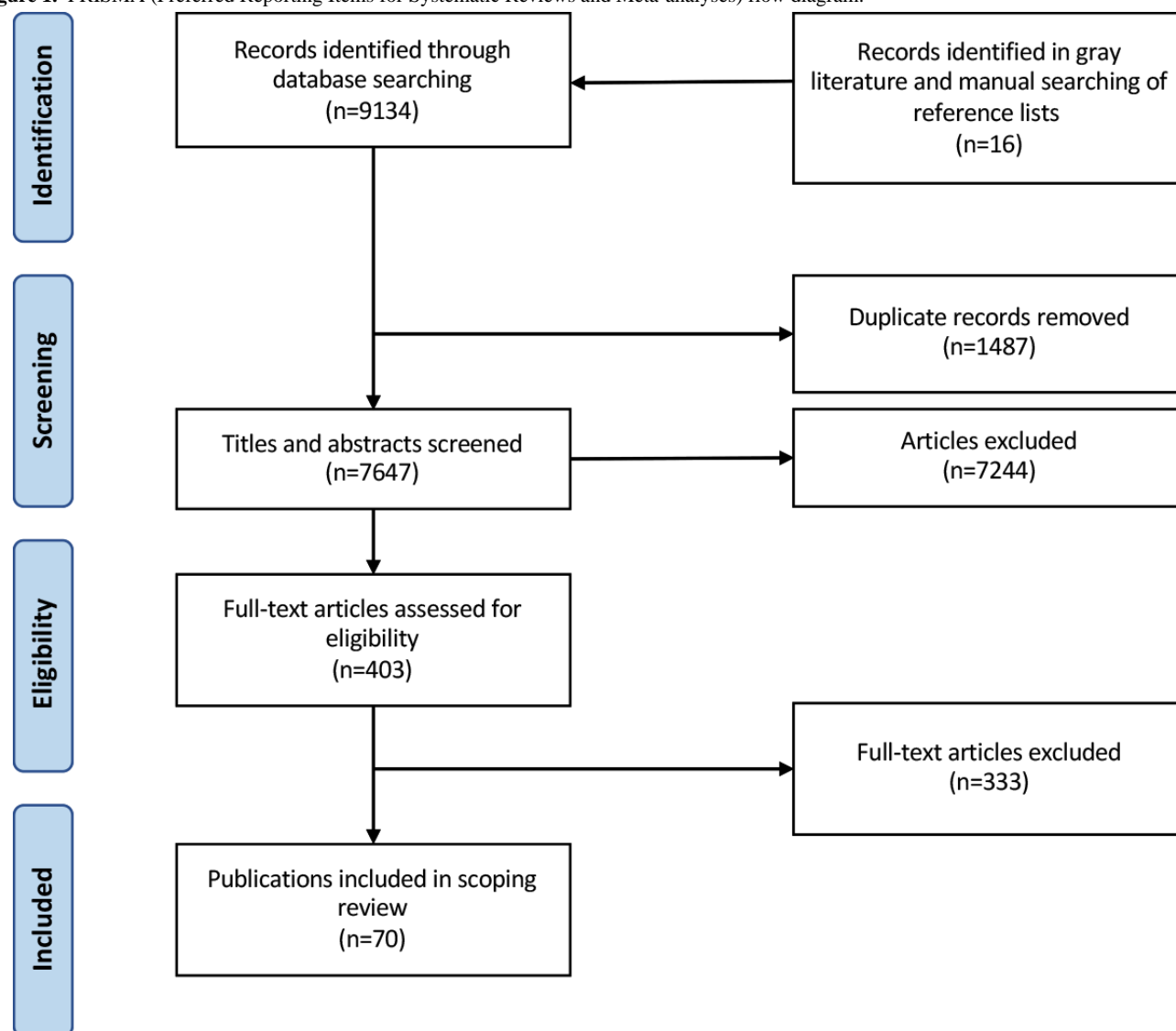
Data Analysis and Synthesis

We synthesized the collated data using descriptive statistics (frequencies and proportions). Microsoft Excel was used to analyze the data.

Results

Study Selection

We identified 9134 publications in our initial search. From these, 1487 duplicates were removed, leaving 7647 records for consideration. Next, titles and abstracts were screened based on our eligibility criteria, and 7244 publications were excluded. A further 333 publications were excluded during the full-text screening stage. The PRISMA flow diagram is presented in [Figure 1](#). The full list of the included studies is provided in [Multimedia Appendix 2](#) [16,26-95].

Figure 1. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-analyses) flow diagram.

Characteristics of Sources of Evidence

Of the 70 articles included in this review, 26% (18) reported positive outcomes following client participation in text-based e-mental health services, whereas only 4% (3) reported that text-based services were not effective in meeting the needs of clients. A total of 16% (11/70) of studies offered an insight into why some individuals are more or less likely to engage in text-based communications. Furthermore, 33% (23/70) analyzed text-based communications to identify predictors of mental health status, and 19% (13/70) specifically analyzed text-based communication during the course of therapy in an attempt to predict future mental health status. More studies were published in 2018 and 2019 than in any other years ($n=10$ and 11 , respectively), and more than half of the studies ($40/70$, 58%) had been published in the last 5 years, with five published in 2020 ($5/70$, 7%). Forty-five studies ($45/70$, 64%) reported participants' sex, and in the majority of those studies ($34/45$, 76%), a greater proportion of participants were female. The table in [Multimedia Appendix 2](#) gives details of the number of participants, their age range, sex, background information/psychological status, and the location of the study for each source cited.

Text-based communication between clients and mental health professionals may involve SMS text messages, mobile phone apps, or internet chats. This review reveals that (1) few studies of these services have been conducted, (2) existing studies focus largely on children and adolescents in urban and suburban areas, (3) the quality of the studies varies considerably, and (4) fundamental questions remain unanswered. We first reviewed studies that reported a positive effect of text-based chat therapy on mental health outcomes.

Effectiveness of Text-Based E-Mental Health Services

In total, 18 studies reported that text-based e-mental health services were effective in treating mental health conditions. A single session of text-based counseling reduced anxiety to a degree comparable to traditional face-to-face counseling [16]. Similarly, text-based counseling increased the level of hope in a sample of young people (16-25 years) at the 6-week follow-up compared with those who did not pursue online counseling [26].

Fukkink and Hermanns examined children's well-being (8-18 years) after accessing the Dutch Kindertelefoon phone help line or online text-based chat service. In the first study [27], 902 children (mostly girls) completed a 2-item mental health survey

before and after a session (339 chats and 563 phones). Text-based conversations lasted approximately 30 min, whereas telephone conversations lasted only approximately 8 min on average. Both counseling modes increased children's sense of well-being and decreased their perceived problem burden. Interestingly, the effect was more pronounced for text-based chats than for telephone communication. A follow-up questionnaire completed by 223 children indicated that benefits persisted 1 month after the intervention, at which time the 2 modes did not differ. In the second study [28], which analyzed a sample of 95 conversations (53 chat and 42 telephone), both service modes improved children's well-being and decreased their perceived problem burden.

An analysis of the Kids Help Line service available to Australian youths [29] revealed that telephone counseling sessions (45-60 min) were superior to text-based sessions (50-80 min), although text-based counseling (chosen by clients experiencing more severe mental health issues) was still rated as helpful.

A series of studies examining the text-based subscription service *Talkspace*—within which clients interact with licensed therapists via text-based chat using an app—also showed positive mental health outcomes. A feasibility study examined clinical outcomes, client satisfaction, and the quality of the therapeutic relationship among 57 questionnaire respondents who had been using *Talkspace* for 3-4 months [30]. Comparisons of pre- and posttherapy scores of psychiatric distress indicated clinically significant improvements in 46% (25/54) of the sample. Self-reports of client satisfaction predominantly rated text therapy as the same as or better than face-to-face therapy regarding convenience, access, effectiveness, and progress with problems. The quality of the therapeutic relationship (accounting for 30% of the variance in reported clinical improvements) was rated significantly lower than that of in-person treatments. Another study evaluated outcomes for 51 *Talkspace* clients (mean age 34 years, SD 9; 67% female) after 14-15 weeks of treatment and found clinically significant posttherapy symptom reduction for depression (31/38, 84%) and anxiety (25/39, 64%) [31]. Data from 267 users indicated that the service was predominantly accessed by females (198/267, 74.2%), aged 21-50 years (243/267, 91.0%; median 34 years), with a college education (212/267, 79.4%), living in (sub)urban locations (232/267, 86.9%). Past barriers to face-to-face treatment reported by 240 participants included cost (130/240, 54.2%), excessive time and inconvenience (101/240, 42.1%), and face-to-face therapy not being helpful (67/240, 27.9%) [32]. These findings indicate that *Talkspace* is effective in addressing a range of mental health issues, although the results should be interpreted with caution because the authors were affiliated with the service.

Evaluating 318 users' experiences with BetterHelp, a multimodal digital psychotherapy intervention using text, video, and/or phone communication, Marcelle et al [33] found that depression symptom severity was reduced after intervention, with no differences found for gender, socioeconomic status, or self-reported physical health status. The intervention involved a significant text-based chat component as well as other modes of service delivery.

One of the most rigorous studies concerning the effectiveness of text-based counseling [34] randomly assigned 297 adults with depression (18-75 years) to online cognitive behavioral therapy (up to ten 55-min sessions) in addition to their regular medical care or to a control condition. At the 4-month follow-up (n=210), 38.1% (43/113) patients in the intervention group had recovered from depression, compared with 24% (23/97) in the control group, with therapeutic gains maintained after 8 months, providing strong evidence that e-mental health services (including text-based counseling) offer effective and lasting treatment for serious mental health conditions.

Young people with depressive symptoms (n=263) were randomly assigned to either an intervention condition (up to 5 real-time chat sessions with a trained health care professional) or a waiting list [35]. Text-based chat was more effective than waiting list control in reducing depressive symptoms, with effects increasing from follow-up to posttest, suggesting benefits extended beyond the intervention. An online cognitive behavioral therapy intervention (8 modules and 8 chat sessions over 8 weeks) was more effective than an attention counseling control condition in reducing depressive symptoms in a sample of 70 adolescents (15-19 years) [36], with improvement maintained after 6 months.

Goldin et al [37] evaluated the effectiveness of the Ascend text-based program for treating depression (8 modules over 8 weeks). Clients were primarily female (22/22, 100% in study 1; 76/95, 80% in study 2), young adults (mean age 23.2 years, SD 1.1 in study 1; mean age 32.0 years, SD 9.9 in study 2), and college educated. On average, the therapist spent 20 min chatting with each patient per week. The intervention reduced symptoms of depression, suggesting that text-based chat may be effective in augmenting therapy.

Recent evaluation of Australian crisis support service, Lifeline Text, linked text message counseling to improved mental health [38]. Help seekers with suicidal ideation and poor mental health symptoms, including anxiety, depression, or issues related to domestic and family violence, showed overall reductions in distress, increased social connection, and greater confidence in their ability to cope after the text conversation.

These studies provide compelling evidence that text-based counseling alleviates mental health issues and is effective in treating psychological distress and depression. It may also be effective for treating substance abuse [39,40], reducing high-risk behaviors [41], and improving the subjective experiences of individuals with attention deficit hyperactivity disorder and/or autism [42].

Limitations of Text-Based E-Mental Services

Three studies did not report positive therapeutic outcomes following text-based counseling. Almost half of a sample of African American women reported that text-based interventions for depression and anxiety were not a desirable form of treatment [43]. A randomized controlled trial [44] showed that depression symptoms were reduced for a standard treatment with automated internet-delivered depression management more than with standard care plus optional text-based chat with a therapist. Despite encouragement, few users chose the chat

option, making it unclear whether the chat component was ineffective or whether lack of engagement limited its usefulness. Lack of engagement was problematic in a trial involving a chat-based intervention aimed at adolescents, which was abandoned because of insufficient recruitment [45]. Interestingly, two-thirds of those who declined to participate also refused usual care; the remaining third cited preferences for face-to-face counseling.

Two previous systematic reviews [46,47], evaluating evidence from a total of 14 studies (a subset of those reviewed here), reported emerging support for the use of online text-based chat as an alternative to face-to-face and phone-delivered therapy, despite some mixed findings that can be accounted for by variability in intervention design (eg, target of treatment, length, and type of intervention). Andersson et al [48-50] argue that therapist-guided internet-delivered treatments are effective in treating a range of mental health conditions, can be as effective as face-to-face treatments, and lead to sustainable improvements. However, there will always be clients who prefer face-to-face treatment. To understand why, we next examined client experiences of text-based e-mental health services.

Client Experiences of Text-Based Counseling

Eleven studies examined client experiences of text-based counseling and how fit and preference affect outcomes. All suggest that people generally disclose emotions similarly in computer-mediated and face-to-face communications, and there is evidence that computer-mediated communication can encourage the expression of emotion [51] and true-self qualities [52]. To understand why text-based modes of delivery might better suit some clients than others, we review studies that explored why some people are more likely to engage in text-based counseling.

For children accessing the Kindertelefoon e-mental health service [28], chat was viewed positively because children appreciated the distance (anonymity, security, privacy, and control over self-presentation), especially when discussing emotional problems. Those who preferred phone conversations perceived chat as impersonal or distant. These opposing assessments of text-based communication (private vs impersonal) are a recurring theme in studies investigating why clients do or do not engage with text-based counseling.

In an interesting case study [53], a client with severe obsessive-compulsive disorder received 40 psychotherapy sessions via videoconferencing during which the client disclosed a number of low-shame issues. Adding text chat in later sessions promoted the disclosure of clinically important information, particularly regarding feelings of shame, guilt, and embarrassment, which the client had difficulty disclosing in video-only sessions. Switching to text chat eliminated anxiety-provoking eye contact when disclosing more personally confronting topics.

Interviews with 24 patients with depression [54] were used to evaluate an online e-mental health treatment [34]. Some patients experienced difficulty expressing themselves in writing, but for others, it facilitated re-examination of thoughts, feelings, and behaviors, and reflection on therapeutic exchanges. Patients

who were not comfortable with online communication disliked the less fluid interactions, reduced content covered during sessions, and waiting for therapist responses. For others, the delays created space to think, reflect, and communicate without interruption. Three studies observed that text-based chat sessions take longer than phone counseling sessions [27,29] and generate fewer words than verbal exchanges [55]. Overall, the findings suggest that when patients with depression are comfortable with online communication and with expressing their feelings in text, the anonymity of an online therapeutic relationship may be attractive, and online therapy is an acceptable and helpful alternative to face-to-face services.

Analyzing Text-Based Communications to Identify Predictors of Mental Health Status

Studies investigating linguistic predictors of mental health status are scarce. Few have linguistically analyzed texts from individuals at risk of mental health problems. In total, 13 studies analyzed text-based therapy transcripts with the aim of predicting future mental health status. We also review 9 studies (from the much larger literature on natural language processing) that mined social media or internet forum posts with the specific aim of identifying linguistic patterns that predict mental health status because these are useful in situating the emerging text-based counseling research within the literature and offer insight into likely future directions. Recent advances in computational linguistics have increased the sophistication and complexity of analyses, enabled by the development of computational linguistic tools such as Linguistic Inquiry and Word Count (LIWC) [56], which produces statistical distributions of words within predefined and psychologically meaningful categories (eg, function words, pronouns, or verbs).

With LIWC (and similar algorithms), researchers can explore language patterns across the mental health conditions of interest. Ten studies have used LIWC to show that people with depression tend to focus on themselves. This was realized linguistically as an increased use of first-person singular pronouns (eg, I, me, my, mine) [57-59]. However, first-person singular pronouns may be a linguistic marker of general proneness to distress or negative emotionality rather than depression [60,61]. Early studies analyzed formal written texts for such patterns. Stirman and Pennebaker [62] compared 300 poems written by 18 poets, half of whom had committed suicide. Suicidal poets made more frequent use of first-person singular pronouns and less use of collective pronouns (eg, we, our). Rude et al [63] analyzed narratives written by college students who were depressed, formerly depressed, or had never been depressed. Depressed students used more first-person singular pronouns, more negative valence words, and fewer positive emotion words than those who had never been depressed. First-person singular pronoun use has been linked to the severity of depression and anxiety symptoms [64,65]. More recently, LIWC was used to examine whether first-person singular pronouns in patient interviews predict future mental health in a clinical sample of 29 inpatients undergoing psychodynamic treatment for depression [66]. First-person singular pronoun use did not predict depressive symptoms at baseline but predicted depressive symptom severity at follow-up 8 months

later, especially the use of objective (*me*) and possessive (*my*) pronouns.

Eleven studies have investigated linguistic indicators of depression other than frequency of pronouns, in text data from social media platforms such as Twitter and Facebook [67] or online forums such as Reddit [68]. In social media posts, the onset of major depressive disorder can be predicted by reduced user engagement, use of negative valence words, and first-person pronouns [69]. Content words that could reliably predict depression included symptoms (eg, anxiety, withdrawal), disclosure (eg, enjoy, care), relationships (eg, home, friends), religion (eg, Jesus, bible), and treatment (eg, side effects, therapy). Regression models based on Facebook language use have been used to predict the degree [70] and incidence of depression [71].

Aspect-based sentiment analysis of online forum posts has been used to determine how individuals with different mental health conditions express themselves about various topics [72]. Al-Mosaiwi and Johnstone [73] found that internet forum users with depression, anxiety, and suicidal ideation used more absolutist words (ie, words indicating certainty). A content analysis comparing letters posted in online self-help groups for suicide, depression, and anxiety with letters posted in a control group [74] found that use of absolutist words was a better predictor of suicidal ideation than use of negative valence words or first-person pronouns [73,74] and can thus be a specific linguistic marker of depression, anxiety, and especially suicidal ideation.

Emotion words may also be predictive of mental health status. Owen et al [75] evaluated the efficacy of an online self-guided coping skills training and support intervention for women with early stage breast cancer. Greater use of words expressing anxiety, sadness (but not anger), and cognitive processing were associated with improved emotional well-being at follow-up, whereas greater expression of sadness (but not anxiety or anger) was associated with improved quality of life. This demonstrates that in a treatment context, limiting the analysis to emotion word use at a categorical level can potentially overlook subtle but meaningful differences in emotional expression.

Using more sophisticated measures that captured subtle changes in emotional state from negative emotion word instability, Seabrook et al [76] reliably predicted depression severity. They also created an emoji and internet slang supplement to the LIWC dictionary, which increased the accuracy of depression identification.

Low complexity in clients' language has been shown to predict depression. Individuals undergoing treatment who were likely to remain depressed used fewer complex syntactic constructions such as adverbial clauses, perhaps because these require greater cognitive effort. Morales [77] also found that a number of LIWC content categories (eg, job, sad, sleep) were positively correlated with depression levels.

A recent study considered sex differences in fictional letters. Depressive symptoms were predicted by the ratios of pronouns to nouns and of verbs to nouns for men but by the ratios of finite verbs to number of sentences and of punctuation to number of

sentences for women [78]. Thus, sex differences may need to be considered when identifying linguistic predictors.

In summary, there is a range of linguistic predictors at both the lexical and syntactic levels, which have been shown to correlate with mental health status and can be reliably identified with modern computational linguistic tools.

Analysis of Text-Based Communication During the Course of Therapy

Ten studies that examined transcripts of therapeutic conversation transcripts revealed changing narrative processes during the course of treatment, and these were linked to treatment outcomes (eg, [79-81]). For example, clients' increasing use of reflexive language and decreasing use of external language in therapeutic conversation were associated with better therapeutic outcomes [79]. Exploratory text-based analysis of therapist emails can also provide insight into therapist behaviors that support therapy adherence [82].

One study examined word use in short essays written by outpatients treated for personality disorders 3 times over 2 years of treatment [83]. The use of first-person singular pronouns, negative emotion words, causation words (eg, because, effect), past tense verbs, and future tense verbs declined over treatment, whereas the use of positive emotion and present tense words increased. However, only a reduction in the use of negative emotion words was a reliable predictor of symptom improvement.

Van der Zanden et al [84] examined 7 word categories (first-person pronouns, positive emotions, negative emotions, causation, insight, discrepancy, and social processes) in text-based chat session transcripts of participants who completed 5-6 sessions in an online group course for young adults with depressive symptoms. Only increasing the use of discrepancy words (eg, should, wish) reliably predicted depression improvement.

Dirkse et al [85] analyzed texts from adults with generalized anxiety symptoms participating in a 12-module course of therapist-assisted, internet-delivered therapy. Greater use of negative emotion, anxiety, and sadness words positively correlated with heightened anxiety ratings; greater use of negative emotion, sadness, and anger words positively correlated with heightened depression ratings; and greater use of negative emotion and anger words positively correlated with heightened panic ratings. Patients' self-rated mental health status correlated with decreasing use of emotion, anxiety, and causation words, and increasing use of past tense words.

Using data from the York I depression study [86], Huston et al [87] examined clients' language use in face-to-face psychotherapy sessions. They analyzed 6 word categories (positive emotion, negative emotion, causation, past focus, negation, and first-person singular pronouns) in 24 sessions, early (T1) and late (T2) for 12 clients identified as having good (n=6) and poor (n=6) treatment outcomes. No significant change in language use patterns occurred from T1 to T2, but greater use of positive emotion words at T1 was associated with good treatment outcomes and greater use of past focus words at T1 with poor treatment outcomes. Acknowledging the limitations

of word count analysis, the authors highlighted the need for research using more frequent sampling to explore language patterns as potential measures of therapeutic progress.

Two studies examined large databases of client-therapist interactions [88,89]. To determine whether discourse features of text message counseling conversations could predict clinical outcomes, Althoff et al [88] examined a large data set (approximately 80,000 conversations of approximately 40 messages each). After the session ended, clients' answers to *How are you feeling now?* became their ground-truth labels. Clients with a smaller amount of self-focus tended to have more successful conversations. Tay [89] examined transcripts from 4 client-therapist dyads each lasting 20 sessions (472,009 words) that were taken from the counseling and psychotherapy transcripts, client narratives, and reference works.

A study of an internet-delivered pain management intervention for adolescents with chronic pain [90] used text mining and analytic techniques to messages between coaches and patients and successfully identified messages that raised concerns. Cluster analysis identified subgroups of individuals with common communication and engagement patterns that could be used to tailor interventions. Such techniques could conceivably also be applied to e-mental health services.

Calvo et al [91] offered a comprehensive review of natural language processing in mental health applications. Their discussion of computational linguistic analyses reveals that demographic, linguistic, behavioral, and social data may be combined to construct sophisticated models to identify at-risk individuals. Although no study to date has succeeded in the ultimate goal of accurately predicting suicide risk and guiding mental health professionals to intervene to save lives, progress has been made in recent years. A study by Ruiz et al [92] built 6 machine learning models to predict suicide risk levels from posts on the Reddit forum using a large training data set of 31,553 posts from 496 users. Naive Bayes was the most accurate model for flagging urgent suicide risks.

Quantitative measures of therapist emails can also shed light on the key aspects of program delivery and client adherence to eHealth programs [82]. Content analysis of 490 therapist emails to clients showed that therapist behaviors were represented by 8 behavior codes: deadline flexibility, task reinforcement, alliance bolstering, task prompting, psychoeducation, self-disclosure, self-efficacy shaping, and empathetic utterances. Client adherence to the program was supported by therapist communication that supported deadline flexibility and task reinforcement.

In summary, modern computational linguistic tools and techniques allow analyses that may help predict progress during treatment and may ultimately identify individuals at risk. They also offer an opportunity to quantitatively assess the interrelationship between therapist behaviors, program adherence, and success.

Discussion

Principal Findings

The aim of this scoping review was to map the research that has explored text-based e-mental health counseling services and studies that have used language use patterns to predict mental health status. One of the aims of this study was to assess whether text-based counseling with a therapist could offer an e-mental health solution appropriate for underserved populations, such as rural and remote communities. Of the 9334 reviewed records, 70 met the eligibility criteria.

Although more research is needed to understand the nuances and complex interactions necessary for personalized care, converging evidence shows that text-based counseling services and interventions are effective in treating a variety of mental health conditions. This review of the relevant literature gives reason to be optimistic regarding the potential for text-based interventions to contribute to addressing the mental health needs of underserved populations. Evidence suggests that text-based counseling produces desirable outcomes for a range of mental health conditions for clients willing to engage with this delivery mode.

However, there is a dearth of research concerning its applicability to underserved communities, including those living in rural and remote regions. Our review has revealed that the characteristics of text-based approaches to service delivery (longer sessions, fewer words transmitted, more anonymous or impersonal interactions) are perceived positively by some cohorts but negatively by others, and this perception is likely to affect engagement with such services. This led Hoermann et al [47] to suggest that *if this mode of intervention delivery generates similar effectiveness but longer session times, generating fewer words, and in some groups, lower satisfaction, this draws into question the clinical practicality of this mode of delivery*. However, our focus on identifying a desirable delivery mode of mental health services for people living in rural and remote communities leads us to a different conclusion. First, if text-based communications are effective, they can provide much needed mental health services. Second, for certain segments of the population, the supposed limitations of text-based communication (slower communication, facelessness, and lack of voice) may actually be advantageous or desirable. Increased anonymity and privacy may make some individuals more likely to engage and reveal more truthful information. Some therapists also prefer chat sessions because they allow editing outside the client's view; thus, minimizing possible awkwardness when fumbling for words in face-to-face communication [16]. Thus, text-based counseling has the potential to both increase access to mental health services and improve clinician-client relationships.

It is important to acknowledge that text-based counseling requires a level of technology literacy, and this may present a barrier for some clients to engage with such e-mental health services (and this is likely to correlate with age). Service providers should heed this limitation by designing their services in accessible ways that minimize the burden for clients who lack technical expertise (eg, SMS may be more accessible than

internet chat). Relatedly, high-cost services will not reach (and therefore not help) some of the population groups that are both high need and high risk. Many such groups have lower socioeconomic status and incomes and are unlikely to be able to afford or engage in high-cost or subscription-based approaches to treatment.

Finally, the transcripts of text-based therapy-related communications not only permit reflection on the part of the client but also allow researchers to conduct linguistic analyses to predict future mental status. The potential applications of an accurate, scalable approach to mental health are far-reaching, with implications for early screening and targeted interventions.

Future Directions in Analyses of Text Data

Computational linguistic techniques will continue to evolve as more sophisticated tools are developed to overcome the current limitations. For example, LIWC is unable to detect or compute context and cannot account for changes in meaning resulting from irony, sarcasm, or idioms [93], nor does it take into account negations [87] or qualifiers before words. Predefined LIWC dictionaries may not be sufficiently broad to account for the categories of interest [93]. Although LIWC does not permit the creation of new categories, new dictionaries can be added. Thus, some limitations can be overcome by using dictionaries composed of nonambiguous adjectives and expanded by a distributional strategy [94], whereas others may be addressed by supplementing LIWC with computational linguistic techniques such as unsupervised natural language processing models. To date, researchers must work around these limitations to conduct computational linguistic analyses of text data.

As chat transcripts automatically document the therapeutic process, the text may be used to predict future mental health status and identify at-risk individuals. The accuracy of such predictive models depends on the integrity of the training data. A biased data set affects the accuracy of the predictions or classifications the model makes. Another concern is how false negatives are dealt with, particularly in cases where an individual's safety is at risk. This is an important consideration to bear in mind when such techniques are used to augment the diagnosis or treatment. It is also worth noting that the ethical and privacy risks associated with text-based counseling can be

mitigated by using encryption and deidentifying transcripts (eg, names of people and places).

In addition, there is evidence that linguistic patterns in children differ from those in adults [95]. Therefore, it should not be assumed that predictive relationships between linguistic patterns and mental health status will apply equally across the lifespan. More research is needed to understand how developmental differences influence these predictive relationships.

Limitations of the Study

This scoping review covers a growing area of research, and thus fundamental questions need to be answered to advance the field. Are findings in one population or region transferable to another (eg, from adolescents in urban areas to adults in rural areas)? What obstacles might potentially limit such generalizability? In addition, the scope here is limited to the literature documenting text-based e-mental health services and is not an evaluation of the technologies used by those services. Given the increased development of mobile apps for many services, a review of e-mental health apps following the MARS protocol [96] would complement this work.

Conclusions

The review reveals a clear need for intensified research into how evidence-based e-mental health practices can reach and serve clients. This is especially important for communities where mental health services are limited, and individuals must overcome multiple barriers to help seeking (as is the case in rural and remote areas). This need is likely to increase as governments and organizations respond to the COVID-19 pandemic by exploring flexible working arrangements that include remote working and exacerbate social isolation due to social distancing policies.

Further investigation is required to determine whether transcripts of text-based communication between clients and therapists can be used to accurately predict mental health outcomes. Our review of the computational linguistic literature on text-based predictors of mental health suggests that large-scale automatic screening of mental illness and identification of at-risk individuals may soon be possible.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

PRISMA-ScR (Preferred Reporting Items for Systematic reviews and Meta-analyses extension for Scoping Reviews) checklist. [[DOCX File, 84 KB - mental_v8i2e19478_app1.docx](#)]

Multimedia Appendix 2

Study information.

[DOCX File , 41 KB - [mental_v8i2e19478_app2.docx](#)]

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Abbreviations

LIWC: Linguistic Inquiry and Word Count

PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-analyses

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Original Paper

An Online Platform to Provide Work and Study Support for Young People With Mental Health Challenges: Observational and Survey Study

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Abstract

Background: Young people, aged 15-25 years, are at a critical stage of life when they need to navigate vocational pathways and achieve work and study outcomes. Those with mental health problems are particularly at risk of disengagement with work and study and need effective support. The headspace Work and Study (hWS) service is an innovative online platform implemented in Australia to support young people aged 15-25 years with mental health problems to achieve work and study goals.

Objective: This study aims to determine whether the hWS service has been implemented as planned, provides appropriate support for young people, and achieves its main goals.

Methods: Data were collected via 2 methodologies: (1) the hWS Minimum Data Set, which includes data on all clients in the service (n=1139), services delivered, and service impact; and (2) a survey of hWS clients who volunteered to participate in an evaluation of the hWS service (n=137).

Results: The service was accessed by its defined target group, young people aged 15-25 years with mental health and work and study difficulties. Young people found the online platform to be acceptable, and the assistance provided and clinical integration useful; many young people achieved positive work and study outcomes, particularly those who engaged more times with the service. More assistance was sought for work than study goals, suggesting that the transition to work may be particularly challenging for young people. One-third (298/881, 33.8%) of the sample for the service impact analyses achieved at least 1 primary work or study outcome, and this increased to 44.5% (225/506) for those who engaged with 5 or more sessions, demonstrating that greater engagement with the service produced better outcomes.

Conclusions: Critical work and study support can be effectively delivered via an online modality to young people with common mental health problems. Digital services are scalable to reach many young people and are of particular value for those with difficulty accessing in-person services.

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KEYWORDS

youth; mental health; unemployment; work; study; online support

Introduction

Background

In late adolescence and early adulthood, young people are at a critical stage of life vocationally; it is a time when they need to complete school, make career choices, navigate employment and training pathways, and move into the workforce [1]. Young people also have a heightened vulnerability to mental health problems [2] due to the major physical, emotional, and social changes that occur at this time of life. Many young people face significant barriers to vocational attainment and the emergence of mental health problems. As such, many young people need interventions that address both these critical needs.

Additional risk factors that can contribute to poor vocational outcomes at this stage of life include (1) structural, societal factors that affect what work is available for young people, as well as the nature of that work (especially with the impact of COVID-19); (2) a disadvantaged socio-economic background; (3) health problems or disabilities; (4) emotional or behavioral issues; (5) academic underachievement; (6) being homeless or having an unsuitable learning environment; (7) being an asylum-seeker or refugee; (8) having parental or caring responsibilities; (9) offending behavior; and (10) substance use issues [3]. Consequently, it is critical to focus on supporting young people at risk to assist them with effectively navigating work and study pathways during this vulnerable period using innovative approaches that are acceptable and effective.

Young people are uniquely at risk of disengaging from education, employment, and training. In Organisation for Economic Co-operation and Development (OECD) countries, an average of 6.3% of 15- to 19-year-olds and 15.1% of 20- to 24-year-olds were neither employed nor in education or training programs in 2018 [4]. For Australia, these figures were 5.3% and 11.9%, respectively. It is estimated that the unemployment rate for young Australians aged 15-24 years will reach 17% in the second half of 2020 [5] due to the impacts of the COVID-19 pandemic.

Disengaged young people are at increased risk of many negative outcomes, including social and economic exclusion, poor physical and mental health, reduced wellbeing, and involvement in antisocial behavior like criminal activity. Impacts can be long-lasting; young people who experience a period of disengagement can be at risk of “long-term socio-economic exclusion and getting caught in a ‘low-pay, no-pay cycle’ that can make it difficult to ever move out of poverty” [3]. In addition to being a potential consequence of disengagement, mental health difficulties can be a causal or correlating factor [6,7].

Mental health difficulties peak during adolescence and young adulthood, with approximately 1 in 4 young people impacted at some point [8]. Three-quarters of all mental health disorders first commence before the age of 24 years [9]. A recent study of young people who had accessed an Australian youth mental health service found that approximately one-third were not engaged in employment, education, or training [10], a proportion substantially higher than the general population. Importantly,

the ability to obtain and maintain meaningful employment has been found to be one of the best indicators of recovery from mental health challenges [11].

As disengagement has major impacts, through lost taxes, public service costs, and costs associated with increased crime and poorer health, various policy and practice measures have been trialed and implemented to reduce young people's disengagement across employment, education, and training [3]. There is strong evidence that integrating vocational interventions with mental health treatment leads to better outcomes for young adults with mental illness and that exposure to vocational interventions at an earlier age is associated with improved long-term employment outcomes [11].

The predominant intervention model that focuses on both mental health and vocational support is the Individual Placement and Support (IPS) model, for which international and Australian studies show strong supportive evidence [12-14]. Developed in the United States, the IPS approach is a vocational rehabilitation program designed to improve employment outcomes for people with severe mental illness. It has 8 practice principles: First, the goal is competitive employment (defined as employment that pays at least minimum wage, provides a commensurate salary with what others undertaking the same work receive, and is not exclusive to those with disabilities). Second, there is a zero-exclusion approach, whereby every individual with mental illness who wants to work is eligible for IPS assistance. Third, employment and mental health assistance are integrated. Fourth, client preferences—not the service providers' preferences—drive the services provided and the types of jobs sought. Fifth, advice around benefits is provided. Sixth, job searching begins early on in a client's engagement with IPS (commonly referred to as “rapid job search”). Seventh, IPS staff develop relationships with employers to ensure they are aware of and have a good understanding of job opportunities relevant to IPS clients. And eighth, time-unlimited, individual support is provided to clients, even after they gain work [15].

The headspace Work and Study Service (hWS)

Launched in August 2016, the design of the hWS service was informed by the IPS model and its strong evidence-base. It is an initiative of headspace, Australia's National Youth Mental Health Foundation. headspace was established in 2006 and represents the world's largest national network of dedicated youth mental health centers [16]. headspace has a key focus on mental health support; however, vocational support is also a core service stream, alongside physical health and alcohol and other drug services [17].

The headspace center network's reach is augmented by eheadspace, an online and phone-based mental health care and information service that was launched nationally in 2011 [18,19], with information and support resources coordinated and distributed by the headspace national office. The main aim of headspace is to provide highly accessible, youth-friendly, early intervention and integrated, evidence-based support to young people aged 12-25 years through its centers, online services, and the national office [20].

Like IPS, the hWS service integrates employment and vocational services with clinical mental health and psychosocial support, focusing on the individual needs of people with mental health problems seeking to enter or remain in education or employment. The IPS model has been implemented mainly for people with serious mental health conditions (including low prevalence disorders, such as first-episode psychosis) rather than people with more common conditions (like depression and anxiety) and relies on direct, face-to-face client engagement. Unlike the IPS model, the hWS service operates predominantly for young people experiencing high-prevalence mental health issues (depression and anxiety) and offers personalized support from a work and study specialist via an online platform rather than in-person engagement. Online service delivery has the potential to overcome many service barriers, particularly for individuals who want support but also prefer some level of anonymity, live in hard-to-service rural and remote areas, or mistrust mainstream services. Online services are growing in popularity given most Australians (even isolated and marginalized groups) have internet access and utilize mobile devices in their daily lives [21]. Australia has a high level of internet penetration, estimated at 88% in 2018 [22]. Technology can be the preferred method of communication for some population groups, particularly young people, and has been given a major boost with the recent, sudden transition of many services to online modalities due to the COVID-19 pandemic.

The overarching goals of the hWS service are to increase the extent to which young people feel equipped to manage their work and study situation and increase the extent to which young people seek, attain, and maintain positive work or study outcomes. The core principles of the service are that it is (1) voluntary: unlike some employment agencies, young people are not required to use the service; (2) flexible: young people can make contact as much or as little as they want to during an episode of care, which is typically 3 months but can be longer; (3) personalized: the support young people receive is tailored to their needs and concentrates on the strengths young people have rather than those they do not have; (4) clinically integrated: hWS staff liaises with young people's mental health providers to ensure work and study supports align with and reinforce their mental health interventions; (5) delivered with a no-exclusion approach: as long as young people are aged 15 to 25 years, experience mental health difficulties, and have work or study needs, they are eligible to use the service; and (6) accessible: no travel is required, operating hours are flexible, and the service is available via a range of online service delivery modes, such as synchronous chat, asynchronous email, telephone assistance, and video conferencing.

The hWS service is staffed by professionals with diverse experiences and backgrounds across the community, education, employment, and career support sectors. hWS staff provide young people with tailored one-on-one support via their preferred online modality. A typical episode of care with the hWS is up to 3 months of contact (approximately 1 full service per fortnight), during which time young people tend to work with the same professional. Support is offered for a period of up to 12 months after a work or study placement is achieved to align with evidence that employment interventions with long

follow-ups are more likely to result in better employment outcomes for young people than those with short follow-up periods [11]. All hWS staff receive training in Mental Health First Aid and motivational interviewing given that the hWS service is designed to be appealing to and appropriate for young people with common mental health conditions, such as depression and anxiety. The service also has dedicated clinical staff who provide clinical governance over the hWS service, support hWS staff in providing clinically integrated care, provide clinical support directly to young people via the online platform, refer young people to other clinical services, and liaise with young people's other clinical service providers.

Our Study

This study aims to determine whether the hWS service has been implemented as planned, provides appropriate support for young people, and achieves its main goals. Specifically, we investigate whether (1) the service is utilized by its target group, namely young people experiencing both mental health and work and study difficulties; (2) young people find the service acceptable in terms of its service model and delivery via an online platform; (3) young people find the work and study assistance provided by the service useful; (4) young people find the service's clinical integration helpful; and (5) young people achieve positive work and study outcomes during their time with the hWS service.

Methods

Design

To obtain data for the study, 2 methodologies were used: (1) the hWS Minimum Data Set (MDS), which provides data on all clients in the service, services delivered, and the service impact (ie, changes in the clients' work or study status over time); and (2) a survey of hWS clients who volunteered to participate in an evaluation of the hWS. Ethics approval for the survey was obtained through the quality assurance approval process of the Melbourne Health Office for Research (QA2017146).

hWS Minimum Data Set (MDS)

Participants

The hWS MDS provided information on 1139 hWS clients who received at least 1 hWS work or study session from August 9, 2016, to December 31, 2019. This sample is referred to as the MDS sample. Data for the analyses of the service impact were restricted to a subsample of 881 clients who received at least 2 work or study sessions (to enable measurement of a change in the work or study situation) and who did not have an open episode of care at the end of the reporting period. This sample is referred to as the MDS subsample.

Procedure

An online platform was used to collect all MDS data, including (1) client demographics, (2) client characteristics, (3) services provided, and (4) changes in a clients' work or study situation. Data were recorded in the online MDS database by hWS staff at the time of first commencement with the service and at each occasion of service.

Measures

Client demographics included the age group the client belonged to at the time of first commencement with the service (15-17 years, 18-20 years, 21-23 years, or 24-25 years) and the client's gender (female, male, another gender).

Client characteristics at the time of first commencement with the hWS service included psychological distress measured by the 10-item Kessler Psychological Distress Scale (K10) [23], which comprises 10 items that measure feelings of depression and anxiety over the past month on a scale that ranges from 10-50, with higher scores indicating greater distress. Distress scores were categorized as low (10-15), moderate (16-21), high (22-29), or very high (30-50) [24]. We also asked whether the client was currently receiving counseling from any other service (*yes/no*) and whether they were currently engaged in employment or training (*yes/no*).

Service provision measures included the number of work and study sessions clients received directly (hWS services such as client follow-up after a work or study placement, liaison with other care providers, case review, and care planning were excluded).

Service impact was measured by change in the clients' work or study situation. At each session, staff could select from a detailed list of work or study changes that were coded into primary and secondary outcomes. Primary work outcomes were "gained work" (including apprenticeships and traineeships) and "gained a better job than the one they had" (ie, one that they enjoyed more, is more aligned with their studies, and had a higher salary). Primary study outcomes were "began study" and "swapped to a course/training that was better than what they were previously studying" (ie, something more likely to lead to good job outcomes and something they enjoyed more). Secondary work outcomes were "increased work hours," "resolved job at risk," "engaged in an Australian government employment service," and "obtained a job or volunteer placement." Secondary study outcomes were "increased study" and "resolved study at risk."

Survey

Participants

Of the 711 hWS clients asked to participate, 137 clients completed the survey, a response rate of 19.3%. This sample is referred to as the Survey sample.

Procedure

All clients who received support from the hWS service between August 9, 2016, and December 4, 2018, (n=711) were asked as part of their registration process whether they agreed to be contacted about future research and evaluation activities. SurveyMonkey software was used to email an invitation to complete the survey to clients who had agreed and had provided a valid email address. For eligible participants who received support prior to November 2017, the email invitation was sent in December 2017; for remaining eligible participants, the email invitation was sent in December 2018. If clients were in both samples and completed the survey twice (n=17), only their first

completed survey was included in our analyses. Clients completed the survey online at their convenience.

Measures

The survey consisted of questions relating to the clients' experiences with and perceptions of the service. The measurement domains relevant to this study were the (1) appropriateness of the hWS service model, (2) acceptability of the hWS service's online service delivery model, (3) usefulness of the hWS service's work and study assistance, and (4) usefulness of the hWS service's clinical integration.

The appropriateness of the hWS service model was measured via 6 positive statements about the service with a 5-point Likert response scale (0=*strongly disagree* to 5=*strongly agree*). Example items were "The service is appropriate for people aged 15-24 years," "I would recommend the Digital Work and Study service," and "I was satisfied with the Digital Work and Study staff I had contact with."

The acceptability of the hWS service's online service delivery model was assessed by 2 items listing 5 potential benefits and 5 potential challenges of online delivery, for which respondents were permitted to select multiple responses for each item.

The usefulness of the hWS service's work and study assistance was based on 8 positive statements about the service measured on a 5-point Likert response scale (0=*strongly disagree* to 5=*strongly agree*). Example items were "I feel supported in pursuing my work and study goals" and "I took steps to achieve my work and study goals."

The usefulness of the hWS service's clinical integration was determined by 5 positive statements about the service measured on a 5-point Likert response scale (0=*strongly disagree* to 5=*strongly agree*). An example item was "I feel supported in managing my mental health and wellbeing issues."

Total scale scores were derived by averaging over all the items in each domain (with the exception of the acceptability measure, which was multi-response). These could range from 1-5, with higher scores indicating more positive views of the hWS service within the domain. All scales attained acceptable internal consistency: Cronbach alpha=.95, .95, and .92 for appropriateness, usefulness of assistance, and usefulness of clinical integration, respectively.

Data Analysis

Data were analyzed using Business Intelligence software (version 2018.1; Tableau Software LLC), Excel (version 15.0.05301.1000; Microsoft), and SPSS (version 25.0; IBM Corp). Descriptive statistics were computed, and chi-square tests of homogeneity and independence were used to examine group differences ($P<.05$).

Results

Demographics and Characteristics

Table 1 presents the demographics and presenting characteristics for each sample group. Chi-square tests revealed that the 3 samples did not differ significantly on age, gender, K10 group,

receipt of counseling at commencement, and the work and study situation at commencement.

Table 1. Demographics and presenting characteristics of study participants (n=1139) by sample group. [Due to missing data, columns may not sum to total n. Answering the 10-item Kessler Psychological Distress Scale (K10) was optional (8.3% chose not to). Other client demographic and characteristic measures were captured for the vast majority of clients, although occasionally, clients chose not to provide these responses.]

Demographic/presenting characteristics	MDS ^a sample (n=1139), n (%)	MDS ^a subsample (n=881), n (%)	Survey sample (n=137), n (%)
Age in years			
15-17	137 (12.8)	104 (12.5)	13 (9.7)
18-20	403 (37.6)	320 (38.3)	50 (37.3)
21-23	389 (36.3)	295 (35.3)	49 (36.6)
24-25	143 (13.3)	116 (13.9)	22 (16.4)
Gender			
Female	624 (58.9)	494 (58.8)	77 (58.3)
Male	391 (36.9)	315 (37.5)	48 (36.4)
Another gender	45 (4.2)	31 (3.7)	7 (5.3)
K10 category at the time of commencement			
Low	62 (5.9)	44 (5.5)	5 (4.1)
Moderate	180 (17.2)	139 (17.3)	25 (20.3)
High	349 (33.4)	270 (33.7)	47 (38.2)
Very high	453 (43.4)	349 (43.5)	46 (37.4)
Receiving counseling at the time of commencement			
Yes	717 (63.7)	551 (63.2)	85 (63.0)
No	409 (36.3)	321 (36.8)	50 (37.0)
Work/study situation at the time of commencement			
Not working or studying	480 (42.1)	373 (42.3)	67 (49.3)
Working and/or studying	659 (57.9)	508 (57.7)	69 (50.7)

^aMDS: Minimum Data Set

Service Utilization by Target Group

The hWS service provided 1139 clients with 7897 work and study support sessions. The number of sessions per client ranged from 1 to 98, with an average of 6.9 (SD 7.7) and a median of 4.0 sessions. Of the 1139 clients, 47 received support over 2 episodes of care, and 2 received support over 3 episodes of care. As shown in [Table 1](#), all clients were in the target age range of 15-25 years, with three-quarters aged 18-23 years, and a higher percentage of clients were women.

MDS data suggest the service reached young people experiencing both mental health and work and study difficulties. [Table 1](#) shows that, of the valid responses, more than three-quarters (802/1044, 76.8%) of the clients presented with a K10 rating that indicated high or very high psychological distress, close to two-thirds (717/1126, 63.7%) were receiving counseling support at the time they presented to the hWS service, and close to half (480/1139, 42.1%) were not working or studying at the time they presented to the hWS service. In terms of reasons for accessing the hWS service, the majority (779/1139, 68.4%) sought work-related assistance, while 16.8% (191/1139) sought career planning assistance and 14.8% (169/1139) sought study-related assistance.

Appropriateness of the Service Model and Usefulness of Assistance

[Table 2](#) displays findings for 3 of the survey measure domains. For the appropriateness of the hWS service, the average score was well above the scale midpoint. The vast majority of respondents (87.8%) agreed overall that the hWS service model was appropriate. For individual scale items, agreement with the appropriateness of the service for young people aged 15-24 years and satisfaction with staff were particularly high. There were 85.8% (109/127) who agreed they would recommend the service, and 81.9% (104/127) agreed that the service was meeting their expectations.

For the domain of usefulness of the hWS assistance, once again, the average score was well above the scale midpoint. The majority of survey respondents (82.5%) agreed that the hWS service's work and study assistance were useful. Satisfaction was particularly high to the extent to which the service helped respondents feel supported in pursuing, identifying, and taking steps toward achieving their work and study goals. More than three-quarters (101/132, 76.5%) of survey respondents indicated that the work and study assistance they received had helped them feel confident that they could manage their work and study situation in the future.

For the domain of usefulness of hWS clinical integration, most survey respondents (72.2%) agreed the hWS service's clinical integration was useful. Satisfaction was particularly high with regard to whether the service helped respondents realize how their mental health and wellbeing impacted their work and study situations. Satisfaction was lower with regard to the extent to

which the hWS service assisted young people to reduce the impact of their mental health and wellbeing issues on their lives more generally. The mean scores for the 3 survey measure domains all different significantly from each other ($P<.001$) with the lowest score for the domain of usefulness of hWS clinical integration.

Table 2. Survey domain percentages and means for the survey sample (n=137). (There were minimal missing data for the total scale scores: 2.2% for appropriateness, 5.1% for usefulness, and 7.3% for integration.)

Survey domain	Respondents in each response category					Average score, mean (SD)
	Strongly disagreed, %	Disagreed, %	Neither agreed nor disagreed, %	Agreed, %	Strongly agreed, %	
Appropriateness of hWS ^a model	1.3	4.0	6.9	33.8	54.0	4.4 (0.8)
Usefulness of hWS ^a service work/study assistance	1.4	6.6	9.5	38.7	43.8	4.2 (0.8)
Usefulness of hWS ^a service clinical integration	0.7	9.4	17.7	39.8	32.4	4.0 (0.9)

^ahWS: headspace Work and Study

Value of Online Platform

The benefits and challenges of the online platform are presented in Table 3. The vast majority of respondents (115/129, 89.1%) experienced benefits, and close to two-thirds (80/129, 62.0%) of respondents did not experience any challenges with online service delivery. Most respondents indicated that they found it

beneficial that no travel was required and that online service delivery was less confronting than in-person service delivery. In terms of challenges, just over one-fifth (28/129, 21.7%) indicated that they would have preferred in-person support, and less than one fifth (19/129, 14.7%) indicated that they experienced some difficulty in explaining their situation via an online platform.

Table 3. Potential benefits and challenges of online service delivery reported by the survey sample.

Benefits and challenges of digital service delivery	Respondents, n (%)
Benefits (n=129)	
No travel was required.	110 (85.3)
It was less confronting than meeting in-person.	63 (48.8)
If in-person support was the only option, I may not have sought help.	30 (23.3)
I live in an area with limited services; access to a national service was helpful.	27 (20.9)
Other benefit(s)	9 (7.0)
Indicated that none of the listed benefits applied	14 (10.9)
Challenges (n=129)	
I would've preferred to meet in-person with someone.	28 (21.7)
I found it difficult to explain my situation via the digital platform.	19 (14.7)
I found it difficult to get through to the Service on the phone.	11 (8.5)
I found the Digital Work and Study Service/headspace website difficult to use.	9 (7.0)
Other challenge(s)	6 (4.7)
Indicated that none of the listed challenges applied	80 (62.0)

Effectiveness at Helping Young People Achieve Positive Work and Study Outcomes

Table 4 shows that more than one-third (298/881, 33.8%) of the MDS subsample achieved a primary work or study outcome, and close to half (396/881, 44.9%) achieved a primary or secondary outcome. For those who received at least 5 work or

study hWS sessions, just under half (225/506, 44.5%) achieved at least 1 primary outcome, and more than half (289/506, 57.1%) achieved a primary or secondary outcome. There was no significant difference according to gender ($P=.409$), but there was a significant age difference ($X^2_1=6.2$; $P=.013$); just over a quarter (49/187, 26.2%) of those under 19 years of age, compared to over one-third (233/648, 36.0%) of those at least

19 years of age, achieved at least 1 primary outcome. There was a significant association between the number of sessions received and achieving both a primary ($X^2_4=94.2$; $P<.001$) and primary or secondary ($X^2_4=109.0$; $P<.001$) outcome, with strong linear trends showing that the likelihood of achieving outcomes increased with more sessions.

Across the 3 broad reasons that clients access hWS support (work, study, career planning), trends were similar, with no significant difference ($P=.678$) in the percentage of clients achieving a primary outcome, with about one-third overall achieving a primary outcome. There was, however, a significant difference in the percentage of clients who achieved either a primary or secondary outcome ($X^2_2=8.3$; $P=.016$), with those seeking study-related support significantly more likely to achieve an outcome compared to those seeking work-related

assistance. Those who were not working or studying when commencing the hWS service were significantly more likely to achieve a primary outcome ($X^2_2=12.8$; $P<.001$), reaching 40.5% (151/373).

Table 4 provides an indication of the association between the total number of sessions received and the likelihood of a positive outcome being recorded. However, further analyses were undertaken to explore the average number of sessions clients received prior to a positive outcome first being recorded. These indicated that of those in the MDS subsample who gained a primary outcome and for whom appropriate data were available ($n=297$), the average number of sessions to achieve the first primary outcome was 8.4 (SD 7.16; range 1-44). Of those who gained a primary or secondary outcome and for whom data were available ($n=395$), the average number of sessions required to achieve the first outcome was 7.6 (SD 6.23; range 1-42).

Table 4. Demographics and characteristics of the Minimum Data Set subsample clients who achieved primary or secondary outcomes during their time with the headspace Work and Study (hWS) service ($n=881$).

Characteristic	Achieved at least 1 primary work or study outcome, n (%)	Achieved at least 1 primary or secondary work or study outcome, n (%)
Full sample ($n=881$)	298 (33.8)	396 (44.9)
Age in years ($n=835$)		
<19 ($n=187$)	49 (26.2)	77 (41.2)
≥ 19 ($n=648$)	233 (36.0)	297 (45.8)
Gender ($n=840$)		
Male ($n=315$)	105 (33.3)	131 (41.6)
Female ($n=494$)	167 (33.8)	232 (47.0)
Another gender ($n=31$)	14 (45.2)	15 (48.4)
Number of hWS sessions ($n=881$)		
2-3 ($n=268$)	44 (16.4)	62 (23.1)
4-5 ($n=175$)	49 (28.0)	74 (42.3)
6-7 ($n=120$)	37 (30.8)	53 (44.2)
8-9 ($n=87$)	39 (44.8)	48 (55.2)
≥ 10 ($n=231$)	129 (55.8)	159 (68.8)
Received the median number of hWS sessions (≥ 5 ; $n=506$)	225 (44.5)	289 (57.1)
Primary goal in working with the hWS service ($n=881$)		
Work-related ($n=590$)	200 (33.9)	246 (41.7)
Study-related ($n=135$)	49 (36.3)	73 (54.1)
Career planning-related ($n=156$)	49 (31.4)	77 (49.4)
Work/study status at commencement ($n=881$)		
Not working or studying ($n=373$)	151 (40.5)	163 (43.7)
Working or studying ($n=508$)	147 (28.9)	233 (45.9)

Discussion

Principal Findings

The results revealed that the hWS service was achieving its main goals. It was being utilized by its defined target group of young people aged 15-25 years with both mental health and

work and study difficulties. Young people found the online platform acceptable, and the assistance provided and clinical integration useful. Moreover, positive work and study outcomes were achieved by many young people, particularly those who engaged more with the service.

The vast majority of young people accessing the service had high or very high psychological distress and were engaged with mental health support services, and almost half were not working or studying at the commencement of the service. This shows that the service was being accessed by the target client group of young people with mental health issues who were disengaged or at risk of disengagement from work and study. Over the first 3 years of the service's development and implementation, over 1000 young people received services. Most were aged 18 years and over (87.2%), revealing that the greatest need is for those in early adulthood transitioning from high school into work or tertiary education. A higher percentage of clients were women. Despite this gender disparity, the hWS service was more successful in reaching young men (36.9%) than eheadspace (the headspace online mental health service), in which less than 20% of clients are men. Australian men are particularly hard to reach in the online mental health environment [18]. Nevertheless, it would benefit the service to find better ways of reaching and providing more appropriate support for young men, who tend to be a harder-to-reach group for all mental health-related programs [25].

Overall, however, young people found the online platform to be acceptable. Most young people reported benefits of the online platform, and few reported challenges. The lack of the need to travel was by far the greatest benefit, but almost half (63/129, 48.8%) said that it was less confronting than meeting in person. There were, however, one-fifth (28/129, 21.7%) who reported that they would have preferred to meet in-person with someone, showing that there is still a preference for face-to-face contact for some young people. A growing body of research shows that while many people are adapting to and prefer online support options, there is still a considerable proportion who prefer in-person services [26]. The online platform is a major point of distinction of the hWS service from IPS models, which use a traditional face-to-face approach. Importantly, by using an entirely online model, the service can be made available to many more young people, including those who live in rural and remote areas or who have other barriers to accessing in-person services.

The hWS was seen to be very appropriate to the late adolescent and early adulthood age range, and the assistance provided and clinical integration of their mental health care were perceived as useful by most young people. Appropriateness to the age group and satisfaction with staff were particularly strong. Primarily positive responses were provided to all the items assessing appropriateness and usefulness. The lowest rated item was for the service reducing the impact of mental health and wellbeing issues on the young person's life more generally. This reflects that while the service integrates mental health support, the service's main focus is on improving work and study engagement rather than more general life-satisfaction factors.

One-third (298/881, 33.8%) of the total sample achieved at least one primary work or study outcome, and this increased to 44.5% (225/506) for those who engaged with 5 or more sessions, demonstrating that greater engagement with the service produced better outcomes. There was a linear relationship of outcome achievement with engagement with more sessions. No comparative studies are available, as the hWS service is the first

to provide work and study support to young people with common mental disorders using an online platform. A study of 146 Australian young people with first-episode psychosis implementing a traditional IPS model reported positive outcomes for 71% of clients engaged in the program for 6 months [27], but this program comprised considerably greater investment and time and was more intensive than the hWS service.

Much more assistance was provided for work than for study. This reveals a greater gap in the need for support for work. It is likely that young people are more aware of avenues for further study, as tertiary study institutions promote their courses and entry processes through open days, marketing, and online information. Tertiary education institutions generally provide significant support for commencing students. In contrast, the workplace is dispersed with multiple entry points to a diverse range of industries and settings that are not coordinated, and consequently, young people need more support to navigate the transition to work.

Limitations

It is important to consider these findings in the context of the limitations of the study. Firstly, the study was observational and there was no comparator group. As such, causation cannot be ascertained. The questions in the survey were developed specifically for the hWS and their validity is not assured. There were also limited options for open-ended questions, which might have provided deeper insights into service satisfaction and impact. The survey was optional and had a modest response rate (albeit typical for such surveys); therefore, findings must be interpreted with caution as they may not reflect the opinions and experiences of other hWS clients. We also did not have information on the specific mental health problems and disorders that were being experienced by the young people accessing the hWS service, and so we cannot determine whether it was more or less acceptable and seen as effective for young people experiencing different types of mental health concerns.

Further, as Australia's Aboriginal and Torres Strait Islander young people experience particularly high levels of disengagement, further research is needed to explore the extent to which the hWS service is reaching Aboriginal and Torres Strait Islander young people, as well as the extent to which the service is appropriate and effective for this population group. Additionally, as a goal of the hWS service is to increase the extent to which young people maintain work and study outcomes, further research should explore the extent to which work and study outcomes are maintained over time (which was outside the scope of this study). Ideally, a randomized controlled trial would be used to establish causality, and an economic evaluation would be undertaken to identify the potential value and long-term cost savings achieved by the service.

Conclusions

The design of hWS was based on strong evidence from many years of research into IPS models, and findings from this study suggest the service is effective in achieving its aims to help young people attain important work and study outcomes and that the online model of the service is appropriate. Now that it is established, the service is potentially scalable to provide

effective work and study support to more young people across the country at a relatively low cost. There is also potential for it to be adapted in other countries.

Authors' Contributions

DR contributed to conceptualization, methodology, analysis, supervision, the writing of the original draft, review, and editing. VK contributed to conceptualization, methodology, data collection, analysis, supervision, and the writing of the original draft, review, and editing. KM contributed to methodology, analysis, writing, reviewing, and editing. NT contributed to conceptualization, methodology, supervision, validation, writing, review, and editing. SC contributed to supervision, writing, reviewing, and editing. EH contributed to conceptualization, funding acquisition, resources, writing, reviewing, and editing. CW contributed to conceptualization, funding acquisition, resources, writing, reviewing, and editing. The hWS service is funded by the Australian Government.

Conflicts of Interest

All authors are or have been employed by headspace National Youth Mental Health Foundation, which delivers the hWS service.

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Abbreviations

hWS: headspace Work and Study

IPS: Individual Placement and Support

K10: 10-item Kessler Psychological Distress Scale

MDS: Minimum Data Set

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Original Paper

Digitalizing a Brief Intervention to Reduce Intrusive Memories of Psychological Trauma: Qualitative Interview Study

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Abstract

Background: The COVID-19 pandemic has escalated the global need for remotely delivered and scalable interventions after psychological trauma. A brief intervention involving a computer game as an imagery-competing task has shown promising results for reducing the number of intrusive memories of trauma—one of the core clinical symptoms of posttraumatic stress disorder. To date, the intervention has only been delivered face-to-face. To be tested and implemented on a wider scale, digital adaptation for remote delivery is crucial. An important first step is to develop digitalized intervention materials in a systematic way based on feedback from clinicians, researchers, and students in preparation for pilot testing with target users.

Objective: The first aim of this study is to obtain and analyze qualitative feedback on digital intervention materials, namely two animated videos and two quizzes that explain the target clinical symptoms and provide intervention instructions. The second aim is to refine the digitalized materials based on this feedback.

Methods: We conducted semistructured interviews with 12 participants who had delivered or had knowledge of the intervention when delivered face-to-face. We obtained in-depth feedback on the perceived feasibility of using the digitalized materials and suggestions for improvements. Interviews were assessed using qualitative content analysis, and suggested improvements were evaluated for implementation using a systematic method of prioritization.

Results: A total of three overarching themes were identified from the data. First, participants were highly positive about the potential benefits of using these digital materials for remote delivery, reporting that the videos effectively conveyed key concepts of the symptom and its treatment. Second, some modifications to the materials were suggested for improving clarity. On the basis of this feedback, we made nine specific changes. Finally, participants raised some key challenges for remote delivery, mainly in overcoming the lack of real-time communication during the intervention.

Conclusions: Clinicians, researchers, and clinical psychology students were overall confident in the use of digitalized materials to remotely deliver a brief intervention to reduce intrusive memories of trauma. Guided by participant feedback, we identified and implemented changes to refine the intervention materials. This study lays the groundwork for the next step: pilot testing remote delivery of the full intervention to trauma survivors.

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KEYWORDS

digital intervention; remote delivery; intrusive memories; psychological trauma; qualitative feedback; cognitive science; posttraumatic stress disorder

Introduction

Background

Most people will experience a psychologically traumatic event in their lifetime, that is, experience or witness actual or threatened serious injury, sexual violence, or death (eg, traffic accidents, assaults, war, or natural disasters) [1,2]. A significant proportion of those who experience traumatic events (about 1 in 4 [3,4] but more for some trauma types [5,6]) will develop posttraumatic stress disorder (PTSD). One of the main criteria of PTSD is the presence of intrusion symptoms such as intrusive memories of the traumatic event [2]. Although there are evidence-based treatments for PTSD, the clinical reality is that globally, most individuals do not receive psychological interventions of any kind after trauma [7]. Multiple barriers impede access to psychological treatment, such as geographical constraints, few or no treatment providers, and stigma surrounding help-seeking [7]. Thus, there is an urgent need for innovative, scalable interventions that can be readily administered to trauma survivors [8]. Advancing remote delivery of psychological interventions is also a significant step in the context of the ongoing COVID-19 pandemic, which has escalated the need for trauma treatments for vulnerable groups such as patients and health care staff [9]. It is essential to develop interventions that can be delivered safely for both target users and clinicians/researchers across the globe.

Recent clinical guidelines for PTSD highlight the utility of targeting single symptoms [3,4], and we have proposed targeting *intrusive memories of trauma*, one of the core clinical features of PTSD [2,10,11]. Intrusive memories are memories of traumatic event(s) that involuntarily and recurrently spring to mind, bringing back sights, sounds, or smells; evoking strong emotions; and hijacking attention [11]. Intrusive memories commonly occur as visual imagery [10], for example, after a car crash, a patient might report terrifying visual memories of blood and glass smashing. Intrusive memories of trauma can be highly distressing, are associated with functional impairment in daily life (eg, concentration difficulties) [12], and are central to the development of PTSD [13].

A Novel Intervention to Reduce Intrusive Memories

Building on laboratory findings using analog trauma (ie, stressful film clips) [14,15], our group has developed a brief cognitive intervention involving a computer game as an imagery-competing task to reduce and prevent the number of intrusive memories of real-world trauma. The intervention is based on translational work combining the cognitive neuroscience of memory with intrusive memories of trauma [16,17] (for a detailed theoretical rationale, see Iyadurai et al [11]). The intervention first involves a brief reminder cue to activate the trauma memory in working memory and, for older memories, a 10-min time gap for the memory to become malleable [16]. Participants then play the computer game *Tetris*, a visuospatially demanding task, for at least 20 min using specific instructions for *mental rotation* to maximize the visual working memory load [17]. The intervention is thought to disrupt the (re)consolidation of traumatic memories, thereby reducing their tendency to intrude in everyday life [18].

Clinical studies have shown preliminary evidence that the intervention may lead to a reduced number of intrusive memories, reported in a daily diary over the course of 1 week, when compared with participants who did not use the intervention (treatment as usual or control task) [19–21] or compared with a baseline number of intrusive memories per week [22,23]. These studies included women who had just gone through a traumatic childbirth (emergency cesarean section) [19], patients recently admitted to the emergency department [20,21], inpatients with complex PTSD [22], and traumatized refugees [23]. So far, these studies have involved face-to-face delivery of the intervention by trained clinicians, researchers, and assistants. However, it is clear that there is great public interest in an *accessible* version of the intervention. After the recent explosion in Lebanon, more than 5000 people commented in a web-based forum about using *Tetris* and other games to alleviate distressing imagery [24]. For this intervention to be tested at scale and be truly accessible to many individuals over a wide geographic area, materials must now be adapted for remote digital delivery [25].

This Study

Remote delivery of digital interventions comes with several challenges, such as generally high attrition [26] and low rates of participant engagement (including recent digital interventions for PTSD) [27], thereby requiring the need for careful and thoughtful intervention development. Frameworks such as the person-based approach (PBA) [28] emphasize the importance of incorporating qualitative user feedback in the iterative development of an intervention. To lay the groundwork for such pilot testing with target users (ie, trauma survivors), it is crucial to first obtain feedback on the digital intervention materials from clinicians, researchers, and students. This approach fits within the broader framework of patient and public involvement (PPI), which can include asking those who are in the same research team for constructive feedback on drafts of intervention materials [29]. The next step is to systematically evaluate the feedback and implement the top-priority changes to the materials. These initial refinements are especially important before piloting an intervention to groups such as trauma survivors, where poorly designed materials could be not only ineffective but inadvertently distressing (eg, if the materials trigger intrusive memories). Thus, the aims of this study are two-fold: (1) obtain and analyze qualitative feedback on digitalized intervention materials, namely, animated videos and quizzes that explain the target symptom and provide intervention instructions and (2) systematically refine the materials based on this feedback.

Methods

Design

We followed guiding principles for the development of the intervention materials, in line with PBA [28] (Multimedia Appendix 1). Qualitative feedback on the materials was obtained from nontarget users, within the framework of PPI [30], and proposed changes systematically evaluated for implementation using the Must have, Should have, Could have, Would like (MoSCoW) method of prioritization [31].

Recruitment

We purposively recruited [32] a sample of researchers, clinicians, and clinical psychology students from an international research training group that regularly met to discuss the intervention and from the same research laboratory that the authors are a part of. Individuals were contacted by KD and invited to participate; all who were contacted accepted.

Procedure

Semistructured interviews were carried out by the first author (KD), who had recently joined the research team and was not involved in the creation of the videos. We created an interview guide (Multimedia Appendix 2) that contained several open-ended questions (eg, *Please describe if you found anything to be helpful or unhelpful, and if so how?*) and a brief script to inform participants of the purpose of the interview (ie, to help design a digital, remote version of the intervention). Links to the videos and quizzes were sent to the participants before or during the interview. After watching the videos and completing the quizzes, the participants were asked to share their thoughts on the materials, suggestions for improvements, and any concerns they had in delivering a remote version of the intervention. Interviews were conducted over a private video call via Zoom (version 4.6.9) and lasted 8 to 32 minutes. Interviews were recorded, and verbal consent was obtained beforehand. Participants were not required to fill in an informed consent form; data collected from participants who were also colleagues involved in the same research team did not need to sign informed consent as part of PPI nor was ethical approval required [33].

Materials

Videos can increase the accessibility and scalability of mental health treatments, which otherwise face barriers to access [34]. To move toward remote delivery of the intervention, we created two animated videos that explain the target symptom and provide instructions for the intervention. Video scripts were based on existing study protocols for in-person delivery of the intervention [25] and were designed and animated by a local artist [35] in collaboration with the core intervention development team (EH, MK, and BG). We followed recommendations on how to depict mental health images in a culturally sensitive way [36] and aimed for the videos to be applicable to a range of individuals with trauma history, for example, by featuring minimal text and a gender-neutral, nonstereotyped character. Materials were initially created in English, with plans to adapt them to other languages.

The first video (“What Are Intrusive Memories?”) defines and describes intrusive memories of trauma, the target symptom of the intervention (3 minutes 17 seconds; screenshots in Figure 1). The video explains, for example, that intrusive memories normally take the form of a visual image or movie clip in the mind’s eye and that they are *not* the same as rumination or deliberate recall (eg, *they are not the same as deliberately choosing to think about the event*). The second video (“How to Play Tetris”) describes how to complete the imagery-competing task in accordance with the intervention protocol (2 minutes 57 seconds; Figure 2). For example, the video explains how to use *mental rotation* to visualize and plan ahead, which is thought to be crucial for the intervention to work.

Figure 1. Screenshots from the “What are Intrusive Memories?” video, which explains the target symptom of the intervention in an accessible way.

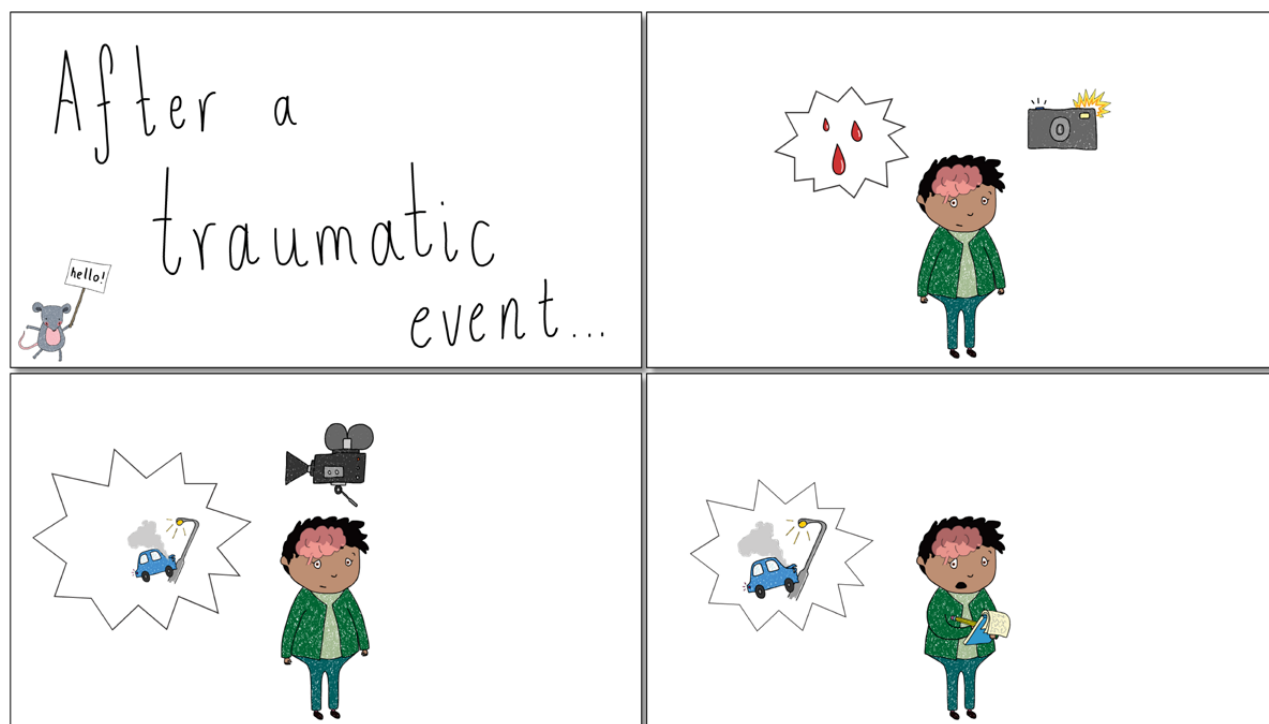
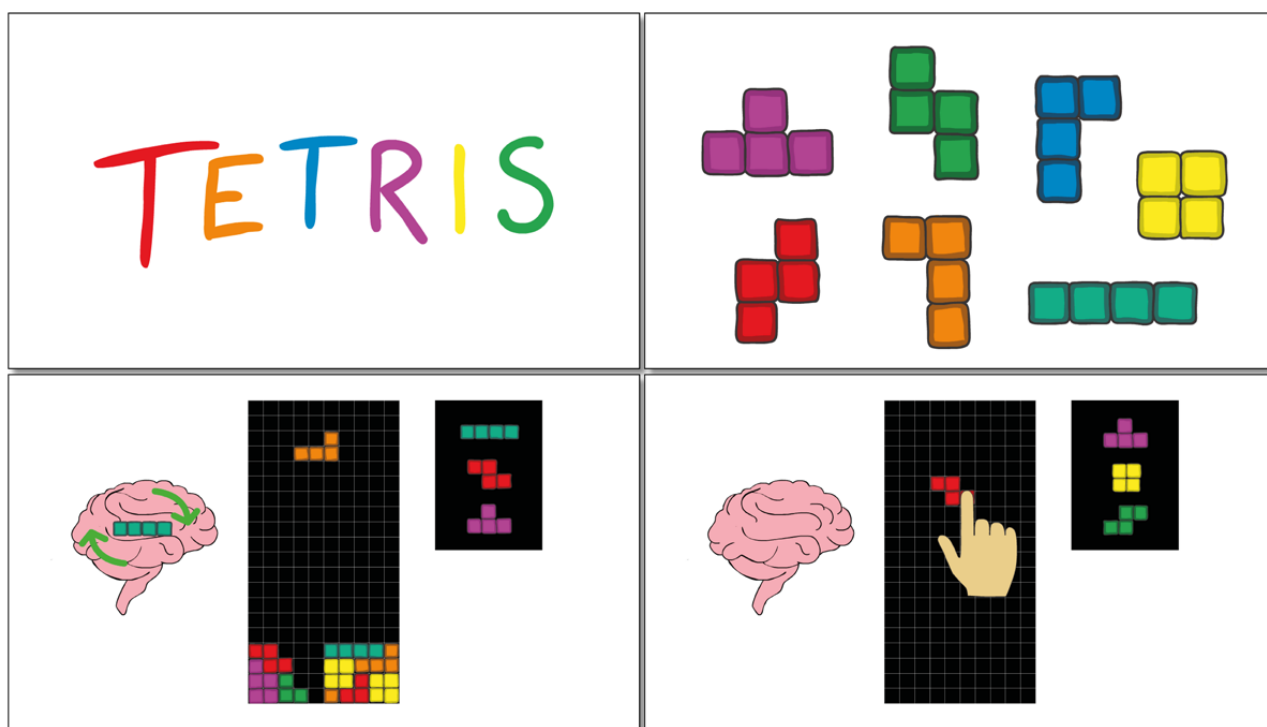


Figure 2. Screenshots from the “How to Play Tetris” video, which instructs participants on how to complete the imagery-competing task in the specific way required (eg, by emphasizing “mental rotation”).



A total of two quizzes, each containing four questions relating to one of the videos, were created using Survey Monkey. The quizzes were designed to check the target user's understanding of the video content (ie, what intrusive memories are and instructions for Tetris gameplay), which would typically be covered in a face-to-face session by the researcher asking the participant to summarize. The quizzes also aim to boost target user understanding and later recall of the content [37]. They were designed to be brief and with the goal that they could be completed in a few minutes. In a target user setting, the quizzes would be given immediately after users have been presented with the videos.

Data Analysis

Interviews were transcribed verbatim and analyzed using qualitative content analysis [38]. Codes (Multimedia Appendix 3) and themes were initially extracted by KD using QDA Miner Lite (version 2.0.7) and iteratively renamed and restructured after input from the research team. Suggested changes to the materials were evaluated using a modified *MoSCoW* method such that changes were prioritized as Must have, Should have,

Could have, or Would like [29]. For this step, the research team evaluated whether a suggested change would likely make a meaningful difference to intervention delivery, in line with our guiding principles, and if the change was feasible based on available resources [29]. Only changes prioritized as *Must have* (ie, both important and feasible) were implemented.

Results

Participants

All the participants (N=12) were female. The mean age of the sample was 31.3 years (SD 7.5). Participants described their ethnicity as Swedish (n=3), Swedish/European (n=1), Italian (n=1), Mixed/White and Asian (n=1), White/European (n=1), Icelandic/Caucasian (n=1), Irish/Caucasian/White (n=1), White/British (n=1), White/Caucasian Australian (n=1), and Caucasian (n=1). The sample comprised 6 researcher clinicians, 3 clinical psychology students, 1 researcher, 1 clinician, and 1 intern. Across the sample, participants worked with a broad range of groups with a history of trauma (Table 1).

Table 1. Participant occupation and relevant experience with the intervention.

ID	Occupation	Experience with the intervention
P1	Researcher clinician	Has delivered the intervention to women who have a history of sexual trauma
P2	Researcher clinician	Involved in the conceptual and clinical development of the intervention
P3	Clinical psychology student	Has delivered the intervention to refugees in Sweden and the United Kingdom
P4	Intern	Has observed the intervention being delivered and worked alongside those who have translated the intervention protocol
P5	Clinical psychology student	Is preparing to use the intervention in a laboratory setting in the near future
P6	Researcher	Has been part of clinical training meetings for the intervention and meetings concerning its development
P7	Researcher clinician	Has delivered the intervention to frontline hospital staff in the emergency department and intensive clinical care
P8	Researcher clinician	Has delivered the intervention to refugees in the United Kingdom
P9	Researcher clinician	Has delivered the intervention to parents of children who have been recently admitted or discharged from the pediatric intensive care unit
P10	Researcher clinician	Has helped create and design the intervention and has delivered it to emergency department patients
P11	Clinical psychology student	Is preparing to use the intervention in a laboratory setting in the near future
P12	Clinician	Has delivered the intervention to patients in the emergency department

Qualitative Content Analysis

The qualitative content analysis generated three main themes, each with a number of subthemes.

Theme 1: Potential Benefits of the Digital Materials for Remote Delivery

Although participants were not probed directly to describe potential benefits of the digital materials, all expressed positive comments about their utility in promoting remote delivery of the intervention.

(i) Animations Effectively Convey Content

Participants reported that intrusive memories were clearly explained and that the illustrations should help target users to understand the symptoms:

I really liked when, [it was showing] it can be like a camera picture, and it had the picture, and the camera sounds, [or] it can be like a movie, and it had a movie reel... I think that really clarified that difference... that was really effective. [Participant 8]

Instructions for the imagery-competing task were said to be clearly conveyed, and the animations may help target users understand the instructions even more so than face-to-face delivery:

I think it's really visually good that you have like, the little brain on the side, and ...you can show the blocks inside the brain to really like, show that you have to think about it, and it becomes very clear how mental rotation works because you have that little brain on the side. [Participant 5]

One participant noted that the videos would be useful because target users can go back and rewatch them at any time to review the information. This participant works with parents of children in the pediatric intensive care unit, a target population that is often under acute stress and/or sleep deprivation and may benefit from the opportunity to revisit instructions:

In fact, you could probably be more helpful over video because parents can pause and stop and rewind. [Participant 9]

(ii) Appropriate Style and Pace

General positive feedback was given on the style of the animation for depicting what can often be a difficult topic:

It's simple, but respectful at the same time, if that makes sense, and without seeming like a cartoon, but doing that in a thoughtful but very accessible way. So, I think that balance has been struck beautifully. [Participant 2]

The videos were also praised for their steady pace and frequent pauses to allow target users to process the content. Feedback suggested that the new materials hold initial promise regarding target user *engagement* because of the animation style and pacing. Participants described the digitalized materials as being something that, “you can pay attention to... which is good” (Participant 8) and said that they were presented at a pace that allows for time to process the materials (Participants 4 and 7). A few participants mentioned that it was perhaps too slow at times and that for certain populations such as frontline hospital staff, the pace of the video may need to be increased because of their busy work schedules.

(iii) Animations Convey Empathy

The depiction of intrusive memories was said to convey empathy for target users, perhaps even more than a face-to-face explanation typically would:

It explains the concept. But I think it also shows participants that you understand what “I’m” going through. And I think that's really, really powerful. [Participant 2]

One participant commented on the facial expression of the character, stating that, from her experience with patients in the emergency department, the character showed an appropriate

amount of distress to depict the experience of an intrusive memory, without being over the top:

...she looked sad or like she was experiencing stress when she got the intrusive memories. But she didn't look like, that scared. [Participant 12]

(iv) Digital Materials Foster Standardization Across Studies

Participants reported that the materials could be used across studies for different groups of target users. For example, if used for research purposes, a standardized approach to intervention delivery would increase experimental control and allow more direct comparison of results across studies:

I think that videos would be great, not only for remote, but also for a more like, improved generalisation of the intervention in both an experimental and clinical setting. [Participant 6]

(v) Quizzes Are Useful Checks for Understanding

It was not required for participants to answer the quiz questions, only to review them. All participants who did submit answers (9 of 12) scored 100%. Participants expressed that the quiz questions overall captured the important concepts from the video and should be useful to check target user comprehension:

[They are] good because it checks out the learning they've had from like, watching the video, making sure they understand what they've watched... They've covered the main points of what you're aiming to get out of it. [Participant 8]

Theme 2: Refining Materials Before Implementation

In addition to the aforementioned positive feedback, participants suggested some changes to help refine the digital materials before being implemented for pilot testing with target users.

(i) Modifications for Clarity of Symptom Explanation

Some participants suggested drawing a clearer distinction between intrusive memories and related concepts such as rumination, by including more specific examples (eg, stating that they are not the same as thinking, "I wish I could have done something differently").

One participant said that the video did not clearly cover flashbacks, that is, a dissociative experience where the individual feels or acts as if the trauma event is happening again [2]:

I don't really think that the video captured flashbacks... if it's explaining intrusive memories, it doesn't have to be explaining flashbacks. But if I were to show this to a participant, I think I would pause and then want to add it can also be a flashback. [Participant 3]

Two participants suggested that a particular aspect of the animation was unclear: the three droplets of blood that depict an example of an intrusive memory. They suggested that it be replaced by a red puddle instead of droplets; therefore, it is more apparent that the character has a memory involving blood:

Why [are] there some drops, red drops?... I [didn't] realise what it was. [Participant 4]

Some small modifications were also suggested to clarify the wording of two quiz questions, such as when multiple answer options could be conceived as technically correct, as opposed to only one, as intended.

(ii) Modifications to Clarity of Intervention Instructions

Some participants expressed that some aspects of Tetris gameplay were not addressed in the video, such as what to do when *Game Over* is reached and that target users tend to have questions about all the functions of the game, including that the game speeds up as time goes on:

...it would be helpful to inform participants that the Tetris will speed up. And so, I know that kind of was asked by participants a couple of times as they were going through the intervention. They were saying, you know, "it's getting faster!" [Participant 9]

It was also suggested that the video should have more emphasis on *mental rotation*, as it is a key component of the intervention, and that this could be at the end of the video to promote a recency effect. One participant mentioned that the video should state that target users are playing Tetris with *special instructions* (instead of just playing Tetris) to reduce the chance that a target user who is already familiar with the game will dismiss the instructions as unnecessary.

Themes 3: Key Challenges for Remote Delivery

During the interviews, participants also raised some key challenges that should be considered in the shift toward full digitalization and remote delivery of the intervention.

(i) Overcoming the Lack of Real-Time Communication

Main challenges raised for remote delivery were how to allow target users to ask questions and how to give real-time feedback or encouragement. This was said to be especially important for target users who have severe dissociation symptoms (ie, the intrusive memory leading to the person losing touch with the here and now). One participant described that from her experience of working with refugees with complex trauma history, guidance when completing the intervention can help keep these users stay *grounded* during gameplay. Furthermore, users may lose focus on the *mental rotation* instructions after a while and need reminders to do this:

The one kind of drawback that I can think of is that, if the participant is wanting to ask a question, or wanting to pause and get that kind of straightaway feedback to answer questions, that might not be possible... The researcher might remind the participant to keep doing the mental rotation, especially when it starts moving quite quickly. I find that people then say, "Oh, I just totally lost track of what I was doing... I was just trying to focus on not filling up the screen." [Participant 7]

Some participants raised the question of how quizzes will be implemented, specifically how to proceed if target users answer any of the questions incorrectly. It was suggested that immediate feedback could be provided within the platform or an answer key provided.

(ii) Additional Videos to Advance Remote Delivery

Participants were asked in each interview if they had recommendations for additional videos that could help advance remote delivery. All participants had at least one suggestion for videos to explain other aspects of the procedure that are normally described face-to-face. This could include how to fill in the intrusive memory diary to assess the target symptom or how to instruct participants to create a list of their intrusive memories for the memory reminder part of the intervention. It was suggested that videos could help instruct how to access the game and troubleshoot common technical problems but that such instructions might differ across studies, for example, when playing Tetris across different platforms. Several participants raised the need to translate the materials for future planned studies that will include participants from other countries, such as women in Iceland, health care staff in Sweden, and refugees across Europe.

(iii) Maintaining a Sense of Bidirectional Relationships

Some participants raised the importance of fostering a sense of a bidirectional relationship between the intervention provider and target user, as this may help with retention:

I think, when we digitalise something we need, as we are losing, you know, the interpersonal component. ... we need to make sure we kind of fill that gap. Relationship still is the key for every treatment.
[Participant 4]

Evaluation and Implementation of Feedback

A total of 9 suggested changes were considered to be *Must have* [29] and were modified accordingly; these are described in Table 2. Other feedback not prioritized as a *Must have* was not directly implemented at this time; however, in some cases, it may be addressed in future iterations and/or study and site-specific protocols (the complete table of feedback and assigned MoSCoW ratings is given in Multimedia Appendix 4). For instance, it was suggested that the word *trauma* should be avoided in the materials, as some target users may be nonclinical participants who receive the instructions in relation to watching stressful film materials, and the word *trauma* could be misleading in that setting. It was decided that this suggestion was too study/site specific to be implemented in the current materials but may be applied to other materials for those studies.

Table 2. Suggested changes to the digital intervention materials that were categorized by the research team as *Must have* and subsequently implemented.

Suggested change during interview	Changes made to the digital intervention materials
Add that intrusive memories come without warning or are <i>involuntary</i> somewhere in the video	Changed the summary sentence at the end of the video from “pop up in your mind without warning” to “pop suddenly into your mind when you don’t want them to” to emphasize that they are involuntary
Clarify the distinction between rumination and intrusive memories, by adding examples of the former, such as thinking “what could I have done differently?” or “why did this happen to me?”	Added to the script for the video on intrusive memories, “they are also NOT the same as thinking in words, like ‘Something awful happened to me’”
Clarify the three red drops of blood image, perhaps by drawing a red puddle instead, as it was difficult to distinguish what this was	Animation in the video was altered to represent blood more clearly
Emphasize mental rotation more as it is thought to be critical to the intervention’s efficacy	Changed the script and rerecorded to say, “for this intervention to work, the most important thing for you to do is focus on the blocks that are coming up next”
Annunciate the word <i>brain</i> more clearly and others a little clearer	Both videos have both been revoiced by a different person, with emphasis on clear annunciation
Say in the video that this is playing Tetris with special instructions	Change the name of the video when it is presented to target users to “Tetris with Special Instructions”
For the “How to Play Tetris” quiz, the first question, two of the possible answers are technically correct	Changed the first alternative for the first question from “Score as many points as possible” to “Getting as many orange blocks as possible” so that latter is more clearly incorrect
Some phrasing from the video is not included in the “How to Play Tetris” quiz, like saying “planning in your mind’s eye”	Changed the first option of the last question from “Visualise and rotate them in your head” to “Visualise and rotate them in your mind’s eye”
The wording of one question in the “What Are Intrusive Memories?” quiz, where the one option says, “intrusive memories usually take the form of...” “a headache” can be true for some participants and should be changed	Changed the third option of the second question stating that intrusive memories usually take the form of “a really high fever” to be more clearly incorrect

Discussion

Principal Findings

In line with our first aim, we obtained and analyzed qualitative feedback on digital intervention materials, which showed that participants were generally positive about the potential benefits of the digital materials for remotely delivering the intervention. The animated videos were thought to effectively explain the

target symptom and to instruct participants in the imagery-competing task. Participants noted that the digital materials were engaging and could likely be used across different demographics of target users, highlighting their potential to standardize delivery of the intervention across studies. Relatively minor suggestions were made to clarify some aspects of the materials and, in line with our second aim, we systematically implemented these changes, making 9 modifications to the videos and quizzes. Participants also raised

some key challenges in moving forward with successful remote delivery of the intervention, such as overcoming the lack of real-time communication between the researcher and target user. We discuss how these considerations will shape the next steps of intervention development.

Comparison With Previous Work

Participants expressed several potential benefits of digital materials that align with previous findings. For example, participants reported that the videos effectively conveyed the content, and previous research has shown that animations with visual cues can be an effective medium for communicating scientific concepts, sometimes leading to better retention than static images [39]. Videos also allow content to be presented to the viewer in bite-size pieces, minimizing the chance of cognitive overload [40].

A number of specific suggestions for refining the materials were also raised, some to clarify the explanation of intrusive memories. Psychoeducation is a staple of most posttrauma interventions, and encouraging participants' understanding of symptoms is a core aspect of psychoeducation [41]. This reflects the need for delivering crystal-clear explanations of the target symptom, as participants raised in our study. Suggestions were also made to clarify the instructions for the imagery-competing task. Previous work has shown that target users who have difficulties with the technological aspects of digital interventions are less likely to engage with them [42], and user errors may negatively affect the relationship between the target users and the health care provider [43], again highlighting the need for clear and straightforward digital materials.

Finally, participants raised key challenges to address in advancing the remote delivery of the intervention. These challenges generally align with those encountered in previous research on digital interventions. Participants raised the question of how to address target user questions if they arise during the session and the need to give real-time feedback. In digital interventions, for individuals with chronic physical health conditions, for example, remote interventions have been found to both empower and motivate participants; however, when feedback is given too often, patients may feel overly reliant on their health care providers [44]. Thus, a balance must be reached between the amount of guidance provided by the intervention providers and the level of independence offered to target users.

Next Steps of Intervention Development

These findings will help guide the next steps of intervention development. One of the next steps, suggested by participants, will be to create additional study-specific videos. For instance, videos could help to guide participants through the intervention, from baseline assessment to accessing the Tetris game to keeping track of the target symptom. Such instructions will often differ across studies, depending on the target group and the platform used for intervention delivery. These study-specific videos may therefore be more practical to make as simple film clips of the researcher giving instructions, rather than highly polished animations that would only be used for a single study. Such clips of the researcher may also help users feel that the material is more personalized, as videos with real people could

foster a more personal connection with the study. On the basis of participants' feedback, the next steps should also include implementing real-time feedback to the quiz questions via the platform to provide encouragement or correct misunderstandings.

Critically, the next step is then to obtain feedback from different populations of target users, who do not have previous experience with the intervention, on the feasibility and acceptability of the digital materials. Given that many digital interventions are hampered by low rates of *engagement* and high *attrition* [26,27], finding ways to boost engagement and minimize dropout will be crucial. Both objective and subjective measures of engagement should be captured from target users in the next stages of pilot testing [27]. Depending on the functionality of the platform used for digital delivery, it may be possible to capture objective metrics such as frequency and duration of self-administered intervention usage. Subjective measures could include self-reported questions about aspects of engagement such as attention, interest, and affect [27] as well as open-ended questions about the intervention experience (eg, suggestions for what would make the intervention more acceptable or easier to complete). Pilot testing will help to inform the extent of real-time support, if any, needed from the researcher for successful delivery of the intervention to target users. By *real-time support*, we mean any guidance provided from the researcher remotely during a session (eg, via telephone or secure video link), such as to clarify task instructions, provide encouragement, or direct participants toward next steps. Real-time researcher support should thus be included as part of the protocol in the next stages of studies, before moving toward a more self-guided (and potentially more scalable) intervention. Findings will help to identify aspects of digital materials that need modification to minimize the amount of support and promote participant independence. For example, the technological literacy of different groups may affect the degree of technical support needed, such as troubleshooting videos, as suggested by some participants in this study.

Regarding quizzes, it will be important to examine (and then optimize) the difficulty level for target users. Target users in different groups should be able to understand the content and answer all quiz questions correctly. Ideally, this brief comprehension check should be in line with face-to-face procedures; quizzes should be a helpful *light-touch* repetition of the most crucial parts of the instructions. We intend to program the quizzes in such a way that if a user selects the wrong option, they will be informed of the correct answer in real time via a friendly pop-up message, similar to how a researcher would clarify any misunderstandings in person. Pilot testing will help to refine these procedures and determine whether such corrective feedback is sufficient or if, for example, target users need to rewatch the videos before proceeding to the intervention.

Many previous works have demonstrated the value of obtaining target user feedback to improve intervention materials, which is core to PBA [28]. For example, feedback from target users on a digital intervention for PTSD in women veterans highlighted the need to incorporate additional advice in the material, such as on seeking social support [45]. Piloting our

digital materials on trauma survivors will likely raise issues to address in future iterations of the intervention that are not yet considered here. Finally, an intervention must not only be engaging and accessible to target users but must also be effective. After initial pilot testing with target users and further refinement of the digital intervention based on those findings, the next step should be rigorous testing of efficacy, starting, for instance, with single-case series designs [46], before scaling up to larger randomized controlled trials.

Strengths and Limitations

This study has several strengths. First, systematic adjustments were made to the materials by first obtaining feedback from nontarget users of the intervention [29]. This should save time and resources by addressing any current flaws in the materials before direct piloting with trauma survivors. Second, interviews were carried out by KD, who had recently joined the research team and was not involved in the creation of the videos, perhaps allowing for more frank feedback on the materials from participants. Third, the sample included a range of professional backgrounds, from psychology students with cursory knowledge

of the intervention, to experienced clinicians actively delivering the intervention, which should have led to a wider perspective on digital materials. However, we note an important limitation in that all participants were women from Europe; a more demographically diverse sample would have produced a broader perspective on, for instance, cultural sensitivities to keep in mind during intervention development.

Conclusions

Digital interventions hold exciting promise for the dissemination of evidence-based treatments globally; however, they must be developed in a careful, stepwise manner to be engaging and effective for target users [27]. We have shown that clinicians, researchers, and clinical psychology students are confident in the use of digital materials to deliver a brief intervention to reduce the number of intrusive memories of trauma. Important challenges remain, such as overcoming the lack of real-time communication with target users. By refining the digitalized intervention materials, this study lays the groundwork for the next step of intervention development: pilot testing with trauma survivors.

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Authors' Contributions

EH, MK, and BG conceived and designed the study. BG and KD drafted the manuscript, with critical feedback and revisions from MK and EH. KD conducted the interviews and data coding as part of her master's thesis. All authors approved the final version of the manuscript.

Conflicts of Interest

EH reports serving on the board of trustees of the charity MQ: Transforming Mental Health but receives no remuneration for this role. EH receives royalties from books and occasional fees for workshops and invited addresses and receives occasional consultancy fees from the Swedish agency for health technology assessment and assessment of social services. The other authors have no conflicts of interest to declare.

Multimedia Appendix 1

Guiding principles for development of the digitalized intervention materials.

[PDF File (Adobe PDF File), 148 KB - [mental_v8i2e23712_app1.pdf](#)]

Multimedia Appendix 2

Interview guide.

[PDF File (Adobe PDF File), 132 KB - [mental_v8i2e23712_app2.pdf](#)]

Multimedia Appendix 3

Qualitative content analysis codes.

[PDF File (Adobe PDF File), 161 KB - [mental_v8i2e23712_app3.pdf](#)]

Multimedia Appendix 4

Suggested changes and MoSCoW categorization. MoSCoW: Must Have, Should Have, Could Have, Would Like.

[PDF File (Adobe PDF File), 217 KB - [mental_v8i2e23712_app4.pdf](#)]

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Abbreviations

MoSCoW: Must Have, Should Have, Could Have, Would Like

PBA: person-based approach

PPI: patient and public involvement

PTSD: posttraumatic stress disorder

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Review

Neurocognitive Assessment Tools for Military Personnel With Mild Traumatic Brain Injury: Scoping Literature Review

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Abstract

Background: Mild traumatic brain injury (mTBI) occurs at a higher frequency among military personnel than among civilians. A common symptom of mTBIs is cognitive dysfunction. Health care professionals use neuropsychological assessments as part of a multidisciplinary and best practice approach for mTBI management. Such assessments support clinical diagnosis, symptom management, rehabilitation, and return-to-duty planning. Military health care organizations currently use computerized neurocognitive assessment tools (NCATs). NCATs and more traditional neuropsychological assessments present unique challenges in both clinical and military settings. Many research gaps remain regarding psychometric properties, usability, acceptance, feasibility, effectiveness, sensitivity, and utility of both types of assessments in military environments.

Objective: The aims of this study were to explore evidence regarding the use of NCATs among military personnel who have sustained mTBIs; evaluate the psychometric properties of the most commonly tested NCATs for this population; and synthesize the data to explore the range and extent of NCATs among this population, clinical recommendations for use, and knowledge gaps requiring future research.

Methods: Studies were identified using MEDLINE, Embase, American Psychological Association PsycINFO, CINAHL Plus with Full Text, Psych Article, Scopus, and Military & Government Collection. Data were analyzed using descriptive analysis, thematic analysis, and the Randolph Criteria. Narrative synthesis and the PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-analyses extension for Scoping Reviews) guided the reporting of findings. The psychometric properties of NCATs were evaluated with specific criteria and summarized.

Results: Of the 104 papers, 33 met the inclusion criteria for this scoping review. Thematic analysis and NCAT psychometrics were reported and summarized.

Conclusions: When considering the psychometric properties of the most commonly used NCATs in military populations, these assessments have yet to demonstrate adequate validity, reliability, sensitivity, and clinical utility among military personnel with mTBIs. Additional research is needed to further validate NCATs within military populations, especially for those living outside of the United States and individuals experiencing other conditions known to adversely affect cognitive processing. Knowledge gaps remain, warranting further study of psychometric properties and the utility of baseline and normative testing for NCATs.

KEYWORDS

military; rehabilitation; head injury; posttraumatic stress disorder; cognition; neurocognitive assessment tool; traumatic brain injury; assessment; brain concussion; mobile phone

Introduction

Background

Mild traumatic brain injuries (mTBIs), also known as concussions, are generally defined as a temporary change in brain functioning caused by an insult to the head, with a period of posttraumatic amnesia lasting less than a day [1]. Symptoms of mTBIs may include cognitive dysfunction, which can compromise the overall functioning at home and work and during other activities [2]. Within military populations, the mechanism of injury (MOI) for mTBIs varies, with some occurring as a result of motor vehicle collisions, falls, sports, explosions, or other forces related to combat and military training. Among Canadian Armed Forces service members deployed in Afghanistan during Operation Enduring Freedom, 5.2% self-reported experiencing an mTBI and, of these, 21% noted postconcussion symptoms (PCSs), referring to symptoms lasting longer than 3 months after MOI [1,3]. In comparison, studies among the US military populations reported mTBI rates of 12% to 22.8% during Operation Enduring Freedom and Operation Iraqi Freedom, with PCS rates of 15.8% to 35% [4-6]. The UK Armed Forces reported a 4.4% mTBI prevalence among service members deployed into these global conflicts [7]. Although the reported rates of mTBIs vary between militaries, the evidence base consistently demonstrates higher mTBI and PCS rates in military personnel versus civilian populations. Incidences of PCS are prevalent at an elevated rate among military populations, with global estimates for civilians of approximately 15% and military estimates ranging from 15.8% to 35% [5,7,8]. A higher prevalence of mental health disorders, exposure to traumatic experiences, and previous mTBIs among military personnel have been identified as potential reasons that PCS is more common in military populations than in civilian populations [3,5]. It is also accepted that factors such as stigma and fear of career repercussions owing to injury also contribute to the underreporting of mTBIs, which contributes to underestimating the actual incidence of this injury among military personnel [3,9].

Neuropsychological Assessments in Military Populations

Premature return to duty after sustaining mTBIs is inherently associated with heightened risk. This includes increased chances of sustaining a subsequent concussion before neurological recovery. This has the potential to amplify the risk for impaired performance, making mission failure more likely, and endangering the safety of self and others [10,11]. Neurocognitive assessments for those who have sustained mTBIs are needed to (1) provide information on function in a timely fashion, (2) assist with diagnoses of mTBIs and/or impaired cognitive functioning, and (3) provide health care professionals with the tools needed to understand and monitor phases of recovery after injury for better-informed clearance for a return to work, duty,

and other activities [12]. Measurement of neurobehavioral and cognitive functioning after mTBIs, often referred to as neuropsychological testing, is considered a component of best practice mTBI management. Neuropsychological assessments provide valuable information that can have important implications for returning to these activities in acute and chronic mTBI scenarios [1,2,13].

Traditional neuropsychological assessments are generally composed of measures with large normative databases and demonstrate evidence of adequate psychometric properties [13]. These assessments are typically administered in one-on-one scenarios by a trained health care professional with paper, pencil, and stopwatch [13]. Neuropsychological assessments range in administration time from less than an hour to multiple sessions over days. These assessments are not meant to be executed on the sidelines in athletic scenarios and are not simply screens of symptoms or cognitive status. Rather, they are in-depth assessments that address behavior, emotional status, and cognitive domains as well as neuropsychological symptoms. Neuropsychological assessments may or may not provide diagnostic information on mental health conditions, mTBIs, or learning disabilities; however, their diagnostic properties are still widely debated within the research [12].

Although neuropsychological assessments have been used in psychology for over 100 years, there remain many questions, logistical issues, and psychometric challenges around their use, especially in the military context. Traditional neuropsychological testing can be time intensive for both the health care professional and the patient, expensive for patients, and less feasible to administer in combat settings [13]. These cognitive assessments may also be dated. Some assessments use decades-old normative data. Others ask the patient to complete tasks that are no longer relevant to the present day. Dated assessment tools can compromise the validity of the assessment and increase the chances of type 1 and type 2 errors [14]. There are limits to the variations in stimuli that can be presented with traditional assessments and scoring (ie, speed and accuracy) and many of these assessments lack ecological validity [9]. Traditional neuropsychological assessments tend to examine isolated components or domains of cognition and may not adequately predict the overall functioning that relates to return to duty after mTBIs [9,14]. Assessment results do not always assist clinicians with treatment planning because performance during assessment tasks may not accurately reflect the real-world performance [14].

Computerized Neurocognitive Assessment Tools

In the last 20 years, alternatives to traditional neuropsychological assessments have emerged in the form of computerized neurocognitive assessment tools (NCATs) [13]. As the use of computers and handheld devices such as tablets and smartphones has become ubiquitous in society, neuropsychological

assessment tasks on these devices may be closer to activities that are commonplace in real life. This may increase the acceptability and ecological validity of computerized assessments.

NCATs developed in recent years are promising for use within military populations, especially with younger demographics. Currently, NCATs are used by military health care providers to assess the effects of mTBIs in both deployed and nondeployed settings [15]. In the United States, military personnel are mandated to undergo assessment with an NCAT referred to as the Automated Neuropsychological Assessment Metrics 4 Traumatic Brain Injury-Military (ANAM4 TBI-MIL) to establish a baseline of cognitive functioning before deployment in a war zone [16].

NCATs may have multiple benefits such as faster administration time, automated scoring and statistical analysis, easier reporting, and ease of deidentification of patients for research purposes [13,17]. NCATs may also allow for cognitive assessment to be obtained in geographic areas where traditional neuropsychological and cognitive assessment resources are limited [13]. Furthermore, NCATs provide the benefit of delivering numerous combinations of stimuli systematically and the ability to precisely track speed and accuracy. This can help mitigate practice effects and possibly increase sensitivity to subtle changes in cognitive performance [9,13]. The standardized tablet or computer interface, standardized script, and reduced conversation between the assessor and the participant may also enhance the interrater and intrarater reliability of NCATs [17]. Bias or issues with reliability that may be related to assessor variability or differences in rapport between the assessor and the patient may be reduced by standardized assessment delivery. Despite the potential benefits of NCATs, many questions remain regarding their effectiveness in both civilian and military populations with mTBIs and other conditions that affect cognitive functioning.

Although NCATs are currently used in military health care practices, a better understanding (or more information) about their feasibility, effectiveness and psychometric properties is needed. Owing to the relatively recent digital evolution, NCATs generally have not undergone the same degree of rigorous evidence-based psychometric evaluation as in traditional neuropsychological testing. Consequently, validity, reliability, specificity, and overall effectiveness may not be as well established for NCATs [13]. NCATs and traditional assessments may be limited regarding their ability to demonstrate cognitive functioning changes when individuals are immersed in stressful situations such as military combat; issues related to ecological validity also exist [9].

Diagnosing mTBIs on an individual basis has, to date, not been possible using a single traditional or computerized assessment. This diagnostic challenge can be attributed, in part, to large variations in baseline neurophysiological function and the presence of transient interferences such as learning effects, fatigue, anxiety, and unrelated states of mental alertness or illnesses [12]. Furthermore, although NCATs are being used in clinical settings and their utility in mTBI management is currently the subject of study, there is a lack of published literature on the use of these assessments among patients with

other conditions known to adversely affect cognitive functioning [15].

Previous Literature Reviews of NCATs

There have been a number of literature reviews published in the past 20 years, focusing on the usage of NCATs to assess sport-related mTBIs [13,18-20]. In 2005, Randolph et al [18] established 5 criteria that must be satisfied with additional research to consider an NCAT for testing after mTBIs. The *Randolph Criteria* included the following: (1) test-retest reliability, (2) the sensitivity of tests in the clinical issue of interest, (3) the validity of the measure, (4) reliable change scores and scoring algorithms for classifying impairment, and (5) determining the clinical utility of the measure [18]. The NCAT literature reviews of sport-related mTBIs after Randolph et al [18] have used these criteria. However, the most recent conclusions suggest that additional research is needed to further validate NCATs within mTBI populations [13]. These past literature reviews were not specific to military personnel.

It is essential that military personnel be considered a unique subset of the adult mTBI population for many reasons. First, military personnel exhibit higher rates of conditions such as posttraumatic stress disorder (PTSD), depression, anxiety, sleep disorders, chronic pain, substance abuse disorders, and mTBIs, which can cause and adversely affect the severity, longevity, and dysfunctionality of symptoms including associated cognitive dysfunction [3-7]. Specifically, traumatic brain injuries and PTSD can arise from the same or separate traumatic incidents and often co-occur, which adds complexity to the diagnosis, treatment, rehabilitation, and return-to-work planning [3-7,21]. Additionally, the MOI of the mTBI experienced by military members can differ from the impact sequelae seen in sport-related mTBIs. Blast injuries, for example, are more unique to military populations, with a portion of the mTBI sustained by military members during Operation Enduring Freedom and Operation Iraqi Freedom being attributable to this MOI [22,23]. A blast mTBI is an injury to the brain leading to dysfunction resulting from an explosion or a blast [22,23]. No significant variations in mTBI-attributed cognitive symptoms caused by blast versus blunt force have been identified; however, research continues to investigate this [22].

There is a need for the improved detection of neurocognitive deficits in the military setting to assist with the diagnosis of mTBIs, rehabilitation planning, tracking recovery, and making return-to-duty decisions while maintaining the productivity and safety of the military population and the civilians they may interact with at home and on deployment. An up-to-date scoping literature review of the current evidence related to NCAT usage among military members who sustained mTBIs is warranted because of (1) the lack of specificity to military populations among previous literature reviews regarding NCATs and mTBIs, (2) the rapid development of NCATs, and (3) the frequency of clinical usage among military health care. This scoping review aims to fill this knowledge gap.

Purpose and Research Questions

The purpose of this scoping review is to (1) explore the existing evidence regarding the use of NCATs among military personnel

who have sustained mTBIs, (2) evaluate the psychometric properties of the most commonly tested NCATs for this population, and (3) synthesize the data to explore the range and extent of NCATs among this population, clinical recommendations for use, and knowledge gaps requiring future research. This scoping review aims to answer the following research questions: (1) To what extent and which NCATs are being used within the military mTBI context? (2) What evidence exists regarding the validity, reliability, feasibility, technology acceptance, usability, and security of NCATs in the military and mTBI context? (3) What are the themes, clinical recommendations, and considerations in the evidence-based literature regarding the use of NCATs for military personnel who have sustained mTBIs? (4) What are the knowledge gaps and future directions of research that need to be addressed regarding the usage of NCATs for military personnel who have sustained mTBIs?

Methods

Scoping Literature Reviews

A scoping review is a form of knowledge synthesis that addresses an exploratory research question aimed at mapping key concepts, types of evidence, and gaps in research related to a defined area or field by systematically searching, selecting, and synthesizing existing knowledge [24]. While systematic reviews are used when answering narrowly focused research questions, scoping reviews are used to answer broad research questions. A scoping literature review is often conducted before the research begins and sets the stage for this research by highlighting gaps in the literature and explaining the need for research to be conducted [25]. Similar to a systematic review, an *a priori* protocol must be developed for a scoping review [26]. Unlike a systematic or critical review, and owing to the more iterative nature of a scoping review, deviations from the predetermined protocol may be necessary [26]. This evidence-based scoping literature review design is ideal for addressing the research questions and assisting with an evolving implementation science strategy to improve the cognitive assessments used with military populations.

This study employed the following overarching steps: (1) formulation of the research questions based on Population, Intervention, Comparison, and Outcome guidelines; (2) identification of relevant studies; (3) selection of studies; (4) charting of data; and (5) collation, analysis, summarization, and reporting of results [27]. As required for scoping reviews, a minimum of 2 reviewers were involved in study selection and analysis [27]. The PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-analyses extension for Scoping Reviews) reporting guidelines were followed [28].

Identification of Relevant Studies

Relevant studies were systematically identified. A description of the information sources, search strategy, inclusion and exclusion criteria, and selection process is provided in the following sections.

Information Sources and Search Strategy

A search strategy was developed based on specific inclusion and exclusion criteria and included the following databases: MEDLINE (Ovid MEDLINE ALL), Embase (Ovid interface), the American Psychological Association (APA) PsycINFO (Ovid interface), CINAHL Plus with Full Text (EBSCOhost interface), Psych Article (EBSCOhost interface), Scopus, and Military & Government Collection (EBSCOhost interface). The search consisted of an extensive list of keywords and subject headings covering 3 concepts: (1) NCATs, (2) military personnel, and (3) mTBIs. The 3 concepts were then combined with the Boolean AND. Studies were limited to peer-reviewed and gray literature papers in English. The initial search for papers took place on April 15 and April 21, 2020, within the aforementioned databases. The full search strategy is available in [Multimedia Appendix 1](#).

Inclusion and Exclusion Criteria

Papers selected for inclusion in this study focused on military personnel who had a primary diagnosis of mTBIs. Targeted papers specifically addressed the usability, feasibility, reliability, validity, sensitivity, and efficacy of one or more NCATs among military personnel who have sustained mTBIs. Studies were excluded if the NCAT was used to measure the outcome of an intervention such as cognitive rehabilitation therapy, hyperbaric oxygen, or psychotherapeutic interventions. If the published work included healthy participants or participants with comorbid conditions, such as other mental health disorders, disrupted sleep, chronic pain, or substance use disorder, it was included if the additional conditions were secondary to the mTBI diagnosis and not the primary focus of the specific research study. Cognitive assessment practices that incorporated virtual reality were permitted for inclusion.

The papers included in the data set were quantitative, qualitative, mixed methods, and meta-analyses, regardless of positive, negative, or neutral findings. Papers were excluded from the review if they did not meet the inclusion criteria. Studies that exclusively addressed civilians or veterans were also excluded.

Selection of Studies

The study selection phases followed a variation of the procedures used by Miguel Cruz et al [29]. First, a member of the research team exported all of the identified studies to the reference manager software ProQuest Refworks. After deduplication, the references were imported into the Covidence Systematic Review Software. Second, members of the research team were trained in applying the inclusion and exclusion criteria (calibration phase) before the title and abstract evaluation phase. Three independent researchers evaluated the titles and abstracts of the remaining studies and compared them with the inclusion and exclusion criteria. Next, the research team met to resolve any differences in decisions to include or exclude studies from the review. During the full-paper reading phase, at least two researchers reviewed the full text of the selected studies. Each of the researchers independently assessed the studies to determine their suitability for inclusion in the data extraction phase. An article's inclusion or exclusion into the data set for analysis required consensus from the research group. The

reference lists of the included full-text studies were also reviewed for articles that the search may have missed.

Charting of Data

The research team extracted data from the final selected papers according to the following domains: population (medical condition, age, specific military conflict, condition, race or ethnicity, sample size [N], and mean age [SD] in years), study features, clinical assessment, assessment of technology usability, technology outcome measures, technology, duration, and data analysis strategies. The researchers met regularly and reconciled the differences through discussion. In case of any disagreement, one of the researchers acted as a third rater.

Analysis, Summarization, and Reporting

All data were analyzed and validated by at least two team members involved in the analysis. The research team met regularly to discuss data extraction, analysis, and synthesis, which were iterative and, in some cases, concurrent. Any discrepancies in the analysis of quantitative or qualitative data were resolved through discussion. This nonlinear process served to improve the rigor and internal validity of the review.

A narrative synthesis was conducted to organize, describe, and interpret the results of the analysis [30]. A deductive analysis was guided by the research questions associated with the use of computerized cognitive assessments among military personnel who have sustained mTBIs [31]. Inductive analysis was conducted from the information in the articles, particularly the

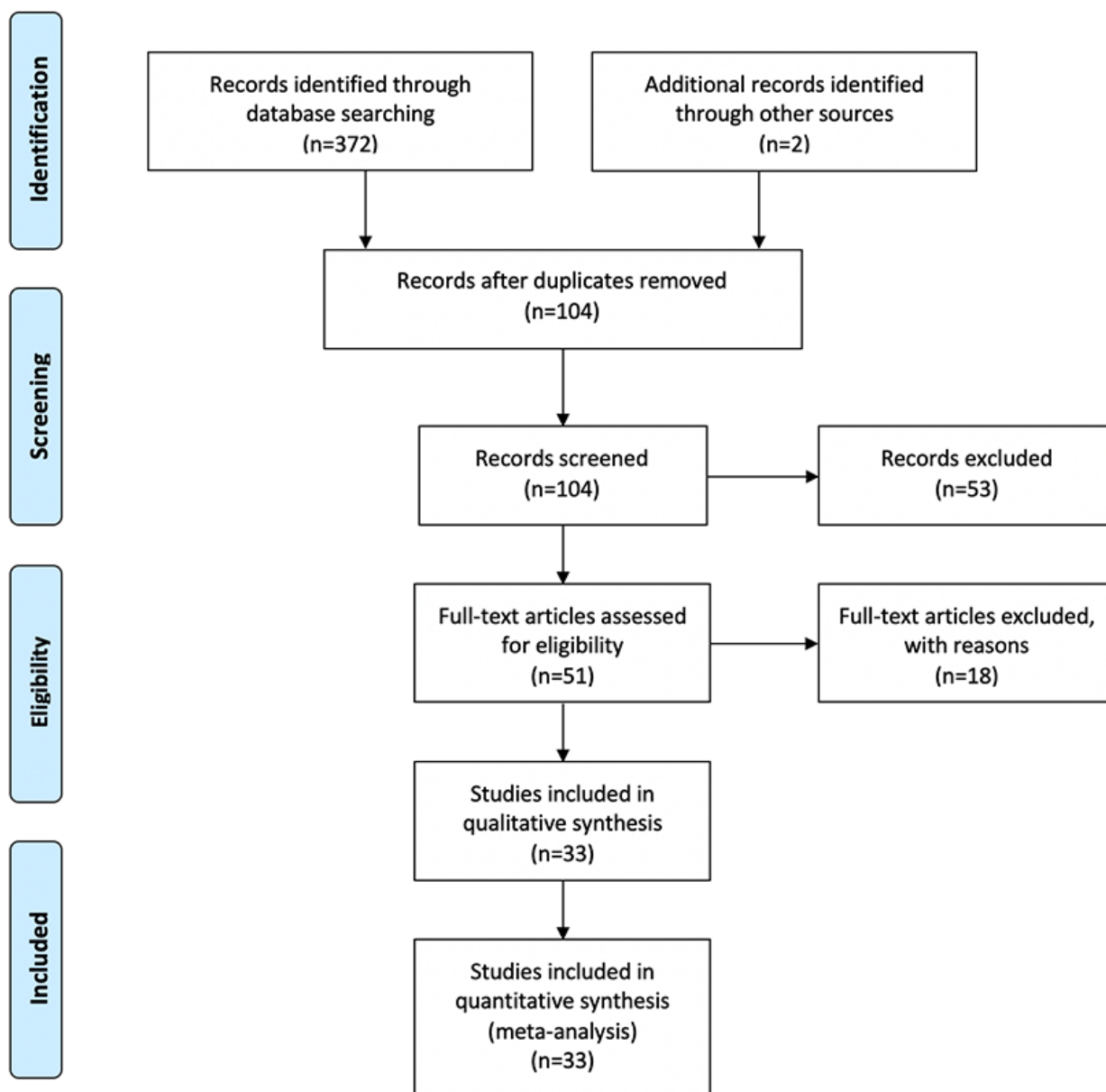
recommendations and directions for future research. Furthermore, each of the 3 most common NCATs and their psychometric properties were considered within the 5 criteria proposed by Randolph et al [18]: (1) test-retest reliability, (2) the sensitivity of the tests in the clinical issue of interest, (3) the validity of the measure, (4) reliable change scores and scoring algorithms for classifying impairments, and (5) determining the clinical utility of the measure [18].

Results

Search Results

The search strategy yielded 372 articles (PRISMA diagram, Figure 1), with a further 2 studies identified through reference searches, resulting in a total of 374 articles. Following deduplication, 104 articles were subjected to a title and abstract review, after which 53 were removed. A total of 51 full-text documents were reviewed, with 18 being excluded for several reasons. Studies that were not specific to the military population, such as those focusing on veterans, pediatrics, caregivers, or athletes were excluded. Studies were also excluded if the research team was unable to verify that the neurocognitive assessment tool was computerized, the assessment tool exclusively evaluated reaction time, or if the primary condition evaluated was not an mTBI (eg, spinal cord injury, emotional distress, chronic traumatic encephalopathy, suicidality, or PTSD). The remaining 33 studies were included in the review.

Figure 1. A PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) extension for Scoping Reviews chart of the scoping review study identification, selection, exclusion, and inclusion.



All included studies ($n=33$) were quantitative, and most studies were published in the United States and used the US military personnel as participants (Multimedia Appendix 2 [9,15,32-62]; Multimedia Appendix 3, Figures S2 and S3). The total number of participants included in the scoping review among all 33 studies was 36,872 (mean 1048.47, SD 2224.70), with an overall mean age of 27.31 (SD 4.10) years. Most participants were healthy (33,521/36,872, 90.90%) and male (31,587/36,872, 85.50%), with only 9.10% (3351/36,872) of all included participants having sustained an mTBI (Multimedia Appendix 3; Figure S6). While mTBI was the primary condition of interest, 3 studies included posttraumatic stress as a secondary condition of interest, and 2 studies included other nonspecified injuries (Multimedia Appendix 3; Figure S9). The time frame of the studies ranged from a single session to a 5-year follow-up.

A summary of the outcomes of the 33 included studies is presented in Multimedia Appendix 3. The outcomes vary greatly by research question, NCAT used, and study design.

The most commonly used NCATs among the 33 studies were the versions of the Automated Neuropsychological Assessment Metric (ANAM; 22/46, 46%), Defense Automated Neurobehavioral Assessment (DANA; 7/46, 15%), and Immediate Post-Concussion Assessment and Cognitive Testing (ImPACT; 5/46, 10%). A variety of secondary measures were collected across the studies, including other neuropsychological assessments and screens related to mTBIs (Multimedia Appendix 3; Figures S10 and S11). The quantitative study design used was not explicitly stated in all studies; however, most appeared to employ cross-sectional cohort designs (Multimedia Appendix 3; Figure S13). A multitude of constructs, including validity, temporal stability, and sensitivity, were measured using a variety of statistical methods throughout

the studies, each with a unique purpose often specific to one NCAT ([Multimedia Appendix 3](#); Figures S12, S14, and S15).

Thematic Analysis and Narrative Synthesis

Thematic analysis and narrative synthesis revealed a number of topics related to the facilitators and barriers of NCAT usage among military populations. The 3 main themes that emerged through the studies included (1) comparing *apples to oranges*, (2) issues with validity, and (3) reliability issues. The narrative synthesis was framed in relation to the aforementioned criteria suggested by Randolph et al [18].

Comparing Apples to Oranges

A number of challenges around the approaches and comparisons used to establish the psychometric properties of the current NCATs were discussed across the included studies. Multiple studies noted that the comparisons made in research when assessing NCATs have important implications on the results and conclusions garnered from the current literature. These can have the potential to adversely affect reliability, validity, sensitivity, detection of reliable change, and overall clinical utility.

As a gold standard NCAT does not exist, comparisons between NCATs and traditional neuropsychological assessments are often used to determine how well tests relate to similar cognitive measures (convergent validity) and differ from dissimilar cognitive tests (discriminant validity) [32]. Simply adapting traditional neuropsychological tests to a computer platform fundamentally changes the test, rendering direct comparisons with the noncomputerized version inappropriate [32,63]. Some of the included studies aimed to address possible correlations with other traditional neuropsychological assessments and other secondary outcome measures related to a range of constructs ([Multimedia Appendix 3](#); Figures S11 and S12).

Similarly, comparing different NCATs among each other can also be problematic when trying to establish validity. Although these assessments may aim to measure similar cognitive domains or constructs; they may measure or calculate scores for a particular construct differently [32]. One NCAT may measure a cognitive domain or construct with an individual subtest, whereas another NCAT may use an index score based on a combination of multiple subtests [32]. NCATs that use normative data, whether specific to military or general populations, have their own data set from which they generate standardized scores [32]. The variation among each NCAT makes it challenging for researchers to perform head-to-head comparisons or a hierarchy of these assessments.

The included studies compared the participants' results with their baseline data, normative data, or both. When synthesizing findings across the studies included in this review, questions were raised regarding whether baseline or normative data comparisons were the most effective for establishing a change in performance among military personnel who had sustained mTBIs. Two papers specifically discussed this issue at length [15,33]. Baseline and normative data comparisons will be discussed further in the following theme and subsequent discussion.

Finally, even the comparison of those who have sustained mTBIs in healthy control groups can affect the results of studies related to NCATs. If some members of the mTBI group were asymptomatic, clinically meaningful differences between controls and those with symptoms could have been washed out, leading to limited effect sizes [32]. It was noted that very few studies in this study addressed within-group differences for the cohort with mTBIs.

Test-Retest Reliability

Four studies specifically addressed test-retest reliability for various NCATs among military populations. Dretsch et al [34] reported that, with the exception of the Simple Reaction Time (SRT) test, the ANAM had adequate or greater test-retest reliability values (intraclass correlation coefficient [ICC] 0.72-0.86) in the deployed environment, suggesting good temporal stability when the retesting interval is less than 11 days. Meyers [35] also addressed the temporal stability of the ANAM in a longitudinal study with follow-up sessions at 1, 3, and 5 years. In this study, the ICCs for all ANAM scales, except SRT1 and SRT2, showed ICCs of 0.7 to 0.8 [35]. Cole et al [36] found that of the ANAM, CogState, ImPACT, and CNS-Vital Sign (CNS-VS), each NCAT had at least one reliability score (ICC) in the *adequate* range (0.70-0.79) and only the ImPACT had a score that was considered high (0.80-0.89), with a time frame between tests of 30 days [36]. Using data from the previously mentioned study, Russo and Lathan [37] compared the DANA with the ANAM, CogState, ImPACT, and CNS-VS [37]. They found that the reliability coefficient measured for the DANA, when matching subjects across test and retest sessions, was higher than those for the ANAM and ImPACT [37]. These 4 studies conflicted in their conclusions on whether test-retest reliability was maintained over varying lengths of time.

Other types of reliability, such as internal consistency, were challenging to establish or judged to be not of adequate quality. Differences in the characteristics of test batteries, the design of test-retest studies, and insufficiently explained and nonstandardized methods of analysis makes it challenging to determine the reliability of NCATs [36,37]. Multiple studies reviewed indicated that the reliability coefficients of NCATs were below what would be considered clinically acceptable for clinical assessment [18,19,37].

Sensitivity of Tests in the Clinical Issue of Interest

One study specifically addressed the sensitivity of the DANA to detect small changes in neurofunctioning related to subconcussive blast pressure. LaValle et al [38] reported that the procedural reaction time (PRT) construct may have sufficient sensitivity to reliably detect a small, transient cognitive impairment among a healthy, undiagnosed population [38].

Validity of the Measure

Multiple studies included in the scoping literature review commented on issues with validity among NCATs both within military and nonmilitary populations who have sustained mTBIs. Studies discussed criterion, convergent, discriminant, and performance validity. Factors that can affect the construct validity of NCATs and traditional neuropsychological

assessments include mental fatigue, physical environment, participant effort, practice effects, and the Monte Carlo effect, among others [34,39,40]. Test-retest reliability can affect validity and has been repeatedly found to be moderate at best and generally lower than that of NCATs [36]. Without an established gold standard, criterion validity cannot be established, which leads to the aforementioned issues caused by comparing NCATs with other NCATs or traditional neuropsychological assessments [32].

Some of the included papers discussed the threats to validity that arise with the variability of normative data sets in which NCAT scores are compared. For example, some NCATs, such as the ANAM, have normative data specific to the military population, whereas others, such as the ImPACT, are compiled from the general population. Some of the studies included in this scoping review discussed the problems that can occur when comparing military and civilian populations [15,33]. As previously discussed, military personnel may be more likely to experience mental health disorders, sleep disorders, chronic pain, substance abuse disorders, and other conditions that can adversely affect cognition and neuropsychological functioning than civilians. Observed decreases in neurocognitive performance following deployment in military personnel with and without mTBIs suggest that the environmental stressors of deployment may affect postdeployment neurocognitive performance [15,41]. Haran et al [15] noted that cognitive performance also correlates and changes with the deployment cycle as military members are more likely to have mental health challenges at specific times.

Recent evidence suggests that PCS is not specific to mTBIs and that symptoms following deployment are better accounted for by mental health diagnoses, such as PTSD, than by the history of mTBIs [3,7,9]. As it is common for healthy service members to have low scores on a cognitive test battery, it is beneficial to understand how many low scores and what cut-off scores are necessary to signify a clinically meaningful change for patients who have sustained mTBIs or other conditions [42]. Brenner et al [42] found that military members who screened negative for both posttraumatic stress and mTBIs had at least one low score on the ANAM shortly after returning from deployment. Another issue with normative data is the lack of consistency in demographic factors, as some are based on age and gender, whereas others are based on one or the other [40].

Many of the reviewed studies discussed the question of ecological validity among NCATs. Both NCATs and traditional neuropsychological assessments are typically administered in controlled clinical or research settings to obtain the best possible performance of the patient [9]. It is unknown if, and how well, this performance will transfer to a combat or deployed environment. It is also important to know how well executive functions measured during these assessments, such as decision making, translate to an individual's performance in stressful situations. In the military context, where premature return to duty can have dire consequences, valid neuropsychological assessments that are specifically designed for use in military populations would be particularly useful [9]. The incorporation of virtual reality within NCATs may be a novel component to explore further [9]. NCATs with increased ecological validity

would better assess operational performance and assist health care professionals in predicting risk for PCS and facilitating rehabilitation, recovery, and return-to-duty decision after mTBIs [44,45].

Four studies specifically addressed convergent, discriminant, and performance validity for various NCATs, including the Virtual Reality Stroop Test (VRST) [9], ANAM [39], CNS-VS, ImPACT, CogState [32], and single-item measures [46]. Armstrong et al [9] found that VRST significantly correlated with Stroop tests from other NCATs and traditional neuropsychological tests. It was also reported that the VRST conditions correlated significantly with the ANAM PRT and moderately with the ANAM Code Substitution [9]. Thomas et al [46] used signal detection item response theory models to provide initial validation of the Penn Face Memory, Test Penn Word Memory, and Test Visual Object Learning Test among US marines who had experienced mTBIs. Roebuck-Spencer et al [39] addressed an embedded performance validity measure for the ANAM that had moderate success [39]. This demonstrated the potential value of performance validity measures and sample-specific cut-off points in groups with cognitive impairments. Roebuck-Spencer et al [39] recommended higher cut-off points for those expected to have more severe cognitive impairments. Cole et al [32] found no clear patterns suggestive of convergent or discriminant validity between the 4 aforementioned NCATs.

Reliable Change Scores and Scoring Algorithms for Classifying Impairments

Only one study specifically addressed reliable change estimates for the ANAM4-TBI-MIL [47]. The authors suggested that reliable change cut-off scores and the base rates of meaningful change can be used to assist with the identification of postdeployment cognitive issues but should be interpreted with caution.

Determining the Clinical Utility of the Measure

Very few of the included studies addressed the clinical utility of the NCATs. Three studies addressed the usage of NCATs in varying environments, concluding that the DANA and the ANAM demonstrated comparable results and validity when comparing results from a controlled clinical setting with battlefield and deployment settings [41,48]. One study addressed the feasibility of using virtual reality for cognitive assessments [43]. The studies generally did not address issues of clinical utility such as acceptability, feasibility, security, appropriateness, practicability, accessibility, or usability from the perspectives of patients or health care professionals [64].

Discussion

Summarization of Findings

The purpose of this scoping literature review was to systematically explore the evidence regarding the use of NCATs among military personnel who have sustained mTBIs, evaluate the psychometric properties of the most commonly used NCATs for this population, and synthesize data around clinical recommendations for use, knowledge gaps, and future research directions. In total, 33 studies were included in this literature

review, covering a range of constructs and topics related to NCATs. Three NCATs—the ANAM, ImPACT, and DANA—were the most commonly analyzed within the 33 studies.

This study was specific to military personnel who had sustained mTBIs. Many published articles have addressed the psychometric properties of NCATs, such as reliability, validity, sensitivity, and clinical utility, when used to assess cognition following mTBI in the general civilian population. Although this evidence was reviewed at length and used to lay the foundation of this paper, it did not meet the inclusion criteria to be included among the final 33 selected articles.

The 5 criteria proposed by Randolph et al [18] acted as a guide for evaluating the psychometric properties of the NCATs. Even with the paucity of information specific to military personnel with mTBIs, this criterion allowed consideration and discussion of the studies included in the scoping review and paves the way for making recommendations for future research on this topic.

For the first criterion of test-retest reliability, preliminary evidence demonstrates good test-retest reliability for the ImPACT and DANA among healthy military personnel and those with mTBIs and good-to-excellent test-retest reliability for the ANAM [34–37]. This finding is consistent with the reliabilities reported in the literature regarding mTBIs and sport-related mTBIs and are lower than desired for clinical decision making [36]. Although studies varied in test methods and time between testing, ICCs were promising for most of the constructs within these tests [34–37]. It must be noted that the time between testing sessions varied between studies, especially among the ANAM, and the available literature contains conflicting evidence on the length of time that temporal stability is maintained [34,37,65]. Additional studies addressing test-retest reliability with a standardized amount of time between tests and studies with larger sample sizes (especially for the DANA, ImPACT, CNS-VS, and CogSport) would assist health care professionals with clinical decision making regarding their choice of NCAT. The standardized time frame determined for test-retest reliability should be comparable with the recommended, eventual, and/or realistic use of NCATs.

The second criterion was the sensitivity of the tests in the clinical issue of interest. This was addressed by one study in relation to the DANA, which showed favorable results among a group of healthy male military members ($n=202$) [38]. Studies addressing sensitivity with NCATs among general populations have demonstrated good sensitivity of the ANAM, suggesting that this assessment [or this NCAT] has the potential to be used as a diagnostic tool for acute mTBI [13]. Two domains of the ImPACT that accurately classified individuals as concussed or not concussed with a high sensitivity and specificity were memory and speed [66]. Despite this finding, there is no universal evidence that the ImPACT adequately differentiates between healthy controls and individuals who have recently sustained mTBIs [13]. Studies have yet to demonstrate that NCATs have sufficient sensitivity to be used to accurately diagnose mTBIs or other conditions that affect cognition [13].

Validity is the most important aspect of test construction and must be considered when evaluating the clinical utility of a

clinical assessment [13]. Owing to its importance, establishing the validity of a measure is the third criterion considered by Randolph et al [18]. For the ANAM, studies among military and general populations generally demonstrate some construct validity demonstrating that this NCAT is testing the constructs it was designed to test, although a review by Arrieux et al [13] stated that this was “*questionable at best*.” A study by Alsalaheen et al [67], using data from the general population, concluded that there is strong evidence for convergent validity of the ImPACT but weak or inconclusive evidence for discriminant validity, criterion validity, or diagnostic accuracy and utility, that is, there is evidence that NCATs measure similar cognitive constructs as traditional neuropsychological tests. Some evidence suggests that specific components of each NCAT can distinguish between individuals with acute concussion and healthy individuals or between individuals with and without mTBI symptoms [13]. Overall, the literature in this field is yet to provide definitive evidence in support of the convergent, discriminant, criterion, or internal validity of any of the NCATs included in this study [13]. It was also noted that predictive validity of future symptoms has yet to be established for any of the NCATs. Predictive validity would be an asset for health care professionals assisting patients during mTBI recovery [13].

The fourth criterion includes establishing reliable change scores and scoring algorithms for classifying impairment. Of the 33 studies, 1 study addressed reliable change scores for the ANAM; however, a reliable change index was established in 2018 for the ANAM using norms from the general population [47,65]. Reliable change criteria are lacking for many NCATs and should be addressed in future research with military and civilian populations to enable health care professionals to recognize meaningful changes in performance.

The fifth criterion, clinical utility, reveals the most significant knowledge gaps pertinent to patients, health care professionals, and health care organizations. Although the psychometric properties of any clinical outcome measure or assessment are important to establish among the population and condition in question, the discussion of feasibility, accessibility, acceptability, usability, appropriateness, specificity, and other factors is also equally important [64]. The results of the studies included in the scoping review are generally psychometric and research focused. The vast majority ($n=30$) of the papers reviewed highlighted knowledge gaps and recommendations for future research. However, facilitators and barriers to the usage of NCATs and clinical recommendations are generally absent from the papers.

Several additional issues were observed regarding the collective studies included in this study. First, the classification or diagnosis of mTBIs varied across all studies. Some studies relied on self-report to categorize participants into either an mTBI group or a healthy group. This practice is problematic for the following reasons. It is known that mTBIs and other injuries are widely underreported among military personnel. Participants may underreport mTBIs, whether intentionally or because they lack the health literacy to determine whether they have experienced a possible mTBI. It is also possible that some participants did not remember the event or pushed through it in a combat situation without recognizing it as an mTBI. Some

studies either classified mTBIs as sustaining loss of consciousness or used symptom reporting to determine the incidence of mTBIs. Other studies used outcome measures with a set threshold to determine if participants would be in the mTBI or healthy group. Many of these outcome measures, which largely depend on self-reporting of somatic symptoms, do not have clear cut-offs to suspect mTBIs and do not have diagnostic utility. However, further studies reviewed medical records and relied on the diagnosis of mTBIs issued by a health care professional. The variability in methods and inclusion criteria for the mTBI group could affect validity and potentially facilitate the inclusion of those with mTBIs in the healthy group, which increases the chances of type 2 error.

The second concern highlighted by this review is the variation in whether or how the included studies screened participants for secondary conditions, such as depression, PTSD, fatigue and pain. These secondary conditions are known to adversely affect cognitive performance and could act as confounding variables [68]. Numerous studies have demonstrated that the severity of PTSD is negatively correlated with performance on multiple neuropsychological test batteries, including the DANA and ANAM, among military and civilian populations [68,69]. Some studies included in the scoping review explicitly stated that if a participant was enrolled in a military organization, it was assumed that he or she was a healthy individual, which may be an inaccurate assumption [68]. In the study by Brenner et al [42], participants with mTBI symptoms were screened for other conditions and were found to be significantly more likely to have a mental health diagnosis than those without mTBI symptoms. Given the evidence that PCS is not specific to mTBIs and that symptoms following deployment are better accounted for by mental health diagnoses rather than by mTBIs, researchers must consider the impact of neurobehavioral disorders that likely affect military members at a rate greater than that of the general population [5,68,69]. The implications of the increased occurrence of conditions that adversely affect the cognitive function among military populations may also change how normative data are used and interpreted for NCATs in research and clinical practice.

The baseline-referenced comparison approach has minimal supportive evidence from clinical trials but is the standard approach used in sports mTBI management and is favored by the US military, particularly with the ANAM [15,16]. Baseline referencing is thought to improve the sensitivity and specificity of NCAT scores as it controls for some intraindividual factors [15]. This approach is resource intensive and has multiple administrative and logistical barriers for many health care, athletic, and military organizations [15]. Normative referenced approaches are less resource intensive and require the establishment of a criterion-referenced standard to compare test results. Some NCATs use normative data compiled from the general civilian population, such as the ImpACT, whereas others, such as the ANAM, have multiple sets of norms, one of which is specific to the US military population [50,70-72].

When comparing results from a military cohort on the ANAM with both normative and baseline data, no statistical differences between the baseline-referenced approach and the norm-referenced approach for determining decrements in

ANAM performance following mTBIs were observed [15]. In another study, no significant differences were found between the 2 approaches with the ANAM; however, both approaches were noted to be highly inconsistent in identifying military members who were found to have decreased cognitive performance, providing both false positives and negatives [33]. These findings suggest that there is no clear advantage of using the baseline-referenced approach over the norm-referenced approach.

In their 2017 paper, Coffman et al [68] considered the task of establishing a normative data set for the DANA in the context of the active-duty military population, focusing on which population-specific features should be accounted for in the process of defining a normative data set. This data set would consider the effect of conditions that adversely affect the scores of cognitive performance on NCATs. Extending beyond the issue of what population should be used to define normative neuropsychological data among active-duty military personnel, this study also recognized the challenge of identifying the features of a population to measure and control for ensuring that a normative data set truly represents the performance of normally functioning individuals [68].

Apart from the aforementioned occurrences of certain comorbidities within the military population, normative data based on a general adult civilian population tend to include wider age ranges from 18 to 85 years. The military population is much younger, often within the age range 18-60 years. Within this study, the average age of the participants included was 27.31 (SD 4.10) years, much younger than the normative age included in the general population norms. Studies addressing norm-based and baseline comparisons within military populations demonstrated variable results and raised more questions on best practices for clinical interpretation of cognitive performance scores on NCATs. This requires future consideration and research with military populations.

Recommendations

A number of key recommendations were isolated from studies that are relevant for health care professionals. Most prominently, NCATs should be used cautiously and only as one source of information from among many other types of clinical tools and observations. It is not advisable that NCATs be used as a definitive or standalone diagnostic tool [40]. Cole et al [32] recommended that health care professionals should use the test they feel best fits their needs and targeted population for screening and follow-up assessments. Studies also noted that health care professionals should expect a decline in cognitive performance as age increases on the ImpACT and ANAM [49-51]. In addition, participants' level of education may affect cognitive performance scores [49-51]. As the evidence-based literature on NCATs evolves, health care professionals must remain aware of forthcoming recommendations. Health care organizations and researchers will play an important role in translating this information promptly and accurately to facilitate improvements in clinical practice.

Future Research

The findings of this scoping literature review have led to the formulation of the following recommendations for future research. First, it is apparent that more research is needed to better establish the psychometric properties of NCATs among military and civilian populations from a global perspective. Studies conducted in countries or military organizations outside of the United States are needed to assess constructs related to clinical utility within their specific contexts and populations. Research on the usage of NCATs within different deployment environments would also be beneficial. Furthermore, longitudinal studies that address temporal stability or test-retest reliability over time with different NCATs would be an asset. Studies that address the psychometric properties and clinical utility of NCATs with other conditions known to adversely affect cognitive functioning among military populations, such as depression, PTSD, sleep deprivation, chronic pain, and others, would be particularly beneficial. This would allow clinicians to better assess cognitive performance allowing them to make more informed clinical decisions. These decisions have the potential to influence the function, productivity, and safety of military members, their units, and those they interact with through their high-stake occupations. This would also assist clinicians in designing rehabilitation plans that target specific domains of cognition, leveraging cognitive strengths, and targeting areas of reduced performance.

Studies with a larger number of military personnel with mTBIs, or other conditions that affect cognition, would be an asset, especially for clarifying recovery trajectories and possibly return-to-duty decisions [45]. Future studies would be improved by applying a consistent definition and diagnoses of mTBI and related secondary conditions. It will also be important for future studies, particularly those focused on a specific condition, to test and control for other injuries or illnesses to minimize confounding variables.

Further research is also needed to better determine if using NCATs for baseline testing is indicated or if normative-based comparisons are valid for use in a clinical setting. Furthermore, the field would benefit from the establishment of standardized NCAT norms for military populations that represent not only healthy individuals but also those with mTBIs and other conditions that affect cognition.

Finally, studies that further address clinical utility, including the feasibility, accessibility, acceptability, usability, appropriateness, specificity, and other pragmatic factors, are needed to contextualize the use of NCATs and assist health care professionals with clinical decision making around which NCAT to use in practice, what rehabilitation is indicated, and how NCATs may guide the return-to-duty decisions. Evidence-based literature and guidelines on best practices that discuss facilitators, barriers, and recommendations for NCATs and digital health technologies would support health care professionals working with military personnel experiencing cognitive dysfunction.

Strengths and Limitations

There are a number of notable strengths of this scoping review. This study was conducted following a planned a priori procedure, with attention to ensuring quality control and minimizing bias. The detailed search strategy was extensive, including 7 databases. The inclusion and exclusion criteria were determined before study onset and adhered to throughout. Appropriate calibration and pilot testing, use of at least two independent reviewers for all stages of the process, and group discussion of conflicts improved the quality of this scoping review.

Several limitations of this scoping review also warrant discussion. First, although the review process was calculated and rigorous, it is possible that relevant studies related to military personnel with mTBIs and NCATs were overlooked. Second, it is noted that other studies specific to civilian populations exist that were not included in this scoping review, which may include important information. Third, with the rapid rate of research and publishing on this topic, it is plausible that additional research has been published before the release of this scoping review. Finally, the limits of aggregate data and specific nuanced details may have become generalized during the synthesis process.

Conclusions

Cognitive functioning is imperative to the day-to-day activities of military personnel in their work, self-care, and leisure activities. Military members must be able to make decisions in precarious and ambiguous situations where risk to self and others is high and must possess an adequate level of cognitive functioning to communicate, use weapons and technological devices, and perform other military duties without error. Assessing cognitive functioning is part of a multidisciplinary best practice protocol for the management and treatment of mTBIs [1,2,13]. NCATs are one such tool that can be used to assist health care professionals with treatment plans and guide recommendations about an individual's readiness to return to activity.

The results of this study indicated that the published literature regarding NCAT usage among military personnel who have sustained mTBIs is quite heterogeneous in study design, construct being measured, and outcome goals. On the basis of the 5 Randolph Criteria [18], the psychometric properties of the most commonly evaluated NCATs among this population have yet to demonstrate adequate validity, reliability, sensitivity, and clinical utility for military personnel with mTBI. In addition, NCATs do not have the established diagnostic utility to identify which military members have sustained mTBIs and which have not. Additional research is needed to further validate NCATs within military populations, especially those outside of the United States and those who experience other conditions known to adversely affect cognitive processing. Further study of psychometric properties, clinical utility, and the utility of baseline and normative testing for NCATs is needed to assist health care professionals in improving clinical decision making and services for military personnel experiencing cognitive dysfunction.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Detailed search strategy.

[DOCX File, 16 KB - [mental_v8i2e26360_app1.docx](#)]

Multimedia Appendix 2

Summary of included studies.

[DOCX File, 31 KB - [mental_v8i2e26360_app2.docx](#)]

Multimedia Appendix 3

Detailed descriptive analysis of studies included in the scoping review.

[DOCX File, 1208 KB - [mental_v8i2e26360_app3.docx](#)]

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Abbreviations

ANAM: Automated Neuropsychological Assessment Metric

CNS-VS: CNS-Vital Sign

CogState: Axon Sports' CogState Sport

DANA: Defense Automated Neurobehavioral Assessment

ICC: intraclass correlation coefficient

ImPACT: Immediate Post-Concussion Assessment and Cognitive Testing

MOI: mechanism of injury

mTBI: mild traumatic brain injury

NCATs: Computerized Neurocognitive Assessment Tools

OEF: Operation Enduring Freedom

PCS: postconcussion symptoms

PICO: Population, Intervention, Comparison, and Outcome

PRISMA-ScR: Preferred Reporting Items for Systematic Reviews and Meta-analyses extension for Scoping Reviews

PRT: prolonged reaction time

PTSD: posttraumatic stress disorder

SRT: simple reaction time

VRST: Virtual Reality Stroop Test

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Original Paper

Characteristics of the Users of Troubled Desire, a Web-Based Self-management App for Individuals With Sexual Interest in Children: Descriptive Analysis of Self-assessment Data

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Abstract

Background: Despite the high prevalence of child sexual offenses and the increasing amounts of available child sexual abuse material, there is a global shortage of preventive interventions focusing on individuals at risk of sexual offending. The web-based app Troubled Desire aims to address this shortage by offering self-assessments and self-management training modules in different languages to individuals with sexual interests in prepubescent and early pubescent children (ie, those with pedophilic and hebephiliac sexual interest, respectively).

Objective: The aim of this study was to describe the characteristics of the users of the Troubled Desire app.

Methods: The fully completed self-assessment data gathered within the first 30 months of this study from October 25, 2017 to April 25, 2020 were investigated. The main outcome measures were (1) sociodemographic information and (2) sexual interests and sexual behaviors of the users of Troubled Desire.

Results: The self-assessment was completed by 4161 users. User accesses were mainly from Germany (2277/4161, 54.7%) and the United States (474/4161, 11.4%). Approximately 78.9% (3281/4161) of the users reported sexual interest in children; these users were significantly more likely to report distress and trouble owing to their sexual interest. Further, child sexual offenses and consumption of child sexual abuse material were significantly more common among users with sexual interest in children than among users with no sexual interest in children. Additionally, the majority of the offenses were not known to legal authorities.

Conclusions: The Troubled Desire app is useful in reaching out to individuals with sexual interest in prepubescent and early pubescent children. However, future research is warranted to understand the prospective relevance of the Troubled Desire app in the prevention of child sexual offending.

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KEYWORDS

pedophilia; hebephilia; child sexual offenses; child sexual abuse material; web-based assessment; web-based treatment

Introduction

Background

Child sexual offenses and consumption of child sexual abuse material (CSAM) are global problems of great magnitude. A recent meta-analysis of 55 studies from 24 countries revealed prevalence estimates of child sexual offenses ranging from 8% to 31% for girls and from 3% to 17% for boys [1]. Additionally, the increasing use of the internet has resulted in considerable growth in the available CSAM content. In 2010, the Internet Watch Foundation identified 1351 webpages providing CSAM. These numbers escalated to 13,182 in 2013 and to 105,047 in 2018—more than a seven-fold increase within 8 years [2]. Experiencing sexual abuse during childhood can have profound negative short-term and long-term effects on the psychological and physiological well-being of children, including substance abuse, depression, suicidal tendencies, sexualized and risk-taking behavior, and increased risk for revictimization [3]. Self-evidently, the high number of sexually abused children and the harmful effects on their health status crucially demand prevention interventions to prevent child sexual victimization. A target group that is particularly suitable for prevention approaches are individuals with pedophilia (sexual interest in prepubescent children) [4] and individuals with hebephilia (sexual interest in early pubescent children) [5]. Pedophilic and hebephiliac sexual interests are not prerequisite for engaging in child sexual offenses or for the consumption of CSAM. However, both pedophilia and hebephilia can be regarded as the major risk factors for committing sexual offenses against children [6,7]. Pedophilic and hebephiliac individuals account for approximately 40%-50% of the officially registered child sexual offenses [8]. The consumption of CSAM seems to be a stronger indicator of pedophilic and hebephiliac sexual interest than committing sexual offenses against children [9].

In Germany, it has been possible to establish a network of outpatient treatment services for self-identified adolescents and adults with sexual interests in prepubescent and early pubescent children, regardless of their offending history [10,11]. The aim of these outpatient treatment services is to support these individuals in guaranteeing continuous sexual self-control to prevent initial or repeated child sexual offenses and consumption of CSAM. These treatment services have been made possible by the pledge of confidentiality for therapists under the German law. Unlike many other countries, Germany does not have a mandatory reporting policy; therefore, health care professionals (ie, therapists, physicians, or social workers) are not obliged to report actual or suspected past offenses. Hence, therapeutic offers are also provided to individuals who voluntarily seek help concerning their sexual attraction to children, even if they have offended in the past. Further, in cases of acute danger to children, the treatment services act according to a structured child protection procedure. To terminate the acute danger, the procedure ranges from implementation of specific and feasible strategies (eg, involvement of third parties to enhance social control, move out of the shared apartment) to consideration of medical interventions to reduce sexual impulses and ultimately, to admission to a psychiatry clinic [12]. In many other countries, such treatment services are not possible. There are mandatory

reporting laws, which require certain professionals to report actual or suspected cases of child sexual offense and the use of CSAM to government authorities. Anyone who does not report actual or suspected cases will be liable to prosecution [13]. Individuals at risk of sexual offending or with history of offending behavior do not, therefore, receive therapeutic support without being reported to the authorities, which may discourage them from seeking help to prevent future sexual offending behavior [14]. However, it must be considered that in-person treatment is not suitable for all individuals in need of help. Besides practical barriers, including long waiting lists, distance to treatment services, travel expenses, or time conflicts between treatment availability and daily work, other emotional/psychological barriers such as shame or fear of stigmatization might prevent individuals from seeking help [15]. Furthermore, the abovementioned German outpatient treatment services are designed for individuals who are not under judicial supervision due to a sexual offense. Individuals who have recently been reported to governmental authorities or with criminal proceedings in process are not included in the program.

Summing up, we are facing a clear undersupply of preventive interventions focusing on relapse or prevention of child sexual offending. An option for individuals who want to seek help but are unable to receive in-person treatment (due to the reasons stated above) is the use of web-based interventions. Web-based interventions can be accessed anytime and anywhere, and anonymity can easily be ensured, which may encourage honesty and openness. There is a diverse range of web-based interventions. Some are solely psychoeducative, while others offer practical training modules. Some interventions also offer professional guidance and personalized feedback, while others are merely self-help websites [16,17]. Several meta-analyses have supported the application of web-based interventions for a variety of psychological disorders [18-25]. A meta-analysis performed on 92 studies investigating the effectiveness of web-based psychological interventions found a medium effect for such interventions (mean weighted effect size of 0.53), which is comparable to the effect sizes of in-person treatments [26].

In recent years, web-based interventions targeting sexology and forensic psychiatry have become established [27,28]; however, the offer is still scarce. The Candeo Treatment Program [29] offers a comprehensive web-based program to help individuals struggling with addictive pornography use. Preliminary results of the cognitive behavioral therapy approach of Candeo were promising as there was a reduction in pornography consumption and masturbation frequency after the treatment was introduced. Additionally, participants reported that Candeo was more helpful than the other treatments they had tried [30]. Kernsmith and Kernsmith [31] examined the process and effectiveness of a self-help group for recovering sex offenders. This group was moderated by 2 nonprofessionals, who themselves had offended in the past, and this group was created to provide a space to discuss feelings and struggles in a safe environment. Preliminary results indicated that this group had a reduction in the risk factors associated with recidivism (eg, cognitive distortions, compulsive behaviors, obsessive thoughts).

Web-based interventions specifically designed for individuals with sexual interest in children barely exist. To our knowledge,

there is 1 German-speaking (Gemeinsam statt allein, Together instead of alone, in English [32]) and 2 English-speaking (VirPed [33] and B4uact [34]) peer-support forums specifically designed for individuals with sexual interest in children. These forums aim to provide peer support and information about the available resources on how to prevent sexual offenses and lead a content life. Furthermore, regarding professional web-based programs, apart from Troubled Desire, there are only 2 other self-help programs for individuals with sexual interest in children: (1) Help Wanted [35] and (2) the self-help program of Stop it now! [36]. Help Wanted was recently developed (published online in 2020) at the Moore Center for the Prevention of Child Sexual Abuse at Johns Hopkins Bloomberg School of Public Health, and it provides video modules and additional material to help individuals manage their sexual attraction and build a healthy nonoffending life. Stop it now! is a project of the UK-wide child protection charity Lucy Faithfull Foundation and offers live chats, secure messaging, and a confidential helpline to individuals who are concerned about their sexual thoughts, feelings, or behavior toward children. Lately, a self-help section has been established offering information concerning sexual interest in children, facts and consequences of sexual offending, and hints on how to abstain from abusive behaviors. To date, evaluation studies of both web-based programs have not been published. Consequently, programs that specifically aim to prevent child sexual offenses and the consumption of CSAM are scarce. The few existing programs are rather short and do not offer self-assessments regarding sexual fantasies and sexual behavior (including child sexual offense and the consumption of CSAM). However, completion of the assessments can already be regarded as a critical reflection of one's own sexual interest and sexual behavior [37]. Moreover, especially the feedback after the completion offers clarification about the problematic sexual behavior. In line with that, behavioral changes have been associated with the individual's perception of their own behavior as "problematic" [38]. The existing programs are mainly available in English, and non-English-speaking individuals have not been addressed so far (except for Gemeinsam statt allein). This is where the innovative potential of Troubled Desire comes in. Troubled Desire was developed at the Berlin Institute of Sexology and Sexual Medicine to provide web-based (1) self-assessments and (2) self-management training modules for individuals with sexual interest in prepubescent and early pubescent children. To reach out to individuals from various countries and regions, Troubled Desire is available in different languages. Troubled Desire aims to prevent child sexual offense and the use of CSAM and to alleviate the distress experienced by those with sexual interest in children.

Study Aim

The aim of this study was to describe the population who completed the self-assessment within the first 30 months after the launch of the Troubled Desire app. We report on the following characteristics of the users of this app: (1) sociodemographics, including gender, age, and country of origin, and (2) sexual interest and offense characteristics.

Methods

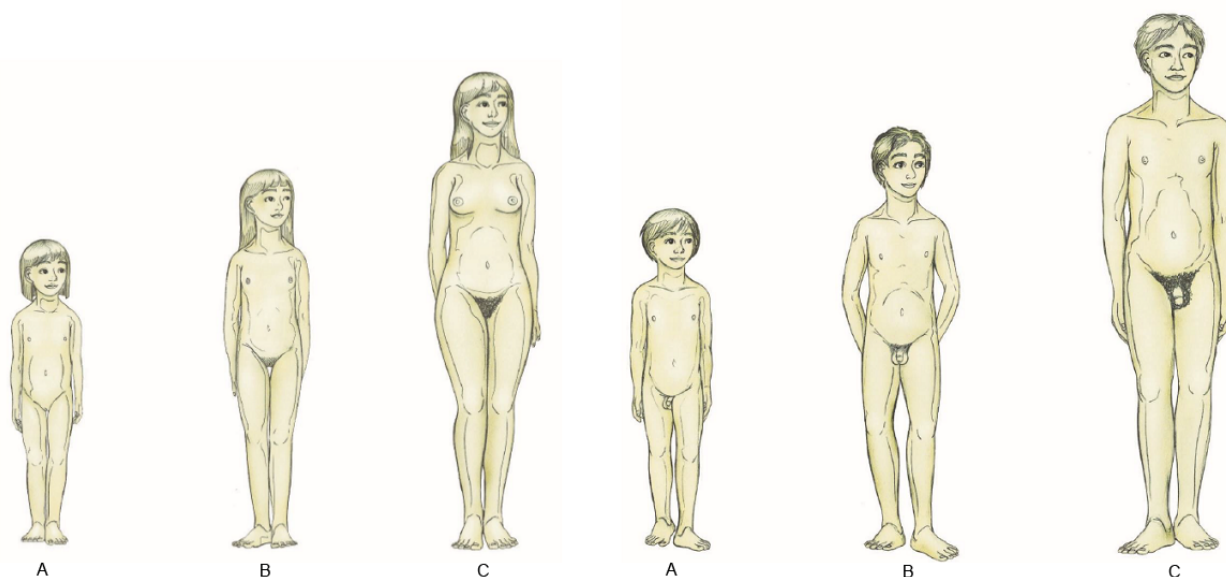
Description of the App

Troubled Desire is a web-based app that requires an internet-enabled device and a common web browser. This app is composed of (1) a self-assessment and (2) self-management training modules for individuals with sexual interest in prepubescent and early pubescent children. During this study, 7 different language versions were gradually implemented: English (since October 25, 2017), German (since April 25, 2018), Spanish (since October 1, 2018), Portuguese (since July 12, 2019), French (since July 19, 2019), Hindi (since September 12, 2019), and Marathi (since December 1, 2018). This app was approved by the institutional review board of the Charité-Universitätsmedizin Berlin.

Self-assessment

At the outset of the self-assessment, the user is provided with a unique personal and randomly generated 9-letter long session ID that allows them to interrupt and continue the session and correct or update the given answers at any time. The self-assessment contains 100-280 questions, which depends on the given answers as there are subquestions depending on the answers given for the main questions, thereby leading to an extended assessment. The processing time takes about 15-30 minutes. The assessment contains questions concerning the sociodemographic background, sexual interest regarding the age and gender of the fantasized partner, the use of CSAM, child sexual offense, and judicial status (if applicable). Illustrations of the Tanner stages (illustrations of the physical development from prepubescent children to adults [39,40]; Figure 1) are displayed throughout the assessment to facilitate responses relating to the age of the sexually fantasized partner. The assessment is solely based on self-report. After completion of the self-assessment, the user receives feedback concerning his/her sexual interest (ie, pedophilic and hebephiliac sexual interest) and sexual behavior, including the child sexual offense and the use of CSAM, if reported.

Figure 1. Developmental age categories according to the Tanner stages. A. Tanner stage 1, prepubescent body scheme; B. Tanner stages 2 and 3, early pubescent body scheme; C. Tanner stages 4 and 5, adult body scheme.



Self-management Training Modules

The self-management training modules are based on the Berlin Dissexuality Therapy Program [12] and address major risk factors for child sexual offense and the use of CSAM. The training modules are psychoeducational and give instructions on, for example, how to exercise emotion regulation, train awareness and mindfulness, or how to integrate the sexual interest in children in the self-concept.

Data Collection

Data from the self-assessment are saved anonymously on a server at the Charité-Universitätsmedizin Berlin. No internet protocol addresses or server log files are stored. This web-based app has not run web analytics processes. Therefore, there was no count of the actual visitors of the website. The user's country of origin, date, and time of access were automatically identified upon entry by an internally hosted module. Countries with 100,000 inhabitants or less were identified as "anonymous" by the module. This was done to increase granularity so that the identification of individual users was not possible, since the identification of individuals would have been possible with a unique combination of characteristics such as number of children together with the precise profession and knowledge about the country of origin.

Dissemination of the App

A strategy for web-based and offline advertising was implemented with a focus on Germany and India. The focus was due to 2 reasons: (1) the availability of a treatment infrastructure that users of Troubled Desire might turn to in case of increased need for assistance and (2) an already existing recruitment strategy with high reach from which Troubled Desire could benefit by being embedded. Web-based activities included advertising on partner websites and social media as well as warnings in search engines and peer-to-peer networks. Offline activities included advertising on television, public transport, and billboards. Media coverage also played a role in

increasing awareness of the service. The app was promoted by the prevention network "Kein Täter werden" (or Don't offend [10]) in Germany and "Program for Primary Prevention of Sexual Violence" in India [41], which offer specialized outpatient treatment for people with sexual interest in children.

Measures

This study investigated the selected questions from the self-assessment. Besides sociodemographic information, the following key variables were examined: (1) presence and absence of sexual interest in children (ie, pedophilic and hebephiliac sexual interest), (2) distress, or (3) trouble due to the given sexual interest, (4) child sexual offense, (5) CSAM consumption, and (6) judiciary status. Sexual interest in children was assessed with dichotomous (yes/no) questions regarding the presence of sexually arousing fantasies of prepubescent children (attracted by the body scheme of Tanner stage 1, ie, pedophilia) or early pubescent children (attracted by the body schemes of Tanner stages 2 and 3, ie, hebephilia) for at least 6 months. This time specification refers to the time criterion for pedophilia of the fifth edition of the Diagnostic and Statistical Manual of Mental Disorders [4]. The following sample item was asked to assess the presence of sexual interest in children: "During masturbation, I find childlike girls/girls with a prepubescent body type (ie, no pubic hair or developed breasts) sexually arousing for at least six months." Sexual interest in children was counted as yes if users either reported sexual interest in prepubescent children or early pubescent children or both (regardless of gender). Sexual interest in children was counted as no if users negated sexual interest in both prepubescent children and early pubescent children (ie, exclusive sexual interest in adults, attracted to the body schemes of Tanner stages 4 and 5). Distress and trouble due to the stated sexual interest was assessed with 2 dichotomous (yes/no) questions (Do these fantasies cause you any distress? or Do these sexual desires cause you any trouble in your romantic, social, or professional life?). To assess child sexual offense, 10 questions were analyzed with increasing gravity of the abuse behavior.

Questions ranged from taking nude pictures of a child (I have engaged sexually with a child, for instance, taking nude photos/videos, watching pornography together, talking about sex, etc) and making a child perform sexual acts (I have made a child perform sexual acts either on himself/herself or with another child while I was watching) to penetrating a child (I have put my penis into a child's butt). To answer the questions, users had to select 1 out of the 4 provided options: (1) never, (2) some time ago, (3) recently, and (4) currently. For this study, if any child sexual offense question was answered with (2) some time ago, (3) recently, or (4) currently, the child sexual offense was counted as yes. If every child sexual offense question was answered with (1) never, the child sexual offense was counted as no. Furthermore, in the presence of the reported child sexual offense, lifetime child sexual offense ([2] some time ago, [3] recently, [4] currently) was differentiated from recent child sexual offense ([4] currently). We analyzed 4 dichotomous (yes/no) questions to assess lifetime consumption of CSAM. Questions ranged from children in erotic poses (Have you used depictions of children in clothed, lightly clothed, or naked in erotic/arousing/provocative poses?) to depictions of sexual acts (Have you used depictions of sexual acts with children and adult/adults?). Four similar questions were asked to assess the consumption of CSAM within the last 6 months (eg, Have you used depictions of children in clothed, lightly clothed or naked in erotic/arousing/provocative poses within the last six months?). If any lifetime CSAM question was affirmed, lifetime CSAM consumption was counted as yes. If any question on CSAM consumption within the last six months was affirmed, recent CSAM consumption was counted as yes. If child sexual offense (lifetime or recent) or CSAM consumption (lifetime or recent) was reported, a question followed enquiring users to indicate whether the offense or the offenses had been detected by legal authorities (Have you ever been in contact with the legal authorities for owning/using/distributing such material? or Have you ever been in contact with the legal authorities for child sexual abuse?). Three options were provided to answer the questions: (1) no, (2) prosecuted, and (3) sentenced. Furthermore, to assess the user's country of origin, we analyzed data, which were automatically identified by an internally hosted module.

Users

Users refer to individuals who answered at least one question of the self-assessment and therefore left at least one data point. We focused our analyses on these users who completed the assessment within the first 30 months after the launch (October 25, 2017 to April 25, 2020). We included users irrespective of whether they engaged in the self-management modules or not. Users were able to access the self-assessment from anywhere (not just in the countries based on the currently available 7 languages) and choose their preferable language option. Users of all predetermined age categories (see Statistical Analysis) were included in this study. Accordingly, the following inclusion criteria were applied: completion of the self-assessment within

the first 30 months after the launch and fully completed assessment.

Statistical Analysis

Data were analyzed using SPSS Statistics Version 25.0 (IBM Corp). Data of the user characteristics were analyzed descriptively. Pearson chi-square tests were employed to assess group differences (users with sexual interest in children vs users without sexual interest in children). The statistical level of significance was set at .05. As participants indicated their age by predetermined age categories ranging from "14-15 years" to "70 years and above," age results were reported by the mode and the respective full range.

Results

A total of 7496 users started the self-assessment of Troubled Desire within the first 30 months after the launch. The assessment was fully completed by 4161 users. Of these, 90.9% (3783/4161) were males, 6.9% (289/4161) were females, and 2.1% (89/4161) did not assign to the binary gender system (referred to as nonbinary). Approximately 80.0% (3329/4161) of the users were younger than 40 years. The most frequently chosen age category was "19-21 years" (mode). The most common geographical accesses were from Germany (2277/4161, 54.7%) followed by the United States (474/4161, 11.4%), France (130/4161, 3.1%), and the United Kingdom (131/4161, 3.1%, Table S1 of [Multimedia Appendix 1](#)).

Approximately 78.9% (3281/4161) of the participants reported sexual interest in children (ie, pedophilic and hebephiliac sexual interest; [Table 1](#)). Users with sexual interest in children were significantly more likely to report distress ($X^2_1 [N=4161]=758.1, P<.001$) and trouble ($X^2_1 [N=4161]=305.2, P<.001$) than users who did not have sexual interest in children. We observed a significant relationship between sexual interest and sexual offense behavior. Users with sexual interest in children were more likely to report both lifetime ($X^2_1 [N=4161]=631.4, P<.001$) and recent CSAM consumption ($X^2_1 [N=4161]=578.1, P<.001$) than users without sexual interest in children. Additionally, both lifetime ($X^2_1 [N=4161]=151.9, P<.001$) and recent child sexual offense ($X^2_1 [N=4161]=13.1, P<.001$) were significantly more common among users with sexual interest in children than among users without sexual interest in children.

Sexual offenses have mainly been undetected by legal authorities. Comparing both groups, the chi-square test showed that users with sexual interest in children were less likely to be in contact with the justice system because of child sexual offense ($X^2_1 [n=1530]=5.2, P=.02$) than were users without sexual interest in children. The proportion of users who had contact with the legal authorities did not differ by sexual interest ($X^2_1 [n=2626]=0.5, P=.83$).

Table 1. Sexual interest and offense characteristics of the users of the Troubled Desire app (N=4161).

Characteristics	Users with sexual interest in children ^a (n=3281), n (%)	Users without sexual interest in children (n=880), n (%)	Chi-square (<i>df</i>)	<i>P</i> value
Sexual interest				
Distress due to sexual interest	2405 (73.3)	200 (22.7)	758.1 (1)	<.001
Trouble due to sexual interest	1673 (51.0)	159 (18.1)	305.2 (1)	<.001
Offense characteristics				
Consumption of child sexual abuse material, lifetime	2390 (72.8)	236 (26.8)	631.4 (1)	<.001
Consumption of child sexual abuse material, recent	2157 (65.7)	180 (20.5)	578.1 (1)	<.001
Prosecuted or sentenced	388 (16.2)	37 (15.25)	0.5 (1)	.83
Child sexual offenses, lifetime	1363 (41.5)	167 (19.0)	151.9 (1)	<.001
Child sexual offenses, recent	163 (5.0)	19 (2.2)	13.1 (1)	<.001
Prosecuted or sentenced	128 (9.4)	25 (15.0)	5.2 (1)	.01

^aPedophilic and hebephiliac sexual interest.

Discussion

Overview of the Findings

This study presents the first assessment of Troubled Desire, a web-based program that offers anonymous and confidential (1) self-assessments and (2) self-management training modules for individuals with sexual interest in children (ie, pedophilic and hebephiliac sexual interest). The data of the users within the first 30 months after the launch of Troubled Desire were analyzed. We compared users who reported sexual interest in children with users who did not report sexual interest in children (ie, exclusive sexual interest in adults). The following main findings were derived: (1) distress and trouble due to sexual interest and (2) child sexual offenses and the use of CSAM were significantly more common among individuals with sexual interest in children than among individuals without sexual interest in children ($P<.001$), and (3) the vast majority of child sexual offenses and CSAM offenses were not known to legal authorities.

Pedophilia has been associated with clinically relevant distress [42], anxiety [43-45], stigmatization, and discrimination [15,46]. This is in accordance with our results that point to a significant association between sexual interest in children and the reported distress and trouble in the romantic, social, or professional life. Jahnke [47] has shown that individuals with sexual interest in children and stigma-related distress rarely seek therapeutic help, which increases the likelihood of offending or reoffending. For those individuals, a web app might provide a good opportunity to receive low-threshold support. However, considering that guided treatment is superior to unguided treatment [24], we cannot yet state whether such a web-based app is sufficient for reducing the risk of offending or reoffending and for increasing the mental well-being. Future studies will be necessary to examine the potential and weaknesses of guided treatments, particularly regarding the reduction in the offending behavior. Child sexual offenses and the use of CSAM were significantly more common among individuals with sexual interest in children. This is in line with the notion that pedophilia and

hebephilia can be regarded as the major risk factors for committing child sexual offense and for the consumption of CSAM [6,7].

First results of the treatment program of the Berlin-based outpatient treatment service for individuals with sexual interest in children revealed a significant reduction in the risk factors associated with the offending behavior (eg, offense-supportive cognition, emotional deficits) and a drop in the offending behavior on a descriptive level [10]. These initial results are promising, and considering user accesses from more than 80 countries, an international expansion is suggested. The need for expansion is also underlined by the fact that access rates highly differed. As the majority of the accesses stem from Germany (2277/4161, 54.7%), it seems to be easier to reach out to the target group when an established project structure with a history of media campaigning and public awareness already exists (eg, the prevention network “Kein Täter werden” [10]). In India, this app has indeed been promoted by the “Program for Primary Prevention of Sexual Violence” [41]. However, this treatment service has just been developed recently. Additionally, we do not yet know whether transferability of the treatment approach to other countries with different cultural backgrounds is feasible. Therefore, it might be interesting to investigate which resources might be necessary and which barriers must be eliminated to apply the treatment approach to other countries.

Most of the sexual offenses remained undetected. This finding emphasizes that disclosed cases of child sexual offending represent only a small portion of the total offenses. The actual number of the cases are much higher. The high number of undetected cases is alarming and stresses that it is indispensable to invest in global preventive measures. Referring to our results, it is questionable why users with sexual interest in children were significantly less likely to be in contact with the justice system because of child sexual offense than users without sexual interest in children. It might be speculated that those users were *better* at covering up their offenses or might have intimidated their victims to a great degree. Additionally, it might be hypothesized that their offenses were acted according to an intended

procedure, whereas users without sexual interest in children might have abused rather impulsively.

In this study, almost half of the users (3335/7496) accessed and started the self-assessment without completing it. It remains unclear why these users were intrigued in the beginning but dropped out at some point. Conceivable reasons are that some participants aborted the assessment because they felt deterred by explicit sexual questions or were afraid of being detected. Future evaluations of Troubled Desire should therefore focus on the dropouts and whether certain questions might have led to more dropouts. More male users than female users (and nonbinary users) accessed Troubled Desire. This indeed coincides with the findings in existing literature showing that sexual interest in children is more common in men than in women [48,49]. At the same time, this also underlines the fact that sexual interest in children is also found in women. Future evaluations should focus more on possible gender differences and on the subgroup of nonbinary users in terms of sexual interest or sexual behavior.

Limitations of This Study

This study has a few limitations. First, Troubled Desire is anonymous and does not store internet protocol addresses or server log files. Therefore, we cannot verify whether the given data in the self-assessment is related to a real-life person. Second, we were not able to verify whether users truthfully

answered the questions. It might have been possible that users suppressed or whitewashed certain information. However, as the self-assessment was anonymous, we do not expect a major confoundment here. Third, we were not able to operationalize recent child sexual offenses and recent CSAM consumption similarly, as questions within the self-assessment varied for both question blocks. The questions on child sexual offenses differentiated between (1) never, (2) some time ago, (3) recently, and (4) currently. Recent child sexual offense was accounted as yes, if any child sexual offense question was answered with (4) currently. However, recent CSAM was assessed with a specified time frame, that is, within the last 6 months. We can, therefore, not certainly state that answers to those questions refer to the same time period.

Conclusions

Troubled Desire was able to reach out to individuals with sexual interest in children. User characteristics confirmed findings in prior studies with evidence for more distress and child sexual offending behavior (ie, child sexual offenses, consumption of CSAM) in individuals with sexual interest in children. Though its prospective relevance in the prevention of child sexual offending remains to be seen, we think that Troubled Desire has, nonetheless, the potential for providing self-assessments and self-assessment training modules for those who do not seek help or cannot obtain help from health care professionals for reasons of mandatory reporting, fear, or lack of accessibility.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Country of origin of the users.

[DOCX File, 19 KB - [mental_v8i2e22277_app1.docx](http://mental.jmir.org/2021/2/e22277_app1.docx)]

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Abbreviations

CSAM: child sexual abuse material

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Original Paper

The Impact of a Digital Intervention (Happify) on Loneliness During COVID-19: Qualitative Focus Group

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Abstract

Background: Loneliness is a growing area of concern, attracting attention as a public health concern due to its association with a variety of psychological and physical health problems. However, interventions targeting loneliness are less common than interventions for other mental health problems, such as depression and anxiety, and existing interventions focus primarily on building social skills and increasing opportunities for social interaction despite research suggesting these techniques are not the most effective. Furthermore, although there is an increasing need for scalable and convenient interventions, digital interventions for loneliness are even less common.

Objective: Using a qualitative approach, we explore how adults (18-64 years of age) who express wanting to be more connected to others experience loneliness and react to a digital mental health intervention targeting loneliness.

Methods: A total of 11 participants were recruited from a pilot randomized controlled trial exploring the impact of a digital mental health intervention, Happify Health, on loneliness among adults aged 18-64 years who indicated wanting to feel more connected to others when signing up for the platform. Participants were invited to participate in a 3-day asynchronous focus group about their experiences with loneliness, with Happify Health, and with social distancing during the COVID-19 pandemic. All 11 participants completed the focus group in May 2020.

Results: Participants' responses were coded using thematic analysis, which led to identifying five themes, each with separate subthemes, that could be applied across the 3-day focus group: loneliness, relationships, social distancing, skill acquisition, and coping. Overall, we observed variability across participants in terms of the source of their loneliness, their perceptions of their social connections, and their motivation to reduce feelings of loneliness; however, participants commonly referred to negative self-perceptions as a cause or consequence of loneliness. Participants also varied in the extent to which they felt social distancing increased or decreased feelings of loneliness. In regard to the intervention, participants showed evidence of adopting skills they used to address their loneliness, particularly mindfulness and gratitude, and then using these skills to shift toward more active coping strategies following the intervention, including during the COVID-19 pandemic.

Conclusions: The heterogeneity in participants' experiences with loneliness described during this focus group emphasizes the subjective and complex nature of loneliness. This highlights the importance of developing loneliness interventions that use a variety of strategies, including both direct and indirect strategies for reducing loneliness. However, based on our data, a key component to loneliness interventions is incorporating strategies for addressing underlying negative self-perceptions that stem from, but also contribute to, loneliness. This data also provides preliminary evidence that digital platforms may be an effective tool for disseminating loneliness interventions while providing the added benefit of offering a productive distraction when feeling lonely.

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KEYWORDS

loneliness; digital interventions; COVID-19; qualitative research; perspective; impact; intervention; lonely; mental health; e-mental health; digital health; focus group

Introduction

Background

Loneliness is the feeling that one's preferred social relations fall short of their actual social relations [1]. In the last decade, loneliness has become a growing area of concern, and with emerging trends suggesting Americans are less socially connected than before, researchers posit loneliness will only become more of an issue over time [2]. In fact, the former 19th US Surgeon General recently argued loneliness is a public health concern [3], labeling problems with loneliness an epidemic [4].

In industrialized countries, researchers estimate that approximately one-third of the population struggle with loneliness, and one-quarter of those will struggle with severe levels of loneliness [5]. In addition, the number of people coping with loneliness may be higher in some regions than in others. For example, although nationally representative surveys of adults 45 years or older living in the United States indicated that about 35% of people are lonely [6], a study of community-dwelling adults in California found that 76% of their sample reported at least moderate levels of loneliness [7]. The reasons for such variability are unclear; however, loneliness appears to be contagious, occurring in clusters and then spreading through social networks [8], which may explain why loneliness may be unusually high in some geographical areas.

However, loneliness is of particular concern because it can then lead to a number of other psychological and physical problems [9]. For example, daily reports of loneliness predict daytime dysfunction [10], and higher levels of chronic loneliness also predict functional limitations [11], increased systolic blood pressure [12], and greater mortality risk [11,13]. Research with cancer survivors suggests loneliness increases the risk for immune dysregulation, leading to higher levels of pain, fatigue, and depression in female breast cancer survivors [14]. Although a lot of research has focused on the bidirectional relationship between loneliness and depression [11,15], loneliness has also been tied to a higher risk of developing severe common mental disorders, including mood disorders, anxiety disorders, and substance use disorders [16], and to elevated risk of developing Alzheimer disease and other forms of dementia, even when controlling for other risk factors [17,18]. In turn, loneliness predicts increased physician visits among older adults [19] and is associated with higher health care costs [20].

Loneliness During COVID-19

In light of the global coronavirus pandemic, loneliness has become even more of a public health concern. Although the social distancing measures implemented in many countries appear to be effective in slowing the spread of COVID-19, the disease resulting from SARS-CoV-2 [21], researchers have expressed concern that social distancing may result in increased loneliness [22]. Some preliminary research supports these concerns; studies have shown that older adults [23] as well as

younger adults (between 18 and 35 years of age) [24] reported elevated levels of loneliness after social distancing measures were implemented. Importantly, although researchers were concerned about the impact of the pandemic on older adults, research suggests that older adults may be more resilient to the negative effects on mental health [25], and younger adults are actually at greater risk for heightened loneliness during the pandemic [26,27]. These heightened levels of loneliness also then place people at greater risk of developing depression or anxiety. In fact, research during the pandemic suggests loneliness may be the strongest predictor of depression and anxiety, even more so than exposure to COVID-19-related situations (eg, self-isolation or knowing someone who had to self-isolate due to COVID-19) and the presence of underlying chronic conditions [26].

Reducing Loneliness

Given the public health implications of chronic and widespread loneliness, there has been increased interest in developing loneliness interventions and even more so during the COVID-19 pandemic [28,29]. However, there is surprisingly little research on loneliness interventions [28]. This could be due, in part, to the fact that historically many clinicians treated loneliness as a component of depression [30]. Although research supports these are related but distinct constructs [29], interventions focusing specifically on loneliness remain limited.

Existing loneliness interventions tend to focus on increasing the individual's opportunities for social contact, enhancing social support, developing social skills, or addressing maladaptive thinking [29,31]. There is evidence that these interventions have a small, but significant, effect on loneliness [31]. Interventions including social cognitive training such as cognitive behavioral therapy appear to be more effective than other types of interventions [31], which suggests loneliness may have more to do with maladaptive thinking than a deficit in social connection per se [29]. Nevertheless, most loneliness interventions continue to be based on an intuitive assumption that loneliness can be treated by improving social connection [29] and, consequently, focus primarily on increasing opportunities for social interaction [32].

In recent years, there has been a push to offer more psychological and behavioral interventions digitally [33]. Digital interventions tend to be more scalable than face-to-face interventions and reduce many of the structural barriers that prevent people from seeking treatment [34-36]. The need for digital interventions has become even more apparent during the global COVID-19 pandemic [37], when many mental health professionals have had to pivot to teletherapy [38], and mental health concerns are expected to become even more prevalent [39]. Although a number of digital mental health interventions have been developed [33,40-42], digital loneliness interventions are in their infancy, and most of the studies testing these interventions are small pilot or feasibility studies published in the past 1-2 years [43-46]. Moreover, some of these

interventions have been tested with a sample of participants with another comorbid condition such as social anxiety disorder [46] or psychotic disorder [47]. There is, however, some preliminary evidence that internet-based interventions can be effective at reducing loneliness [43,48].

Understanding the Experience of Loneliness

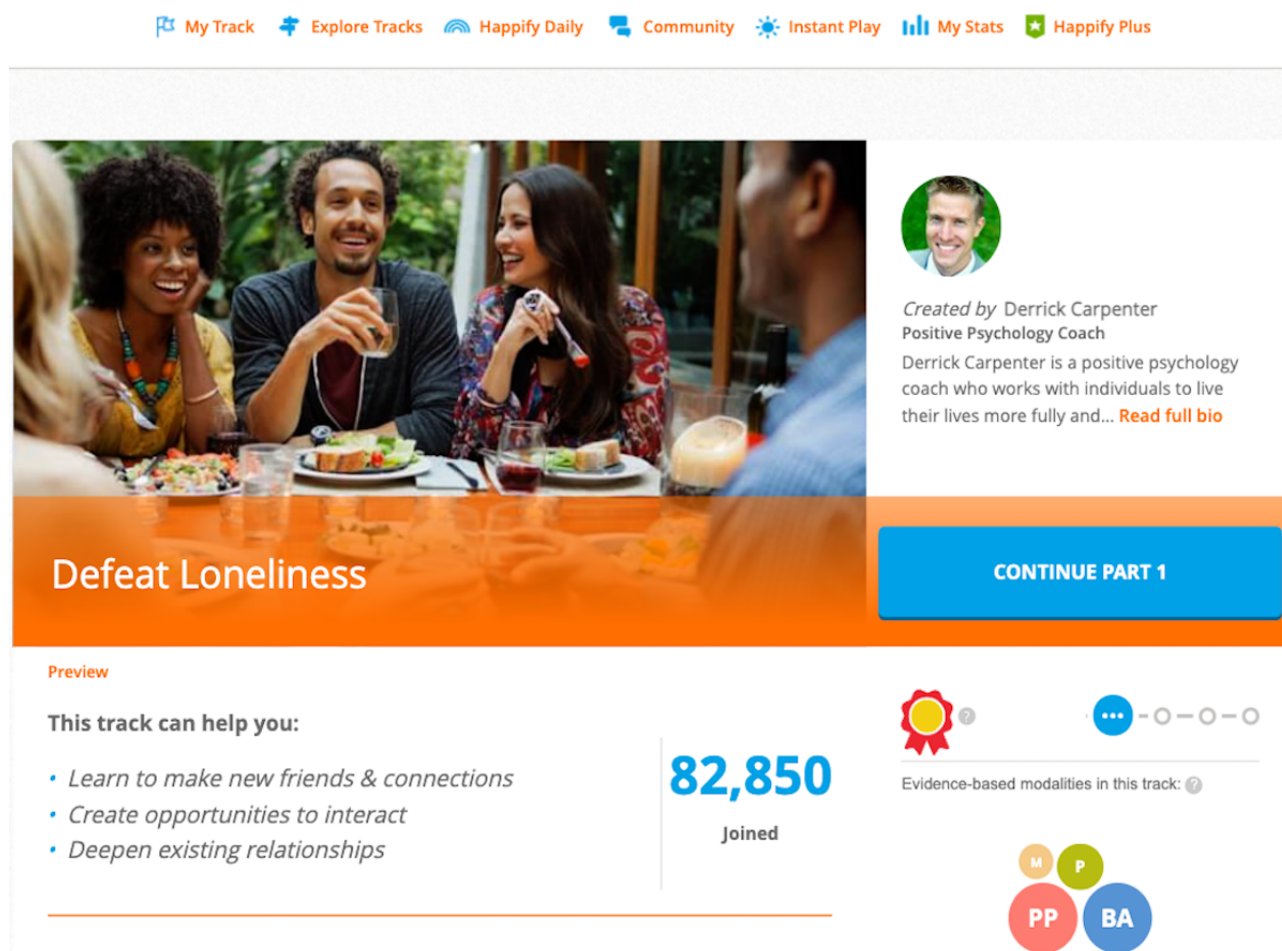
To date, most loneliness research has been quantitative in nature, exploring the prevalence, correlates, and consequences of loneliness or testing the effectiveness of loneliness interventions. There are comparatively few qualitative studies on the topic of loneliness, particularly studies exploring lonely people's reactions to loneliness interventions. Given the complex and subjective nature of loneliness [29,49], better understanding people's experiences with loneliness and with loneliness interventions may be key to developing effective loneliness interventions. Qualitative insights may permit identifying themes in the etiology or source of loneliness and the way they engage with loneliness interventions or why such interventions may not be effective. For example, in one qualitative study of older adults who reported feeling lonely, older adults were more likely to view their loneliness as a complex and private matter, rather than an illness, and thus were unlikely to seek help [50]. However, loneliness appears to have different causes and consequences in early and middle adulthood compared to late adulthood [51], and thus, similar insights from a younger population of adults would be valuable.

Study Design and Objectives

This study draws on a sample of participants who completed a pilot randomized controlled trial (RCT) of the effects of Happify

Health among lonely adults between the ages of 18 and 64 years. Happify Health is a digital intervention platform that addresses mental health and its impact on other diseases by drawing on several key theoretical approaches including cognitive behavioral therapy [52], mindfulness-based stress reduction [53], and positive psychology [54]. Users complete gamified versions of evidence-based therapeutic activities (ie, activities with demonstrated effectiveness in at least two different studies with different samples [55]), which are combined into *tracks* that focus on a specific area of concern, like addressing loneliness (ie, "Defeat Loneliness," see Figure 1).

In the pilot RCT, participants engaged with the Happify Health platform or a psychoeducation control for 8 weeks. We found preliminary evidence that participants who completed more Happify Health activities over 8 weeks had greater improvements in loneliness compared to those who completed fewer activities [56]. To gather additional context, this qualitative study was designed to explore participants' experiences with loneliness and the Happify Health platform through a multiday virtual, asynchronous focus group. Specific goals included understanding participants' experiences with loneliness and coping strategies before and after using Happify Health; understanding participants' experience using Happify Health; and, given that the study was conducted during the COVID-19 pandemic when most of the United States was under some form of a stay-at-home order at the time [57], understanding participants' experience with social distancing and its relation to perceptions of loneliness.

Figure 1. Screenshot of Defeat Loneliness track featured in the pilot randomized controlled trial.

Methods

Participants

Focus group participants were recruited from a pool of individuals who participated in a pilot RCT exploring the impact of Happify Health on loneliness. In the RCT, new users arriving to the Happify Health platform were recruited to participate if they were between the ages of 18 and 64 years, were US residents, and responded “very” to the question “Do you wish you were more connected with others?” when signing up on the platform. Individuals who consented were then randomly assigned to use the Happify Health platform or a corresponding psychoeducation control for 8 weeks (see Parks and Boucher [56] for more discussion of this study). We then invited participants who had been assigned to the active intervention to participate in this focus group if they had completed at least 16 activities on Happify Health (ie, the recommended dosage) and completed the pre- and posttest measures in the pilot study. We emailed 50 participants who met these criteria, and, based on sample sizes in studies with similar focus group designs [58-60], the first 12 participants to indicate interest were accepted into the focus group. Of the 12 individuals, 11 (91.6%) provided informed consent and completed all assigned activities. Of the participants, 9 were female; other demographics were not collected as part of the focus group.

Procedures

Interested participants were directed to Digsite, a web-based qualitative research tool that enables asynchronous focus groups to provide informed consent and complete a brief introductory activity welcoming them to the group. Participants were given 48 hours to complete these tasks before the first of 3 days of focus group activities were introduced. For each day of the focus group, participants were asked to complete three “activities” on a general topic (see Table 1 or a list of sample questions; full list of focus group questions available in Multimedia Appendix 1). Activities included open-ended discussion prompts and questions as well as a few multiple choice and fill-in-the-blank questions. For the first day, activities focused on learning more about participants’ general perceptions of and experiences with loneliness including coping techniques, while the second day focused on understanding participants’ experiences with Happify Health. On the third day activities focused on understanding participants’ experiences with social distancing due to the COVID-19 pandemic and how this may have impacted their experience of loneliness (the focus group was conducted from April 27 to May 3, 2020; during this time, many of the stay-at-home orders that had been implemented across the United States were still in effect or just recently lifted [61]). Activities were asynchronous, and participants did not interact with each other or the moderator in real time; however, their responses were visible to other focus group participants after they completed each activity, and they were encouraged to read

and react to each other's posts. Similarly, the focus group moderator could pose follow-up questions to participants' posts.

Participants had 7 days to complete all assigned activities. To encourage participation, participants were compensated US \$10 for completing each day of focus group activities and were offered an incentive of US \$5 for completing the introductory

activity and each of the 3 days of focus group activities within 24 hours of those activities being posted. Consequently, participants could earn up to US \$50 for their participation. Participants were also offered free premium subscriptions to Happify Health upon completing the study. All procedures for this study were reviewed and approved by IntegReview, an independent Institutional Review Board.

Table 1. Objective and sample questions or prompts by focus group day.

Objective	Sample questions and prompts
Day 1: To understand participants' general perceptions of and experiences with loneliness including coping techniques	<ul style="list-style-type: none"> • When you first joined Happify, you said that you wished you were more connected to others. Reflecting back, can you tell me about what was going on in your life at the time? In what way(s) were you wishing to be more connected? • In your experience, what makes you feel lonely? • What do you do when you feel lonely? How do you cope? • Can you tell me about the last time you felt lonely and why? When was this? • What role does your support system play when you feel lonely?
Day 2: Understand participants' experiences using Happify Health	<ul style="list-style-type: none"> • What made you want to join Happify? What were you hoping to achieve? • When Happify recommended the "Defeat Loneliness" track what did you think? Why? • For this task I'd like you to reflect on your journey over the past few months, from the time you started using Happify to today. Tell me about your experience with loneliness during this time. How has Happify played a role in this experience? • What did you think about the activities you were asked to complete? Which ones were most and least helpful? Why? • Two skills I learned on Happify were _____ and _____.
Day 3: Understanding participants' experiences with social distancing	<ul style="list-style-type: none"> • How has social distancing changed your day-to-day life in the past month? • What is the hardest part of social distancing for you? Why? • On a scale of 1 (not at all) to 5 (extremely), when thinking about the next few months, how much is loneliness a concern for you? Please describe why or why not. • How are you coping with loneliness during this time? • Reflecting on Happify, what skills have you learned that are helping you cope at this time?

Data Analysis

A verbatim transcript of all focus group activities was exported from Digsite and served as the data corpus for the study. Note that participants' comments to each other (n=2) and private messages between the moderator and participants (n=23) were also exported; however, upon review, these additional comments did not contribute anything above and beyond participants' responses to the focus group activities and thus were not included in the thematic analysis. Thematic analysis using an inductive, semantic approach was performed to identify themes and subthemes within the data [62]. To begin, the data were independently reviewed by two members of the study team to create a preliminary set of themes and subthemes for each day of the focus group. These preliminary themes and subthemes were then discussed by both reviewers and a third member of the study team, and overlapping observations were used to create a revised set of themes and subthemes that could be applied

across all 3 days of the focus group. The data were then reviewed a second time, applying the revised themes and subthemes. Results were discussed and, as needed, an additional iterative review was conducted until consensus was achieved between the reviewers resulting in a final set of themes and subthemes. Themes were defined as prevalent topics that were observed in responses from the majority of participants. Patterns that were observed less frequently, but were still well-represented within participants' responses, were classified as subthemes and organized under the appropriate parent theme.

Results

Coders identified five major themes across responses for the 3-day focus group: loneliness, relationships, social distancing, skill acquisition, and coping. These major themes were further divided into subthemes (see [Textbox 1](#)).

Textbox 1. Themes and subthemes extracted from participants' focus group responses.

<p>Loneliness</p> <ul style="list-style-type: none"> • Source of loneliness • Negative self-appraisal • Motivation to manage <p>Relationships</p> <ul style="list-style-type: none"> • Negative perception of current relationships • Desire to improve social connection • Value of social connection <p>Social distancing</p> <ul style="list-style-type: none"> • Impact of social distancing on social connection • General impact of social distancing • Use of technology <p>Skill acquisition</p> <ul style="list-style-type: none"> • Savoring • Thanks • Aspire • Give • Empathize <p>Coping</p> <ul style="list-style-type: none"> • Direct active coping • Indirect active coping • Passive coping

Loneliness

Participants highlighted 3 salient factors that characterized their experiences with loneliness, specifically emphasizing the causes and consequences of loneliness, as well as their motivation to manage their feelings associated with loneliness.

Source of Loneliness

When reflecting on their experiences with and perceptions of loneliness, participants commonly described circumstantial reasons for their loneliness; these included life events; relocation; and changes in relationships, employment, and education. Notably, as illustrated by the following participants' description of loneliness, participants often referred to a constellation of these factors:

I was traveling every week for work and working extremely long hours. A lot of the time I would have colleagues with me, but many times it was just me in a new city. At the same time, I was trying to adjust to my life as an empty nester. I was feeling exhausted from traveling and missing my family, colleagues, and friends.

Similarly, another participant referred to a combination of major life changes in contributing to their loneliness:

At that juncture in my life, my marriage was crumbling, I was experiencing anxiety, and was feeling isolated. I had finished school and had no clue as to how to continue day to day.

In addition to circumstantial triggers for loneliness, participants also mentioned a chronic sense of loneliness. Some participants referred to a history of loneliness since childhood (eg, "Being an only child, I've struggled with loneliness from a young age"), whereas others described their loneliness more as a consequence of long-standing mental health issues (eg, "I've always struggled with social anxiety and was diagnosed with SAD a few years ago, so I've never been good at cultivating and maintaining social relationships.").

Negative Self-appraisal

In describing their loneliness, participants often expressed negative self-appraisals of their perceived self-worth and value to others. Importantly, rather than being another source of loneliness, these negative self-appraisals were typically described as a consequence of their loneliness. In some cases, participants described how lacking social connection led to questions about whether they were to blame for the lack of social connection. For example, as one participant described it:

I began to doubt myself and begin to think, what if it's because my former friends did not perceive me as being of bringing value into their lives and thus that is why, on their end, they did not feel the need to connect with me.

In a similar vein, another participant explained:

Over the years, my loneliness has developed into thoughts of 'not being good enough to be around,' 'being too annoying and clingy,' and even 'hating myself so much that I never want to be alone.'

In other cases, it was the lack of social connection that appeared to make participants feel negatively about themselves (eg, "I haven't done anything today and I'm all by myself - what a waste of space").

Motivation to Manage

The extent to which participants were motivated to address their loneliness varied; this was particularly evident when we asked them to reflect on their reasons for signing up for Happify Health and their reactions when we recommended the *Defeat Loneliness* track as part of the pilot RCT they participated in. Some participants referenced a strong desire to address their feelings of loneliness and cited it as one of their primary reasons for signing up for Happify Health. For example, one participant explained they joined Happify Health because:

I wanted to use evidence-based practices to work on my feelings of loneliness. I wanted to work on feeling more connected.

Another participant described their positive reaction to being recommended the *Defeat Loneliness* track because they currently felt motivated to address their loneliness:

I thought that was the appropriate track to recommended (sic) to me given my feelings of isolation. I felt that I was in a place to finally address this feeling.

Among some participants, however, loneliness was not described as their primary concern and they were drawn to the Happify Health platform because of general concerns with their mental health:

I was feeling a lot of stress and having panic attacks, trouble sleeping, and just generally unhappy. I wanted to have less anxiety and sleep better.

Nevertheless, participants generally expressed positive reactions to the recommended *Defeat Loneliness* track, even when they were not primarily driven to the Happify Health platform because of their loneliness. For instance, the participant who described their reasons for joining Happify Health as they "wanted to have less anxiety and sleep better" described feeling happy when the *Defeat Loneliness* track was recommended:

I was happy because of all things, loneliness is hard to explain to some people. They will say "you have friends or family." I wanted ways to not feel lonely and also a neutral place to talk about how I felt.

Another participant who described being drawn to Happify to "help me cope with my realities and feel better day to day"

described their reaction to the track recommendation as motivating by giving them something concrete to focus on:

I was excited to have a focus. I never identified with the word "loneliness" and then ended up relating to so many of the thoughts and feelings within the track!

Relationships

Reflecting on their experiences of loneliness often prompted participants to reference their relationships and perceptions of their social network. These comments ranged from expressing dissatisfaction with their current connections and their desire for new or improved connections to emphasizing the importance of social connection.

Negative Perception of Current Relationships

Not surprisingly, given that loneliness stems from dissatisfaction with existing social connections [1], several participants described negative perceptions of their current relationships. For example, when asked about the role their support system plays when they are feeling lonely, one participant remarked "I really don't have one...which sucks." Another participant described having a support system but feeling different, which contributed to feelings of loneliness:

Usually my friends are super sweet, but talking to them sometimes reminds me of our differences, which then makes me want to isolate.

Participants also often referenced not feeling included by their existing social network. One participant described, "I also noticed that not many people reached out to me," whereas another described thinking "Why hasn't anyone called me? Are they doing things without me?" the last time they felt lonely. Such feelings of exclusions were also evident in comments expressing a desire for people in that social network to make greater efforts to include the participant. Some participants noted feeling as though they are always the ones to extend invitations and wanting to be invited for a change (eg, "I did wish that people would approach me- ask me to sit next to them and hang out after class- I was just always the one asking and finding myself rejected by others."), whereas others referred to a sense of feeling on the outside looking in:

I could see people doing fun things without me

I watched what seemed like everyone around me keep doing college while I stayed in my room.

In several cases, participants noted feeling responsible for the problems with their existing relationships, echoing the negative self-appraisals we saw in other responses. For instance, when reflecting on their current connections, one participant said those connections were "not reliable, mostly my fault for not investing deeper in more meaningful friendship," while another expressed "I did not make calling friends and family a priority." Several participants also noted difficulties with opening up to their support system, which contributed to feeling disconnected from others. One participant described a lack of close others they could open up to: "Not feeling comfortable enough to share my thoughts and feelings with anyone besides my wife due to my developing social skills and lack of opportunity to connect with past friends"; whereas another described a general difficulty

with opening up to others: “I have a hard time sharing my feelings with other people.”

Desire to Improve Social Connections

In addition to identifying issues with their existing social connections, participants expressed a desire to improve their social connections. Some participants described the desire for increased connection within existing relationships as one of their motivating factors for joining Happify Health. For example, when describing how they were feeling when they joined Happify Health, one participant remarked: “I was wishing that I was more connected to my friends and to my family members.” Another participant similarly commented:

I was wishing to be more connected in that, I wanted what my wife had. In addition to me, she has two close friends she talks to constantly, of whom she has known since high school and in her sorority, respectively. I had a similar experience but failed to maintain those friendships, and I wanted that back or least (sic) be able to cope with my loneliness as I worked towards rebuilding those friendships.

Several participants also expressed a desire to form new relationships. In some cases, this desire was related to changes in circumstances, such as a relocation, that led to a perceived lack of social connection (eg, “I wanted to connect with my local community and new friends which can be hard in a new city”). In other cases, participants expressed wanting connections that were better suited to their needs (eg, “I was looking for alignment and understanding how to bring the right friendships and people into my life to be more happy.”), whereas others noted a genuine lack of connection overall:

I really don't have that one person I could call just because.

Wish I had a reliable friend who could just cheer me up.

Value of Social Connection

Generally, participants saw tremendous value in social connection, even when they felt it was lacking. For example, when asked what role their support system played when they were feeling lonely, one participant remarked: “The biggest role, connecting helps me to not feel lonely anymore.” Another participant who described themselves as not having a support system noted: “If I had a support system, I would feel a lot better.” This was particularly evident when people reflected on their recent experiences with social distancing. Some participants felt social distancing measures made the value of social connectedness even clearer.

A sad reality that we've taken away the most important element of life - deep, human connection.

We will all value the time we spend together when this is over - and I think that is one positive outlook I've gained on social distancing and quarantine.

Others referenced the importance of social connection in helping them cope with the pandemic:

Social connections are very important for helping me cope with this loneliness. During this time, I would crumble(theoretically) without them

In addition, they referenced a sense of comfort from knowing that others are sharing the same experience (eg, “We are helping each other with getting through physical distancing, the struggles and anxiety of unemployment, and reminding one another that we care about each other.”).

Social Distancing

The final day of the focus group focused explicitly on participants' experiences during the COVID-19 pandemic. Participants referred to ways in which social distancing measures affected social connectedness as well as other aspects of their life.

Impact of Social Distancing on Social Connection

Consistent with preliminary research on the impact of social distancing on loneliness, some participants referred to increased feelings of loneliness and negative affect during this time (eg, “I miss my friends a lot and know how beneficial it was for my health to be able to spend time with them - and I am scared of how I will be able to cope without them.”). However, others referenced positive effects of the pandemic, including opportunities to improve their social connections:

Shelter-in-place has enabled me to dedicate more time to communicate with my support system than I was previously able to while working my normal hours

I interact with more of my friends and family more frequently over zoom and text.

In addition, they referenced a sense of comfort due to the knowledge that most people were feeling the same way:

I would say I don't feel more lonely now. It's somewhat comforting to me more people are coping through loneliness and social distancing right now. Where as (sic) before it felt like I was the only one.

General Impact of Social Distancing

Participants also described other ways in which the pandemic impacted their lives, ranging from changes in employment and education, the inability to do things they did before, and the impact on their mental health broadly speaking. Given the focus of this paper, we focused primarily on the latter effects. For instance, some participants referenced how restrictions due to the pandemic interfered with their traditional coping mechanisms:

The hardest part is not being able to go to the beach or gym. These two places were my saving grace from everything going on in my life.

In addition, they referenced the restrictions led to other negative consequences like lowered motivation (eg, “Not going in to work and school made me less motivated and productive”). However, again, some participants referred to positive effects, such as offering a respite from their day-to-day lives: “I also feel that social distancing has allowed me to be still and process

some of those racing thoughts, while becoming more okay with being by myself.”

Use of Technology

Participants also described their increased use of technology for work, school, and social connection as a result of social distancing measures and the COVID-19 pandemic. They often referenced technology as a means of maintaining social connection during the pandemic:

I am coping with loneliness during this time by being on social media alot (sic) more. I have been going to virtual parties and events. I do feel these strategies are helping.

However, they also noted the downsides of technology, particularly *zoom fatigue* (eg, “Zoom meetings are helpful for about an hour, and then I get screen or zoom fatigue and it feels like an obligation because much of my work is via zoom also”). Participants also described that, although technology was necessary for social interaction currently, it was not a replacement for face-to-face interaction: “I’ve learned that digital communication is not a replacement for in-person, but it is significantly better than nothing.”

Skill Acquisition

During the last 2 days of the focus group, we asked participants about the skills they learned from Happify Health and how they were applying those skills to cope with the pandemic. Notably, although participants were not reminded of the underlying skills promoted within Happify Health, many responses could be classified into our savor, thank, aspire, give, and empathize (STAGE) model. This model reflects categories of activities, each of which emphasize a different skill: *savor* activities focus on mindfulness skills; *thank* activities focus on gratitude; *aspire* activities focus on optimism, goal setting, and finding meaning and purpose; *give* activities focus on kindness, forgiveness, and prosocial behavior; and *empathize* activities focus on self-compassion and perspective-taking.

Savoring

Several participants referred to mindfulness, savoring, or meditation when asked to identify two skills they learned from Happify Health. Participants also described using these skills to cope with the pandemic:

Meditation helps with the anxiety. Savoring is useful too. I’m trying to savor the moments that I have inside instead of worrying about what I’m missing on the outside.

In addition, they identified these skills when describing how Happify Health would be helpful in the future: “It can help me in the future with positivity and mindfulness because it is still a strategy I will need to use in my daily life to stay calm and focused.”

Thanks

Gratitude was also commonly reported as one of the skills participants learned from Happify Health. Some participants also referenced gratitude activities as those that they found most helpful:

One of the most helpful was sending the letter of appreciation to someone. This exercise was not only gratifying for myself, but for the person I sent it to.

They reference gratitude particularly in terms of helping with their loneliness: “Some of the gratefulness related activities that made me think about people I hadn’t talked to in a while or had taken for granted were helpful in dealing with loneliness.”

Aspire

Although references to optimism, goal setting, and finding meaning and purpose were less frequently reported as explicit skills participants learned through Happify Health, they made reference to these skills in other responses. Oftentimes these comments were indirect references to optimism (eg, “I do think of positivity as the primary lesson I’ve learned from Happify, even if I can’t remember each individual lesson off the top of my head.”) and goal setting (eg, “It’s given me ideas and motivation to overcome loneliness and made me think of things in a new light”), suggesting perhaps these skills felt less concrete than savoring or gratitude.

Give

Direct references to kindness and prosocial behavior were also less commonly reported as explicit skills participants learned from Happify Health but were referenced when participants described the skills from Happify Health they found helpful during the pandemic: “I remember from Happify that saying something nice or doing something nice for others is helpful for me, so I’ve tried to be more encouraging to my friends”; and their overall journey with Happify Health: “I learned how to focus on what I can do for myself and others to brighten my mood on happily (sic).”

Empathize

Finally, indirect references to self-compassion were noted as explicit skills learned within Happify Health (eg, patience and self-acceptance) as well as what they found most helpful about Happify Health: “I can’t control loneliness or how people respond to me.” Similar themes appeared when participants described their journey with Happify Health: “I realize that it’s not that I am unloved, it’s that everyone is busy and has trouble reaching out.”; and how they were using skills from Happify Health to cope with the pandemic: “Patience, awareness, breathing, empathy.”

Coping

The way in which participants discussed their coping strategies appeared to shift across the 3 days, suggesting they implemented the skills referenced earlier to cope with their feelings of loneliness. Over the course of the 3-day focus group, participants referenced using active coping strategies, including strategies that directly or indirectly targeted their loneliness, as well as passive coping strategies. However, participants seemed to reference more active and direct coping strategies, as they reflected on their experiences with loneliness after using Happify Health, compared to day 1, when they reflected on their general experiences with loneliness.

Direct Active Coping

Some coping strategies participants described were more problem-focused and directly addressed their feelings of loneliness. One strategy often referenced by participants was making an active effort to connect with friends and family: “I call or text a friend or family member; connecting helps me to not feel lonely anymore.” Notably, however, references to this type of strategy were more frequent when participants were asked to comment on their experiences with loneliness after using Happify Health. Indeed, some participants directly referenced a change in their use of such problem-focused strategies as they reflected on their journey since joining Happify Health. For example, one participant noted:

Happify was the catalyst for really kick-starting my journey towards tackling loneliness. As I worked through the activities, I began to reach out to my friends and rebuild those relationships.

Another participant similarly stated:

I was very busy and disconnected from my friends and family when I started Happify. I am still busy, but I take the time to send a text or make a phone call now. I was a little upset before that people do not reach out to me. But with Happify I was motivated to take the initiative and I have had positive responses.

When reflecting on how Happify Health would help them in the future, another participant noted that the activities would help remind them to proactively reach out to others: “Happify will help me keep connected with people by doing activities where I have to reach out and interact with them.”

Indirect Active Coping

Participants also described more indirect strategies to actively address their loneliness. These strategies involved methods to generally improve mental health while not necessarily directly targeting loneliness or social connections, such as practicing mindfulness or self-care. For example, when reflecting on how they cope with loneliness in general on day 1, one participant noted:

I cope with loneliness by finding and doing things that I enjoy when alone. I watch my favorite shows, make my favorite beverages, and do my favorite activities like writing, doodling, listening to music, cleaning, or self-care.

Another participant indicated:

talking instead of bottling up my feelings helped. I also did yoga and got a physical outlet for my anger.

As with the more direct techniques, indirect coping strategies were mentioned more frequently, and with increased contemplative detail, in the latter 2 days of the focus group, when participants reflected on their experiences since joining Happify Health. When one participant described their journey with Happify Health, they noted the following:

I have learned to breathe. This is something I often never really do with intention. I have also learned to slow down and accept the things I can't change.

Others are not judging me or worrying about the things I am. It's all in my head.

Another stated: “I have learned not to take everything so seriously and stay in the present moment when needed.” Some participants also referred to these indirect coping strategies when asked how Happify Health could help them in the future. For example, one participant noted the benefits of Happify Health in the future were:

meditation guidance, relaxation, etc. I feel like I would use Happify as a standard relaxation app

Similarly, when asked to reflect on how skills they learned by using Happify Health have helped them cope with the pandemic, one participant responded:

Meditation has been huge for me right now. It brings me back to my center and keeps me out of my head. I've been practicing every morning to start my day and it really helps.

Another stated:

I learned to knock out negative thoughts by refocusing on the positive. I have learned to slow down and meditate when I am anxious.

Passive Coping

Participants also shared passive coping techniques they used to manage feelings of loneliness. Passive strategies included watching television, listening to music and podcasts, staying busy with tasks and activities, etc. For example, one participant described their methods for coping with loneliness as:

cooking, listening to music, medication, reading, and zoning out in front of the TV. I don't feel as lonely when I hear music or TV voices in the background.

Another shared:

Staying busy and focusing on completing all the things I need to get done will help me manage my loneliness. When I set my mind to something I can usually only focus on that and keep the bad lonely thoughts at bay

Importantly, in comparison to active strategies, the motivation behind these actions did not appear to address the underlying issues with loneliness or improve mental health in general. Rather, these strategies reflected more temporary attempts to distract oneself from the negative feelings associated with loneliness.

Although these strategies were referenced more frequently when participants reflected on their experiences prior to using Happify Health, passive strategies were still mentioned as coping techniques following their use of Happify Health as well. In fact, some participants referenced using the platform itself as a form of distraction. One participant described the games within the platform having “distracted from the negative feeling and provided a replacement activity,” whereas another noted “I think it could be a good distraction for me” when asked how Happify Health could help them in the future.

Discussion

Loneliness has been identified as a growing public health concern due to its increasing prevalence [3] and association with other mental and physical health problems [9-13]. However, surprisingly little research has explored the impact of interventions for loneliness, particularly digital interventions. Moreover, much of the existing literature has focused on older adults, and consequently, we know less about the experience of loneliness for younger adults or their reactions to digital interventions targeting loneliness. The goal of this study was to explore how self-identified lonely adults aged 18-64 years experience loneliness and their experience with a digital mental health intervention using a qualitative, asynchronous focus group design.

Experience With Social Distancing

Although the primary aim of this study was to explore adults' experiences with loneliness and reactions to the Happify Health platform, the focus group occurred amid the COVID-19 pandemic when most of the United States was under stay-at-home orders. Consequently, a secondary aim of the study was to explore participants' experiences with loneliness during the pandemic. This was of particular interest because researchers have expressed concern that social distancing measures in place to prevent the spread of COVID-19 may result in widespread increased loneliness [22].

Some participants in this study did reference feeling more loneliness and negative effects as a result of social distancing measures; however, some participants also described positive effects of the pandemic and social distancing measures. Positive effects included more opportunities for social contact (often facilitated by technology), a sense of comfort resulting from the fact that everyone was facing similar circumstances, and respite from one's day-to-day life. Although references to these positive effects might be surprising given the focus on the potential negative effects of social distancing and some preliminary evidence suggesting increases in loneliness [24], other research also suggests that loneliness may not have increased as much as people feared during the beginning of the COVID-19 pandemic [63]. For instance, one nationwide study assessed US residents at 3 different periods of time: before the COVID-19 outbreak in the United States, in late March 2020, and in late April 2020 (the same time frame when this focus group was conducted). They found no significant changes in average levels of loneliness over time. Although older adults specifically showed an increase in loneliness during the acute phase of COVID-19, loneliness actually decreased following the implementation of stay-at-home orders, when social distancing measures would have been the most strict [64]. In fact, participants reported an increase in perceived social support from the first assessment (before the COVID-19 outbreak) to subsequent assessments, with no significant change in perceived social support from late March to late April 2020 [64]. Another study found less than a 3% increase in the prevalence of loneliness between 2018 and during the pandemic in 2020 [65]. In other words, the effect of the COVID-19 pandemic on loneliness is not as clear as researchers originally predicted.

One potential explanation for this is that we underestimated the impact of digital technology during this crisis. Digital technology can be leveraged to create opportunities for social connection [22,66], helping to curb feelings of loneliness. Indeed, social networking apps like *Facetime* and *Skype* were recommended to older adults during the COVID-19 pandemic [67] because research suggests these apps help to reduce their risk of depression [68]. Video chat platforms also increased in popularity during the pandemic [69], which might help to explain the increase in perceived social support early on. Participants in this study also often referenced using technology to maintain social connection during the pandemic, including social media, text messaging, and video chat. Some even referenced being more connected than before because of their use of these technologies.

However, it is important to note that the focus group was conducted just 2 months into the pandemic, and much of the published research on trends in loneliness during the pandemic similarly reflect early responses to the COVID-19 crisis and social distancing measures. Given that participants also referenced fatigue related to the increased use of technology and that virtual communication did not replace face-to-face interaction, it is conceivable that communication patterns have changed over time. If increased virtual communication was a temporary reaction to stay-at-home orders and was not maintained over time, it is possible that the predicted increase in loneliness associated with the pandemic was merely delayed. Thus, more research is needed to better understand how trends in virtual communication and loneliness may have changed throughout the COVID-19 pandemic.

Experience With Loneliness

Researchers have defined loneliness as a feeling stemming from the perception that one's social network is insufficient or unsatisfactory [1]. Contrary to popular belief, these feelings do not necessarily result from social isolation but rather from perceptions that one's expectations are not being met [70]. Consequently, loneliness is a subjective state—although two people may experience similar circumstances, like relocating often, one may feel lonely while the other does not [71].

Although our sample consisted only of individuals who indicated they desired feeling more connected to others when signing up for Happify Health, the subjective nature of loneliness was evidenced in the heterogeneity of participants' descriptions of their relationships and the causes for their loneliness. Participants did predominantly reference negative perceptions of their existing social network; however, some participants felt they lacked a support system altogether, whereas others clearly identified close others but felt disconnected from their support system. Furthermore, among those who felt more disconnected from their support system, there was variability in their reasons for feeling disconnected, including feeling "different" from close others, feeling excluded or ignored by close others, or feeling as though they were the ones responsible for the lack of intimacy and contact.

Similarly, participants differed in how they described their experiences with, or sources of, loneliness. Some participants attributed their feelings of loneliness to more proximate,

circumstantial triggers. Others, however, described a chronic pattern of loneliness, sometimes coupled with other mental health concerns like social anxiety.

The heterogeneity in participants' experiences with loneliness could have important implications for treatment. Although research suggests that loneliness interventions that incorporate social cognitive training are more effective than other types of loneliness interventions, most loneliness interventions continue to focus primarily on increasing opportunities for social interaction [31]. Conceivably, individuals who lack a support system altogether or who are experiencing temporary loneliness due to a change in circumstances may benefit from behavioral interventions that focus on social skills training and increased social interaction to build a support system. However, individuals whose loneliness stems from feeling misunderstood or excluded by their social network, or those with chronic patterns of loneliness, may require interventions with more of a cognitive component to address maladaptive cognitions that may contribute to their perceptions of their existing support system. Indeed, participants' responses throughout the focus group suggested that participants differed in their motivation to address their loneliness and whether their primary goal was to create new social connections or to improve existing connections. Thus, to be effective, loneliness interventions may need to draw on a variety of strategies, not just increasing opportunities for social contact, and allow for personalization to directly address the individual's unique experience with loneliness.

Negative Self-perceptions

Another common theme in participants' responses throughout the focus group was negative self-appraisal. Consistent with research suggesting loneliness and low self-esteem have a reciprocal relationship [72], the ways in which participants referred to negative self-appraisals included both causes for and consequences of their loneliness. For example, in some cases, participants attributed the problems with their relationships to themselves, whether it was due to a lack of self-disclosure to close others or because they did not invest enough energy into their relationships. However, participants also described a process whereby feeling lonely led to questions about their self-worth. For instance, some participants described how they interpreted the lack of social contact as evidence that they were annoying or worthless. For some participants, the negative self-appraisals even reflected more sweeping feelings of self-disgust (eg, "I haven't done anything today and I'm all by myself - what a waste of space."), a variable that has become increasingly important in relation to loneliness and appears to mediate the relationship between loneliness and depression [73,74].

These data point to the importance of incorporating strategies for addressing underlying negative cognitions about the self when treating loneliness. Indeed, in a recent paper, Ypsilanti [75] argued that loneliness interventions should address feelings of self-disgust that often coincide with loneliness, which may contribute to social avoidance and maintain loneliness. Thus, interventions focusing primarily on increasing opportunities for social contact may not be effective without addressing the

negative self-appraisals that may interfere with forming social connections.

Experience With the Digital Intervention

Given the lack of research on loneliness interventions, particularly digital interventions, another goal of this study was to better understand participants' experiences with the Happify Health platform. The pilot study we recruited participants from provided preliminary evidence that completing more activities on the platform may help to reduce feelings of loneliness among lonely adults between 18-64 years of age [56]. However, the aim of this focus group was to obtain more in-depth information about participants' reactions to the intervention, including the extent to which they adopted new skills and coping strategies as a result of completing the program.

Notably, Happify Health is not a specific loneliness intervention and not all participants were drawn to the program because of their loneliness. Given the aforementioned argument that interventions may need to be flexible and individualized because of the subjective nature of loneliness, offering people struggling with loneliness choice in interventions may be important in the same way person-activity fit influences the impact of interventions [76]. Some participants appeared to prefer addressing their loneliness more indirectly and even as part of a broader program addressing other issues, as evidenced by the fact that not all participants started or completed the recommended loneliness intervention. However, other participants appeared to enjoy the prospect of tackling their loneliness directly, as illustrated by the fact that some participants who did not even label themselves as "lonely" described feeling empowered and motivated when the loneliness intervention was recommended to them.

In addition, participants showed evidence of learning various skills taught via Happify Health activities and, more importantly, implementing those skills to use more active coping strategies for loneliness. That is, there was a noticeable change in how participants described their coping mechanisms when asked to reflect on their experiences with loneliness prior to using the Happify Health platform compared to the latter 2 days of the focus group, when they were asked to reflect on their experiences with Happify Health and during the pandemic. Although references to passive coping strategies did not appear to change over the course of the focus group, participants referred to more active coping strategies when reflecting on their experiences since joining Happify Health. Moreover, their descriptions of these coping strategies felt richer and more intentional. For example, participants were able to explain why they used a particular skill or coping strategy and how it helped with their loneliness. Although this study cannot speak to whether these participants were able to reduce their loneliness by using such coping strategies, these data suggest participants felt they gained both direct (eg, actively reaching out to others) and indirect (eg, mindfulness exercises) strategies they could use when feeling lonely as a result of completing the intervention.

Interestingly, we found that the two skills participants commonly referred to explicitly were mindfulness skills and gratitude. Recall that most loneliness interventions focus on increasing

opportunities for social contact [31]; however, neither of these skills directly focus on social contact or social skills. Nevertheless, participants described how these exercises helped them with their loneliness and how they would continue to use them in the future. This further points to the importance of moving beyond the notion that social skills training and increasing opportunities for social contact are sufficient for addressing loneliness. Indeed, there is a growing body of literature that building mindfulness skills can help to reduce loneliness and even increase social contact [48,77]. Although the mechanism by which mindfulness reduces loneliness is unclear, participants in this study described how savoring and focusing on the present helped to reduce maladaptive cognitive patterns associated with loneliness that elicited anxiety and negative self-concepts. Similarly, cross-sectional research suggests gratitude and loneliness may be inversely related [78,79]. Again, although the reasons for this inverse relationship are unclear, participants described how practicing gratitude, particularly when it involved expressing gratitude to a close other, helped to reframe their perceptions of existing social connections and introduced opportunities for social contact, all while promoting positive self-appraisals and affect.

Interestingly, some participants also described completing Happify Health activities as a means of distracting themselves when they felt lonely. In other words, the program itself acted as a passive coping strategy. However, unlike other passive coping strategies participants referenced, like “zoning out in front of the TV,” users also gained helpful skills while distracting themselves. This points to yet another potential benefit of digital loneliness interventions: they are available on demand, offering lonely people a productive means of distracting themselves when they may not want to actively and directly address their loneliness.

Limitations and Future Directions

This study provides rich information about participants' experiences with loneliness and with a digital mental health platform; however, there are limitations to the design that may reduce the generalizability of these findings. First, although we asked participants about their general experiences with loneliness and noted changes in how participants described coping strategies when describing their experiences before and after using the Happify Health platform, all of the participants' responses were collected after they had used the Happify Health platform for 8 weeks or longer. Consequently, it is plausible that their reflections on their experiences with loneliness before using the digital intervention may be biased based on their experiences with the platform or their current level of loneliness. Similarly, although we were able to collect valuable information about participants' experiences with loneliness during the COVID-19 pandemic, the fact that we conducted the focus group during the early stages of the pandemic and when most of the United States was under stay-at-home orders, it is also plausible that participants' current experiences influenced their reflection on their general experience with loneliness as well as their experience with Happify Health. In addition, although we explored participants' reactions to the Happify Health program, including their reasons for joining Happify Health and their thoughts on the activities and tracks they completed,

we did not inquire about negative side effects. Although participants did not spontaneously refer to negative side effects while using the platform in their responses, direct questions asking participants if they had negative side effects or reactions while using the platform should be included in future research to better assess participants' experiences.

Another limitation is potential selection bias that reduces the representativeness of the focus group. As with many qualitative studies, this group consisted of a small number of participants that may not be representative of the general population. Due to a technical issue, we were unable to link participants' responses in the focus group to their demographics and questionnaire responses from the pilot study, making it difficult to determine the extent to which our focus group was diverse in terms of age, level of loneliness, geographical location, etc.

In addition to the small sample, participants were invited to participate in this study if they had participated in the preceding pilot study and were assigned to the active intervention, completed at least 16 activities on Happify Health during that study, and completed the pre- and posttest assessments for the pilot study. Consequently, the reflections on loneliness and the digital intervention we coded may only represent the experiences of successful Happify Health users, and the experience of those who completed fewer intervention activities or stopped using the program altogether remain unclear. Moreover, given the small number of participants overall, the insights drawn from participants' responses should be considered preliminary, as different themes may have emerged with a larger sample of participants.

Considering these limitations, it will be important to explore these themes with a larger, more representative sample. In particular, a study in which participants reflect on their experiences with loneliness before they start using the platform and then again after using the platform would help to reduce the potential bias of retrospective reports.

Conclusions

Loneliness is a growing public health concern, perhaps even more so given the recent global pandemic that resulted in widespread social distancing measures. However, interventions targeting loneliness are limited and often focus primarily on increasing opportunities for social interaction and improving social skills. Meanwhile, a growing body of literature points to the importance of cognitive-behavioral techniques, mindfulness, and gratitude for effectively addressing loneliness. Although more research with a larger and more representative sample is needed, the responses we reviewed from adults aged 18-64 years who self-identified as lonely over the course of a 3-day focus group can be summarized into three broad recommendations for loneliness interventions.

First, given the subjective and complex nature of loneliness, loneliness interventions should incorporate a variety of techniques to address loneliness, and these should include both direct (eg, social skills training and cognitive behavioral techniques) and indirect (eg, mindfulness and gratitude) strategies to accommodate different levels of motivation for addressing loneliness. Second, given the role of negative

self-appraisals and self-disgust as a cause and consequence of loneliness, to be effective, loneliness interventions need to incorporate strategies to address these underlying beliefs as well. Finally, digital interventions may be particularly useful

for addressing loneliness, as they may provide a convenient but productive option for passive distraction when someone is feeling lonely.

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Authors' Contributions

EMB contributed to designing and implementing the study, and wrote the initial draft of this paper. ECN was primarily responsible for designing and implementing the study, served as the primary coder, and contributed to the manuscript. NH served as the second coder and contributed to the manuscript. JLS assisted with study implementation and provided general manuscript support. ACP contributed substantially to the study aims and scope, and to designing the study

Conflicts of Interest

EMB, JLS, and ACP are employees of Happify Health. ECM and NH are paid consultants with Happify.

Multimedia Appendix 1

Full list of questions and activities by focus group day.

[DOCX File, 17 KB - [mental_v8i2e26617_app1.docx](#)]

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Abbreviations

RCT: randomized controlled trial

STAGE: savor, thank, aspire, give, and empathize

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Review

A Perspective on Client-Psychologist Relationships in Videoconferencing Psychotherapy: Literature Review

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Abstract

Background: During the COVID-19 pandemic, people have been encouraged to maintain social distance. Technology helps people schedule meetings as remote videoconferencing sessions rather than face-to-face interactions. Psychologists are in high demand because of an increase in stress as a result of COVID-19, and videoconferencing provides an opportunity for mental health clinicians to treat current and new referrals. However, shifting treatment from face-to-face to videoconferencing is not simple: both psychologists and clients miss in-person information cues, including body language.

Objective: This review proposes a new theoretical framework to guide the design of future studies examining the impact of a computer as a mediator of psychologist-client relationships and the influence of videoconferencing on the relationship process.

Methods: We conducted a literature review including studies focused on communication and key concepts of the therapeutic relationship and therapeutic alliance.

Results: Studies have reported that clients are generally satisfied with videoconference therapy in terms of the relationship with their therapists and the establishment of the therapeutic alliance. Conversely, studies indicate that psychologists continue to highlight difficulties in establishing the same quality of therapeutic relationship and therapeutic alliance. The contrasting experiences might underlie the differences in the type of emotional and cognitive work required by both actors in any therapy session; furthermore, the computer seems to take part in their interaction not only as a vehicle to transmit messages but also as an active part of the communication. A new model of interaction and relationship is proposed, taking into account the presence of the computer, along with further hypotheses.

Conclusions: It is important to consider the computer as having an active role in the client-psychologist relationship; thus, it is a third party to the communication that either assists or interferes with the interaction between psychologists and clients.

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KEYWORDS

videoconference; psychotherapy; professional-patient relations; client-psychologist relationships; therapeutic alliance; telehealth; mobile phone

Introduction

Background

Since the beginning of 2020, the COVID-19 health pandemic has induced people to avoid face-to-face interactions. The phenomenon is impacting several professions, and features of videoconference (VC) platform have been currently adapted for business meetings. In the case of psychologists, professional

association boards across the world have encouraged professionals to keep treating clients using videoconference technologies (VCTs). The assumption is that VCTs might also help clients who live in rural and remote areas, extending access to mental health services [1].

Psychotherapy sessions are traditionally delivered face-to-face in the psychologist's consultation room. In this physical space, the therapist and the client start to build their relationship and

create strong mutual trust. The uninterrupted sharing of a physical space enables the therapist to identify clients' reactions and vice versa. Moreover, presence enables therapists to be at once *physically, emotionally, cognitively, spiritually, and relationally* [2] in touch with themselves and the clients. Thus, this concrete experience of presence becomes therapeutic and enables clients to experience neurophysiological safety, and consequently, their relationship is enhanced, and the healing process is favored [3].

According to Rogers [4-6], presence is a crucial factor in therapy: it allows psychologists and clients to connect by experiencing the same moment, permits the development of empathy, and leads therapists to develop a *therapeutic relationship* (TR) with their clients. This term identifies an effective relationship that underpins therapeutic processes such as the building of trust and empathy between the therapist and the client [7,8].

However, an effective TR is also associated with the formation of a good cooperation between psychologists and clients defined as *therapeutic alliance* (TA) [7,9]. This has been established as a good predictor of effective psychotherapy [10]. TA consists of 3 critical factors: (1) the sharing of clear expectations and goals by both clients and psychologists; (2) a clear definition of responsibilities, rules, and commitments; and (3) a relationship between psychologists and clients that involves their bonds, mutual trust, and respect [11].

Thus, effective cooperation between psychologists and clients is crucial to the therapeutic processes involved in the therapeutic context and to establish a beneficial TR. A lack of either of these two factors, of TA and TR, prevents psychologists and clients from laying the foundation for clients' future changes.

The strict correlation between the therapist and client relationship and treatment outcomes has also been recognized in the literature [12-17]. For instance, Lorr [13] conducted an interesting study focusing on the clients' perception of the TR: he highlighted that the 5 dimensions included in the client-therapist relationship, that is, accepting, understanding, authoritarian, independence-encouraging, and critical-hostile data, are strictly linked to positive or negative outcomes. His research underlines that the relational factors of accepting and understanding are related to clients' improvements [13]. Another study has implemented the research by Lorr [13], extending the explorations to psychologists' perceptions. This study found that the therapists' self-perception of the independence-encouraging dimension was associated with client-rated improvements. Instead, different perceptions and ratings of understanding and accepting factors concerning the TR highlighted negative client and therapist outcomes [18].

Hence, the ability of any medium to support the development of effective TR and TA is therefore critical. Videoconference therapy has been growing, but the COVID-19 pandemic has accelerated the demand for it. There are foreseeable, potential risks in moving therapy to the web by using videoconferencing psychotherapy (VCP). Therapists are not trained to conduct clinical treatments by videoconferencing (VC) as they normally rely on face-to-face interactions; thus, the establishment of a concept termed *presence* becomes essential. This term has been

used in VC as a concept that encapsulates 2 elements: (1) the degree to which the web-based experience of another person is analogous to a real-world meeting and (2) the degree to which the user experiences agency and control that impacts the real world [19]. Psychologists are aware of the importance of presence in the development of the therapeutic process and how it is crucial to be connected with clients *on what is going on* [20]. In this paper, we adopted this understanding of presence as a subjective psychological state mediated through VCTs [19]. Consequently, we will provide some pathways to enhance the perception of psychologists' *presence* in VC sessions. Previous research has indicated that in some cases, therapists have struggled with the absence of physical presence, lack of information from the client's body language, and reduced visibility of facial microexpressions [21]. Detecting the nuances of the voice is another known problem [22]. Both are vital tools for psychotherapeutic work.

Omodei and McClennan [23] reported that VCP is better received by clients than by psychologists. Although clients assess VCP sessions positively, psychologists perceive the technology as an element that limits the therapeutic processes. Rees and Stone [24] inform that psychologists find VCP inferior to face-to-face consultations in terms of building an effective TA. However, research has revealed that clients' experiences are more positive than those of psychologists, and little is known about the reasons for psychologists' major reservations.

In this paper, we focused on the interactions between TA and VC experiences to develop propositions for future research. Through this investigation, we addressed the following question: "How do psychologists and clients experience the TR and TA in videoconference psychotherapy?"

Nonetheless, before going through the VCP studies, we describe a pivotal theoretical framework that has impacted research and practice in psychology. This framework, the General System Theory (GST) [25], will also frame our analysis of VCP. This theory replaced the linear dominant stimulus-response model (robot model); here, the relationship and the interaction were identified in a frame involving an observing subject (the psychologist) and an observed object (the client). The GST reframed this conceiving one broader system of two interacting parts, the psychologist and the client, which influence each other and the whole system. GST helps researchers to detect behavioral patterns, interconnections, and interactions within the TR [26]. By applying this theoretical framework to the VCP context, the broader system mentioned above should also consider the computer as part of the interaction between psychologists and clients. Thus, in this updated framing, we will conduct our analysis considering the computer as an active third party in the communication. Hence, it is crucial to understand how psychologists communicate and deal with the new presence in the VC interaction system, since both might impact the development of therapeutic processes.

In the following sections, we will look at face-to-face psychotherapy, highlighting the impact of presence on the TR. The rest of the paper will propose an overview of the studies related to communication and conducted on computer-mediated communication (CMC). We aim to underline studies relating

to cooperative environments where the collaboration and the development of trust among users is crucial for reaching the final goal. Cooperation and trust are essential, key elements for the development of the TA and TR in the clinical context. We will then present the research methodology applied by explaining how the screened, selected articles have been processed. Afterward, we present the literature on both clients' and psychologists' experiences of TA and VCP. The last section will be dedicated to the discussion of the results and the presentation of some propositions, followed by the conclusion and suggestions for future research.

The Influence of Face-to-Face Interaction on the TR

This section introduces face-to-face psychotherapy and the role of presence in developing effective TR and TA. We also expanded on the important role of cognitive and emotional factors in TR.

Research has shown the improvement of clients participating in psychotherapy compared with people who had not received any psychological treatment [27,28]. According to that research, the face-to-face relationship impacts the effectiveness of psychotherapy, enables clients to acknowledge their issues, and creates the basis for a change. In this relationship, therapists act and communicate with their clients by adopting psychotherapy techniques that draw on theories of the TR [29]. Psychologists use all their communication channels when interacting with their clients. One of the most important nonverbal channels is vision, which helps both sides understand each other's thoughts, intentions, and emotions. Moreover, eye-contact is important to regulate and *control the communication* among people; this aspect of human communication is called meta-communication [30].

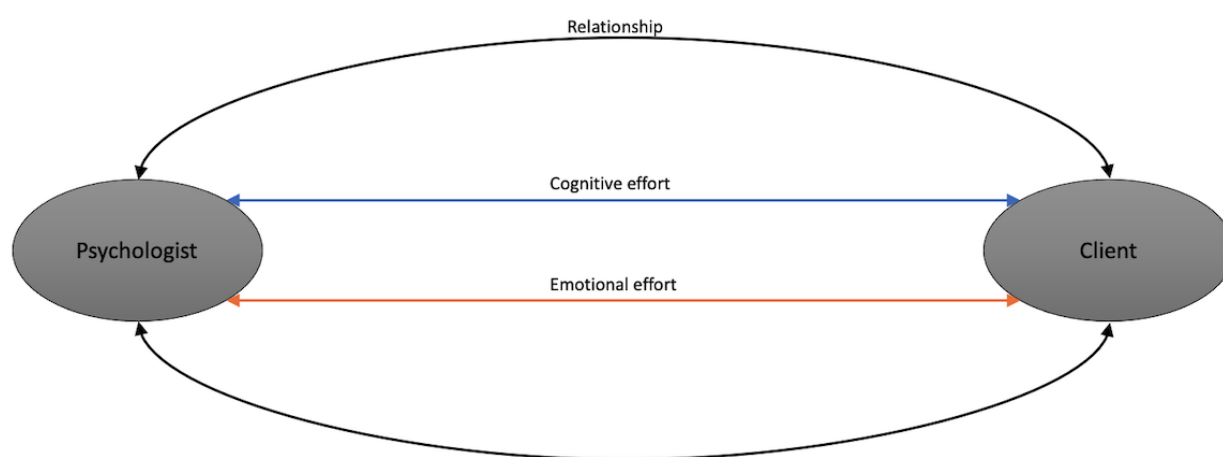
As for therapeutic rapport, some studies [11,31,32] suggest that the role of the TR is more significant than either the therapist's

correct identification of the client's issues or their assessment of the psychological concern. Early studies on the development of effective relationships in face-to-face treatment showed that a few aspects of the TR play a pivotal role, such as "therapist's personal reactions, [...] the quality of their communications, diagnostic impression and treatment plans" [33]. All these factors, along with the development of TA, should be considered as interrelated rather than independent [34].

Another study noted that psychotherapy is ineffective when therapists struggle to create a relationship based on warm communication and empathy [35]. Thus, TR needs to be formed to determine a change in clients' lives, and TA must be established to guarantee treatment effectiveness.

In human beings, the interaction processes include 2 aspects: cognition and emotion. According to emerging neuroscience studies, cognition and emotion are 2 separate mental functions that communicate through the mediation of interrelated, separate brain schemes [36]. Tucker et al [37] has shown that cognition and emotion are strictly connected: emotional communication is cognitive work where all the related information is combined and collected from several fonts of the brain. This is important because in every interaction, people process information cognitively and emotionally. Thus, Figure 1 aims to show the circular relationship (not linear but circular, based on the General System Theory [GTS]) linking psychologists and clients during their communication. Although clients are not required to be aware of these underpinning processes, psychologists' awareness is necessary within the consultation room. Consequently, psychologists process the interaction with their clients taking into account different levels of cognitive and emotional communication but also consider them in an interconnected assessment.

Figure 1. Face-to-face psychotherapy relationship.



To conclude, the effectiveness of traditional psychotherapy is based on face-to-face interactions that trigger therapeutic and relational processes. An effective sense of presence leads psychologists and clients to interact more successfully: improving communication and the chance to verify the accuracy of the therapists' diagnosis. By building effective TR and TA, both actors can better achieve the final goal: the client's

wellness. Hence, how do therapists and clients deal with the *absence of presence* in the VCP approach? Does VC technology affect TR and TA formation?

To address these questions, a proper understanding of the concept of trust in CMC is crucial because trust is related to the formation of an effective TR and TA in a therapeutic environment. Hence, analyzing the establishment of trust

between people interacting in CMC, it will be possible to gain data regarding the development of trust in computing environments. The presence of trust in face-to-face relationships is necessary for establishing a cooperative rapport aimed toward the achievement of common goals. Trust can then be defined as “a willingness to be vulnerable, based on positive expectations about the actions of others” [38].

In the next section, we present an extended study related to trust in CMC; we aim to gain a proper understanding of trust establishment in the case of relationships mediated by computers.

CMC Studies in Communication—Trust

Research findings related to trust in CMC are inconsistent. Although studies show that cooperative trust can be easily achieved with a software system [39], other research appears to disagree with that statement, pointing out the difficulty in establishing trust in CMC. According to Handy [40], “trust needs touch,” and other studies highlight the importance of face-to-face interaction clues for building trust. For instance, Nardi and Whittaker [41] claimed that within work environments, traditional face-to-face communication is essential to work efficiently and the CMC affects users in generating *interpersonal bonds*. Drolet and Morris [42] showed how people were more collaborative in face-to-face contact than by phone. Another piece of research [43] revealed that the 6 people involved in the experiment demonstrated higher levels of collaboration when communicating face-to-face rather than mailing.

Some authors [44,45] recognize that the development of trust is very closely related to proximity. Wilson et al [44] explained it as a consequence of sight limitation, which impacts the establishment of trust in remote exchanges: it is harder to detect

interaction signals that are potentially useful for achieving the shared task. However, Wilson et al [44] showed how trust is also likely to be developed in CMC, even after a delay: sharing *social information* by CMC involves the commitment of time. They affirm that people are prone to establish social relationships, either through face-to-face communication or through CMC. Wilson et al [44] also explained that trust formation is delayed for groups using computer-mediated systems (CMSs) because the interaction requires almost four times the number of messages transmitted by face-to-face interaction [46,47]. In their experiment, the cognitive and affective trust (in 3 different CMS texts) was negatively affected by the changes in communication media (happening at every meeting) while they increased when passing from CMSs to face-to-face. However, they were lower at the end of the first meeting, but by the end of the third meeting, the levels of trust were similar to face-to-face interaction.

Bos et al [48] analyzed trust development through different communication channels such as face-to-face interaction, VC, 3-way phone conference, and text chat. They confirmed that trust development is possible but unavoidably characterized by a higher delay and fragility compared with face-to-face meetings, even though the respondents subjectively reported high levels of collaboration. Thus, with regard to VC, trust appears to be present but is quite vulnerable. However, it has also been shown that if a spatially faithful VC system (multiview design) is provided, there is no substantial difference in terms of trust between face-to-face and VC group meetings [49].

In summation (Table 1), the literature examined showed that trust establishment is possible but, at the same time, highlights its fragility. However, it should be noted that when we move to psychotherapy, trust cannot be fragile in face-to-face or videoconference [50].

Table 1. Trust in computer-mediated communication.

Study	Title	Study design	Study participants	Task	Methodology	Outcome
Bickmore et al [39] (2005)	Establishing the computer–client working alliance in automated health behavior change interventions	3 treatment groups: <ul style="list-style-type: none"> Control Nonrelational Relational 	<ul style="list-style-type: none"> Healthy participants interested in increasing their physical activity 	Interaction with a software	Mixed methods	Trust is reachable even with a software
Bos et al [48]	Effects of four computer-mediated communications channels on trust development	<ul style="list-style-type: none"> 66 groups (3 persons per group) interacting face-to-face and through video, audio, and text chat 	<ul style="list-style-type: none"> People related to the university (mostly students) 	Interacting during a social dilemma game: Daytrader	Quantitative	Trust emerges with delay and is fragile
Nguyen and Canny [51]	Multiview: spatially faithful group video conferencing	3 experiments (7 groups of 3 individuals and 1 group of 2 individuals): <ul style="list-style-type: none"> Partial and full spatial awareness with respect to gaze Same as A with higher attention to gesture Mutual spatial awareness with respect to gaze 	<ul style="list-style-type: none"> Sample from the University of California, Berkeley (undergraduate and graduate students) 	The sample was asked to judge the pupils' direction	Qualitative	Presentation of the multiview design
Nguyen and Canny [49]	Multiview: improving trust in group video conferencing through spatial faithfulness	29 groups of 2 individuals and 37 groups of 3 divided in the following groups: <ul style="list-style-type: none"> face-to-face groups Directional VC^a Nondirectional VC 	<ul style="list-style-type: none"> 169 participants (from the Social Science Laboratory, University of California, Berkeley) 	Modified version of the social dilemma game developed by Bos et al [48]	Mixed methods	Spatial distortion in group meeting by video negatively impacts the development of trust, while trust is established when a spatially faithful VC system is provided
Drolet and Morris [42]	Rapport in conflict resolution: Accounting for how face-to-face contact fosters mutual cooperation in mixed-motive conflicts	<ul style="list-style-type: none"> 2 experiments. Solving conflict in side by side or face-to-face–phone or face-to-face 	<ul style="list-style-type: none"> Experiment 1: 134 master's students from Stanford University (Department of Business Administration) Experiment 2: 42 persons (master's and bachelor's students) from Stanford University 	People needed to negotiate having access to nonverbal behavior and cultivating relationships that enable reciprocal collaboration	Quantitative	People were more collaborative in face-to-face interactions rather than by phone

^aVC: videoconferencing.

Nonetheless, research conducted on CMC provided inconsistent outcomes related to whether the psychotherapy sessions could be face-to-face or CMC. In our previous study [8], we highlighted 2 positions. Based on one view, there are some unknown factors and features of traditional face-to-face communication that cannot be replaced by a computer. For example, according to Russell [52], some functions of communication are strictly correlated to physical presence. Henceforth, physical proximity is deemed necessary [53] by some for certain communication. The second point of view, in contrast, claims that the face-to-face “functions can potentially be choreographed...and potentially analogued”; thus, the

computer can replace some signals and be able to reproduce the *functions* typical of face-to-face communication [54].

To conclude, all these studies highlighted the difficulty of establishing a strong trust between users in CMC. Moreover, with regard to the possibility of having psychotherapy sessions face-to-face or through CMC, the literature mentions 2 different points of view; in particular, due to the fragility of trust in CMC, the building of an effective TR is more likely to be compromised.

Before presenting the results of the literature review on the clients and psychologists' experiences of VCP, we will provide our article selection criteria.

Methods

Search Design

This literature review follows the design approach described by Webster and Watson [55] applicable to information system (IS) fields to gather source material for reviewing extant literature. The authors propose identifying the main contributions in leading journals on a selected topic, taking into consideration the interdisciplinary character of the field of IS. Once those contributions to the topics have been identified, Webster and Watson [55] suggest proceeding with a *back and forth* strategy to gather additional studies to be considered in the review. By going *backward*, the authors mean to proceed with a review of the citations included in the articles identified in the first place as leading contributions, to determine which previously published studies should be included in the review process. By going *forward*, the authors mean to use an existing database to identify articles that mention the studies identified in the *backward* phase. This strategy ensures a relatively complete sample of the relevant literature.

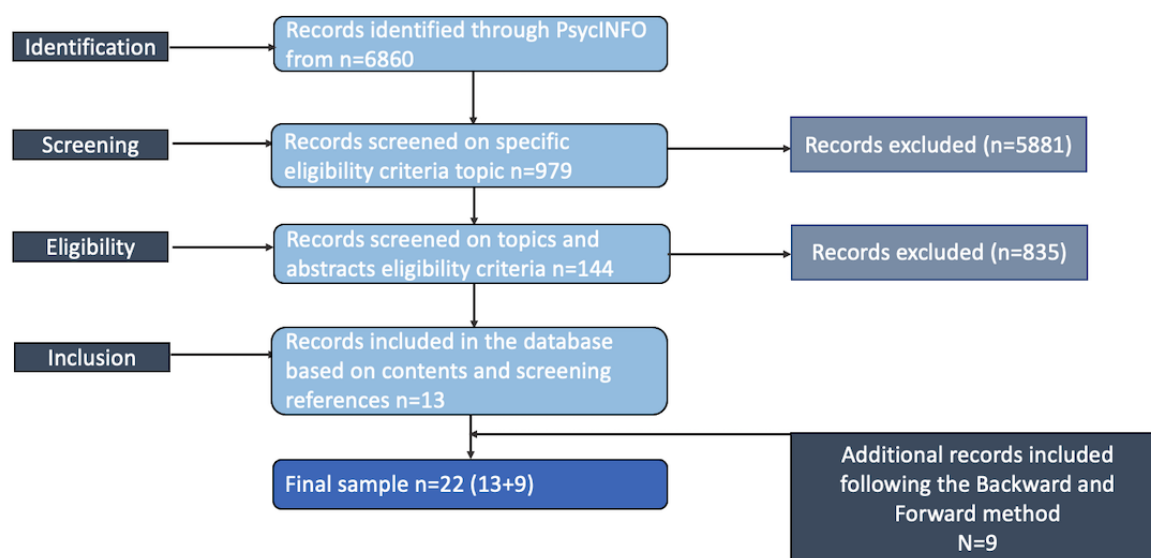
Search Strategy

We started our search on PsycINFO, launching several inquiries. Our strings included keywords selected through the analysis of the works identified in the two prior steps: *VC*, *psychotherapy*, *telehealth*, *online counseling*, *face-to-face*, *TR*, *TA*, *working*

alliance (WA), and *trust*. Through different combinations of these searches, we obtained thousands of results that were then refined using filters and advanced research tools. We proceeded with a fast screen of the titles to significantly refine the sample of articles, retaining only those that aligned with the scope of our study. This sample was analyzed following previously established eligibility criteria, such as the type of studies (analyses related to the TA and TR experienced by psychologists and clients, and all the studies not covering our topic area), study design (we considered empirical and other research designs including questionnaires, experiments, theoretical papers, etc), data source (leading journals, high class conference proceedings, and the theoretical studies considered significant to our topic), and publication status (we considered studies supported by clear references to journals and places where conference papers have been presented).

Consequently, we started our *backward* and *forward* review process from the analysis of the most relevant papers related to videoconference and psychotherapy and published in leading journals. Simultaneously, we examined the articles' reference lists to identify prior relevant research and the work of leading authors in the field. By applying the aforementioned criteria, the articles of interest resulted in the final sample of 22 studies (Figure 2). We then proceeded with the inclusion in our analysis of those works that appeared to be fitting the topic of this study. As we were not encountering new concepts and the reading of new papers did not offer any new contribution, we gauged the analysis as concluded. The most relevant studies analyzed are reported in Multimedia Appendix 1 [22,24,56-75].

Figure 2. Flowchart. Selection of studies.



Results

Clients and Psychologists' Videoconference Experiences

This section focuses on the previous literature reviews that explore the cooperation between clients and psychologists, namely the TA, and processes such as trust and empathy building between both actors of the TR. This section considers the following important studies that have provided significant data, especially considering the needs to deeply comprehend the formation of the TR.

Sucala et al [56] investigated the TR in online web-based therapy; most of their examined research considered TA as a key feature of TR. The results of this study suggest that e-therapy might be comparable with face-to-face interactions, although more studies are necessary to understand the online TR: in fact, its establishment is still doubtful. This study, along with Backhaus et al [57], who investigated potential differences in TR comparing face-to-face and VC modalities, suggested that VCP might be considered a valid alternative to the face-to-face, since clients and psychologists highlighted their general satisfaction. Simpson and Reid [58] explored the TA in VC as a central element for a successful therapy: they claimed there is evidence that suggests that TA is as well supported by VC for both clients and psychologists, although therapists' rates were often lower than those of clients.

By focusing on these reviews and according to Sucala et al [56], our study aims to explore the possible dynamics hidden in the development of TR by VC. Although research supports VCP as a useful, alternative way to deliver treatments, especially relying on clients' experiences, there is little information on the ongoing skepticism and difficulties of psychologists. The scarcity of data and the difficulties of researching the establishment of the TR by VC led us to focus on the elements that might change and impact the relationship between psychologists and clients.

By reporting previous studies providing useful insights on clients' and psychologists' videoconference experiences, this research will offer a new perspective aimed at understanding the relational dynamics buried in the foundation of the TR by VC. The following investigations suggest positive clients' experiences, but the literature also reports that psychologists struggle to deliver VC treatments. For this reason, it is essential to understand the different experiences in terms of the psychologist-client relationship.

Clients' Videoconference Experiences

Before presenting the following studies, it is important to mention that some research replaced the term TA with WA. The latter, according to Bordin [11], is a *universally applicable* term and refers to people willing to cooperate for a change. Thus, in the context of psychology, the expressions of WA and TA refer to the same meaning and are interchangeable.

In this section, we introduce the previous literature on clients' experiences of VCP: while there are some doubts about the opportunities to generate interactive VCP features similar to

those of face-to-face treatment [59], there is evidence of psychotherapeutic efficiency and a correlation between VCP and healthy behavioral changes [60].

Schopp et al [61] conducted an experiment on 98 adults with cognitive debilities. Half of the sample was treated through face-to-face interactions, while the other half was included in a control group treated through VC. The results showed that clients were generally satisfied, while psychologists rated the face-to-face interactions better than VC. A similar result has been shown in the preliminary study by Storch et al [62], which reported positive results from the young sample affected by obsessive compulsive disorder by VC. However, psychologists expressed their concerns due to the difficulty in establishing the TA, especially with children.

In another study, we noticed that some clients might be influenced by the lack of face-to-face communication, which limits trust establishment. Haberstroh et al [63] focused on web-based counseling sessions, proving the importance of trust for the research sample. Although some participants were encouraged by the lack of face-to-face communication to develop a sense of security as clients, others stated that the same factor had impacted their development of trust. In fact, according to Cook and Doyle [64], in web-based counseling, many obstacles hinder the TA, as nonverbal information is considered vital in generating relationships and intimacy [76] in counseling relationships [77]. The absence of these factors seems to impact the general picture of the relationship and the effectiveness of the treatment.

Nevertheless, with regard to the WA, Day and Schneider [65] analyzed and compared 3 groups treated by face-to-face, telephone, and video communication. The sample concluded at least 5 sessions: while a low level of participation was detected in face-to-face clients, no substantial difference was found in the formation of WA and the session outcomes.

The same result was confirmed by Glueckauf et al [66]. They conducted a study applying VCTs, speakerphone, and face-to-face channels, involving 22 young individuals affected by epilepsy. The research did not attest for any discrepancy in WA inventory and treatment adherence. All participants experienced a significant decrease in the grade of harshness and occurrence.

Studies conducted with participants affected by PTSD showed great results. A study conducted by Germain et al [67] with 46 participants showed that the sample did not present any significant difference in establishing TA. Gray et al [68], in a preliminary study on people living in a rural area, highlighted a positive response from psychologists, crisis center staff, and clients. The same result of feasibility and safety has been noticed by Acerno et al [69] with a large sample of veterans.

Carpenter et al [70] have also shown that TA can be established by VC in a study involving young people (with anxiety) and their families.

From the analyzed studies, although some inconsistencies emerge, it appears that clients could easily establish the TA and a proper relationship with their psychologists, as technology

would support them in enhancing interaction, attention, and intimacy.

Psychologists' Videoconference Experiences

In this section, we present the psychologists' VCP experiences, which strongly differ from the clients' VCP experiences. Indeed, psychologists had concerns about the establishment of a relationship with their clients.

Wray and Rees [71] explored psychologists' skepticism toward VCT. The authors found that psychologists agree that sessions conducted by VCT are not as effective as the face-to-face ones. They highlight psychologists' apprehensions about the difficulties to manage clients with personality disorders, suicide instinct, etc, who are harder to manage via video rather than face-to-face, and communication, as they find it difficult to be warm and comprehensive when trying to transmit empathy by VC.

However, while Cohen and Kerr [72] did not find an important difference in the TA when comparing web-based and face-to-face sessions, a study conducted by Hanley [73] registered a different response as psychologists reported dissatisfaction with the TA.

Rees and Stone [24] wanted to further investigate the development of TA in face-to-face versus VCP. In their study, one of the authors replicated with an actor an authentic session, which was video recorded as an face-to-face session and then repeated in a VC session. The session results were identical, and an external psychologist was contacted to prove that both videos of the sessions were satisfactorily comparable. Both videos, 20 min each, were then shown to psychologists. Therapists have been asked to watch both sessions and rate the TA. The overall results highlighted that VC sessions scored lower than face-to-face sessions.

A more recent study [74] captured a range of psychologists' concerns about the possibility of creating and/or maintaining TA by VC. Another study on parental counseling [75] claimed the overall satisfaction of clinicians and clients. However, some therapists struggled to establish the TR and clients expressed their preference for mixed therapy (face-to-face and VCP). Nonetheless, it was noticeable that psychologists gained confidence throughout the project's lifetime.

According to Fletcher-Tomenius and Vossler [22], psychologists need to trust their mental picture of clients and vice versa. In their study, therapists pointed out that there are several *elements of uncertainty* referred to in their mental pictures and the only possible solution would be to trust it, although there are no possibilities of understanding whether it is truthful.

Summing up these studies, psychologists' difficulties in establishing relationships with their clients emerge. These are summarized in [Multimedia Appendix 1](#).

Discussion

Principal Findings

In this study, clients and psychologists' experiences of VCP were presented. The analyzed investigations reported

inconsistent results. Some research claims VCP efficiency and its correlation to clients' beneficial changes [60]. However, despite research having underlined clients' positive responses in terms of TA and gratification, other research highlights clients' difficulty in establishing a good TA. The literature on psychologists' experiences is more consistent. Psychologists express that technology inhibits them from establishing a TR with their clients as effective as in face-to-face therapy.

By examining clients' VCP experiences, it seems that they take advantage of the VCP in terms of developing TA without experiencing discernible differences with face-to-face psychotherapy [58,65,66] and with higher levels of participation [65]. It seems that digital communication increases intimacy and eases the interaction when compared with a physical context, and this would benefit psychologists and clients in determining the acceleration of the psychotherapy process [78,79]. Moreover, the lack of face-to-face contact seems to encourage clients to develop a strong sense of security [63]. However, some studies in contrast discovered difficulties in establishing a strong TA due to the lack of body language and nonverbal communication [64,76,77].

It appears that the lack of presence might impact the general picture of the relationship and, consequently, the effectiveness of the treatment. Although there are inconsistent data regarding TA establishment, clients are gratified and obtain beneficial results by VCP.

Conversely, considering psychologists' VCP experience, we observed more consistently negative responses. They feel *limited* by technology, especially with clients with strong mental and emotional disorders. Psychologists feel that it is difficult to be transparently warm, understanding, and empathic [71]. Feedback on the quality of TA in VCP showed a general displeasure among psychologists [24,62,73]. With regard to the experience of VCP, they complain of the lack of information (especially visual data). This leads them to generate and rely on their own *mental picture* of the client's state due to the *element of uncertainty* and on their internal trust toward the whole process, both about themselves and their clients. They appear to feel unable to adequately *reach* their client via VC [22]. Furthermore, the absence of sight and physical proximity appears to be a key issue in CMC, since it does not allow users to acquire the information needed to establish trustworthy cooperation. As a result, trust appears fragile.

Considering all of the aforementioned studies, the incongruence, and the inconsistency of both clients' and psychologists' VCP experiences, we developed a theory aimed at providing a new framework for understanding the relationship connecting both the actors of the VCP interaction. Thus, in the next section, we introduce the model of the invisible third party.

Furthermore, according to the aforementioned studies, we explored the following propositions:

- Proposition 1: VCP might help clients to rapidly reach a strong TA by using digital technologies that enhance communication and intimacy with the psychologist.

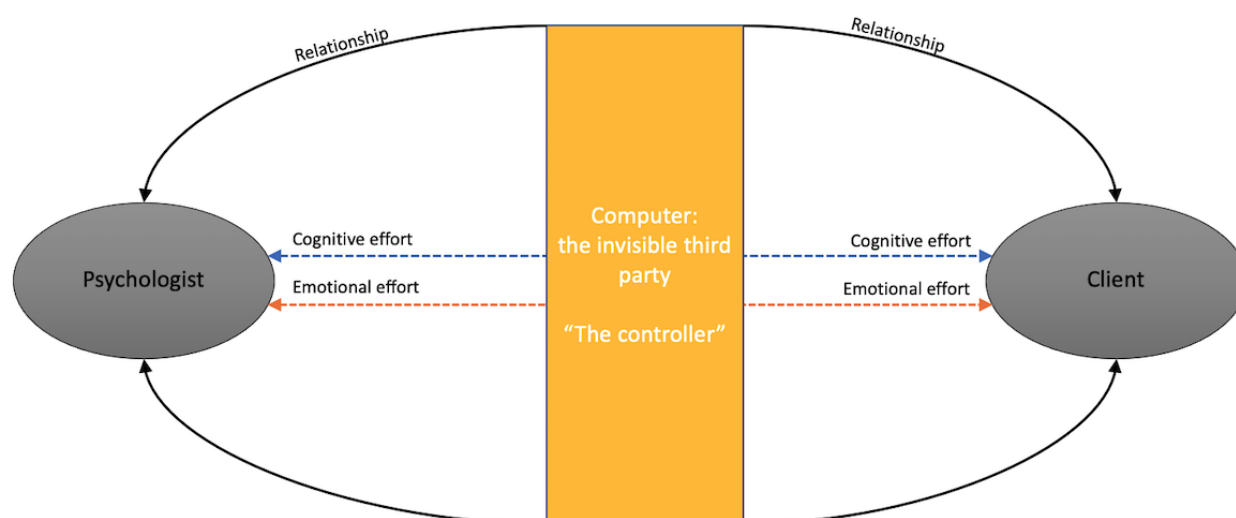
- Proposition 2: VCP might require clients to put more emotional than cognitive effort in the relationship with their psychologists.
- Proposition 3: VCP impacts the psychologists' ability to establish a strong TA because of the lack of information and control over the relationship.
- Proposition 4: VCP might help psychologists establish a strong relationship with their clients by increasing the quantity and quality of information.
- Proposition 5: VCP might impact the confidence of psychologists, as they have to build a mental picture of their clients without proving it.

Model of the Invisible Third Party

The contribution of this paper draws attention to the role of the computer not only as a vehicle of communication but mostly

as a *presence*. Indeed, following the study by Birdwhistell [80], we claim that any person is part of the communication process; we believe that all the components involved in the video communication are part of the system: psychologist, client, and computer. This position combined with the GST [25] leads us to propose a model of the invisible third party (Figure 3). Here, we consider the computer as a new member of the VCP. In this new scenario, the linear stimulus-response model has been replaced by the GST, which includes both psychologists and clients in a broader system of mutual influence. Hence, the computer is to be considered a new member of the circular relationship holding a new influence over the system. However, how does the computer impact the relationship between psychologists and clients?

Figure 3. Videoconference psychotherapy relationship model of the invisible third party.



According to Haley [81], the therapist's control over the TR is important for successful psychotherapy. Here, control is referred to as an interpersonal dynamic where *each participant is able to control or constrain the behavior of the other*; however, while therapists employ less control than clients according to the relational perspective, they employ extensive *control and influence* in specific and impacting areas with regard to TR [82].

In our model, we introduce the computer as the third invisible party (Figure 3) impacting the dynamics of *control* within the relationship between psychologists and clients. This perspective changes the traditional psychological framing and justifies the lack of confidence of psychologists in working with VC. In VCP there is the technical presence of the computer, which has *technical control* over the relationship between psychologists and clients. In this framework, the computer is not only the interaction vehicle between psychologists and clients, but it is a *presence*. Thus, the circular interaction of communication and the relationship is impeded and impacted by everything happening outside the psychologists' control. Therefore, we deduce that the cognitive mental effort might be highly demanding for psychologists who have to work around the new presence and to deal with external technical factors not strictly depending on themselves or their clients. This might require psychologists to create a virtual mental picture of their clients.

Moreover, they apparently need to *meta-communicate* bypassing the technology. Meta-communication might require psychologists to make greater cognitive and emotional effort, since they must overcome the obstacles posed by the video.

This new member of the interaction continuously gives new rules to the concept of relationship building. The computer-mediated application of meta-communication might result in high complexity, along with psychologists' required emotional efforts. Consequently, psychologists might prefer face-to-face psychotherapy to VCP due to the lower cognitive effort required by face-to-face psychotherapy.

According to our model, the following propositions should be explored:

- Proposition 6: VCP might require psychologists a specific cognitive effort, rather than an emotional one, in meta-communication with their clients.
- Proposition 7: VCP might challenge psychologists in dealing with the cognitive overload effort to mentalize and solve the unpredictable presence of the computer, which might control the relationship.

Conclusions

Studies based on CMC highlighted that communication can be impacted by audio-video quality [83], the lack of body language information [51], and the confusion of users in exchanging gazes, as it is hard to understand where people are looking [84].

Of course, if all these aspects challenge the communication mediated by the technology, they can also have a severe impact on the effectiveness of psychological treatment. Psychologists are trying to provide their support to their clients, even in large organizations [85], through the VCTs, yet the literature on the topic so far has underlined several communication barriers. These obstacles might hinder the establishment of an effective TR.

Our review of the literature on the experiences of clients and psychologists in the VCP highlighted that they have opposite perceptions of TA and TR established by VC. The role of the VCP in supporting psychologists and clients appears particularly crucial, especially in the current pandemic period. The current situation has also required an incremented use of smartphones for VCP, and according to Kim et al [86], there is no substantial difference in using mobile VCP and face-to-face.

Based on the results of this investigation, the model of the invisible third party has been presented; this includes the computer as one of the actors of the psychotherapy relationship. This actor's role has not been considered so far in studies

conducted on VCP. Nonetheless, we argue that its presence in the relationship impacts the development of the elements required for the emergence of empathy, trust, and emotional bonds. These processes are in fact necessary to establish a successful TA and determine VCP positive outcomes. With COVID-19 giving rise to global growth in the adoption of VC platforms, it is more likely that therapists are going to be increasingly relying on VCTs [87]. Initial studies have indicated that therapists, after familiarizing themselves with the VCP and VCTs, might increase their confidence in using such technologies and the quality of their TA and TR [75]. Therefore, it could be argued that therapists need specific training to deal with the features of a computer-mediated interaction with their clients. Based on our investigation in this paper, such training and professional development must include building presence (as defined by Rogers [4-6]) to develop TA and TR through CMC. By using the video as a resource and not as a limitation, psychologists might try to be *present* and connect with their clients *on what is going on*. Finally, future studies should explore if this enforced period of VCP (due to COVID-19) has impacted psychologists' work, facilitating the development of different therapeutic skills for dealing with their difficulty in *reaching out* to their clients. Furthermore, future research needs to continue to shed light on the role of the computer as an actor in the VC communication between psychologists and clients, leading to the possible development of new technological tools and interfaces to better respond to psychologists' requirements.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Overview of the studies examined in our analysis.

[DOCX File, 24 KB - [mental_v8i2e19004_app1.docx](#)]

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Abbreviations

CMC: computer-mediated communication
CMS: computer-mediated system
GST: General System Theory
IS: information system
TA: therapeutic alliance
TR: therapeutic relationship
VC: videoconferencing

VCP: videoconferencing psychotherapy

VCT: videoconference technology

WA: working alliance

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Original Paper

Use of Telehealth in Substance Use Disorder Services During and After COVID-19: Online Survey Study

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Abstract

Background: Social distancing guidelines for COVID-19 have caused a rapid transition to telephone and video technologies for delivering treatment for substance use disorders (SUDs).

Objective: This study examined the adoption of these technologies across the SUD service continuum, acceptance of these technologies among service providers, and intent of providers to use these technologies after the pandemic. Additional analysis using the validated technology acceptance model (TAM) was performed to test the potential applications of these technologies after the pandemic. The study objectives were as follows: (1) to assess the use of telehealth (telephone and video technologies) for different SUD services during COVID-19 in May-June 2020, (2) to assess the intended applications of telehealth for SUD services beyond COVID-19, (3) to evaluate the perceived ease of use and value of telehealth for delivering SUD services, and (4) to assess organizational readiness for the sustained use of telehealth services.

Methods: An online survey on the use of telephonic and video services was distributed between May and August 2020 to measure the current use of these services, perceived organizational readiness to use these services, and the intent to use these services after COVID-19. In total, 8 of 10 regional Addiction Technology Transfer Centers representing 43 states distributed the survey. Individual organizations were the unit of analysis.

Results: In total, 457 organizations responded to the survey. Overall, the technology was widely used; >70% (n>335) of organizations reported using telephone or video platforms for most services. The odds of the intent of organizations to use these technologies to deliver services post COVID-19 were significantly greater for all but two services (ie, telephonic residential counseling and buprenorphine therapy; mean odds ratio 3.79, range 1.87-6.98). Clinical users preferred video technologies to telephone technologies for virtually all services. Readiness to use telephone and video technologies was high across numerous factors, though telephonic services were considered more accessible. Consistent with the TAM, perceived usefulness and ease of use influenced the intent to use both telephone and video technologies.

Conclusions: The overall perceived ease of use and usefulness of telephonic and video services suggest promising post-COVID-19 applications of these services. Survey participants consistently preferred video services to telephonic services; however, the

availability of telephonic services to those lacking easy access to video technology is an important characteristic of these services. Future studies should review the acceptance of telehealth services and their comparative impact on SUD care outcomes.

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KEYWORDS

COVID-19; substance use disorders; technology acceptance model; telehealth

Introduction

COVID-19 has led to rapid virtualization of health care services, as in-person care needs to be delivered using telephone or video technologies. For example, nearly half of Medicare-covered primary care consultations were delivered virtually in April 2020 compared to 0.1% delivered before the pandemic in February 2020 [1]. Although Seema Verma (administrator, Centers for Medicare & Medicaid Services) stated that telehealth “will never replace the gold-standard of in-person care” [2], experts have acknowledged that rapid uptake of telehealth since the onset of COVID-19 may transform the health care system.

Undoubtedly, COVID-19 has accelerated the use of technology to deliver substance use disorder (SUD) services. However, technology usage for health care services has been gradually trending upward before COVID-19 [3,4] owing to five factors. First, smartphone ownership in the United States increased from 35% in 2011 to 81% in 2019 [5], thereby increasing access to online health resources. Second, mobile phone ownership has increased among low-income individuals. A recent study reported that 94% of homeless adults had access to a mobile phone, suggesting new opportunities to increase access to care in underserved populations [6]. Third, provider interest and the adoption of patient-centered technologies have strengthened [7]. Fourth, the feasibility and effectiveness of technology to deliver SUD treatment services have increased with the advent of both asynchronous internet-based technologies [3,8] and synchronous telephone- [9-11] and video-based [12-14] therapies. Fifth, increasing evidence is available regarding telehealth across health care services, and telehealth has increased patient access, adherence, and retention to care services [15]. Several preliminary studies have reported that telehealth yields equivalent outcomes to in-person care [16-18].

Despite these emerging trends, the actual adoption of telephonic and video SUD services has been slow [7,13]. Emerging data suggest that organization type (eg, health system, specialty treatment clinics, etc) [19] and location (eg, suburban, rural, urban, etc) [20] can potentially influence the readiness to use these technologies. Other organization-level factors influencing the readiness to adopt these technologies include financial resources for their deployment and perceptions of their ease, customization, clinical efficacy, and ability to enhance workflow [21-23]. Time for staff training and acceptance, technology accessibility, and access to information technology experts are additional key considerations [20,22,24]. In addition, patients’ perceptions and preferences toward technology are also important. Patients’ acceptance of these technologies affects the patient-clinician relationship and can influence staff acceptance of patient care technologies [25,26]. The perceived ease of use and value of these technologies influence both staff

and patient acceptance of them, which, in turn, influence decisions regarding their continued use [27-29].

This study aimed to fill an existing knowledge gap by surveying the use of telephone and video technologies in SUD services, while simultaneously assessing the projected use of these technologies beyond COVID-19 and evaluating the readiness of organizations to use them. Furthermore, this study investigated whether the technology acceptance model (TAM)—which has linked the intent to use a technology and actual technology use in numerous trials [30]—can predict the intent to use these technologies. We hypothesized that (1) >50% of organizations use telephone and video technologies, (2) the odds of increased post-COVID-19 use of these technologies among organizations would be significant, and (3) consistent with the TAM, the perceived usefulness of telephone and video technologies would mediate the effect of their ease of use on the intent to use them. Owing to the scarcity of data in these areas, we did not propose *a priori* hypotheses on preferences for telephone vs video technologies.

Methods

Study Design

We developed an online survey ([Multimedia Appendix 1](#)) to measure the use of telephone and video technologies for delivering a specific set of SUD services [7], gauge the intent to use telephonic and video services after COVID-19, and explore the perceived readiness to use telephonic and video services, using TAMs previously developed by Gustafson et al [21] and Davis et al [31]. Designated regional Addiction Technology Transfer Centers (ATTCs) distributed the survey in their respective regions. Substance Abuse and Mental Health Services Administration (SAMHSA)-funded ATTCs support the workforce for addiction treatment and recovery. These regional ATTCs correspond to the 10 regional offices of the US Department of Health and Human Services. In total, 7 of 10 regional ATTCs representing 43 states partnered in this survey. The 3 nonparticipant regional ATTCs represented the remaining 7 states; these ATTCs declined participation, citing survey overburden due to other unrelated surveys in the field.

Data Collection

The survey was distributed and data were collected from May 15 to August 31, 2020. Principal investigators at the regional ATTCs distributed survey links to SUD treatment and recovery support administrators or personnel (physicians, counselors, and peer recovery coaches). They used various methods to disseminate the survey and obtain a convenience sample as large and representative as possible, including the use of regional ATTC listservs and partnering with state policymakers to share the invitation widely. The survey questionnaire contained 79

questions. The respondents could change their answers before submitting the survey. Cookies were not used to identify unique users, but no incentive was provided to the respondents for completing the questionnaire, thus limiting the likelihood of duplicate survey submissions. Multiple responses from the same organization were averaged and accounted for in regression analysis. Only submitted surveys were analyzed. The University of Wisconsin's institutional review board approved the survey distribution and the recruitment of study participants (approval number 2020-0551). All data were collected using REDCap, a secure web application [32].

Survey Instruments

The survey included the following components and scales: organization type (ie, health system, opioid treatment programs, recovery community organizations, and specialty addiction treatment providers [nonopioid treatment programs]), organization location (ie, rural, small city, suburban, and urban), and organizational role of the respondents (ie, administrators and personnel providing treatment and recovery services, including counselors, physicians, and recovery coaches). Since rural individuals with SUDs are typically underserved [33] and are more markedly impacted by the opioid epidemic [34], and rural providers are more prone to adopt telehealth [20], the rural representativeness of the sample will be assessed using data from the National Treatment Center study [33].

For telehealth use, the survey assessed (1) the use of telephone and video technologies for the following services: screening and assessment, buprenorphine therapy, case management, intensive outpatient treatment, peer recovery support, regular outpatient treatment, and residential counseling sessions with binary yes/no variables; and (2) the projected intent to use telephonic and video services after implementing COVID-19 safety measures for these services, as per the following categories: "less than before," "about the same," "little more than before," or "much more than before."

The Organizational Readiness for Technology Use predictive tool developed by Gustafson et al [21] was used to assess dimensions of organizational readiness for the use of telephone and video technologies. Each item was evaluated using a 5-point Likert scale with endpoints of 1="strongly disagree" and 5="strongly agree." The inventory assessed the perceived feasibility of reimbursement for the technology during and after COVID-19; access to information technology experts, clinical champions, and billing experts to support the use of these technologies; ease of technology integration into the workflow; staff, facilities, and equipment to promote the technology; leadership, staff, and patient support; technology accessibility and affordability; and staff training.

The technology acceptance survey included two subscales from the TAM [35,36]: ease of use and perceived usefulness. The ease of use scale assesses the ease of learning, customizing, and using the technology. Perceived usefulness assesses the extent to which the technology is perceived to enhance effectiveness, improve performance, increase productivity, and be useful. Items in these subscales were scored on 5-point Likert scales with endpoints ranging from "strongly disagree" to "strongly

agree." These subscales were used in conjunction with the projected intent to use determined by the survey participants.

Data Analysis

Frequency distributions were used to describe organizational characteristics (setting and type), participant job descriptions, the use of telephone and video technologies for different SUD services, and the intent to use these technologies to deliver various services post COVID-19. In 3 regions, an overall survey response rate was calculated using a query on unique organizations identified from regional ATTC databases. For Regional ATTCs that lacked the capacity to conduct this query (n=5), SAMHSA's Treatment Episode Database was used to estimate the available number of total SUD treatment organizations in that region's states. The rural representativeness of the sample was calculated using data from the National Treatment Center Study [33], in accordance with a robust literature base indicating that rural organizations have been disproportionately affected by the opioid epidemic [34] and are more likely to adopt telehealth [20]. We used linear mixed-effects models (LMMs) to investigate differences in the intent to use telephone and video technologies based on organization location or setting and the job functions of the survey respondents, accounting for multiple respondents within the same organization. These models are expressed using the following equation:

$$\text{Intent}_{ij} = \beta_0 + \beta_1 X + u_i + \epsilon_{ij} \quad (1)$$

where X denotes either the organization location, setting, or job function of the survey respondent; u_i is the random intercept for organizations, and ϵ_{ij} is the within-organization random error.

Composite scores for the intent to use telephone and video technologies were generated by averaging those of the intent to use services after the implementation of COVID-19 safety measures across the different SUD services considered herein. To compare the odds of using telephone vs video technologies for the different post-COVID-19 services, a generalized LMM was used. These analyses compared the odds of reporting "more use"/"little more use" of these technologies post COVID-19 to those of reporting "about the same"/"little less" for telephone and video technologies post COVID-19. These models are expressed using the following equation:

$$\text{Response}_{ij} = \beta_0 + \beta_1 \text{Technology} + u_i + \epsilon_{ij} \quad (2)$$

where u_i denotes the random intercept for organizations, and ϵ_{ij} is the within-organization random error.

Variables determining organizational readiness for technology adoption were analyzed by comparing the scores for organizational readiness for the use of telephone and video technologies by using LMMs to investigate differences in factors between these technologies. These models are expressed using the following equation:

$$\text{Readiness}_{ij} = \beta_0 + \beta_1 \text{Technology} + u_i + \epsilon_{ij} \quad (3)$$

where u_i denotes the random intercept for organizations, and ϵ_{ij} is the within-organization random error.

Lastly, the TAM data were analyzed through mediation analysis, which compared the perceived ease of use and perceived usefulness variables to the composite intent of use variables for telephonic and video services. These mediation analyses were conducted using linear regression models to predict the use of technology [36]. These models are expressed using the following equations:

$$\text{Future Intent} = \beta_{10} + \beta_{11}\text{Ease of Use} + \varepsilon_1 \quad (4)$$

$$\text{Perceived Ease of Use} = \beta_{20} + \beta_{22}\text{Perceived Usefulness} + \varepsilon_2 \quad (5)$$

$$\text{Future Intent} = \beta_{30} + \beta_{33}\text{Ease of Use} + \beta_{33}\text{Perceived Usefulness} + \varepsilon_3 \quad (6)$$

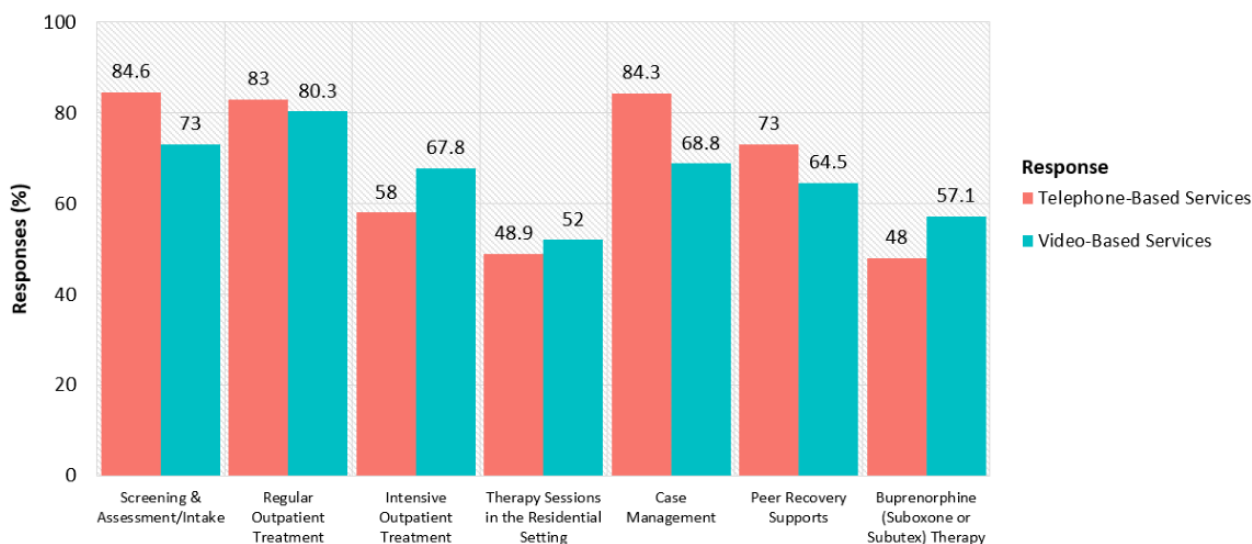
where ε is the error in the estimation of the intent and ease of use. All analyses were conducted using the lme4 package (RStudio).

Results

The survey respondents represented 457 unique organizations from 43 states. The survey was distributed to an estimated 2785 organizations that provide SUD services, with an estimated return rate of 16%. A total of 92 (20.1%) organizations identified themselves as rural, which closely approximated that reported in the National Treatment Center study (19.9%). In total, 268 (58.6%) organizations provided specialty treatment (excluding opioid treatment programs), whereas 101 (22.2%) were health organizations.

Figure 1 shows the current rates of using telephonic and video SUD services by service type. In total, 387 (84.6%) organizations used telephonic SUD services most frequently for screening and assessments. Furthermore, 367 (80.3%) organizations used video SUD services most frequently for regular outpatient treatment. We observed the most marked difference in the use of telephone ($n=386$ [84.4%] respondents) and video ($n=314$ [68.8%] respondents) technologies for case management.

Figure 1. Rates of use of different telehealth services.



As a first step in investigating future use, we examined whether the intent to use telephonic or video services beyond COVID-19 varied as a function of organization location or type or staff type. No significant differences resulted from the organization location (ie, rural, urban, suburban, or urban). Regarding organization type, the intent to use telephonic services post COVID-19 was significantly greater for health systems (mean

2.99; 95% CI 2.66-3.32) than for specialty treatment sites (mean 2.77; 95% CI 2.65-2.88) ($P=.04$) (Table 1). In total, among the survey respondents, 187 (38.7%) were administrators and 270 (61.3%) were personnel who provide treatment and recovery services, and no significant difference in the intent to use telephonic or video services post COVID-19 were observed between them ($P=.51$).

Table 1. Characteristics of the participating organizations (N=457).

Predictor	Organizations, n (%)	Future intent of using telephonic services		Future intent of using video services	
		Estimate (95% CI)	<i>P</i> value	Estimate (95% CI)	<i>P</i> value
Organization setting					
Rural	92 (20.1)	2.83 (2.64 to 3.02)	<.001	2.97 (2.78-3.16)	<.001
Small city	94 (20.5)	−0.02 (−0.28 to 0.25)	.90	−0.02 (−0.29 to 0.24)	.87
Suburban	80 (17.4)	0.23 (−0.05 to 0.05)	.11	0.08 (−0.19 to 0.36)	.56
Urban	191 (42)	−0.06 (−0.29 to 0.18)	.63	0.07 (−0.17 to 0.31)	.55
Organization type					
Specialty treatment	268 (58.6)	2.77 (2.65 to 2.88)	<.001	3.04 (2.93 to 3.16)	<.001
Health system	101 (22.2)	0.22 (0.01 to 0.44)	.04	−0.01 (−0.23 to −0.20)	.90
Opioid treatment programs	47 (10.2)	0.14 (−0.15 to 0.42)	.35	−0.17 (−0.47 to −0.14)	.29
Recovery community	41 (9)	0.22 (−0.11 to 0.55)	.19	−0.03 (−0.36 to −0.29)	.84
Respondent job function					
Administrator	187 (41)	2.87 (2.72 to 3.01)	<.001	3.13 (2.99 to 3.28)	<.001
Personnel providing treatment and recovery services	270 (59)	−0.06 (−0.25 to 0.12)	.51	−0.17 (−0.35 to −0.02)	.08

As shown in [Table 2](#), all the SUD services had a positive odds ratio (OR) for the intent to use telephone or video technologies, reporting responses of “much more” or a “little more” after COVID-19 compared to those of “about the same” or a “little less” before COVID-19. The only exceptions were for nonsignificant ORs for using telephonic services in the

residential setting or for buprenorphine therapy post COVID-19. In general, the odds of using video technology were greater than those of using telephone technology for all services, except for case management (OR 1.37, 95% CI 0.94-2.01; $P=.10$) and peer recovery services (OR 1.06, 95% CI 0.70-1.61; $P=.78$, prospectively).

Table 2. Odds of using telehealth post COVID-19.

Service	Telephone technology		Video technology		Video vs telephone technologies	
	OR ^a (95% CI)	P value	OR (95% CI)	P value	OR (95% CI)	P value
Screening and assessment/intake	3.06 (1.91-4.90)	<.001	5.49 (3.28-9.19)	<.001	1.79 (1.25-2.57)	.001
Regular outpatient treatment	4.01 (2.41-6.68)	<.001	6.98 (3.99-12.19)	<.001	1.74 (1.20-2.52)	.003
Intensive outpatient treatment	1.59 (1.02-2.48)	.04	3.85 (2.33-6.34)	<.001	2.42 (1.53-3.81)	<.001
Residential therapy sessions	1.87 (0.98-3.56)	.06	4.09 (2.04-8.22)	<.001	2.19 (1.26-3.83)	.006
Case management	3.74 (2.24-6.25)	<.001	5.12 (2.98-8.80)	<.001	1.37 (0.94-2.01)	.10
Peer recovery supports	4.06 (2.33-7.06)	<.001	4.31 (2.47-7.52)	<.001	1.06 (0.70-1.61)	.78
Buprenorphine (Suboxone or Subutex) therapy	1.18 (0.62-2.26)	.61	3.69 (1.81-7.55)	<.001	3.12 (1.68-5.81)	<.001

^aOR: odds ratio.

[Table 3](#) summarizes the organizational readiness for technology use measures. For telephonic services, three factors had the highest average rating on the 5-point Likert scale: (1) telephonic counseling is affordable to patients (3.83, 95% CI 3.72-3.94), (2) our leadership supports the implementation of telephonic counseling (3.78, 95% CI 3.67-3.89), and (3) most of our patients have access to telephonic counseling (3.78, 95% CI 3.67-3.89); video services: (1) our leadership supports the

implementation of video counseling (3.87, 95% CI 3.75-3.98), (2) staff want video counseling to be sustained (3.72, 95% CI 3.61-3.84), and (3) video counseling easily integrates into our workflow (3.66, 95% CI 3.55-3.77) and is affordable to patients (3.66, 95% CI 3.55-3.77).

Analysis of ORs for video vs telephonic services revealed several significant differences between these technologies ([Table 3](#)). Video services were considered less advantageous for the

following factors: most of our patients can access the technology (-0.71 , 95% CI -0.83 to -0.59 ; $P<.001$), patients find that telephonic/video counseling is easy (-0.51 , 95% CI -0.63 to -0.40 ; $P<.001$), patients want telephonic/video counseling to be sustained (-0.17 , 95% CI -0.28 to -0.07 ; $P=.001$), and counseling is affordable to patients (-0.17 , 95% CI -0.28 to

-0.05 ; $P=.004$). Video services were considered more advantageous for the following factors: there is a clinical champion for the promotion of counseling (0.29 , 95% CI 0.17 - 0.40 ; $P<.001$), and we anticipate being adequately reimbursed for the services we provide with counseling after COVID-19 (0.11 , 95% CI 0.01 - 0.21 ; $P=.04$).

Table 3. Organizational readiness for using telephone and video technologies.

Factor	Telephone technology, OR ^a (95% CI)	Video technology, OR (95% CI)	Video vs telephone technologies	
			OR (95% CI)	P value
Most of our patients can access telephonic/video technologies	3.78 (3.67 to 3.89)	3.07 (2.95 to 3.18)	-0.71 (-0.83 to -0.59)	$<.001$
Our leadership supports the implementation of telephonic/video counseling	3.78 (3.67 to 3.89)	3.87 (3.75 to 3.98)	0.09 (-0.01 to 0.19)	.09
Patients find telephonic/video counseling is easy to use	3.75 (3.64 to 3.85)	3.23 (3.12 to 3.34)	-0.51 (-0.63 to -0.40)	$<.001$
Patients want telephonic/video counseling to be sustained	3.68 (3.56 to 3.79)	3.50 (3.39 to 3.62)	-0.17 (-0.28 to -0.07)	.001
Staff has been properly trained in telephonic/video counseling	3.35 (3.23 to 3.48)	3.39 (3.26 to 3.51)	0.03 (-0.08 to 0.14)	.59
Staff, facilities, equipment, job descriptions, and policies are in place for sustaining telephonic/video counseling	3.43 (3.32 to 3.55)	3.53 (3.41 to 3.65)	0.09 (-0.01 to 0.20)	.09
Staff want telephonic/video counseling to be sustained	3.66 (3.55 to 3.77)	3.72 (3.61 to 3.84)	0.06 (-0.05 to 0.18)	.30
Telephonic/video counseling easily integrates into our workflow	3.63 (3.52 to 3.74)	3.66 (3.55 to 3.77)	0.03 (-0.08 to 0.14)	.62
Telephonic/video counseling is affordable to patients	3.83 (3.72 to 3.94)	3.66 (3.55 to 3.77)	-0.17 (-0.28 to -0.05)	.004
There is a clinical champion for the promotion of telephonic/video counseling	3.14 (3.01 to 3.26)	3.42 (3.30 to 3.54)	0.29 (0.17 to 0.40)	$<.001$
We anticipate being adequately reimbursed for the services we provide with telephonic/video counseling after COVID-19	3.27 (3.14 to 3.39)	3.38 (3.25 to 3.50)	0.11 (0.01 to 0.21)	.04
We are adequately reimbursed for the services we provide with telephonic/video counseling during COVID-19	3.32 (3.20 to 3.44)	3.38 (3.26 to 3.50)	0.06 (-0.04 to 0.16)	.23
We have the billing expertise to support use of telephonic/video counseling in our organization	3.55 (3.43 to 3.66)	3.59 (3.47 to 3.71)	0.04 (-0.05 to 0.14)	.38
We have the information technology expertise to support the use of telephonic/video counseling in our organization	3.53 (3.41 to 3.65)	3.53 (3.42 to 3.65)	0.01 (-0.10 to 0.12)	.90

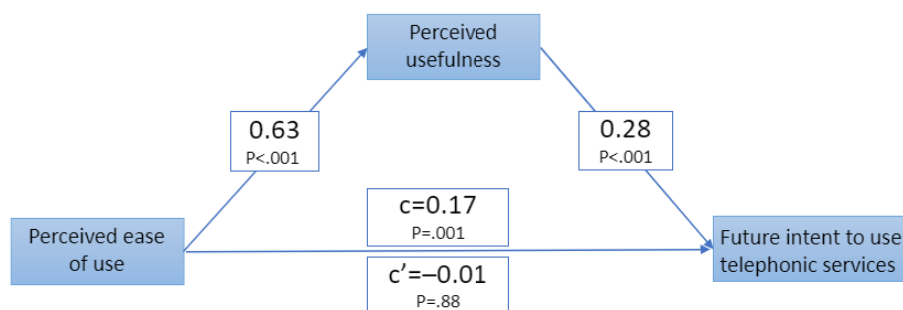
^aOR: odds ratio.

Figure 2 presents the findings of the TAM. Specifically, these analyses tested the perceived usefulness of these technologies as a mediator of the effects of the ease of their use on the intent to use them. Separate analyses were conducted for telephonic and video services. On mediation analysis for telephonic services, perceived ease of use was significantly associated with future intent of use ($P=.001$). Inclusion of perceived usefulness to the model resulted in significant associations between perceived ease of use and perceived usefulness ($P<.001$) and

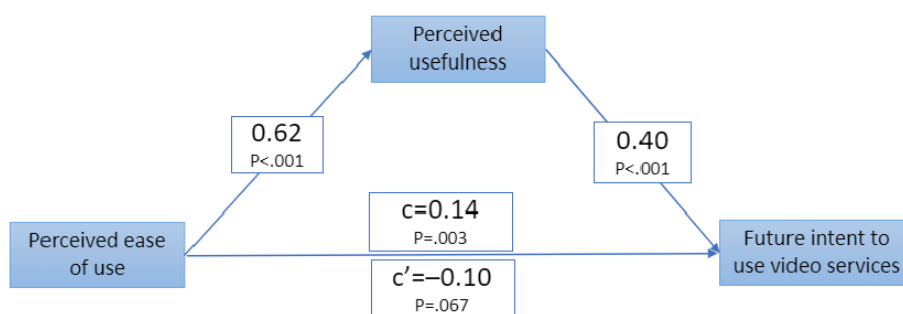
between perceived usefulness and future intent of use ($P<.001$). The association between perceived ease of use and future intent of use was not significant ($P=.88$), indicating complete mediation. Mediation analysis revealed similar associations for the intent to use video services, wherein the path between perceived ease of use and future intent to use was significant ($P=.003$). This path was no longer significant ($P=.07$) upon including perceived usefulness in the model (Figure 2).

Figure 2. Technology acceptance model for telephonic services and video substance use disorder services.

Mediation Analysis: future intent to use telephonic services



Mediation Analysis: future intent to use video services



Discussion

Principal Findings

This study surveyed administrators and personnel from SUD treatment and recovery organizations to evaluate their current and projected use of telehealth for different SUD services during the early months of the COVID-19 pandemic. We examined key concepts for telephonic and video services separately, including the current use of technology, intent to use these technologies post COVID-19, and organizational readiness for using these technologies. We hypothesized that organizations would report high usage rates (>50%) of the current telephone and video technologies across a range of SUD services and would report significant odds of intending to increase their usage of these technologies post COVID-19. Furthermore, we conjectured that consistent with the TAM, perceived usefulness of technology would mediate the effects of ease of use on the intent to use these technologies. We did not propose *a priori* hypotheses about which SUD services would be most conducive to telehealth or whether differences would emerge between telephonic and video services.

Regarding the use of telehealth services during the survey, consistent with our hypotheses, most organizations used various

services. Screening was the most common telephonically delivered service, whereas outpatient treatment was the most common video-delivered service.

These results are encouraging, since numerous studies have suggested that drug and alcohol screens can be administered telephonically with high levels of reliability and validity, and that outpatient treatment delivered via videoconferencing has comparable effectiveness to in-person care [37].

Regarding the future intent to use these services, consistent with our hypotheses, organizations reported significant odds of increasing their use of telehealth and video services after COVID-19. The two services for which respondents did not anticipate using telephonic services were buprenorphine therapy and residential counseling. For both of these services, respondents reported their willingness to use video-based services, suggesting their receptiveness to using technology in general, but they expressed specific concerns about using the telephone. The reticence to prescribe buprenorphine telephonically could reflect various factors, including provider mistrust and stigma toward patients with opioid use disorders, as well as concerns about diversion [38]. Use of video services was viewed more favorably, compared to telephonic services, for most SUD services.

Regarding organizational readiness for technology use, systematic differences emerged between telephone and video technologies. Relative to video services, respondents perceived telephonic services as more advantageous in terms of access, ease of use, affordability, and ease of sustainability. By contrast, video services were perceived as more valuable in terms of the likelihood of reimbursement and having the support of a clinical champion. Respondents preferred video services to telephonic services for all but two services. These findings are consistent with those of previous studies reporting that video-based counseling is associated with higher patient satisfaction but is substantially more expensive and not necessarily associated with superior levels of abstinence [39]. With the emergence of new videoconferencing tools, telephonic counseling would likely still have value owing to its simplicity, affordability, and reach, particularly among patients with limited access to video-based technologies.

Finally, on performing TAM analysis, the mediation model supported our hypothesis that the perceived usefulness of technology would mediate the association between the ease of use and the intent to use. This model emphasizes the critical role of the perceived usefulness in the adoption and current use of technologies. The survey outcomes were encouraging, in that SUD program administrators and personnel perceived the use of telephone and video technologies as useful during and after COVID-19.

Limitations

However, our results should be considered within the context of several limitations. First, participants were recruited through convenience sampling of administrators and leaders contacted by principal investigators of regional ATTCs via email. Hence,

the sampling methods might have resulted in a selection bias, such that individuals most comfortable with technology were most likely to complete the electronic survey. Furthermore, this sampling approach limits direct comparisons between participants who completed the survey and those who did not, though we could estimate a response rate and examine the rural representativeness of the sample on the basis of publicly available nationwide data. Second, even though the survey respondents represented 43 states and a range of organizational settings, the present findings based on a limited response rate may not be extrapolated to the general population. Third, patient-level data were not collected during sampling, thus limiting the representativeness of this sample and nationwide SUD organizations on the basis of the characteristics of the patients they serve.

Conclusions

Nonetheless, our results provide a promising outlook toward the use of telephonic and video services after COVID-19. Regarding the future applications of telehealth, this study suggests that the rapid transition to widespread use of telephonic and video services—necessitated almost overnight owing to COVID-19 stay-at-home orders and social distancing guidelines—is associated with high levels of provider receptivity to telephone technology. Clinicians perceived video services more appealing but telephonic services more accessible, suggesting that both channels play a role in the delivery of SUD services. Respondents' perceptions of the continued use of telehealth post COVID-19 and their general readiness to use it support the positive outlook toward the role of telehealth in SUD services. Future studies are required to review the acceptance of these different service delivery approaches and their impact on care outcomes.

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Conflicts of Interest

TM has <1% stock ownership in CHESS Mobile Health. CHESS Mobile Health does not provide or facilitate the delivery of telephonic or video care services. TM has worked extensively with his institution to manage any conflicts of interest. Other authors have no conflicts to declare.

Multimedia Appendix 1

Telehealth survey questions.

[DOCX File, 94 KB - [mental_v8i2e25835_app1.docx](https://mental.jmir.org/2021/2/e25835_app1.docx)]

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Abbreviations

ATTC: Addiction Technology Transfer Center

LMM: linear mixed-effects model

OR: odds ratio

SAMHSA: Substance Abuse and Mental Health Services Administration

SUD: substance use disorder

TAM: technology acceptance model

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Corrigenda and Addenda

Correction: Psychological Impact of the COVID-19 Pandemic on Chinese Health Care Workers: Cross-Sectional Survey Study

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In “Psychological Impact of the COVID-19 Pandemic on Chinese Health Care Workers: Cross-Sectional Survey Study” (*JMIR Ment Health* 2021;8(1):e23125) the authors noted four errors.

In the originally published manuscript, author Yujie Zhou was listed twice. The duplicate instance of this author has been removed in the corrected version.

The originally published manuscript had no equal contribution footnote. This has been corrected so that authors Jie Ni, Fang Wang, and Yihai Liu are noted as equal contributors.

Affiliations for all authors have also been corrected. The full list of authors and affiliations in the originally published version of the paper was:

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Mingyue Wu, MD; Yan Jiang, MD; Yujie Zhou, MD;
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Taking into account all of the above corrections, the full list of authors and affiliations has been corrected to:

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The correction will appear in the online version of the paper on the JMIR Publications website on February 2, 2021, together with the publication of this correction notice. Because this was made after submission to PubMed, PubMed Central, and other full-text repositories, the corrected article has also been resubmitted to those repositories.

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Original Paper

The Efficacy of WeChat-Based Parenting Training on the Psychological Well-being of Mothers With Children With Autism During the COVID-19 Pandemic: Quasi-Experimental Study

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Abstract

Background: During the COVID-19 pandemic, special education schools for children in most areas of China were closed between the end of January and the beginning of June in 2020. The sudden interruption in schooling and the pandemic itself caused parents to be anxious and even to panic. Mobile-based parenting skills education has been demonstrated to be an effective method for improving the psychological well-being of mothers with children with autism. However, whether it can improve the psychological states of mothers in the context of the COVID-19 pandemic is a subject that should be urgently investigated.

Objective: The aim of this study is to evaluate the efficacy of WeChat-based parenting training on anxiety, depression, parenting stress, and hope in mothers with children with autism, as well as the feasibility of the program during the COVID-19 pandemic.

Methods: This was a quasi-experimental trial. A total of 125 mothers with preschool children with autism were recruited in January 2020. The participants were assigned to the control group (n=60), in which they received routine care, or the intervention group (n=65), in which they received the 12-week WeChat-based parenting training plus routine care, according to their preferences. Anxiety, depression, parenting stress, hope, satisfaction, and adherence to the intervention were measured at three timepoints: baseline (T0), postintervention (T1), and a 20-week follow-up (T2).

Results: In total, 109 mothers completed the T1 assessment and 104 mothers completed the T2 assessment. The results of the linear mixed model analysis showed statistically significant group \times time interaction effects for the intervention on anxiety ($F=14.219$, $P<.001$), depression ($F=26.563$, $P<.001$), parenting stress ($F=68.572$, $P<.001$), and hope ($F=197.608$, $P<.001$). Of all mothers in the intervention group, 90.4% (48.8/54) reported that they were extremely satisfied with the WeChat-based parenting training. In total, 40.0% (26/65) logged their progress in home training each week and 61.5% (40/65) logged their progress more than 80% of the time for all 20 weeks.

Conclusions: The WeChat-based parenting training is acceptable and appears to be an effective approach for reducing anxiety, depression, and parenting stress, as well as increasing hope in mothers with children with autism during the global COVID-19 pandemic. Future studies with rigorous designs and longer follow-up periods are needed to further detect the effectiveness of the WeChat-based parenting training.

Trial Registration: Chinese Clinical Trial Registry ChiCTR2000031772; <http://www.chictr.org.cn/showproj.aspx?proj=52165>

KEYWORDS

coronavirus disease 2019; autism spectrum disorder; parenting training; psychological well-being; social media; WeChat; COVID-19; autism; parenting; mental health; well-being; anxiety; depression; stress

Introduction

COVID-19 emerged in Wuhan in late 2019 and then spread throughout China. Now, it has swept through more than 200 countries and has been identified as a public health emergency of international concern and characterized as a pandemic by the World Health Organization (WHO) [1]. COVID-19 is caused by SARS-CoV-2, which is genetically similar to severe acute respiratory syndrome coronavirus (SARS-CoV). In addition, it seems to be less pathogenic but more transmissible than SARS-CoV and Middle East respiratory syndrome coronavirus (MERS-CoV) [2-4]. The Chinese government initiated a first-level public health response to prevent the spreading of the outbreak. For example, the city of Wuhan was locked down on January 23, 2020, and the government implemented compulsory measures that restricted gatherings [5]. Nationwide school closures were implemented by the Ministry of Education, and 47 million preschool children were confined to their homes until the outbreak was mostly under control [6]. Most of the special education schools in China resumed classes at the beginning of June. This closure period lasted for about four months or even longer. As such, these preschool children were not able to engage in various forms of learning activities. The sudden interruption in learning and the impacts of the pandemic itself caused anxiety and even panic among parents.

Autism spectrum disorder (ASD) is a heterogeneous neurodevelopmental disorder typically characterized by restricted interests, repetitive behaviors, and deficits in social reciprocity and communication [7]. These impairments not only affect children's physical development but also their mental development, especially social-emotional development, which may result in their parents experiencing psychological stress and economic burden [8]. In recent years, the prevalence rate of children with ASD has been as high as 10.18 per 10,000 and has been increasing in China [9]. Children with ASD require continuous long-term training to improve their cognitive development and behaviors. Due to the deficits in social reciprocity and communication, the special training teachers, regular training activities, and training place for each child are relatively fixed. However, the sudden COVID-19 outbreak interrupted familiar and routine training activities for preschool children with ASD, and restrictions of the children's physical environments may exacerbate their behavioral problems [10]. Coupled with the impacts of the pandemic, parents, especially mothers, who may have already been under great psychological pressure may become more helpless and hopeless. Additional support should be provided to individuals with ASD who are identified to be in a group with higher risk of complications from COVID-19. Furthermore, support for the mental well-being of families is essential during the outbreak to avoid increases in parental stress [11].

Parenting training, a promising approach for teaching specific techniques and strategies, is recommended for parents with children with autism; such techniques can include parent-mediated social communication therapy and parent-child joint engagement [12,13]. However, access to face-to-face support for parents is often restricted in China due to factors such as parents' time constraints, distance, and uncontrollable weather conditions. According to the WHO, telehealth interventions can deliver health care using telecommunications and virtual technologies [14]. Given the advantages of telehealth interventions (eg, low cost, easy dissemination, and high accessibility), they can be used in parental training [15]. In addition, telehealth interventions can ensure the consistency of teachers and places, and the continuity of the intervention, which may be more suitable for children with ASD—and their parents—who lack access to face-to-face training. Recent studies have shown that telehealth interventions can improve the behaviors of children with ASD [16-19]. Telehealth interventions based on computer and internet technologies have also served as effective methods for improving the psychological well-being of mothers with children with autism [17,20]. However, whether mobile phone-based parenting training can improve the psychological states of mothers in the context of a pandemic is an urgent subject to be investigated. Therefore, this study aimed to evaluate the efficacy of WeChat-based parenting training on the psychological well-being of mothers with children with autism during the COVID-19 pandemic. We had the following hypotheses:

1. The WeChat-based parenting training program is feasible and acceptable for mothers with children with autism.
2. When compared to those in the control group, mothers in the intervention group will report lower levels of anxiety, depression, and parenting stress, and higher levels of hope during the COVID-19 pandemic.

Methods

Study Design

An assessor-blind quasi-experimental trial with a nonequivalent control group and nonrandom distribution was conducted. The study protocol was formulated to standardize the study.

Ethical Considerations

Ethical approval was obtained from the Research Ethics Committee of Fujian Medical University and the study hospital (Fujian Provincial Maternity and Child Health Hospital; 2017-105). All participants were informed that participation was voluntary and that they could refuse to participate in or withdraw from the study at any time without negative consequences to any other treatments. Written informed consent was obtained from each participant in the form of photographs. The data were kept anonymous and confidential and were only used for this study.

Setting and Sample

We enrolled the participants from several campuses of a special education school in Fuzhou, China. Mothers with preschool children with autism were recruited in January 2020. The original purpose of the study was to verify the effectiveness of the WeChat-based parenting training. However, as the COVID-19 pandemic occurred before recruitment was completed, the purpose of this study was adjusted to evaluate the effectiveness and feasibility of the WeChat-based parenting training in the context of a pandemic. Considering the pandemic situation, after a consultation with the hospital ethics committee, the participants were allowed to choose their group according to their preferences. Although a prospective quasi-experimental study with nonrandom distribution is less rigorous than a randomized controlled trial design, a parallel control group was used to make the study methodology as rigorous as possible. Assessor blinding was performed through the Questionnaire Star platform.

The inclusion criteria were the following: (1) mothers who were the primary caregivers of preschool children aged 3-7 years old who were diagnosed with ASD according to the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5), (2) mothers who owned a smartphone and had a WeChat account and were willing to enroll in a training class with their WeChat ID, and (3) mothers who were able to read and understand Mandarin Chinese.

The exclusion criteria were the following: (1) mothers whose children were diagnosed with Rett syndrome, childhood disintegrative disorder, or other terminal illnesses, (2) mothers whose children (and/or mothers themselves) had received psychosocial treatments (such as mindfulness-based training, journal writing, and parent-mediated social communication therapy) in the past 8 months, and (3) mothers whose children (or mothers themselves) were diagnosed with COVID-19 or terminal illnesses during the intervention.

Sample Size

G*Power (Version 3.1.9.6; Franz Faul, Universität Kiel) was used to calculate the sample size. Assuming a power of 0.80, an α of 0.05, and an effect size of 0.56 for parenting stress based on a preliminary test, the corrected sample size was 60 per group with a 15% dropout rate. We recruited 125 participants.

Interventions

Control Group

The mothers in the control group received routine care, which included the following:

1. An electronic manual entitled “108 Strategies to Overcome the Pandemic at Home” [21], organized by the Fujian Provincial Health Commission and the Fujian Provincial Press and Publication Bureau and compiled by members of the research team, was uniformly distributed to guide families through the pandemic at home. The contents of the manual included six modules: home protection, outside protection, diet, coping strategies for common problems, medical guidance, and parent-child games and sports. A comic cartoon was inserted into the manual to facilitate

parent-child reading and understanding. The manual was also interspersed with animations and other videos in the form of two-dimensional codes for intuitive interpretations.

2. A home training plan for children was distributed to the parents and training progress was checked in the form of homework once per week for 12 weeks.

Intervention Group

The mothers in the intervention group received routine care plus the WeChat-based parenting training. The WeChat-based parenting training included the following:

1. The Joint Attention, Symbolic Play, Engagement, and Regulation (JASPER) online course delivered via WeChat [13]. The JASPER course focused on targeted social communication strategies in the format of parent-child coaching sessions that went on for 45-60 minutes per session, with two sessions each week for 12 weeks. Specific strategies for high-quality responses to children's communication and behaviors were provided by one special training teacher with more than five years of special training work experience. Another teacher was responsible for demonstrating any scenario simulations.
2. An online question-and-answer session. A question-and-answer session (30-40 minutes) was conducted each week for 12 weeks.
3. An online parental psychological intervention course based on pandemic situations. The course was conducted by team researchers with second-level psychological counseling qualifications. The contents included home protection strategies, emotional management, parental stress coping strategies, and psychological counseling strategies to cope with the pandemic situation (eg, mindfulness breathing training, muscle relaxation training, and the traditional Chinese Qigong exercise “Ba Duan Jin”) and lasted 45-60 minutes per session, with one session every two weeks and 6 sessions in total. For all online courses, live links were generated by the class assistant software Little Goose (Shenzhen Xiao'e Network Technology Co) and then sent to the WeChat group.

Outcome Measurements

Primary Outcomes

Anxiety

The Self-rating Anxiety Scale (SAS) [22] was used to assess the mothers' anxiety levels. The scale has 20 items that are measured by a 4-point Likert-type scale, ranging from 1 (none or a little of the time) to 4 (most or all of the time), with a total score of 20-80. A higher score indicates a higher anxiety level. The total score is then multiplied by 1.25 to get a standard score. A standard score of <50 indicates no anxiety, 50-59 indicates mild anxiety, 60-69 indicates moderate anxiety, and ≥ 70 indicates severe anxiety. Good validity and reliability were demonstrated when the SAS was used in China [23]. In this study, the total Cronbach α value was 0.882 and the rest-retest reliability was 0.872.

Depression

The Self-rating Depression Scale (SDS) was used to measure the mothers' depression levels [24]. The scale has 20 items that are measured on a 4-point Likert-type scale, with a total score ranging from 20 to 80. The total score is multiplied by 1.25 to obtain a standard score. A standard score of <53 indicates no depression, 53-62 indicates mild depression, 63-72 indicates moderate depression, and ≥ 73 indicates severe depression. The Chinese version of the SDS was validated in the Chinese population with good reliability [25]. In this study, the total Cronbach α value was 0.838 and the rest-retest reliability was 0.818.

Parenting Stress

The Parenting Stress Index-Short Form (PSI-SF) [26] was used to measure parenting stress. The scale has 20 items that are measured by a 5-point Likert-type scale, ranging from 1 (strongly disagree) to 5 (strongly agree), with a total score ranging from 36 to 180. The PSI-SF comprises three dimensions: parenting distress, parent-child dysfunctional interaction, and difficult child. A total score on the PSI-SF above 90 (≥ 90 th percentile) indicates that further professional intervention is required [26]. The original version has a good internal consistency, with Cronbach α values ranging from 0.80 to 0.91, as well as good rest-retest reliability ($r=0.68-0.85$), and the Chinese version was also validated with good psychometric properties [26-28]. In this study, the total Cronbach α value was 0.899 and the test-retest reliability was 0.801.

Secondary Outcomes

Hope

Hope levels were assessed by the Herth Hope Index (HHI), a 12-item scale containing three dimensions: temporality and future, positive readiness and expectancy, and interconnectedness [29]. The scale adopts a 4-point Likert-type scale, ranging from 1 (completely disagree) to 4 (completely agree), with a maximum total score of 48. A total score of 12-23 indicates a low level of hope, 24-35 indicates a medium level of hope, and 36-48 indicates a high level of hope. The Chinese version of the HHI has appropriate internal consistency, content validity, and convergent and discriminant validity [30]. In this study, the total Cronbach α value was 0.762 and the rest-retest reliability was 0.837.

Feasibility

Feasibility measures included acceptability and demand. Acceptability was measured with a postintervention satisfaction survey in the intervention group. A total of five self-reported statements for the satisfaction assessment in the questionnaire are answered with ratings of "strongly disagree," "slightly disagree," "neutral," "slightly agree," and "strongly agree."

Demand was measured using adherence to the WeChat-based parenting training intervention. Adherence to the intervention was recorded in weekly reports from the WeChat progress log for home training using the WeChat mini-program (a "sub-app" based on the WeChat platform that can be used without installation) for each participant.

Data Collection

Data were collected through the survey invitation links generated by the Questionnaire Star platform (Wenjuanxing [31]) at baseline (T0), on the second or third day after the intervention (T1, Week 12), and two months after the intervention (T2, Week 20). The assistants (who were blinded to the assignments) collected the participants' demographic characteristics and measured the outcomes from the platform to reduce bias.

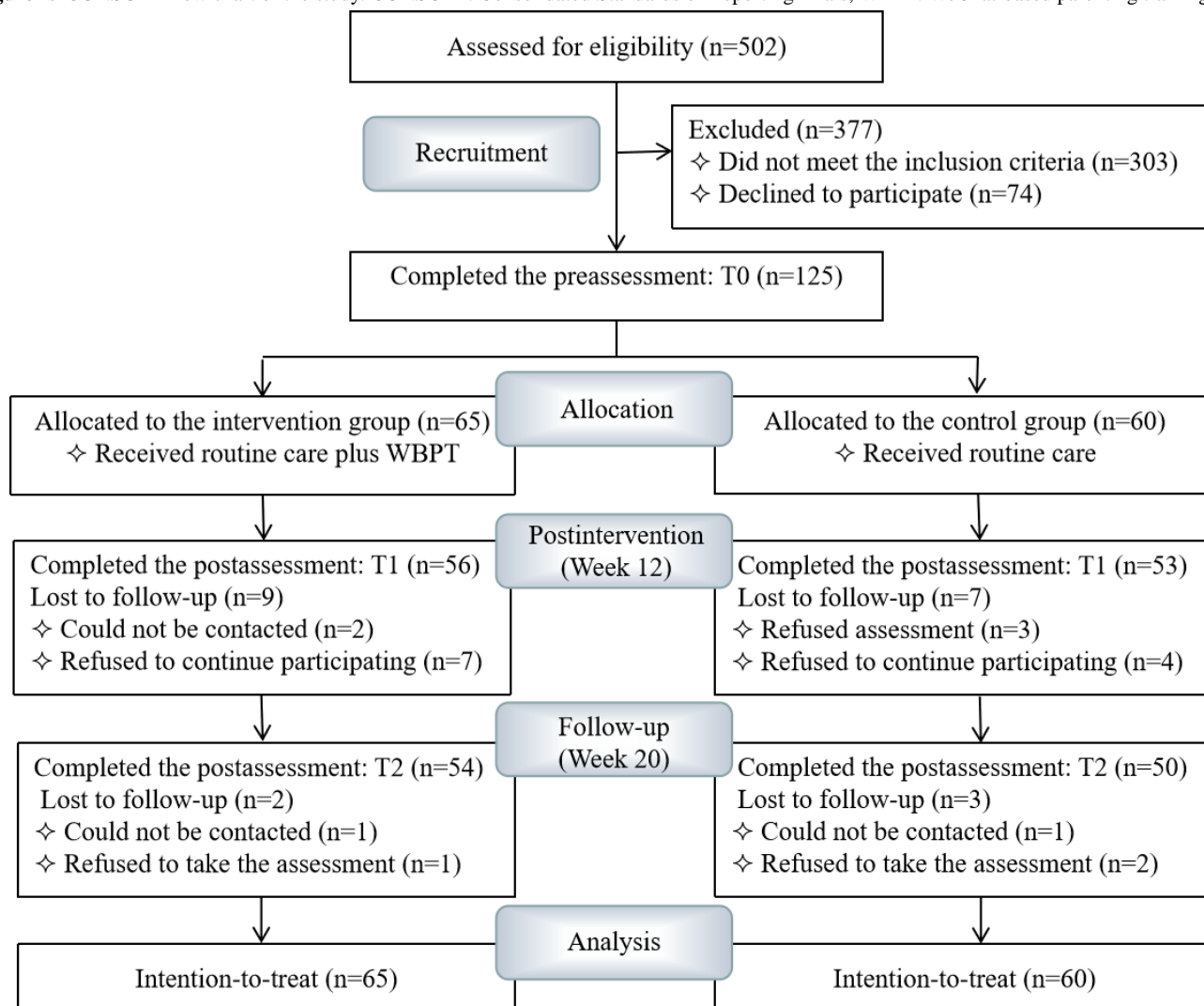
Statistical Analysis

IBM SPSS (Version 25.0; IBM Corp) and GraphPad Prism (Version 8.0.2; GraphPad Software Inc) were used to analyze the data and prepare the figures. An intention-to-treat analysis (ITT) and a linear interpolation were performed. Descriptive statistics, such as mean, standard deviation, frequency, and percentage, were used to report the demographic and outcome variables. Independent two-sample *t* tests, chi-square tests, and Mann-Whitney *U* tests were used to compare the baseline characteristics between the two groups. A linear mixed model was used to examine group effects, time effects, and group \times time interaction effects on anxiety, depression, parenting stress, and hope levels over time. Cohen *d* effect size analysis was performed to compare the magnitude of the effects at each timepoint, and 0.2, 0.5, and 0.8 were considered as small, medium, and large effects, respectively [32].

Results

Participant Enrollment

Among the 502 mothers who were approached, 303 of them did not meet the inclusion criteria (230 mothers whose child was diagnosed with mental retardation, 55 with language retardation, 5 with attention deficit and hyperactivity disorder, 5 with developmental coordination disorder, 3 with Rett syndrome, 3 with Down syndrome, and 2 with medically active diseases) and 74 mothers declined to participate in the study (67 with schedule conflict and 7 who refused to do the preassessment). Eventually, 125 mothers were recruited and assigned to one of two groups (60 in the control group and 65 in the intervention group) based on their preferences. After a 20-week research period, 7 mothers were uncontactable, and 14 mothers refused to participate in the assessments. In total, 104 mothers completed the follow-up assessments (Figure 1).

Figure 1. CONSORT flow chart of the study. CONSORT: Consolidated Standards of Reporting Trials; WBPT: WeChat-based parenting training.

Participants' Characteristics

There were no significant differences in the participants' characteristics between the two groups at baseline (all $P > .05$).

The participants' demographic and clinical characteristics are presented in [Table 1](#).

Table 1. Participants' baseline characteristics (N=125).

Variables	Total (n=125), n (%)	Control (n=60), n (%)	WeChat-based parenting training (n=65), n (%)	$\chi^2/Z/t$ values	P value
Mothers and family					
Age (years), mean (SD)	32.89 (3.68)	32.57 (3.45)	33.18 (3.89)	0.937	.35 ^a
Number of children				-0.879	.38 ^b
1	93 (74.4)	47 (78.4)	46 (70.8)	N/A ^c	N/A
2	29 (23.2)	11 (18.3)	18 (27.7)	N/A	N/A
≥3	3 (2.4)	2 (3.3)	1 (1.5)	N/A	N/A
Residence				0.020	.89 ^d
Urban	112 (89.6)	54 (90.0)	58 (89.2)	N/A	N/A
Rural	13 (10.4)	6 (10.0)	7 (10.8)	N/A	N/A
Marital status					.67 ^e
Married	120 (96.0)	57 (95.0)	63 (96.9)	N/A	N/A
Divorced/separated	5 (4.0)	3 (5.0)	2 (3.1)	N/A	N/A
Occupation				0.937	.33 ^d
Employed	92 (74.4)	47 (78.3)	46 (70.8)	N/A	N/A
Unemployed	32 (25.6)	13 (21.7)	19 (29.2)	N/A	N/A
Religious belief					.17 ^e
Yes	116 (92.8)	58 (96.7)	58 (89.2)	N/A	N/A
No	9 (7.2)	2 (3.3)	7 (10.8)	N/A	N/A
Education				-0.376	.71 ^b
Junior middle school or below	25 (20.0)	12 (20.0)	13 (20.0)	N/A	N/A
High school/technical secondary school	37 (29.6)	19 (31.7)	18 (27.7)	N/A	N/A
College	39 (31.2)	18 (30.0)	21 (32.3)	N/A	N/A
University degree	20 (16.0)	10 (16.7)	10 (15.4)	N/A	N/A
Graduate degree or above	4 (3.2)	1 (1.6)	3 (4.6)	N/A	N/A
Average monthly household income, ¥ (US \$)				-0.120	.90 ^b
<2000 (<310)	10 (8.0)	4 (6.7)	6 (9.2)	N/A	N/A
2000-5999 (310-929)	51 (40.8)	26 (43.3)	25 (38.5)	N/A	N/A
6000-10,000 (929-1549)	38 (30.4)	18 (30.0)	20 (30.8)	N/A	N/A
>10,000 (>1549)	26 (20.8)	12 (20.0)	14 (21.5)	N/A	N/A
Family structure				0.161	>.99 ^e
Nuclear family (parents and minor children living together)	39 (31.2)	19 (31.7)	20 (30.8)	N/A	N/A
Other immediate family (grandparents and nuclear)	82 (65.6)	39 (65.0)	43 (66.1)	N/A	N/A
Single-parent family	4 (3.2)	2 (3.3)	2 (3.1)	N/A	N/A
Children					
Gender				0.012	.91 ^d
Male	89 (71.2)	43 (71.7)	46 (70.8)	N/A	N/A
Female	36 (28.8)	17 (28.3)	19 (29.2)	N/A	N/A
Age (years), mean (SD)	4.52 (1.19)	4.72 (1.14)	4.34 (1.06)	-1.241	.22 ^a

Variables	Total (n=125), n (%)	Control (n=60), n (%)	WeChat-based parenting training (n=65), n (%)	$\chi^2/Z/t$ values	<i>P</i> value
Disease course (years), mean (SD)	1.58 (1.10)	1.70 (1.82)	1.46 (1.82)	0.228	.82 ^a
Childhood Autism Rating Scale score, mean (SD)	32.07 (1.82)	32.03 (1.21)	32.11 (1.16)	−1.770	.08 ^a

^a*T* test.

^bMann-Whitney *U* test.

^cN/A: not applicable.

^d χ^2 test.

^eFisher exact test.

Primary Outcomes

Anxiety

The results of the linear mixed model analysis indicated a significant group effect ($F=4.906$, $P=.029$), a significant time

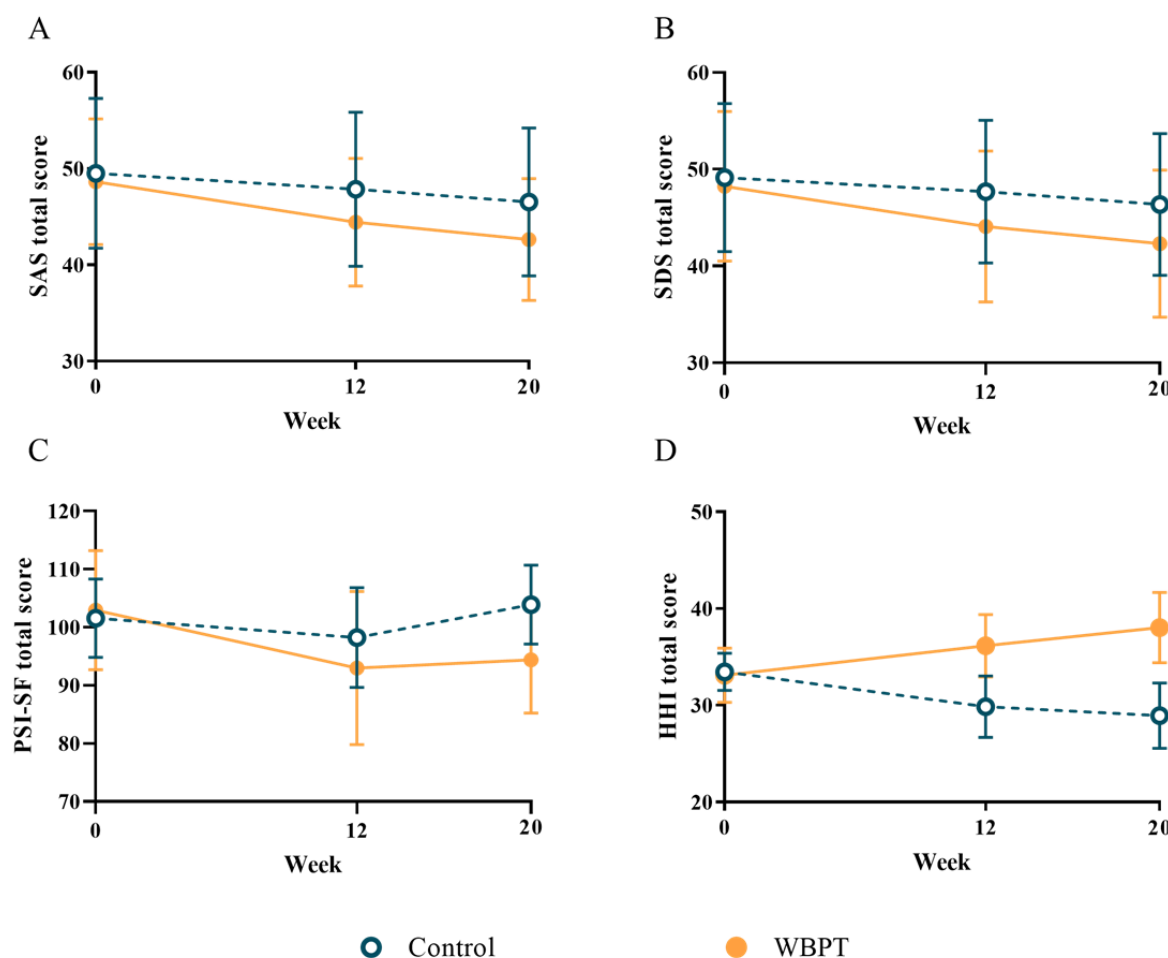
effect ($F=93.760$, $P<.001$), and a significant group \times time interaction effect ($F=14.219$, $P<.001$) on the SAS (Table 2). A significant difference was observed between the two groups at T1 (Cohen $d=-0.465$) and T2 (Cohen $d=-0.556$) for the SAS (Figure 2A).

Table 2. Comparisons of scores between groups over time using a linear mixed model (N=125).

Variables and groups	Baseline (T0)	Week 12 (T1) ^a	Week 20 (T2) ^a	Group	Time	Time × group
	Mean (SD)	Mean (SD)	Mean (SD)	<i>F</i> value (<i>P</i> value)	<i>F</i> value (<i>P</i> value)	<i>F</i> value (<i>P</i> value)
Self-rating Anxiety Scale						
Control (n=60)	49.52 (7.78)	47.85 (8.02)	46.53 (7.67)	4.906 (.03)	93.760 (<.001)	14.219 (<.001)
WBPT ^b (n=65)	48.65 (6.53)	44.44 (6.63)	42.64 (6.32)	N/A ^c	N/A	N/A
Self-rating Depression Scale						
Control (n=60)	49.13 (7.66)	47.69 (7.38)	46.36 (7.33)	4.457 (.04)	154.830 (<.001)	26.563 (<.001)
WBPT (n=65)	48.24 (7.72)	44.09 (7.80)	42.32 (7.60)	N/A	N/A	N/A
Parenting Stress Index-Short Form						
Parenting distress						
Control (n=60)	35.49 (3.23)	34.88 (2.95)	35.45 (3.96)	4.083 (.045)	53.994 (<.001)	38.792 (<.001)
WBPT (n=65)	36.31 (4.29)	33.57 (3.97)	32.09 (3.62)	N/A	N/A	N/A
Parent-child dysfunctional interaction						
Control (n=60)	34.88 (2.95)	32.31 (3.07)	33.60 (3.78)	6.350 (.01)	34.508 (<.001)	60.743 (<.001)
WBPT (n=65)	33.57 (3.97)	30.48 (4.46)	28.80 (4.14)	N/A	N/A	N/A
Difficult child						
Control (n=60)	35.45 (3.96)	34.01 (3.40)	34.82 (4.07)	2.507 (.12)	11.629 (<.001)	.741 (.45)
WBPT (n=65)	32.09 (3.62)	32.74 (4.63)	33.52 (4.28)	N/A	N/A	N/A
Parenting Stress Index-Short Form total score						
Control (n=60)	101.56 (6.77)	98.22 (8.59)	103.88 (6.82)	8.176 (.005)	69.315 (<.001)	68.572 (<.001)
WBPT (n=65)	102.92 (10.27)	92.98 (13.18)	94.41 (9.17)	N/A	N/A	N/A
Herth Hope Index						
Temporality and future						
Control (n=60)	10.75 (1.24)	9.60 (1.32)	9.23 (1.41)	49.276 (<.001)	1.685 (.12)	85.808 (<.001)
WBPT (n=65)	10.67 (1.27)	11.53 (1.51)	12.23 (1.75)	N/A	N/A	N/A
Positive readiness and expectancy						
Control (n=60)	11.46 (1.03)	10.01 (1.44)	9.70 (1.35)	74.080 (<.001)	2.228 (.11)	89.652 (<.001)
WBPT (n=65)	11.28 (1.28)	12.21 (1.35)	12.76 (1.44)	N/A	N/A	N/A
Interconnectedness						
Control (n=60)	11.25 (1.12)	10.25 (1.84)	10.00 (2.02)	50.344 (<.001)	5.690 (.004)	67.373 (<.001)
WBPT (n=65)	11.16 (1.33)	12.42 (1.46)	13.05 (1.53)	N/A	N/A	N/A
Herth Hope Index total score						
Control (n=60)	33.46 (1.92)	29.86 (3.18)	28.93 (3.39)	105.581 (<.001)	4.787 (.009)	197.608 (<.001)
WBPT (n=65)	33.11 (2.81)	36.16 (3.22)	38.04 (3.62)	N/A	N/A	N/A

^aLinear interpolation.^bWBPT: WeChat-based parenting training.^cN/A: not applicable.

Figure 2. Means and 95% CIs for SAS, SDS, PSI-SF, and HHI scores from baseline to follow-up. HHI: Herth Hope Index; PSI-SF: Parenting Stress Index-Short Form; SAS: Self-rating Anxiety Scale; SDS: Self-rating Depression Scale; WBPT: WeChat-based parenting training.



Depression

The linear mixed model analysis revealed a significant group effect ($F=4.906$, $P=.04$), a significant time effect ($F=154.830$, $P<.001$), and a significant group \times time interaction effect ($F=26.563$, $P<.001$) on the SDS (Table 2). A significant difference was observed between the two groups at T1 (Cohen $d=-0.474$) and T2 (Cohen $d=-0.541$) for the SDS (Figure 2B).

Parenting Stress

The results of the linear mixed model analysis showed a significant group effect ($F=4.083$, $P=.045$), a significant time effect ($F=53.994$, $P<.001$), and a significant group \times time interaction effect ($F=38.792$, $P<.001$) for parenting distress; a significant group effect ($F=6.350$, $P=.01$), a significant time effect ($F=34.508$, $P<.001$), and a significant group \times time interaction effect ($F=60.743$, $P<.001$) for parent-child dysfunctional interaction; and a significant group effect ($F=8.176$, $P=.005$), a significant time effect ($F=69.315$, $P<.001$), and a significant group \times time interaction effect ($F=68.572$, $P<.001$) for the PSI-SF total score (Table 2). There was a significant time effect ($F=11.629$, $P<.001$) but no significant group effect ($F=2.507$, $P=.12$) or group \times time interaction effect ($F=.741$, $P=.48$) for difficult child (Table 2). A significant difference was observed between the two groups at T1 (Cohen

$d=-0.467$) and T2 (Cohen $d=-1.165$) for the PSI-SF total score (Figure 2C).

Secondary Outcomes

Hope

The results showed a significant group effect ($F=49.276$, $P<.001$) and a significant group \times time interaction effect ($F=85.808$, $P<.001$) for temporality and future; a significant group effect ($F=74.080$, $P<.001$) and a significant group \times time interaction effect ($F=89.652$, $P<.001$) for positive readiness and expectancy; a significant group effect ($F=50.344$, $P<.001$), a significant time effect ($F=5.690$, $P=.004$) and a significant group \times time interaction effect ($F=67.373$, $P<.001$) for interconnectedness; and a significant group effect ($F=105.581$, $P<.001$), a significant time effect ($F=4.787$, $P=.009$) and a significant group \times time interaction effect ($F=197.608$, $P<.001$) for the HHI total score (Table 2). There were no significant time effects for temporality and future or positive readiness and expectancy (all $P>.05$; Table 2). A significant difference was observed between the two groups at T1 (Cohen $d=1.968$) and T2 (Cohen $d=2.594$) for the HHI total score (Figure 2D).

Feasibility

At T2, 90.4% (48.8/54) of all mothers in the intervention group reported that they were extremely satisfied with the WBPT

course and 6.7% (3.6/54) indicated that they were slightly satisfied with the WBPT course (Table 3).

At T1, 53.8% (35/65) logged their progress each week and 80.0% (52/65) logged their progress in home training more than 80% of the time during the 12 weeks of the intervention. At T2,

51.8% (29/56) logged their progress each week and 76.8% (43/56) logged more than 80% of the time for 8 weeks after the intervention. In total, 40.0% (26/65) logged their progress each week and 61.5% (40/65) logged their progress more than 80% of the time for all 20 weeks.

Table 3. Satisfaction rates of the participants in the intervention group at the T2 assessment (N=54).

Variables	Strongly agree, n (%)	Slightly agree, n (%)	Neutral, n (%)	Slightly disagree, n (%)	Strongly disagree, n (%)
I think that the contents of the WeChat-based parenting training course are very practical.	50 (92.6)	3 (5.6)	1 (1.8)	0 (0.0)	0 (0.0)
I think that the contents of the WeChat-based parenting training course are very comprehensive.	47 (87.0)	5 (9.3)	2 (3.7)	0 (0.0)	0 (0.0)
I think that the WeChat-based parenting training course is very interactive.	48 (88.9)	4 (7.4)	2 (3.7)	0 (0.0)	0 (0.0)
I think that the contents of WeChat-based parenting training course can meet the needs of me and my child.	49 (90.7)	3 (5.6)	2 (3.7)	0 (0.0)	0 (0.0)
Overall, I am satisfied with the WeChat-based parenting training course.	50 (92.6)	3 (5.6)	1 (1.8)	0 (0.0)	0 (0.0)
Average	48.8 (90.4)	3.6 (6.7)	1.6 (2.9)	0 (0.0)	0 (0.0)

Discussion

Principal Findings

This was the first study with a pretest-posttest alternative treatment comparison group design to evaluate the impact of the WeChat-based parenting training on mothers with children with autism during the COVID-19 pandemic. The results indicated moderate to large improvements in mothers' anxiety, depression, parenting stress, and hope levels.

Effects of the WeChat-Based Parenting Training

In this study, the WeChat-based parenting training that was targeted at mothers with children with autism had statistically significant impacts on anxiety and depression levels, which is consistent with previous studies' findings [20,33]. Several studies reported that anxiety and depression levels among mothers with children with autism were higher than among mothers with neurotypical children [34-36]. During the COVID-19 pandemic, the public felt anxiety, depression, despair, and many other emotional reactions [37]. Mothers raising children with ASD who might already be under a lot of pressure might suffer from greater psychological distress due to the pandemic. Supporting mothers in the process of caring for children is likely to address the high psychological burden that they face and enhance their overall quality of life [34]. The development of more serious negative maternal outcomes can also be reduced by targeting mothers' negative thought patterns that are associated with parenting challenges [38]. No-contact consultations by phone, QQ, and WeChat were adopted to help the public cope with the psychological pressure caused by COVID-19 [39]. The WeChat-based parenting training, as one of the no-contact approaches, was conducted to support mothers with children with autism in coping with the pandemic and home training, which may play an important role in alleviating mothers' anxiety and depression.

The results also revealed that the WeChat-based parenting training was effective in decreasing mothers' parenting stress. Possible reasons may be as follows. The WeChat-based parenting training, concentrated on the JASPER course, provided an opportunity for mothers to improve their childcare knowledge systems and home training management levels. Furthermore, scenario simulations were provided to help the mothers master specific strategies in response to their children's communication and behaviors, which is more intuitive and makes parenting knowledge extraction easier. Moreover, online question and answer sessions could also address the mothers' parenting confusion at the right time. Thus, the dimension scores of parenting distress and parent-child dysfunctional interaction decreased. Another important reason could be that parents who are parenting children with autism face high levels of parenting stress and other negative emotions, both in normal times and in pandemic situations, especially those with recent special service needs [40-42]. The parental psychological intervention course was provided to relieve parenting stress and other negative mental states. ASD has no cure and the WeChat-based parenting training was also unable to change the natures of children with ASD, which is why the dimension scores for difficult child between the two groups had no statistical differences. However, future studies are needed to verify the effect of the WeChat-based parenting training.

The results also demonstrated that the WeChat-based parenting training exerted a significant influence on the hope of the mothers. This may be related to the enhancement of mothers' childcare knowledge systems and home training management levels. The mothers might have been filled with hope in the process of training children. Hope is defined as the perceived capability to achieve a desired goal and stimulate oneself to follow through using agency thinking [43]. Higher hope is associated with better outcomes in psychological adjustments [43]. The alleviation of psychological pressure and parenting stress during a pandemic may also raise a mother's hope level.

The possible impact of novelty effects is another interpretation for the moderate to large effect sizes. As there was little access to support for the mental well-being of families at the early stage of the COVID-19 pandemic, the WeChat-based parenting training can be considered a novelty, and even a privilege. Novelty effects may cause participants to be more enthusiastic and pay more attention to interventions, thereby resulting in moderate to large effects [44].

Feasibility

The mothers' high-level satisfaction suggested that the WeChat-based parenting training appeared to be a pleasant experience for them and that this approach was acceptable to these mothers with children with autism during the COVID-19 pandemic. In fact, there were no complaints or other problems with the WeChat-based parenting training during the study. The WeChat-based parenting training enabled mothers to conduct progress logging for home training using the WeChat mini-program, which allowed the researcher to observe the participants' adherence to the intervention and promote researchers to better master the course schedule. The rate of progress logging also indicated an urgent demand for parent training from mothers with children with autism during the outbreak.

Limitations

There were several limitations in this study. First, due to the pandemic situation, a nonrandomized design was used, which might have led to deviations in the research results. Some scholars point out that findings from nonrandomized trials can

be as valid as those of randomized controlled trials, depending on the study quality [45]. In this study, a parallel control group, assessor blinding, and study controls for the baseline characteristics were used to make the study methodology as rigorous as possible. It was rated as high quality using the Newcastle-Ottawa Scale (NOS) [46]. Second, this study was limited to a group of mothers. Further studies should try to explore the differences between fathers and mothers or the differences between only one parent participating in the intervention versus both parents. Third, due to having only one study setting, the generalizability of the findings may be limited. Therefore, future multicenter research with a randomized controlled trial design is necessary. Finally, due to the COVID-19 pandemic, the questionnaire survey was conducted using the online Questionnaire Star platform, which made it impossible to know whether the respondents completed the questionnaire independently and what the respondents' environments were when answering questions, thereby affecting the judgment of the questionnaire's quality. Researchers should evaluate the long-term effects of the WeChat-based parenting training using other measurements after the COVID-19 pandemic.

Conclusions

The WeChat-based parenting training is a promising training method for reducing anxiety, depression, and parenting stress and increasing hope in mothers with children with autism during the COVID-19 pandemic. A rigorous design is needed to further assess the effectiveness of the WeChat-based parenting training in the future.

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Conflicts of Interest

None declared.

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Abbreviations

ASD: autism spectrum disorder

DSM-5: Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition

HHI: Herth Hope Index

JASPER: Joint Attention, Symbolic Play, Engagement, and Regulation

PSI-SF: Parenting Stress Index-Short Form

SAS: Self-rating Anxiety Scale

SDS: Self-rating Depression Scale

WBPT: WeChat-based parenting training

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Original Paper

Intentions to Seek Mental Health Services During the COVID-19 Pandemic Among Chinese Pregnant Women With Probable Depression or Anxiety: Cross-sectional, Web-Based Survey Study

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Abstract

Background: Mental health problems are prevalent among pregnant women, and it is expected that their mental health will worsen during the COVID-19 pandemic. Furthermore, the underutilization of mental health services among pregnant women has been widely documented.

Objective: We aimed to identify factors that are associated with pregnant women's intentions to seek mental health services. We specifically assessed pregnant women who were at risk of mental health problems in mainland China.

Methods: A web-based survey was conducted from February to March, 2020 among 19,515 pregnant women who were recruited from maternal health care centers across various regions of China. A subsample of 6248 pregnant women with probable depression (ie, those with a score of ≥ 10 on the 9-item Patient Health Questionnaire) or anxiety (ie, those with a score of ≥ 5 on the 7-item General Anxiety Disorder Scale) was included in our analysis.

Results: More than half (3292/6248, 52.7%) of the participants reported that they did not need mental health services. Furthermore, 28.3% (1770/6248) of participants felt that they needed mental health services, but had no intentions of seeking help, and only 19% (1186/6248) felt that they needed mental health services and had intentions of seek help. The results from our multivariate logistic regression analysis showed that age, education level, and gestational age were factors of not seeking help. However, COVID-19-related lockdowns in participants' cities of residence, social support during the COVID-19 pandemic, and trust in health care providers were protective factors of participants' intentions to seek help from mental health services.

Conclusions: Interventions that promote seeking help for mental health problems among pregnant women should also promote social support from health care providers and trust between pregnant women and their care providers.

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KEYWORDS

pregnant women; COVID-19; depression; anxiety; help-seeking; mental health services; social support; trust; intention; mental health; pregnancy; survey

Introduction

Overview of the COVID-19 Pandemic

COVID-19 is an emerging infectious disease that has resulted in considerable public health risks across the globe. As of November 3, 2020, 91,921 COVID-19 cases and 4746 deaths have been reported in China, and 45,876,878 cases and 1,188,165 deaths have been reported outside of China [1]. The World Health Organization declared the COVID-19 epidemic a public health emergency of international concern on January 30, 2020. It was then declared a pandemic on March 11, 2020 [2]. The COVID-19 pandemic has also resulted in widespread fear, worry, and anxiety in the general public [3]. Documented evidence has shown that anxiety, depression, posttraumatic stress disorder, and psychological distress have been highly prevalent among the general public during the COVID-19 pandemic [4].

Pregnant Women are at Risk of Mental Health Problems During the Pandemic

Mental disorders are the leading causes of disease burden among adult women [5]. Depression and anxiety are the most common mental disorders that occur during pregnancy; depression and anxiety affect 10%-30% of pregnant women [6,7]. During the COVID-19 pandemic, pregnant women may experience greater mental health burdens than the general population, as pregnant women face the challenges of both pregnancy and the epidemic. Pregnant women are more susceptible to SARS-CoV-2 infection due to their immunosuppressive state and their reduced tolerance to hypoxia, which are caused by pregnancy-induced physiological changes [8]. As such, pregnant women are an at-risk group that is in need of COVID-19 prevention and management services [9]. It is therefore expected that the severity of mental disorders among pregnant women will increase during the COVID-19 pandemic. Empirical studies have documented a high global prevalence of depression (ie, 5.2%-40%) and anxiety (ie, 3.8%-72%) among pregnant women during the COVID-19 pandemic.

Prenatal mental disorders not only impair social, cognitive, and psychological functions, but also lead to numerous adverse outcomes in both mothers and children, such as a high risk of preterm birth, intrauterine growth restrictions, maternal depressive disorder after birth, poor mother-child interactions, and poor child psychopathology and development [10-14]. Mental disorders also increase the risk of infection, including the risk of SARS-CoV-2 infection. This may be due to cognitive impairments, low risk perceptions, poor compliance with personal protection measures, and confined conditions in psychiatric wards [15].

The Low Prevalence of Seeking Psychological Help Among Pregnant Women With Mental Problems

Despite the high prevalence and detrimental consequences of mental disorders, most people who exhibit mental disorder symptoms do not seek professional help and proper treatment [16,17]. It has been estimated that only 30% of individuals with mental illnesses across the globe have received treatment [16,17]. Studies have found that only 13.6%-33.3% of women

with perinatal depression or anxiety have sought help from a health care professional [18-20]. This poor help-seeking pattern is even more pronounced in Chinese women [21]. In China, an intense level of stigma is attached to mental illness. The ongoing COVID-19 pandemic can further reduce the use of mental health services [22,23]. Identifying factors of seeking help for mental disorders during an epidemic period is important in guiding public education efforts that promote help-seeking and alleviate the barriers that prevent pregnant women from seeking mental health services.

Factors Associated With Seeking Mental Health Services

Several studies have identified a number of facilitators and barriers with regard to seeking mental health services among perinatal women. Background factors such as young age [18,20], low levels of education [24], and first-time births [24] have been associated with a low likelihood of seeking mental health services among perinatal women. Alternatively, a history of psychiatric or psychological treatment [18], increased symptom severity, and long disease durations have been associated with a high likelihood of seeking mental health services. Several studies have also found that favorable attitudes toward psychiatric and psychological treatment are facilitators of seeking help from mental health services [7,18]. However, poor knowledge about mental symptoms, the inability to recognize mental symptoms [25-27], a lack of knowledge about available psychosocial services and their benefits [20,28], the stigma associated with perinatal mental illness [7,29,30], a fear of being labelled as mentally ill [25,28], the inability to self-disclose information due to feelings of embarrassment [25,26], and a tendency to conceal distressing and negative personal information [27,30] are common hindrances to seeking mental health services among perinatal women. Practical or structural barriers such as concerns of monetary costs, work constraints, childcare responsibilities, and the limited accessibility of mental health service are also common hinderances to seeking help from mental health services among perinatal women [7,19,20,25,28].

The Roles of Social Support and Trust in Care Providers in Seeking Mental Health Services

Despite the wealth of factors identified in literature, relatively few studies have assessed the roles of interpersonal factors in Chinese pregnant women's intentions to seek mental health services. Theoretically, psychological reactions at both the individual and societal level are relevant to managing behaviors and improving emergency preparedness during pandemics [31]. Several studies have reported that significant others have a positive influence on people's intentions to seek help from professionals [32,33]. Studies among perinatal women have revealed that perceived encouragement from their partners can predict perinatal women's intentions to seek formal help [34], and mediate the association between perinatal women's intentions to seek informal help and their intentions to seek professional help [35]. Studies among women with postpartum depression have also reported that a lack of social support is a significant barrier to seeking mental health services [25,26,28]. It has been contended that behavioral intention is more subject

to influences from significant others when a behavior is not well incorporated into one's repertoire [36]. In terms of the performance of a behavior, a lack of personal experience can lead an individual to further rely on their significant others' views and encouragements [37]. We believed that the participants in our study would value the influence that social support has on their decisions to seek mental health services during the COVID-19 period.

Health professionals' positive influence on the promotion of help-seeking behaviors has been documented in literature. A meta-synthesis of factors that affect women's decisions to seek help for perinatal distress has identified the influence of health care professionals as one of the major factors of help-seeking [30]. Trust and familiarity with care providers may play an even more important role than perceived need in terms of shaping help-seeking intentions and behaviors [38]. Several mothers have also listed empathy and kindness as key attributes that ideal health professionals should have when providing mental health services [28]. Alternatively, disappointment and a lack of trust in care providers have been cited as barriers to seeking mental health services among pregnant women [27,39].

It has been contended that the importance of social support and trust in care providers in psychological help-seeking is evident in China. It has long been documented that the Chinese culture values interpersonal relatedness, which encompasses harmony with others and the consideration of the self, in terms of family and community relationships [40,41]. Additionally, being obedient to authority figures is emphasized in Chinese culture [42]. Pregnant women may be obligated to seek and receive professional help for mental problems when they think that their significant others and care providers will support them in doing so.

Research Gaps and Study Objectives

Despite the wealth of literature on help-seeking among perinatal women with mental disorders, little is known about help-seeking intentions among Chinese pregnant women with probable depression or anxiety during the COVID-19 pandemic. This study aimed to examine intentions to seek mental health services among pregnant women who are at risk of mental health problems during the COVID-19 period in China, and to identify the background, pregnancy-related, contextual, and interpersonal factors that are associated with help-seeking intentions.

Methods

Inclusion and Exclusion Criteria

In this study, a subsample of pregnant women who were at risk of depression and anxiety were identified from a whole sample of pregnant women. The inclusion criteria for the whole sample were as follows: (1) female sex, (2) age of ≥ 18 years, (3) current pregnancy, and (4) the intention to continue the pregnancy. Pregnant women who planned to terminate their pregnancy were excluded from this study.

Procedure

A web-based, cross-sectional survey was conducted from February 24 to March 10, 2020. Eligible participants were

identified from the records of maternal health care centers from various regions of China, and invited to take part in the web-based survey through a phone app (ie, WeChat [Tencent Inc]). Interested participants visited the web-based survey through a link or quick response code and provided informed consent before starting the survey. Participants were assured that the study was anonymous and confidential, and that declining to take part in the survey would not affect the services they obtained. The survey took 15-20 minutes to complete. Ethical approval was obtained from the authors' institution.

A total of 19,515 completed responses were collected from the web-based survey. Our subsample consisted of pregnant women who were at risk of mental health problems, which were defined as scores that exceeded the cutoffs for probable depression and probable anxiety. Of the 19,515 participants, 6248 (32%) participants fulfilled the criteria (both probable depression and probable anxiety: 2595/19,515, 13.3%; only probable depression: 552/19,515, 2.8%; only probable anxiety: 3101/19,515, 15.9%) and were included in the analysis. The levels of depression and anxiety among the 19,515 participants are shown in [Multimedia Appendix 1](#).

Measures

Sociodemographic and Pregnancy-Related Characteristics

Participants were asked to report their age, education level, parity, gestational age, and whether they had any pregnancy-related complications.

Isolation Due to COVID-19

Participants were asked to report whether their city of residence was locked down, and whether they were being quarantined due to COVID-19.

Social Support

Participants were asked to rate the level of social support that they received during the COVID-19 pandemic (eg, support from family, friends, or significant others) on a 10-point Likert scale (ie, 1=very little, 10=very much). Similar items have been used in previous studies [43].

Trust in Care Providers

Trust in care providers was measured with the affect- and cognition-based trust (ACT) scale, which was developed by McAllister [44]. The ACT scale consists of 8 items, of which 4 assess cognition-based trust and 4 assess affect-based trust. Items are rated on a 5-point scale (ie, 1=strongly disagree, 5=strongly agree). Higher scores indicate higher levels of trust in care providers. The internal reliability of the scale was satisfactory in this study (Cronbach $\alpha=.95$).

Intention to Seek Mental Health Services

Participants were asked to rate their intentions to seek mental health services by choosing 1 of the following 3 options: option 1, which stated "I don't need mental health services"; option 2, which stated "I need mental health services, but I will not seek help from these services"; and option 3, which stated "I need mental health services and I will seek help from these services."

Those who chose option 3 were considered to have intentions to seek mental health services.

The following two measures were used to screen those participants for probable depression or anxiety: 9-item Patient Health Questionnaire (PHQ-9) scores and 7-item Generalized Anxiety Disorder Scale (GAD-7) scores.

Probable depression was measured by using the Chinese version of the PHQ-9 [45], which has been widely used in the Chinese population [46,47]. Participants were asked to rate how often they were bothered by the symptoms in the 2 weeks before taking the survey, on a 4-point Likert scale (ie, 0=not at all, 3=almost every day). The total score can range from 0 to 27. Higher scores indicate higher levels of depression. Those with a score of ≥ 10 were considered to have probable depression [48].

Probable anxiety was assessed by using the Chinese version of the GAD-7 [49], which has been used in the Chinese population [50,51]. Participants were asked to rate how often they were bothered by each symptom in the 2 weeks before taking the survey, on a 4-point Likert scale (ie, 0=not at all, 3=nearly every day). The total GAD-7 score can range from 0 to 21. Higher scores indicate higher levels of anxiety. Those with a score of ≥ 5 were considered to have probable anxiety [49].

Statistical Analysis

We provided descriptive statistics. A Spearman correlation analysis was conducted to examine the relationships between

social support and trust in care providers and sociodemographic/pregnancy-related characteristics. Univariate logistic regression analyses were conducted to examine the association between independent variables and intentions to seek mental health services, and respective univariate odds ratios (ORs) and 95% confidence intervals were calculated. To produce a final model that accounted for all independent variables, a multivariate logistic regression analysis was conducted with all independent variables by using the forward enter method, which allowed us to calculate multivariate odds ratios (ORMs). Data analyses were performed with SPSS version 21.0 (IBM Corp), and a *P* value of $<.05$ was considered statistically significant.

Results

Descriptive Statistics of the Participants

Slightly less than two-thirds (3984/6248, 63.8%) of participants were aged ≤ 30 years. A similar number of participants (3681/6248, 59%) had a postsecondary level of education. More than half (3594/6248, 57.5%) of the participants were nulliparous, and around half (3146/6248, 50.4%) were in their third trimester. A small number (598/6248, 9.6%) of participants reported that they experienced pregnancy-related complications. About two-thirds (4065/6248, 65.1%) of participants reported that their city of residence was locked down due to COVID-19, and a small number (311/6248, 5%) of participants were quarantined due to COVID-19 at the time of this study (Table 1).

Table 1. Descriptive statistics of the participants (N=6248).

Sociodemographic characteristics	Value, n (%)
Age (years)	
≤19	107 (1.7)
20-25	1229 (19.7)
26-30	2648 (42.4)
31-35	1756 (28.1)
36-40	435 (7)
≥41	73 (1.2)
Education level	
Primary or below	134 (2.1)
Junior secondary	1168 (18.7)
Senior secondary	1265 (20.2)
Matriculation	1635 (26.2)
Undergraduate	1703 (27.3)
Postgraduate or above	343 (5.5)
Pregnancy-related characteristics	
Parity	
Nulliparous	3594 (57.5)
Primiparous	2347 (37.6)
Multiparous	307 (4.9)
Gestational age (weeks of pregnancy)	
First trimester (≤12)	808 (12.9)
Second trimester (13-26)	2294 (36.7)
Third trimester (≥27)	3146 (50.4)
Pregnancy-related complications	
No	5650 (90.4)
Yes	598 (9.6)
Isolation due to COVID-19	
City of residence locked down due to COVID-19	4065 (65.1)
Quarantined due to COVID-19	311 (5)
Intention to seek mental health services	
I don't need mental health services	3292 (52.7)
I need mental health services, but I will not seek help from these services	1770 (28.3)
I need mental health services and I will seek help from these services	1186 (19)

Social Support, Trust in Care Providers, and Intentions to Seek Mental Health Services

In the subsample of participants who had probable depression and probable anxiety, the mean score for social support that participants received during the COVID-19 pandemic was 8.06 (SD 2.28). The mean score for trust in care providers was 33.02 (SD 5.34). More than half of the participants (3292/6248, 52.7%) felt that they did not need mental health services, and about a quarter (1770/6248, 28.3%) felt that they needed mental health services, but would not seek help from these services. Only

19% (1186/6248) of participants stated that they needed mental health services and had the intention to seek help from these services.

Correlations Between Social Support and Trust in Care Providers and Sociodemographic/Pregnancy-Related Characteristics

Social support that participants received during the COVID-19 period significantly correlated with older age ($r_s=.03$; $P=.007$) and high parity ($r_s=.05$, $P<.001$). Social support did not significantly correlate with education level ($r_s=.003$, $P=.79$),

the presence of pregnancy-related complications ($r_s = -.01$, $P = .70$), or gestational age ($r_s = -.01$, $P = .38$). Trust in care providers significantly correlated with high parity ($r_s = .03$, $P = .03$), but not with age ($r_s = .01$, $P = .43$), education level ($r_s = .01$, $P = .56$), gestational age ($r_s = -.01$, $P = .30$), or the presence of pregnancy-related complications ($r_s = .02$, $P = .25$).

Regression Models for Intentions to Seek Help From Mental Health Services

The results from the univariate logistic regression analyses (Table 2) showed that among the background characteristics, older age (ORs ranged from 0.43 to 0.60), high levels of education (ORs ranged from 0.43 to 0.68), and high gestational age (ORs ranged from 0.65 to 0.69) were associated with having no intention to seek mental health services, while multiparity (ORu 1.45, 95% CI 1.10-1.91) was associated with having the intention to seek mental health services. Among the isolation-related factors, COVID-19-related lockdowns in participants' cities of residence (ORu 1.26, 95% CI 1.10-1.44) were associated with having the intention to seek mental health

services. Among the interpersonal factors, both trust in health care providers (ORu 1.04, 95% CI 1.02-1.05) and social support that participants received during the COVID-19 pandemic (ORu 1.07, 95% CI 1.04-1.10) were associated with having the intention to seek mental health services.

The results of the multivariate logistic regression (Table 2) were similar to those of the univariate logistic regressions. Among the background characteristics, older age (ORms ranged from 0.49 to 0.67), high levels of education (ORms ranged from 0.47 to 0.68), and high gestational age (ORms ranged from 0.66 to 0.70) were associated with low intentions to seek mental health services. Among the isolation-related factors, COVID-19-related lockdowns in participants' cities of residence (ORm 1.17, 95% CI 1.01-1.35) were associated with having the intention to seek mental health services. Among the interpersonal factors, both trust in health care providers (ORM 1.03, 95% CI 1.02-1.04) and social support that participants received during the COVID-19 period (ORM 1.05, 95% CI 1.02-1.08) were associated with having the intention to seek mental health services.

Table 2. Logistic regression analysis of intentions to seek mental health services among pregnant women with probable depression and anxiety (N=6248).

Sociodemographic characteristics	Intention to seek mental health services			
	ORu ^a (95% CI)	P value	ORM ^b (95% CI)	P value
Age (years)				
≤19	1 (referent)	N/A ^c	1 (referent)	N/A
20-25	0.60 (0.39-0.92)	.02 ^d	0.67 (0.44-1.04)	.08
26-30	0.43 (0.28-0.64)	<.001 ^e	0.50 (0.32-0.77)	.002 ^f
31-35	0.46 (0.30-0.71)	<.001 ^e	0.53 (0.34-0.82)	.005 ^f
36-40	0.47 (0.29-0.75)	.002 ^f	0.50 (0.30-0.83)	.008 ^f
≥41	0.49 (0.24-0.99)	.047 ^d	0.49 (0.23-1.01)	.05
Education level				
Primary or below	1 (referent)	N/A	1 (referent)	N/A
Junior secondary	0.68 (0.46-1.01)	.06	0.68 (0.46-1.01)	.06
Senior secondary	0.52 (0.35-0.76)	<.001 ^e	0.55 (0.37-0.83)	.004 ^f
Matriculation	0.43 (0.29-0.63)	<.001 ^e	0.47 (0.32-0.71)	<.001 ^e
Undergraduate	0.46 (0.31-0.67)	<.001 ^e	0.53 (0.36-0.80)	.002 ^f
Postgraduate or above	0.52 (0.33-0.82)	.005 ^f	0.66 (0.41-1.06)	.08
Pregnancy-related characteristics				
Parity				
Nulliparous	1 (referent)	N/A	1 (referent)	N/A
Primiparous	1.04 (0.91-1.18)	.61	1.02 (0.88-1.19)	.78
Multiparous	1.45 (1.10-1.91)	.007 ^f	1.24 (0.92-1.68)	.16
Gestational age (weeks of pregnancy)				
First trimester (≤12)	1 (referent)	N/A	1 (referent)	N/A
Second trimester (13-26)	0.65 (0.53-0.78)	<.001 ^e	0.66 (0.55-0.81)	<.001 ^e
Third trimester (≥27)	0.69 (0.57-0.84)	<.001 ^e	0.70 (0.58-0.84)	<.001 ^e
Pregnancy-related complications				
No	1 (referent)	N/A	1 (referent)	N/A
Yes	1.02 (0.82-1.26)	.87	1.12 (0.90-1.40)	.31
Isolation due to COVID-19				
City of residence locked down due to COVID-19				
No	1 (referent)	N/A	1 (referent)	N/A
Yes	1.26 (1.10-1.44)	.001 ^f	1.17 (1.01-1.35)	.03 ^d
Quarantined due to COVID-19				
No	1 (referent)	N/A	1 (referent)	N/A
Yes	1.28 (0.97-1.68)	.08	1.19 (0.90-1.56)	.23
Interpersonal factors				
Trust in health care provider	1.04 (1.02-1.05)	<.001 ^e	1.03 (1.02-1.04)	<.001 ^e
Received social support during the COVID-19 period	1.07 (1.04-1.10)	<.001 ^e	1.05 (1.02-1.08)	.001 ^f

^aORu: univariate odds ratio; the odds ratio derived from the univariate logistic regression analysis.

^bORM: multivariate odds ratio; the odds ratio derived from multivariate logistic regression analysis. This analysis was conducted by using the forward enter method.

^cN/A: not applicable.

^dStatistically significant at a level of $P < .05$.

^eStatistically significant at a level of $P < .001$.

^fStatistically significant at a level of $P < .01$.

Discussion

Principal Findings

The COVID-19 pandemic has resulted in considerable distress and has potentially worsened the mental health of the public [3]. Pregnant women are one of the at-risk groups that may have elevated mental risks. It is important to understand the factors of help-seeking intentions among pregnant women with mental health risks during an epidemic period, as early intervention can reduce the negative impact that mental problems can have on both mothers and children in the long term. It is important to note that among our sample of pregnant women who were at risk of mental problems, less than half (2956/6248, 47.3%) of the participants felt the need to seek mental health services. Our findings are in line with those of several studies that have documented a low level of perceived need for mental health services [52,53]. This low level of perceived need could be explained by low levels of knowledge and awareness with regard to the importance of mental health problems [54,55]. Studies on perinatal Chinese American women have revealed that several women believe that postpartum depression does not exist in China [56]. Furthermore, the somatization of mental illness has been commonly reported in China [57]. If pregnant women's psychological distress appeared in the form of somatic symptoms, they may be more likely to seek medical help. Pregnant women might also tend to view a disturbed mood as a normal part of pregnancy [27,56], thereby resulting in the underreporting of the need to seek help.

Despite having mental symptoms, it is surprising that only 19% of our sample reported that they needed and intended to seek mental health services. Our findings were in line with the underutilization of mental health services, which has been documented across several countries and populations [17,53,58,59]. Negative perceptions toward mental health services have been frequently documented among pregnant women. Studies have found that perinatal women often view psychological treatment as ineffective, and describe mental health providers as uncaring, impersonal, and emotionally detached [27,60]. The low levels of psychological help-seeking intentions can also be explained by the incompatibility between Chinese culture and the general public's views on mental illness. For example, in Chinese culture, psychological distress and mental illness are often viewed as a lack of self-control in solving one's own problems, personal weaknesses, bad thoughts, or a lack of will power [56]. Such negative perceptions of mental illness might result in the intense stigmatization and discrimination of people with mental illnesses [61]. Being dismissive of mental health problems and having concerns about feeling embarrassed when seeking help might also reduce people's intentions to seek mental health services when they are faced with mental problems [61]. Furthermore, due to the

influence of traditional Chinese culture, the participants in this study might have preferred to seek help from traditional/indigenous healers or spiritual outlets for alleviating their mental symptoms, rather than seek help from mental health professionals [62].

This study identified a number of background factors that were associated with seeking mental health services. In contrast to studies that have stated that older age was associated with high levels of help-seeking among perinatal women [18,20,63], our study revealed that older perinatal women had low intentions to seek mental health services. Older pregnant women are at a high risk of pregnancy-related complications. Therefore, they might be more attentive to their pregnancy-related needs than their own mental needs. Furthermore, studies have shown that older individuals exhibit negative attitudes toward seeking mental services and are more sensitive to stigmas that are associated with mental illness [64,65]. Older women might avoid seeking help from mental health professionals to minimize the feelings of shame that come from seeking help.

In contrast to studies that have stated that high levels of education are associated with high levels of psychological help-seeking in perinatal women [18,63], our study showed that pregnant women with high levels of education tended to report that they had no intentions to seek mental health services. It is plausible that women who are more educated than others are more likely to attribute their mental symptoms to other causes (eg, work stress) or believe that they can handle mental health challenges on their own [66], thereby reducing their intentions to seek mental health services. It has been suggested that perinatal women with higher education levels have more difficulties in recognizing the presence of psychological problems than those with lower education levels [18]. These difficulties act as considerable barriers to help-seeking.

Among the pregnancy-related characteristics that were assessed in this study, high gestational age was associated with low intentions to seek mental health services. Compared to pregnant women with low gestational ages, those with high gestational ages might be more likely to believe that increased stress and distress are normal as the time to delivery becomes shorter.

The effects of interpersonal factors on help-seeking are indispensable. In this study, participants who received high levels of social support during the COVID-19 pandemic were more likely to seek psychological help than those who received low levels of social support. Our findings corroborate those of existing studies that report significant associations between social support and positive attitudes toward seeking mental health services [67,68], social support and the perceived need for psychological help [69], and social support and psychological help-seeking intentions and behaviors [67,70,71]. The effects of social support on help-seeking intention may be more

important in a collectivistic culture that respects normative values. The level of people's intentions to seek help for mental problems is likely to increase when they receive support from significant others, especially during the COVID-19 pandemic.

Several studies have emphasized that health care providers play a role in facilitating the process of professional help-seeking. Our study demonstrates that pregnant women who had high levels of trust in care providers were more likely to report an intention to seek mental health services than those with low levels of trust in care providers. This finding confirms that perceiving health care providers as helpful and trustworthy people is an important factor of help-seeking behaviors [27,28]. Compared to individuals who have a low level of trust in health care providers, those who have a level of trust in care providers might be more likely to believe that their health care providers are dependable and view care providers' advice and services as helpful and effective. They may also be more likely to experience higher levels of comfort when expressing their negative thoughts to people who they believe are caring and trustworthy [27]. Our findings further support the belief that trust in care providers plays an important role in facilitating help-seeking intentions among people in collectivistic societies, wherein interpersonal relatedness and strong kinship bonds are particularly emphasized.

Implications

Our study has important implications for increasing the acceptance and use of mental health services among Chinese pregnant women. The low perceived needs and intentions to seek mental health services that were documented in this study emphasize the need to increase people's awareness of perinatal mental disorders, and promote positive attitudes toward psychological help-seeking among pregnant women. Mental health education has been found to be effective in improving knowledge, attitudes, and behaviors that are associated with mental health [72]. Mental health education for pregnant women should provide them with methods for identifying, understanding, and responding to signs of mental symptoms. Increasing pregnant women's understanding of distress triggers during pregnancy will also promote positive attitudes toward perinatal mental disorders and increase their willingness to seek help. Such education should also be specifically adapted to perinatal mental disorders, and delivered through community or health care settings.

Our study also indicates that significant others who provide support to pregnant women who experience mental health challenges increase help-seeking intentions among pregnant women. The significant effects of social support in this study suggest that significant others, such as partners, family members, and close friends, should put more effort into promoting health-seeking intentions. Health professionals should also encourage discussions (ie, discussions about emotional problems and concerns) between significant others and pregnant women. This not only strengthens pregnant women's perceived level of support, but also promotes the disclosure of personal issues,

which is an essential first step in seeking mental health services. Significant others should also be included in mental health promotion programs for pregnant women.

The findings of our study also suggest that women are more likely to discuss their concerns with, and seek help from, mental health professionals if they believe that health care workers trustworthy. Empathetic communication and relationships between patients and care providers, and customized patient-centered care promote people's trust in care providers and increase the use of mental health services [73]. Health care professionals should receive training on providing quality services for pregnant women. Such training should emphasize attitude, respect, and sensitivity toward the specific needs of pregnant women. Health care professionals should also receive training on interpersonal skills that help establish rapport and promote communication in clinical settings.

Limitations

Our study has several limitations that should be noted. First, this study was cross-sectional in nature. Therefore, causality among the variables cannot be assumed. Second, we only measured probable depression and anxiety, as clinical diagnoses of depression and anxiety cannot be obtained from web-based surveys. Third, due to the cross-sectional design of this study, information on actual help-seeking behaviors was not obtained, as it seemed inappropriate to assess the association between independent variables and past help-seeking behaviors. Fourth, due to concerns about the length of the questionnaire, social support was only measured with a single survey item. Therefore, our survey results do not show the specific sources (eg, family or friends) and nature (eg, emotional or instrumental support) of the social support that participants received during the pandemic. Similarly, the ACT scale does not capture certain aspects of people's trust in care providers, such as specific reasons for people's trust and the nature of people's trust (eg, fidelity, competence, and honesty) [74]. Hence, the potentially disproportionate effects of different types of social support and people's trust in care providers could not be assessed in this study. Fifth, this study only assessed participants' intentions to seek help from mental health services. Participants' intentions to seek help from other sources were not assessed in this study. Future studies should be longitudinal in design and identify participants with depression and anxiety disorders by using validated diagnostic tools.

Conclusion

This study shows that the perceived needs and intentions to seek mental health services during the COVID-19 period were low among Chinese pregnant women who were at risk of mental health problems. Social support during the COVID-19 pandemic and trust in care providers were protective factors of help-seeking intentions. There is an urgent need to improve perceived social support and promote trusting relationships between pregnant women and their care providers. These factors increase pregnant women's intentions to seek help for mental health problems.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Levels of depression and anxiety among the total sample of 19,515 participants.

[DOCX File, 14 KB - [mental_v8i2e24162_app1.docx](#)]

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Abbreviations

ACT: affect- and cognition-based trust
GAD-7: 7-item Generalized Anxiety Disorder Scale
ORm: multivariate odds ratio
ORu: univariate odds ratio
PHQ-9: 9-item Patient Health Questionnaire

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Original Paper

Efficacy of a Six-Week-Long Therapist-Guided Online Therapy Versus Self-help Internet-Based Therapy for COVID-19–Induced Anxiety and Depression: Open-label, Pragmatic, Randomized Controlled Trial

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Abstract

Background: The COVID-19 pandemic has led to a notable increase in psychological distress, globally. Oman is no exception to this, with several studies indicating high levels of anxiety and depression among the Omani public. There is a need for adaptive and effective interventions that aim to improve the elevated levels of psychological distress due to the COVID-19 pandemic.

Objective: This study aimed to comparatively assess the efficacy of therapist-guided online therapy with that of self-help, internet-based therapy focusing on COVID-19–induced symptoms of anxiety and depression among individuals living in Oman during the COVID-19 pandemic.

Methods: This was a 6-week-long pragmatic randomized controlled trial involving 60 participants who were recruited from a study sample surveyed for symptoms of anxiety or depression among the Omani public amid the COVID-19 pandemic. Participants in the intervention group were allocated to receive 1 online session per week for 6 weeks from certified psychotherapists in Oman; these sessions were conducted in Arabic or English. The psychotherapists utilized cognitive behavioral therapy and acceptance and commitment therapy interventions. Participants in the control group received an automatic weekly newsletter via email containing self-help information and tips to cope with distress associated with COVID-19. The information mainly consisted of behavioral tips revolving around the principles of cognitive behavioral therapy and acceptance and commitment therapy. The primary outcome was measured by comparing the change in the mean scores of Patient Health Questionnaire-9 (PHQ-9) and General Anxiety Disorder-7 (GAD-7) scale from the baseline to the end of the study (ie, after 6 sessions) between the two groups. The secondary outcome was to compare the proportions of participants with depression and anxiety between the two groups.

Results: Data from 46 participants were analyzed (intervention group n=22, control group n=24). There was no statistical difference in the baseline characteristics between both groups. Analysis of covariance indicated a significant reduction in the GAD-7 scores ($F_{1,43}=7.307$; $P=.01$) between the two groups after adjusting for baseline scores. GAD-7 scores of participants in the intervention group were considerably more reduced than those of participants in the control group ($\beta=-3.27$; $P=.01$). Moreover, a greater reduction in mean PHQ-9 scores was observed among participants in the intervention group ($F_{1,43}=8.298$; $P=.006$) than those in the control group ($\beta=-4.311$; $P=.006$). Although the levels of anxiety and depression reduced in both study groups, the reduction was higher in the intervention group ($P=.049$) than in the control group ($P=.02$).

Conclusions: This study provides preliminary evidence to support the efficacy of online therapy for improving the symptoms of anxiety and depression during the COVID-19 crisis in Oman. Therapist-guided online therapy was found to be superior to self-help, internet-based therapy; however, both therapies could be considered as viable options.

Trial Registration: ClinicalTrials.gov NCT04378257; <https://clinicaltrials.gov/ct2/show/NCT04378257>

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KEYWORDS

COVID-19; depression; anxiety; Oman; online therapy; randomized controlled trial; telehealth; therapy; mental health; e-mental health; self-help; distress

Introduction

Background

In order to contain and minimize the impact of the COVID-19 pandemic, countries across the world have resorted to physical distancing, quarantining, and social isolation. This has remodeled health care services through the implementation of web-based and/or remote treatment [1,2]. This transition has also been applied to mental health care services, wherein it has been highly recommended owing to the expected rise in psychological distress during the pandemic [3]. The rise in the use of web-based services catering to patients' psychological well-being has also been observed in Oman, where these services are generally provided in government hospitals or in the private sector. However, there is a dearth of literature regarding the efficacy of this treatment model globally, including in Oman.

On March 11, 2020, the World Health Organization declared COVID-19 a pandemic. More literature is now available detailing the impact of the pandemic on the mental health of people, even among those who are not infected or less at risk [4]. As a result of the pandemic, all members of society are now considered to be "vulnerable" to the infection. As such, there is now an increase in ethical practice education regarding online therapy services, despite it being available for the last two decades. Mental health practitioners were previously resistant to implementing an online or remote-based system as a lot of emphasis has been placed in the value of face-to-face health care practice [5]. However, contrary to this popular belief, online psychotherapy or e-therapy guided by a psychotherapist has shown favorable outcomes, particularly in cases of anxiety or clinical depression [6,7]. In fact, there is a growing need for guided online therapy, particularly catering to populations in regions where access to treatment facilities for mental health care is limited [2,8].

Conversely, online therapy can also be inaccessible to large populations, owing to insufficient network connectivity, lack of economic feasibility, personal and social stigma, and the lack of availability or awareness of accessing such facilities. Considering these factors, an increasing number of self-help applications, including mobile apps and websites, now provide users with free, basic mental and physical health care remedies and strategies to cope with psychological distress due to the COVID-19 pandemic. Previous studies have suggested that the outcomes of face-to-face interventions (ie, in-person or online) and self-help online resources have yielded effective results

[9,10]. However, these trends are yet to be explored in Oman and in the Middle East, in general.

Studies in Oman have suggested that people are at a high risk of experiencing psychological distress during the COVID-19 pandemic [11]. Marital status, gender, pre-existing health conditions and financial status have been found to play a significant role in enhancing the risk of developing psychological distress during this ongoing health crisis [11]. On April 10, 2020, the Omani government issued a lockdown in order to manage the COVID-19 outbreak in the country. At the time of writing this manuscript, 7770 confirmed COVID-19 cases were reported in Oman [12]. Mental health sectors across Oman have launched various self-help and online services to provide health care from a distance. It is of value to understand the efficacy of these services in enhancing the mental health status in order to assist the Omani health authorities to provide focused and high-quality mental health services to vulnerable populations. Additionally, such tools, if well-developed, would have far-reaching potential, particularly for those in Oman who are unable to access mental health services.

Hypothesis

We hypothesized that compared to internet-based (email-delivered) self-help therapy, therapist-guided online therapy is more efficient in reducing COVID-19-induced symptoms of anxiety and depression among individuals in Oman during the COVID-19 pandemic.

Objective

This study aimed to investigate and comparatively assess the efficacy of a 6-week-long therapist-guided online therapy course with that of internet-based (email-delivered), self-help therapy focusing on COVID-19-related symptoms of anxiety and depression among individuals in Oman during the COVID-19 pandemic.

The findings of this study can assist mental health practitioners in Oman to effectively provide their services in a remote-based format to vulnerable populations and also provide policy makers with insights into the usefulness of mental health aids delivered online during the COVID-19 pandemic, and any potential future health crises, in Oman.

Methods

Study Design and Location

In this 6-week, open-label, comparative trial, participants were randomized to receive either therapist-guided online therapy or

internet-based self-help therapy, using a fixed randomization schedule that allocated participants to the two treatment arms in a 1:1 ratio. This study was conducted virtually, using a secure encrypted video conference platform to deliver the online therapy to participants in the intervention arm who were located across Oman.

Participant Allocation and Randomization

A software randomizer generated block randomization sequence (block size is 6) in a 1:1 ratio to balance the number of the participants in each study arm. Participant allocation to either the intervention or control arm was concealed from the study participants and researchers before the trial was initiated to avoid selection bias. This was done through a centralized service at the Department of Behavioral Medicine, Sultan Qaboos University, Muscat, Oman. Each coded, sealed, opaque envelope containing the participant's treatment allocation was opened by research personnel not involved in the study or in the process of data collection. All participants had a code number allocated to them. As this was an open-label trial, the participant and the therapist who conducted the therapy were aware of the

intervention status after the randomization process was completed. However, the outcome assessor, or the person who received the outcome assessment emails, was blinded to the participant's allocation.

Sample Size

The sample size was calculated using nMaster 2.0 software (Department of Biostatistics, CMC, Vellore). The Superiority hypothesis parallel clinical trial model was adopted to calculate the required sample size in each study arm to achieve a mean effect size of Glass' $\Delta=0.75$, as previously described [13]. Considering the power as 80% and a 5% rate of type-I error, the required sample size was 30 participants for each arm, after considering a 20% attrition rate.

Participant Selection and Eligibility

Participants were screened for specific inclusion and exclusion criteria before they were enrolled into this study (Textbox 1). This study followed the guidelines outlined in the CONSORT (Consolidated Standards of Reporting Trials) checklist (Multimedia Appendix 1).

Textbox 1. Study inclusion and exclusion criteria.

<p>Inclusion criteria</p> <ul style="list-style-type: none"> • All Omanis and non-Omanis living in Oman • Male or female • Aged 18-65 years • Patient Health Questionnaire-9 total scores ≥ 12 or Generalized Anxiety Disorder-7 total scores ≥ 10 • Access to the internet and video conferencing • Able to participate in the trial and adhere to the trial protocol • Provided written informed consent to participate in the trial <p>Exclusion criteria</p> <ul style="list-style-type: none"> • Pre-existing mental health disorders • Diagnosis of moderate-to-severe intellectual disability • Presence of alcohol or other substance use disorders (except for nicotine or caffeine) • Suicidal or homicidal ideation at the baseline

Intervention Arm: Therapist-Guided Online Therapy

Participants allocated to the intervention arm received weekly sessions from a trained and licensed psychologist in Oman via Zoom Video Conferencing platform (Zoom Video Communications, Inc.). The therapist sent an e-invitation URL to the participant via email prior to the scheduled meeting. The URL directed the participant to a screen where they would be able to see and interact with their therapist. The sessions were conducted once a week in either Arabic or English, as per the participant's preference.

The initial sessions focused on building a rapport and providing psychological first aid. The following sessions employed principles of cognitive behavioral therapy (CBT) and acceptance and commitment therapy (ACT) interventions based on the therapist's training background and what was determined as the

best fit for the participant. Ongoing supervision was provided in 1-hour weekly online group meetings with other therapists, as well individual sessions with each therapist, if required. No treatment manuals were used; instead, therapists were asked to use therapy models for which they have received training. The following skills were determined to be relevant for these sessions: active listening, empathy, providing focus and structure, goal setting, and providing feedback. Behavioral interventions were considered applicable to treatment, including behavior activation, exposure, homework, and skills training. Components designated as unique to CBT such as discussion of automatic thoughts, core beliefs, and schemas; identification of cognitive distortions; and cognitive restructuring were also applied. Unique ACT components such as experiential acceptance and willingness, de-fusion, mindfulness training, and encouragement of value-driven living, were also applied

by therapists while ensuring adherence to the same orientation throughout the sessions.

The final sessions primarily focused on relapse prevention and terminating the therapeutic relationship. After 6 sessions, participants received an email to complete the postintervention outcome assessment.

Control Arm

Participants allocated to the control arm received an automatic weekly newsletter via email, containing self-help information and tips to cope with distress associated with COVID-19. The information mainly consisted of behavioral tips based on principles of CBT and ACT, such as focusing on positive cognitive reinforcement, strengthening relationships, and mindfulness practices. Participants were requested to use this information to manage any distress that they might experience. After 6 weeks, participants in the control group were assessed for their mood and anxiety symptoms via email-based questionnaires.

Outcome Measures

Patient Health Questionnaire-9 (PHQ-9) is a self-administered measure used to make a tentative diagnosis of depression and monitor its severity. PHQ-9 has been validated in a number of studies involving different populations [14-16]. Al-Ghafri et al [17] examined the applicability and psychometric characteristics of the PHQ-9 among an Omani sample. A cutoff score of 12 gave the best trade-off between sensitivity (80.6%) and specificity (94%). Therefore, in this study, a cutoff score of 12 was used to indicate the presence of significant depression.

General Anxiety Disorder-7 (GAD-7) scale consists of a self-reported, 7-item questionnaire that allows for the rapid detection of generalized anxiety disorder [18]. Participants were asked if they were bothered by anxiety-related problems over the past 2 weeks by 7 questions on the GAD-7 scale, evaluated on a 4-point scale. The total scores ranged from 0 to 21. At a cutoff score of 9 based on the GAD-7 yielded a sensitivity of 89% and a specificity of 82% for detecting anxiety compared with a structured psychiatric interview [18]. However, the validation of an Arabic version of the GAD-7 scale indicated that a cutoff score of 10 had the best trade-off between sensitivity and specificity [19,20]. Therefore, in this study, we considered a total score of 10 and above as the cutoff for significant anxiety.

Data related to participants' age, gender, marital status, number of children, highest qualification, studying abroad, occupation, working in health care, financial strains, physical health problems, mental health problems, self-quarantine, coping with illicit drugs, and email addresses were also collected.

The primary endpoint was to compare the differences in the mean scores of PHQ-9 and GAD-7 from the baseline to the end of the study (ie, after 6 sessions) between participants in the intervention and the control arms. The secondary endpoint was to compare the proportion of participants with significant psychological distress (ie, PHQ-9 total score ≥ 12 or GAD-7 total score ≥ 10) between the two study arms.

Recruitment and Consent Procedure

Recruitment of participants took place between April 14 and May 30, 2020. Participants were recruited from a list of online survey respondents based in Oman with significant psychological distress during the COVID-19 pandemic [4]. This survey was conducted by the current trial team during the first two weeks of April 2020 and included 1539 respondents from different regions of Oman. The prevalence of psychological distress among the trial sample was 30%. The research assistant contacted eligible participants by email, and interested participants were briefed about the trial protocol. Potential participants received a detailed explanation of the objectives, procedures, and risks of the trial protocol. Based on the autonomy principle, the subject had the right to decline to participate or to withdraw from the study at any time without prejudice. After the consent form was read and discussed with their family, if participants wished to get their family's opinion, the participants signed an electronic informed consent to participate in this study. All interaction with the study participants, including explanation and consent process, was conducted over private telephonic or video interviews.

Follow-up Visits and Assessment Procedures and Data Management

After baseline assessment and receiving 6 sessions of therapist-guided online therapy or self-help therapy, the study participants were assessed for outcome measures at week 6. For this, participants were sent email links to the questionnaires (GAD-7 and PHQ-9). Over the first 6 weeks, each remote therapy session included checking the consent, compliance with protocol, and whether any adverse effects such as worsening of anxiety or depression symptoms persisted; this was carried out for participants in both the intervention and control arms. In the self-help (control) arm, we asked the participants, via weekly emails, to confirm receipt of the therapy material via an email to the research assistant. Additionally, we asked them to report any adverse events by contacting the research assistant through a phone number provided to them at the beginning of the study.

Each participant's data were assigned a unique code (serial number). All data collected were initially recorded in a specified file for each participant for every session completed and then transferred to the EpiData sheet at the end of all remote sessions.

Statistical Analyses

The data were double-entered into an electronic database EpiData (V.2.2, EpiData Association, 2000-2008) to ensure accuracy and then exported to SPSS software (version 20.0; IBM Corp.). Continuous variables were summarized as means and SD, and categorical variables were presented as frequencies. Analysis of covariance was used in examining pre- and postintervention differences in the mean scores of PHQ-9 and GAD-7 between the intervention and control arms while considering the influence of uncontrolled independent variables, such as preintervention scores. Categorical variables and proportions of participants with anxiety or depression were investigated using the chi-square test or Fisher exact test, when appropriate. Significance level was set at $P < .05$.

Ethics Approval

This study followed the guidelines of the Declaration of Helsinki, 2001 [21]. Participation was voluntary; each participant had the right to withdraw from the trial at any time for any reason, and their withdrawal did not affect them in any way. This study was granted ethical approval by the research ethics committee at the College of Medicine and Health Science, Sultan Qaboos University, Muscat, Oman (MREC#2103). This trial was registered at ClinicalTrials.gov, registration number NCT04378257.

Data Availability Statement

Data are available upon reasonable request directed to the corresponding author (MA).

Results

Data related to 46 participants were analyzed in this trial (Table 1). Of the 46 participants, 22 (48%) were allocated to the intervention arm and 24 (52%) were allocated to the control arm. The mean age of the participants was 28.51 (SD 8.70) years, and approximately 78% (36/46) of them were female. Most participants (26/46, 57%) were single and about one-third had children (15/46, 33%). Furthermore, most participants (34/46, 74%) had completed education up to the college level, and 33% (15/46) of the participants were working in the health care industry. Financial instability was reported by 28% (13/46) of the study participants. The majority (30/46, 65%) of the participants were self-quarantining because of the COVID-19 pandemic. The difference in baseline scores and proportions of anxiety and depression among participants in the two arms were not statistically significant. Additionally, there was no statistically significant differences in the baseline characteristics of participants in the two arms. Attrition rate was 26% for the

intervention arm and 20% for the control arm. Overall, the characteristics of participants who were lost to follow-up did not differ from the characteristics of the remainder of the participants. Regarding adverse events, 1 participant who was allocated to the intervention arm reported safety concerns before starting the therapy. The participant was immediately referred for a psychiatric assessment at Sultan Qaboos University Hospital.

A univariate analysis of covariance was conducted to compare the effectiveness of the intervention between the two study arms, while adjusting for the preintervention scores (covariant). Levene test and normality checks were carried out, and the assumptions met. There was a significant difference in the GAD-7 score reduction ($F_{1,43}=7.307$; $P=.01$) between the two arms. Parameter estimates showed that the GAD-7 scores for the intervention group were significantly reduced ($\beta=-3.27$; $P=.01$), with an adjusted R^2 value of 0.106. There was a significant difference in the PHQ-9 score reduction as well ($F_{1,43}=8.298$; $P=.006$) between the intervention and control groups. Parameter estimates showed that the PHQ-9 scores in the intervention group were significantly reduced ($\beta=-4.311$; $P=.006$) with an adjusted R^2 value of 0.173 (Tables 2 and 3).

Figures 1 and 2 show the comparisons of the proportions of postintervention anxiety and depression, respectively, between the two study arms. Although the levels of anxiety and depression had reduced in both study arms, the proportions of participants with anxiety and depression were significantly lower in the intervention arm than in the control arm ($P=.049$ and $P=.02$, respectively). The difference is more pronounced with regard to the impact of the intervention on depression, as none of the participants in the intervention arm met the cutoff score for depression after they received the intervention.

Table 1. Baseline characteristics of the participants in the randomized control trial (N = 46).

Variable	Intervention group (n=22)	Control group (n=24)	Total (N=46)	P value ^a
Age (years), mean (SD)	27.0 (8.72)	29.96 (8.63)	28.51 (8.70)	.14 ^b
Gender, n (%)				.07
Male	2 (9.1)	8 (33.3)	10 (22)	
Female	20 (90.9)	16 (66.7)	36 (78)	
Marital status, n (%)				.15
Single	15 (68.2)	11 (45.8)	26 (57)	
Married	7 (31.8)	13 (54.2)	20 (43)	
Do you have children? n (%)				.22
Yes	17 (77.3)	14 (58.3)	15 (33)	
No	5 (22.7)	10 (41.7)	31 (67)	
Education level, n (%)				.18
Secondary school	8 (36.4)	4 (16.7)	12 (26)	
College and above	14 (63.6)	20 (83.3)	34 (74)	
Employment status, n (%)				.38
Employed	9 (40.9)	14 (58.3)	23 (50)	
Unemployed	13 (59.1)	10 (41.7)	23 (50)	
Are you a health care worker? n (%)				.93
Yes	7 (31.8)	8 (33.3)	15 (33)	
No	15 (68.2)	16 (66.7)	31 (67)	
Are you financially stable? n (%)				.75
Yes	15 (68.2)	18 (75)	33 (72)	
No	7 (31.8)	6 (25)	13 (28)	
Have you been diagnosed with chronic illness? n (%)				.22
Yes	2 (9.1)	0 (0)	2 (4)	
No	20 (90.9)	24 (100)	44 (96)	
Did you self-quarantine during the COVID-19 pandemic? n (%)				.36
Yes	16 (72.7)	14 (58.3)	30 (65)	
No	6 (27.3)	10 (41.7)	16 (35)	
Are you in quarantine now because of the COVID-19 pandemic? n (%)				.25
Yes	15 (68.2)	12 (50)	27 (59)	
No	7 (31.8)	12 (50)	19 (41)	
Disorder, n (%)				.97
Anxiety	7 (31.8)	8 (33.3)	15 (33)	
Depression	5 (22.7)	6 (25)	11 (24)	
Anxiety and depression	10 (45.5)	10 (41.7)	20 (43)	

^aChi-square test unless otherwise specified.^bMann-Whitney test.

Table 2. Adjusted postintervention anxiety score (dependent variable) and treatments using analysis of covariance.

Parameter	β	95% CI	<i>t</i> test (<i>df</i>)	<i>P</i> value
Intercept	6.79	2.97-10.62	3.59 (1)	<.001
Pre-GAD-7 ^a score	0.02	-0.24 to 0.27	0.15 (1)	.89
Intervention group	-3.27	-5.71 to -0.83	-2.70 (1)	.01

^aGAD-7: Generalized Anxiety Disorder-7 scale.

Table 3. Adjusted postintervention depression score (dependent variable) and treatments using analysis of covariance.

Parameter	β	95% CI	<i>t</i> test (<i>df</i>)	<i>P</i> value
Intercept	5.25	0.80-9.71	2.38 (1)	.02
Pre-PHQ-9 ^a score	0.23	-0.03 to 0.49	1.77 (1)	.08
Intervention group	-4.31	-7.33 to -1.29	-2.88 (1)	.006

^aPHQ-9: Patient Health Questionnaire-9.

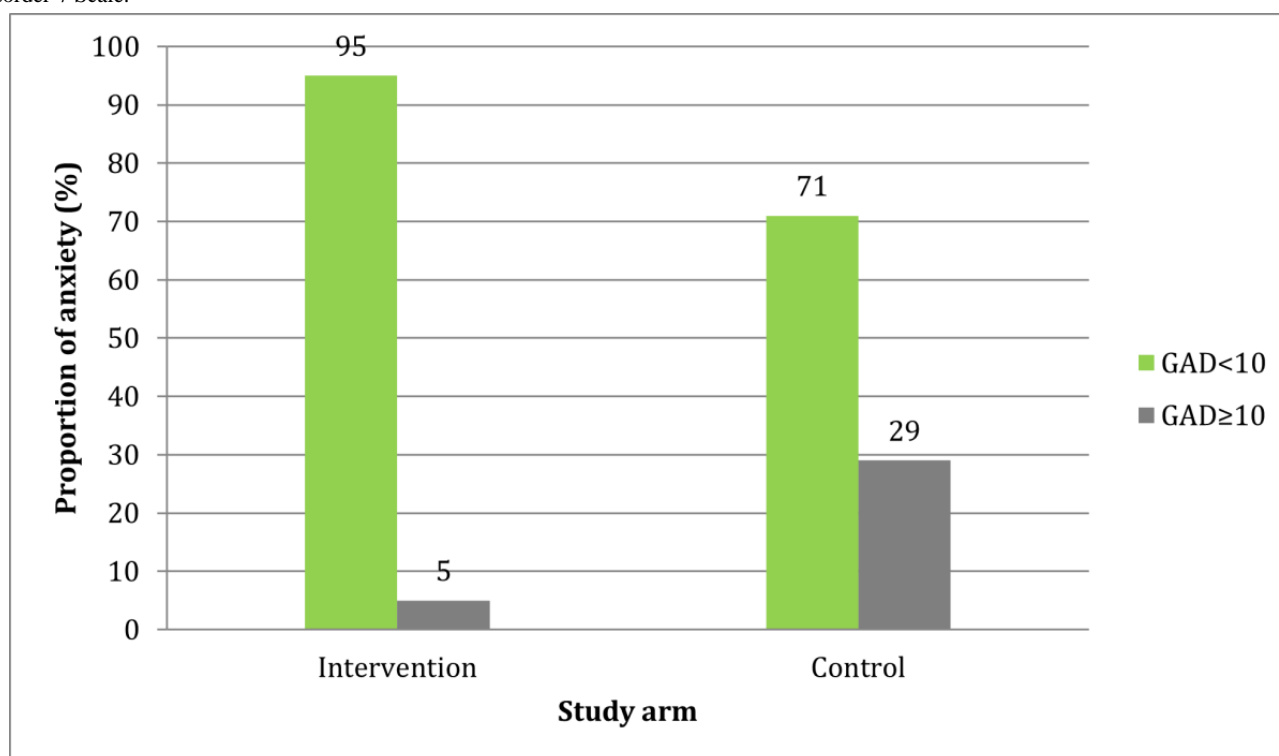
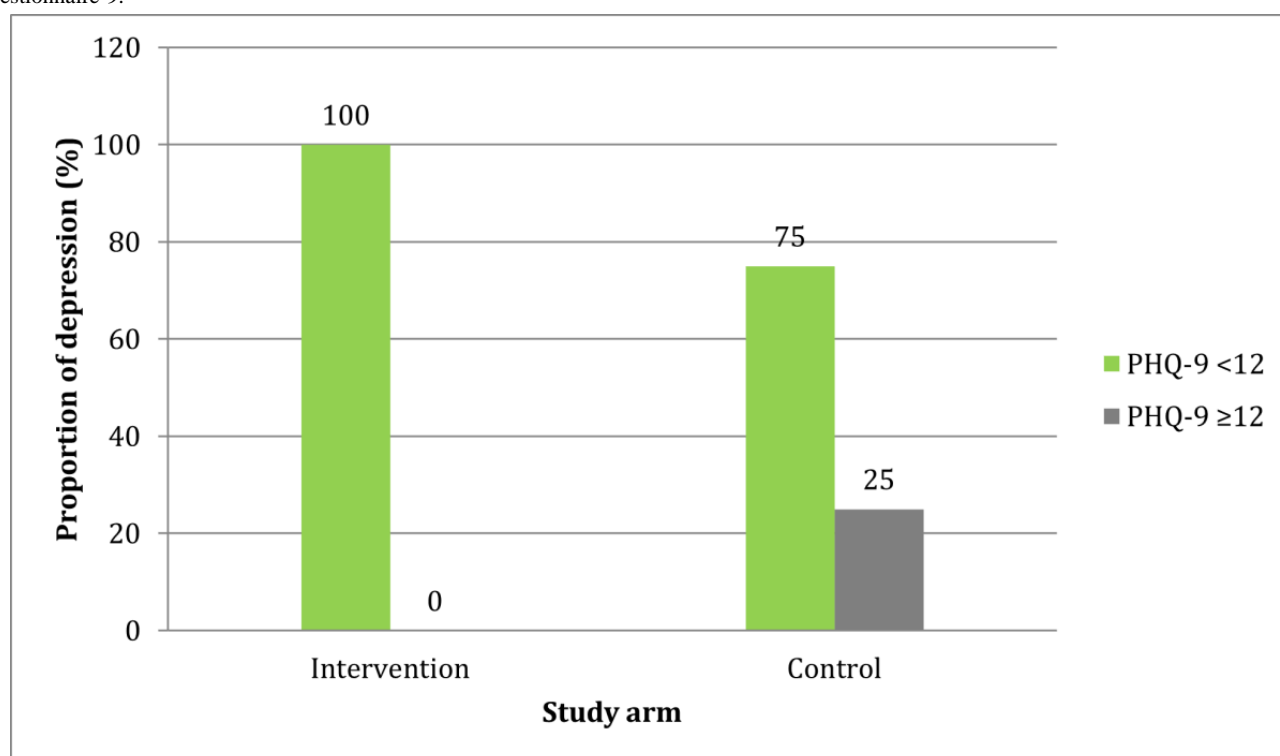
Figure 1. Comparison of the postintervention proportions of anxiety between the two study arms using the chi-square test. GAD-7: Generalized Anxiety Disorder-7 Scale.

Figure 2. Comparison of the postintervention proportions of depression between the two study arms using the chi-square test. PHQ-9: Patient Questionnaire-9.



Discussion

Principal Findings

The primary objective of this study was to measure the efficacy of therapist-guided online treatment protocols versus self-help, emailed-delivered therapy in a sample of the Omani community during the COVID-19 pandemic. In our sample of 46 participants, we found that therapist-guided online therapy led to a significant reduction in psychological distress as determined by the participants' experience of depression or anxiety. This evidence supports previous studies that have found that online therapy is efficient and provides increased access to treatment for people experiencing anxiety and depression [6,7]. The results of this study align with the existing literature with regard to this alternate mode of delivery of psychotherapy services.

With the rapid spread of the COVID-19 pandemic worldwide, social systems have had to adapt to a changed society, characterized with physical distancing, working from home, and increased levels of uncertainty and fear [1,2]. The pandemic has acted as a catalyst for change in the delivery of health care services. The remote delivery of psychological treatment services has been researched; studies conducted before the pandemic have found that the efficacy of remote-based treatment services is as high as that of face-to-face treatment programs [9,10].

The second objective of this study was to comparatively assess the effectiveness, as defined by proportions of anxiety and depression, of therapist-guided online treatment protocols with that of an internet-based, self-help treatment protocol. Overall, improved therapeutic outcomes were noted for both treatment approaches. However, the strength of these associations varied.

In both conditions, effect sizes were large, and most participants demonstrated clinically significant improvements as a function of the treatment. Nevertheless, compared to the self-help (control) group, therapist-guided online therapy resulted in a greater reduction of anxiety and depression. These findings support the notion that therapist-guided online therapy and self-help materials are functionally distinct from one another [22].

The randomized allocation ensured balancing baseline characteristics of the study participants in the two arms to control for and monitor factors that could potentially contribute to differential outcomes. Therefore, there were no observed differences in the participants' expectations of the efficacy for the two treatment approaches. Nevertheless, participants in the control group did show an improvement as a result of the efficacy of the self-help materials, presumably due to the regression of the mean and the natural progression of these conditions with time [22].

In addition to the role of the therapist-client relationship established via an electronic medium, there are other factors that could contribute to the existing results. The reduction in distress levels may have been impacted by the role of the community in times of crisis in a collectivistic society [23], the predicted adjustment to the "new normal" through increased resilience [24] and a decline in pandemic-related information in the media [25].

Strengths and Limitations

The present study has a number of notable strengths. To the best of our knowledge, this is the first study in the Middle East region to evaluate the efficacy of therapist-guided online therapy services that have been implemented in the region since the

onset of the COVID-19 pandemic. Second, treatments were not manualized, thereby allowing therapists to individualize the delivery of each treatment-specific intervention for each participant as they deemed appropriate. Nonetheless, nonmanualized therapy limits the reproducibility of the study.

A limitation of the study is the generalizability of the results. The participants were relatively well-educated and could be classified as “younger adults,” limiting the conclusions with respect to feasibility. In addition, although participation in this study only required basic email skills, not all households in Oman have a broadband internet connection, making our sample less generalizable to the general public. Although it can be argued that most internet users are women [26], it is also worth noting that an overall stigma towards seeking mental health services is evident in Oman [27]. Furthermore, men may be less open to discussing emotional difficulties in Oman and in Eastern culture [28]. Another limitation is that the design of this study did not allow for adequate follow-up of participants, and it is, therefore, unknown whether the treatment effects will be similarly maintained in the long term. Further, the compliance to self-help therapy could not be ascertained fully, and this may limit the interpretation of the findings.

Conclusions

The findings of this study are consistent with a growing body of the literature demonstrating the effectiveness of online therapy on the psychological impact of COVID-19. Furthermore, the results indicate that therapist support makes a substantial difference in terms of effectiveness of online interventions. Therefore, it can be useful to integrate internet-delivered services with traditional mental health services by using a stepped care model, starting with e-guided self-help and thereafter moving to therapist-guided therapy. Individuals identified to be suitable for online interventions could be directed to therapist-guided programs, whereas those deemed unsuitable can be provided with face-to-face interventions or a hybrid approach. Long-term follow-up may be more valuable and is required to identify the effects of online therapy on anxiety and depression levels. Finally, a more direct investigation of the extent of training and supervision is required to train effective therapists, as well as a plan for further specialized services in Oman. There is a limited number of qualified therapists in Oman, with current services focusing predominantly on a medical model for treatment. Further studies on therapist compatibility and training in evidence-based interventions are needed to make online therapy a more abundant and acceptable option in Oman.

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Authors' Contributions

MA, HA, HA, RK, AS, and AA designed and conceptualized the study. SP, TA, NA, AG, MA, RK, and AS performed data collection, statistical analyses, and interpretation. SP, MA, and HA were involved in validation of the statistical analyses. MA, HA, TA, NA, HA, RK, and AS were involved in drafting of the manuscript. MA, HA, AG, AA, and HS provided intellectual contributions in the interpretation of findings, edited the initial draft, and provided critical revisions on the manuscript. All authors have read and approved the final version of the manuscript for publication.

Conflicts of Interest

None declared.

Multimedia Appendix 1

CONSORT-EHEALTH checklist (V 1.6.1).

[PDF File (Adobe PDF File), 6906 KB - [mental_v8i2e26683_app1.pdf](#)]

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Abbreviations

ACT: acceptance and commitment therapy

CBT: cognitive behavioral therapy

GAD-7: General Anxiety Disorder-7

PHQ-9: Patient Health Questionnaire-9

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Short Paper

Impact of the COVID-19 Pandemic on Online Obsessive-Compulsive Disorder Support Community Members: Survey Study

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Abstract

Background: People with obsessive-compulsive disorder (OCD) have faced unique challenges during the COVID-19 pandemic. Research from the first two months of the pandemic suggests that a small proportion of people with OCD experienced worsening in their OCD symptoms since the pandemic began, whereas the rest experienced either no change or an improvement in their symptoms. However, as society-level factors relating to the pandemic have evolved, the effects of the pandemic on people with OCD have likely changed as well, in complex and population-specific ways. Therefore, this study contributes to a growing body of knowledge on the impact of the COVID-19 pandemic on people and demonstrates how differences across studies might emerge when studying specific populations at specific timepoints.

Objective: This study aimed to assess how members of online OCD support communities felt the COVID-19 pandemic had affected their OCD symptoms, around 3 months after the pandemic began.

Methods: We recruited participants from online OCD support communities for our brief survey. Participants indicated how much they felt their OCD symptoms had changed since the pandemic began and how much they felt that having OCD was making it harder to deal with the pandemic.

Results: We collected survey data from June through August 2020 and received a total of 196 responses, some of which were partial responses. Among the nonmissing data, 65.9% (108/164) of the participants were from the United States and 90.5% (152/168) had been subjected to a stay-at-home order. In all, 92.9% (182/196) of the participants said they experienced worsening of their OCD symptoms since the pandemic began, although the extent to which their symptoms worsened differed across dimensions of OCD; notably, symmetry and completeness symptoms were less likely to have worsened than others. Moreover, 95.5% (171/179) of the participants felt that having OCD made it difficult to deal with the pandemic.

Conclusions: Our study of online OCD support community members found a much higher rate of OCD symptom worsening than did other studies on people with OCD conducted during the current COVID-19 pandemic. Factors such as quarantine length, location, overlapping society-level challenges, and differing measurement and sampling choices may help to explain this difference across studies.

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KEYWORDS

obsessive-compulsive disorder; COVID-19 pandemic; online support communities; mental health

Introduction

The COVID-19 pandemic has led to population-level decreases in psychological well-being globally [1]. However, people with obsessive-compulsive disorder (OCD) may experience distinct pandemic-related stressors compared to the general population. Although many people with OCD might be particularly sensitive to pandemic-related stressors (eg, stressors related to contamination fears), social distancing measures might also provide a welcome respite from typical OCD triggers outside of one's home. Research across various populations and timepoints is needed to learn how people with OCD have experienced the COVID-19 pandemic.

Online OCD support communities are a useful sample to consider as people seek support from online mental health communities for various reasons [2]. Online support communities may provide some unique advantages to traditional forms of support, including anonymity and use of access, which may enable greater self-disclosure and social support [3]. These communities may also be especially helpful in a pandemic context, wherein many in-person support sources may be lacking. Thus, exploring the impact the COVID-19 pandemic has had among individuals who participate in online support communities may be useful to understand the impact of the pandemic on help-seeking populations.

Several surveys among people with OCD were conducted between April and May 2020 in Israel [4], Italy [5], India [6], and Japan [7] to explore how OCD symptoms had changed since the onset of the pandemic. About 7%-37% of the participants in these surveys experienced worsening OCD symptoms since the COVID-19 pandemic began. Although our survey study used a methodology highly similar to these studies, we found a much higher rate of OCD symptom worsening. In this paper, we describe our survey of online OCD support community members and discuss possible reasons that contribute to the different patterns of results.

Methods

We recruited the majority of our study participants from three anonymous online OCD peer support communities and the rest via posts on OCD-related social media pages. Participants indicated how much their symptoms in each of the four OCD symptom dimensions ("unacceptable thoughts," "symmetry and completeness," "responsibility for harm," and "contamination"), as defined by the Dimensional Obsessive-Compulsive Scale

[8], had changed since the pandemic began, with values ranging from 0 (much worse) to 6 (much better) that were transposed to -3 to 3, respectively, in our analyses for interpretability. Participants also indicated how much their OCD symptoms made living during the pandemic more difficult, with scores ranging from 0 (not at all more difficult) to 4 (much more difficult). The significance level for the statistical analysis was set at $P<.05$. Our preregistered study materials and analysis plan, as well as the survey data and R code used for analyses, are available online [9]. All available survey data has been reasonably de-identified by the research team and is being shared for research purposes with the consent of all study participants.

Results

We conducted the survey and collected data between June 28 and August 10, 2020, and received 196 survey responses from individuals who stated they were professionally diagnosed with OCD, self-diagnosed, or suspected they had OCD. Not all participants answered all demographics questions. Most participants ($n=163$) were young (mean 24.77, SD 5.96 years), Caucasian (123/166, 74.1%), lived in the United States (108/164, 65.9%), and had their daily life affected by a stay-at-home order (152/168, 90.5%). In all, 71.4% (115/161) of the participants were female, 21.8% (35/161) were male, and 6.8% (11/161) reported their gender as other. We also excluded from the analyses an additional 134 respondents who exited the survey before completing the OCD measure.

We found that 92.9% (182/196) of the participants experienced worsening of their OCD symptoms since the COVID-19 pandemic began (mean -1.10, SD 0.80; $t_{195}=-19.35$; $P<.001$; Cohen $d=1.38$). Notably, however, symmetry and completeness symptoms were considerably less worsened (Cohen $d=0.38$) than all other symptom dimensions of OCD (Cohen $d>0.94$), and the differences in symptom change between symmetry and exactness symptoms and other symptom dimensions were large and significant ($P<.001$; Figures 1 and 2). Moreover, 95.5% (171/179) of the participants felt that having OCD made it more difficult to deal with the pandemic, and 36.3% (65/179) of them indicated that having OCD made it much more difficult (mean 2.79, SD 1.16). When we included only those participants who stated that they had been professionally diagnosed with OCD in our analyses ($n=142$), the results were roughly the same (ie, <5% difference across samples in point estimates for OCD symptom worsening and OCD making it more difficult to deal with the pandemic).

Figure 1. Changes in obsessive-compulsive disorder symptom severity across dimensions, as defined by the Dimensional Obsessive-Compulsive Scale. White diamonds correspond to sample means. Participants indicated the extents to which their symptoms across the four dimensions of obsessive-compulsive disorder (“unacceptable thoughts,” “symmetry and completeness,” “responsibility for harm,” and “contamination”) had changed since the onset of the COVID-19 pandemic, with scores ranging from –3 (much worse) to 3 (much better).

Change in OCD symptoms across domains

In the full sample (n=196)

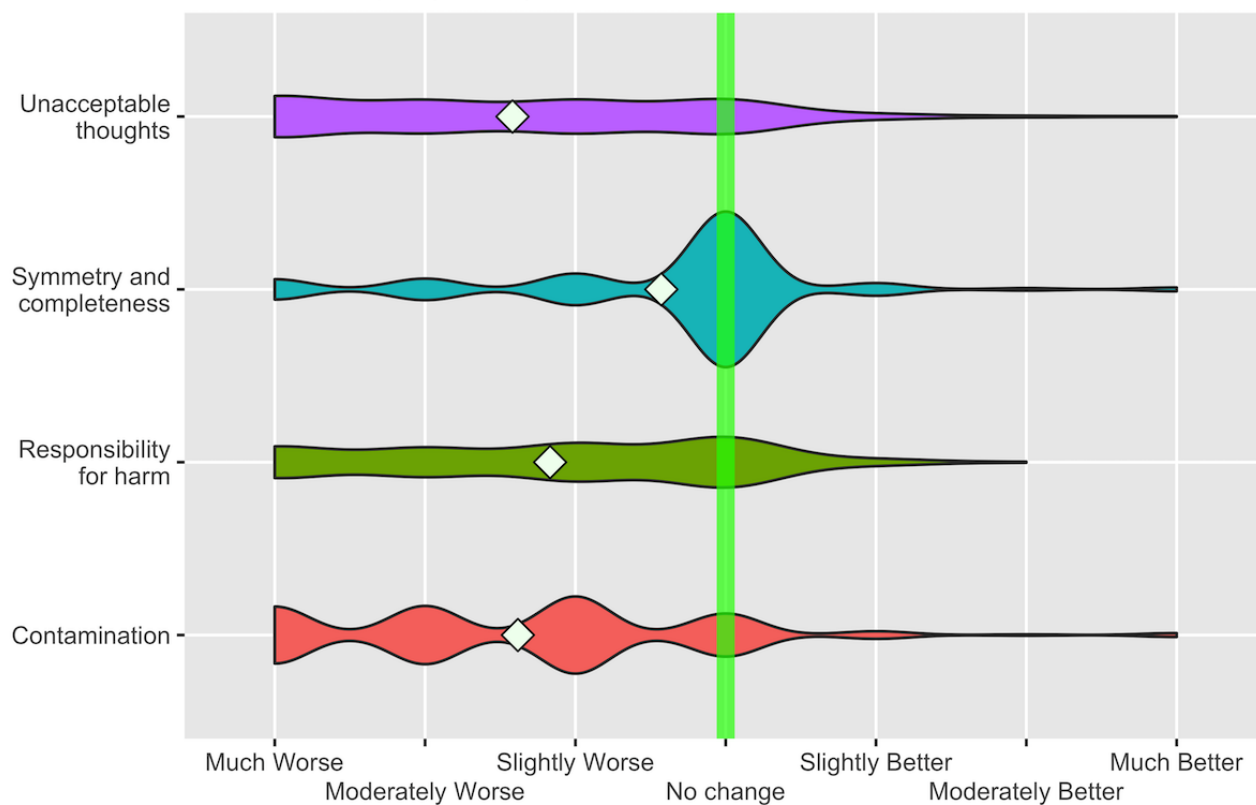
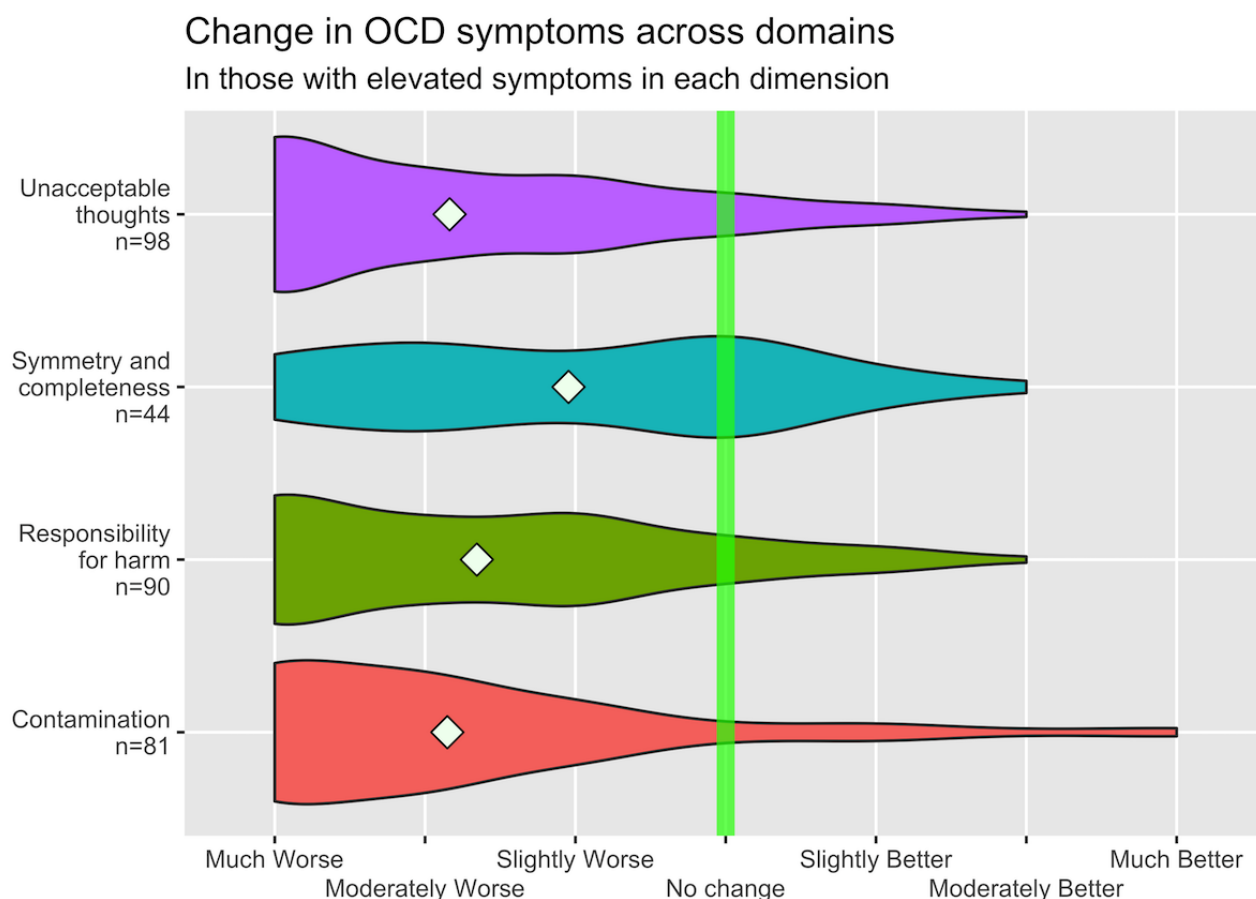


Figure 2. Changes in obsessive-compulsive disorder symptom severity across dimensions evaluated among only those participants with clinically elevated symptoms for a given dimension of obsessive-compulsive disorder, as defined by the Dimensional Obsessive-Compulsive Scale. We considered participants to have clinically elevated symptoms for a given symptom dimension if they scored an average score of 2 (range 0-4) across each item in that symptom dimension, which corresponds to moderate symptoms. White diamonds correspond to sample means. Participants indicated the extents to which their symptoms across the four dimensions of obsessive-compulsive disorder (“unacceptable thoughts,” “symmetry and completeness,” “responsibility for harm,” and “contamination”) had changed since the onset of the COVID-19 pandemic, with scores ranging from –3 (much worse) to 3 (much better).



Discussion

Principal Findings

Our results align with those of similar studies in some regards but differ importantly in other ways [4-7]. Similar to the findings reported by Littman et al [4], our results indicate that symmetry and completeness symptoms were less likely to worsen during the pandemic than symptom dimensions typically associated with harm. Overall, however, a much higher proportion of participants in this study reported worsening OCD severity during the pandemic, as compared with other studies. We believe that several factors may underlie the different results.

Comparison With Prior Work

First, other studies were conducted in April and May 2020, that is, only a few weeks after quarantine measures were first instituted in their respective participants' communities, whereas we conducted surveys between June 28 and August 10, 2020, that is, roughly 3 months after quarantine measures began for most of the US population. The mental health toll of pandemics may increase over time as anxiety, boredom, and frustration compound (as reviewed in [10]). Indeed, in the United States, symptoms of anxiety and depressive disorders in the population

increased considerably more between April and June 2020 than they did between April and June 2019 [11].

Second, previous similar studies were conducted in Israel [4], Italy [5], India [6], and Japan [7], whereas most participants in our survey were from the United States. The mental health toll of COVID-19 is inextricable from location-specific factors; these include government decisions about the pandemic, media reports that might influence beliefs and reduce or increase psychological distress [12], and co-occurring collective challenges such as political unrest [13].

Third, online OCD support communities are likely disproportionately used by people seeking help because they are experiencing elevated symptoms. As a result, the communities we surveyed might have had higher proportions of people who felt their symptoms worsened since the COVID-19 pandemic began, compared to in-person populations (such as patients of an OCD clinic). Although Littman et al [4] also recruited a majority of their study sample from online OCD support groups, the communities they studied may have differed from the ones we studied with regard to the proportion of people seeking help in them.

Limitations

We must note some limitations to our study. First, because we recruited our sample by posting advertisements on online OCD support communities and we do not know which members of these communities chose not to take the survey, our sample is not representative of any population of people with OCD. Second, our measure of OCD symptom change relied on retrospective self-report about the impact of the COVID-19 pandemic, asking participants how much their symptoms changed since the pandemic began; however, comparable studies either directly compared OCD measures before and after the pandemic using longitudinal data or did not mention the pandemic when asking respondents about their symptom change. As such, it might be most accurate to describe our findings as perceived worsening of symptoms. Despite these important limitations, we believe the extremely high rate of OCD symptom worsening among our survey participants remains noteworthy.

Conclusions

Intersecting moderator variables such as quarantine length, location, overlapping society-level challenges, and public sentiment about quarantine measures complicate efforts to identify how the COVID-19 pandemic has affected people with OCD. Further, participants recruited from online support communities might be more likely to have sought help and experienced elevated symptoms at the time of data collection than typical in-person samples. The marked difference in the results between our study and other studies with similar goals and methodologies highlights the importance of considering these variables. As more studies on this topic are published, future works should use meta-analyses to investigate which sociocultural variables (eg, health care availability and trust in government) and researcher variables (eg, sampling and measurement choices) predict observed changes in OCD symptom severity during the COVID-19 pandemic.

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Conflicts of Interest

SMS reports personal consulting fees from Otsuka Pharmaceuticals, outside the submitted work. BK, KC, and JS declare no conflicts of interest.

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Abbreviations

OCD: obsessive-compulsive disorder

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Original Paper

Factors Influencing Depression and Mental Distress Related to COVID-19 Among University Students in China: Online Cross-sectional Mediation Study

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Abstract

Background: The COVID-19 epidemic may elevate mental distress and depressive symptoms in various populations in China.

Objective: This study investigates the levels of depression and mental distress due to COVID-19, and the associations between cognitive, behavioral, and psychosocial factors, and depression and mental distress due to COVID-19 among university students in China.

Methods: A large-scale online cross-sectional study (16 cities in 13 provinces) was conducted among university students from February 1 to 10, 2020, in China; 23,863 valid questionnaires were returned. The Patient Health Questionnaire-9 was used to assess depression. Structural equation modeling was performed to test mediation and suppression effects.

Results: Of the 23,863 participants, 47.1% (n=11,235) reported high or very high levels of one or more types of mental distress due to COVID-19; 39.1% (n=9326) showed mild to severe depression. Mental distress due to COVID-19 was positively associated with depression. All but one factor (perceived infection risks, perceived chance of controlling the epidemic, staying at home, contacted people from Wuhan, and perceived discrimination) were significantly associated with mental distress due to COVID-19 and depression. Mental distress due to COVID-19 partially mediated and suppressed the associations between some of the studied factors and depression (effect size of 6.0%-79.5%).

Conclusions: Both mental distress due to COVID-19 and depression were prevalent among university students in China; the former may have increased the prevalence of the latter. The studied cognitive, behavioral, and psychosocial factors related to COVID-19 may directly or indirectly (via mental distress due to COVID-19) affect depression. Interventions to modify such factors may reduce mental distress and depressive symptoms during the COVID-19 epidemic.

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KEYWORDS

COVID-19; depression; mental distress; psychological responses; mediation; China; online survey

Introduction

COVID-19 started in Wuhan, China in December 2019 [1] and was declared a pandemic on March 11, 2020 [2]. As of January 10, 2021, there were 87,364 deaths and over 89.4 million confirmed cases in China and overseas [3]. In China, the initial phase of the COVID-19 outbreak induced numerous stressors, as it impacted almost every aspect of daily life, from work and entertainment to service use and social interactions [4]. For instance, entry to and exit from Wuhan and many cities and regions have been prohibited since the Chinese Lunar New Year (CNY). Other personal and public control measures include closure of offices and public areas (eg, shopping areas, offices, and restaurants), massive quarantines, staying at home for a long period of time, suspension of school classes, and cancellation of events [4]. It is important to study the negative psychological responses potentially caused by the COVID-19 epidemic, as previous studies have reported high prevalence of depression and other mental health problems in various populations during the 2003 severe acute respiratory syndrome (SARS) epidemic, the 2009 novel influenza A (H1N1) pandemic, and the 2014-2016 Ebola outbreak [5-8]. Mental health problems have significant public health implications, as they affect the public's use of measures for prevention [9]. The study of negative psychological responses and associated factors related to the COVID-19 outbreak in China allows global public health and mental health workers to assess related service demands and design effective interventions.

Although a number of studies have looked at the factors of depression during the COVID-19 period, fewer studies were conducted in the initial phase of the outbreak, which started after the Chinese government announced the disease's person-to-person transmission property on January 20, 2020, and started the first controversial Wuhan lockdown 3 days after [10]. To our knowledge, no similar studies were conducted outside China around that period of time, as COVID-19 had not become a pandemic until March and gained less attention outside China in early February 2020. Psychological responses are context specific. The initial phase of the COVID-19 outbreak

(in terms of the first few weeks) in the world meant uncertainties and a lack of information. It is imperative to document the community responses at the initial stage of new emerging infectious diseases (especially those that eventually become a pandemic) to inform preparations for future outbreaks.

Furthermore, the first COVID-19 outbreak occurred in China during the CNY, which involved high mobility, as billions of people were returning to their hometowns and, hence, created a high risk of spreading the virus to the entire country. Mobile populations have special relevance in this specific time and country context, one of which was university students, as the majority of students were studying in cities away from their hometowns. This study investigates psychological responses of depression and associated factors among university students in China from 10 to 20 days since COVID-19 was believed to involve person-to-person transmission. Our literature search found only four similar university student studies conducted during the same time period [11-14]. Three of them covered only one or two cities and provinces, and the fourth one claimed to involve 29 provinces but had a sample size of only 2216, while this study covers 16 cities in 13 provinces (n=23,863). Moreover, this study is population-based, while no sampling frame was mentioned in the four other studies.

Although factors of depression during the COVID-19 period have been widely reported. There are still substantial research gaps that are being filled by this study besides the aforementioned fact that such studies were scarce during the initial weeks. Cognitive, behavioral, and psychosocial factors related to COVID-19 were all found to be potential determinants of depression [15-17]. Although a lot of studies have investigated associations between COVID-19-related cognitive factors and preventive behaviors [18,19], only a few studies have looked at COVID-19-related cognitive factors of depression. For instance, the four Chinese university student studies conducted during the initial outbreak mainly mentioned lifestyle factors such as sleep and psychological attributes such as resilience but not COVID-19 cognitive factors [11-14]. Several studies of the population in China and overseas looked

at cognitive factors such as perceived susceptibility and severity, which were positively associated with depression [15,20-23].

According to the fear appeal theory, perceived threat comprises perceived susceptibility and perceived severity [24]. The theory provides a framework to include cognitive factors in this study. Perceived chances for oneself or one's significant others in contracting a disease (perceived susceptibility) [9] was significantly associated with psychological problems such as depression during the SARS, H1N1, and Ebola outbreaks [5,7,8]. In general, perceived severity of a disease was significantly associated with negative psychological responses [7,8]. The public's belief that H1N1 could cause severe irreversible bodily damage was associated with mental distress [7]. Anticipation about the likelihood and scale of a potential outbreak reflects perceived severity of the epidemic at the community level. For instance, perceived chances of having large H1N1 and Ebola outbreaks were associated with mental health problems [5,7]. We contended that perceived chance of controlling the COVID-19 epidemic would be positively associated with depression, as such a perception may reduce perceived severity due to potential negative impacts (eg, finance, work, and social relationship).

Misconceptions that H1N1 could be transmitted via some unconfirmed modes of transmission such as waterborne transmissions increased perceived susceptibility, which was associated with mental distress [8]. The association between misconceived mode of COVID-19 transmission and depression was less clear. One study conducted in the general population during the initial phase of COVID-19 in China found that the perceived mode of transmission via droplets increased risk of depression, while perceived transmission via contaminated objects or airborne transmission was nonsignificant. As people were forming their perceptions based on the risk, severity, and mode of transmission during the initial outbreak phase amid uncertainties and a lack of knowledge, their associations with depression might be different from those obtained from subsequent studies conducted during the later phases of the pandemic.

COVID-19-related behavioral factors of depression are also important, as behavioral responses would occur during initial outbreaks of new emerging infectious diseases. An important and unprecedented response was staying at home during the CNY in China, keeping in mind that there were then no clear strict social distancing policies in China, and there was no penalty for going out in most Chinese cities. It is important to understand the level of staying at home during the critical initial outbreak phase, as it had contributed to the control of COVID-19 in China by reducing social contacts. Research has found that quarantine was positively associated with depression [25], but staying at home during the holidays is different from quarantine and working from home. Other studies found that social distancing, or more precisely compliance to social distancing policies, was positively associated with depression [26,27], while nonsignificant results have also been reported (eg, [28]). No study has looked at the association between voluntarily staying at home and depression during the initial COVID-19 period in China. Another important unique behavioral factor was close contacts with people from Wuhan, which was the

first and most important epicenter of COVID-19. At the time of the survey, a majority of the COVID-19 cases in China were detected from Wuhan, while many cases detected outside Wuhan were related to visitors of Wuhan [10]. Close contacts with such people was a unique stressor that was investigated only in this study. Choosing to stay at home as a prevention strategy may reduce perceived susceptibility, as it lowers the likelihood of contracting COVID-19. Having closely contacted high-risk people such as those who had travelled to Wuhan may increase perceived susceptibility. Thus, it is essential to look at whether they have associations with depression after adjusting for perceived severity and susceptibility.

Potential psychosocial factors related to COVID-19 may be associated with mental distress at the community level. For instance, perceived discrimination is a risk factor of depression [29] and has been associated with mental distress in SARS research [30]. Health care workers and patients who recovered from SARS were discriminated against by the public [31]. As of January 10, 2021, there were 50,340 confirmed COVID-19 cases in Wuhan and 17,809 in the rest of the Hubei Province (where Wuhan is located) [32]. Five million people had traveled out of Wuhan during the CNY [33]. Those who had visited Wuhan or Hubei might have encountered discrimination. In addition, people at risk of contracting the virus were prone to encountering discrimination (eg, hospital workers and their close contacts, and family members, coworkers, and neighbors of infected cases). No study has looked at COVID-19-related discrimination and its potential effect on depression during the COVID-19 outbreak in China.

Mental distress due to COVID-19 (eg, panic, anxiety, and emotional agitation) is potentially associated with depression. It is understood that prevalence of depression among university students prior to the COVID-19 outbreak was not low; not all depressive symptoms were caused by COVID-19 although the pandemic could have inflated the risk of depression. This study thus has the novelty of measuring both general depressive symptoms and the level of self-reported mental distress directly attributed to COVID-19, based on a scale used in understanding mental distress due to SARS and H1N1 [7,34,35]. It is imperative to understand the associations between cognitive, behavioral, and psychosocial factors, and both mental distress due to COVID-19 and depressive symptoms, which were tested in this study.

Another research gap is that few studies have looked at the mechanisms between COVID-19-related factors and depression during the pandemic period. According to the common sense model of illness representation, cognitive perceptions, how a person feels about a disease (ie, emotional representation), and their coping responses such as behavioral responses would determine health outcomes, including mental health status [36,37]. Thus, it is contended that cognitive, behavioral, and psychosocial factors, and mental distress due to COVID-19 would be positively associated with depression. Furthermore, this study tested the mediation hypothesis that emotional responses (ie, mental distress due to COVID-19) mediated between the studied cognitive factors (eg, perceived bodily damages and perceived infection risk of COVID-19), behavioral factors (eg, staying at home and having close contacts with

people who visited Wuhan), and psychosocial factors (eg, perceived discrimination related to COVID-19), and depressive symptoms. No study has looked at such mediations, and thus, this study contributes to the literature of mental distress during the initial COVID-19 period.

This study investigates the level of depression among 23,863 university students of 26 universities located at 16 cities in 13 provinces of China 10 days after the official recognition of person-to-person transmission by the Chinese government and during the 8th to 17th days of the CNY in China, which was the initial rising phase of COVID-19. Based on the literature search, besides background and contextual factors, this study investigates the associations between the following factors and both mental distress due to COVID-19 and depression: *cognitive factors* (ie, misconceptions about modes of transmission; perceived risks of contracting COVID-19 for self, family members, and classmates; perceived permanent bodily damages of COVID-19; and perceived chance in controlling the epidemic in China in the coming 6 months), *behavioral factors* (ie, staying at home behavior during the CNY and close contacts with people who had visited Wuhan before the CNY), and *psychosocial factors* (ie, perceived discrimination) related to COVID-19. We further tested the hypothesis that mental distress due to COVID-19 would mediate between the aforementioned cognitive, behavioral, and psychosocial factors, and depression. The literature has not reported similar studies.

Methods

Participants and Procedure

This cross-sectional study was conducted during the 8th to 17th days of the CNY (February 1-10, 2020). Data were collected from 26 universities of 16 cities in 13 out of the 32 provinces, municipalities, and autonomous regions in the country. A total of 681 classes were sampled by convenience within a number of faculties (arts, sciences, social sciences, engineering, medicine and public health, and others). The median number of students selected per university was 1165 (IQR 2271). All students of the selected classes were sent a QR (Quick Response) code through Wechat to access an anonymous online questionnaire that took about 10-15 minutes to complete. They were informed about the study's background, anonymity, restriction to academic use, and that return of the completed questionnaire implied informed consent. A lucky draw gave out five prizes of ¥50-¥200 (about US \$7-\$28) per city, while half of the students randomly received a symbolic CNY *lucky money* (red pocket) of ¥1 (about US \$ 0.15).

A total of 36,560 invitations were sent out; 25,647 completed questionnaires were returned, 1197 (4.7%) of which did not pass the consistency checks and were excluded from data analysis together with 47 (0.2%) others who were diagnosed COVID-19 positive, 515 (2.0%) who were quarantined, and 25 (0.1%) who were outside mainland China. The effective sample size was 23,863 (93.0%). The response rate was 70.2% (25,647/36,560).

The study was approved by the Survey and Behavioral Research Ethics Committee of the Chinese University of Hong Kong (No. SBRE-19-400).

Measures

Personal Background

Personal background information included sociodemographic data (ie, sex), school-related information (ie, grades and faculty), and self-reported physical health status.

Contextual Factors

Contextual factors included living arrangement during the CNY (ie, whether staying in their university's city), whether staying with their families at the time of the survey, whether their localities of stay were *shut down* by the local government during the CNY, and the number of confirmed COVID-19 cases detected in the provinces that the participants' localities belonged to.

Depression

Depression was assessed by using the Patient Health Questionnaire-9 (PHQ-9). It has been validated in Chinese populations and has shown good psychometric properties [38]. The items asked about the frequency that some symptoms occurred during the past 2 weeks; sample items involved "little interest or pleasure in doing things" and "feeling down, depressed, or hopeless." Each item was rated with a four-point Likert scale (from 0, not at all, to 3, nearly every day). Summative scores of 5, 10, 15, and 20 represent cutoff points for defining mild, moderate, moderately severe, and severe depression, respectively. The Cronbach alpha of the PHQ-9 was .92 in this study.

Mental Distress Due to COVID-19

Three items were used to assess the levels of mental distress due to COVID-19 (ie, panic, anxiety, and emotional agitation). The items were rated with a four-point Likert scale (from 1, very low, to 4, very high); higher levels of the summative score indicate higher levels of mental distress due to COVID-19. The summative scale has been used in a number of H1N1 studies [7,8]. The Cronbach alpha was .93 in this study.

Cognitive Factors Related to COVID-19

First, the item on *airborne transmission* stated "COVID-19 can be transmitted long distance through air" (responses: 1, yes; 2, no; or 3, uncertain); the responses were recoded into two groups (1, yes, or 0, no or uncertain). Second, three items were used to assess the levels of *perceived infection risk* of COVID-19 in the coming year for oneself, family members, and classmates (responses: from 1, very low, to 4, very high, and 5, do not know or not applicable); the responses were recoded into two groups (1, very high or high, and 0, less than high). The Perceived Infection Risk Indicator was then formed by counting the number of ones (range of 0-3). Third, the item on *perceived permanent bodily damage* stated "COVID-19 will easily cause severe permanent bodily damage" (response: 1, agree; 2, disagree; or 3, do not know); the responses were recoded into two groups (1, agree, and 0, disagree or do not know). Fourth, the item *perceived chance of controlling the COVID-19*

epidemic in China stated “What is the chance that the COVID-19 epidemic will be controlled in China in the coming six months” (responses: from 1, definitely yes, to 6, definitely no, and 7, uncertain); the responses were recoded into two groups (1, definitely yes or very high, and 0, less than very high).

Behavioral Factors Related to COVID-19

First, the *staying at home* item assessed the total number of hours spent out during the 7-day CNY (0 hours, 1 hour to 4 hours, 5-10 hours, 11-14 hours, or ≥ 15 hours). Second, the item *close contacts with people who had visited Wuhan* asked “Have you closely contacted people who had visited Wuhan within the two weeks before CNY?” The response was recoded into two groups (1, yes, or 0, no or do not know).

Perceived Discrimination

One item assessed the level of perceived discrimination encountered due to COVID-19 (from 1, very low, to 4, very high).

Statistical Analysis

The summative score of the PHQ-9 was used as the continuous dependent variable. The associations between the background personal variables, contextual variables, and depression were analyzed by simple regression models; Spearman correlation coefficients were derived to assess the correlations among the studied cognitive, behavioral, and psychosocial factors; the potential mediator (ie, negative psychological responses to COVID-19); and the dependent variable (ie, depression). Collinearity diagnosis of the aforementioned independent variables and mediators was conducted by examining the variance inflation factor (VIF); a VIF value greater than five would suggest existence of collinearity. By using structural equation modeling (SEM) with maximum likelihood estimation, the potential mediation and suppression effects of mental distress due to COVID-19 between the cognitive/behavioral/psychological factors and depression were tested, adjusting for all studied background personal and contextual variables. Three latent variables were created for the SEM analysis: perceived infection risk (derived from the original

three items), mental distress due to COVID-19 (derived from the original three items), and depression (derived from three parcels that were randomly grouped from the original nine items). The random parceling approach has been recommended for SEM analysis [39]. Other independent variables were represented by single items. The recommended model fit index included the comparative fit index ≥ 0.90 , the normed-fit index ≥ 0.90 , the Tucker-Lewis index ≥ 0.90 , and the root mean square error of approximation ≤ 0.08 . The SEM was conducted using AMOS 17.0 (IBM Corp), while other analyses were performed using SPSS 21.0 (IBM Corp). The significance level was defined as a two-tailed $P < .05$.

Results

Descriptive Statistics

Descriptive statistics are presented in Table 1. Out the 23,863 responses for the cognitive variables, there was perceived airborne transmission ($n=5590$, 23.4%); a perceived high or very high risk of contracting COVID-19 for oneself ($n=2672$, 11.2%), family members ($n=2814$, 11.8%), or classmates ($n=4367$, 18.3%); perceived permanent bodily damage ($n=8523$, 35.7%); and a perceived high chance of controlling COVID-19 in China in the coming 6 months ($n=16,714$, 70.0%). Behaviorally, 49.3% ($n=11,757$) stayed at home all the time during the 7-day CNY period (the modal response); 4.9% ($n=1159$) reported that they had close contact with people who visited Wuhan 2 weeks prior to the CNY. Regarding the psychosocial factor, 21.5% ($n=5124$) perceived high or very high levels of discrimination due to COVID-19.

Regarding psychological responses, 47.1% ($n=11,235$) reported high or very high levels of one or more types of mental distress, panic ($n=9483$, 39.8%), anxiety ($n=8483$, 35.5%), or emotional agitation ($n=8045$, 33.7%) due to the COVID-19 epidemic; the composite variable of mental distress due to COVID-19 summed up the item scores of these three types of responses. The mean was 6.9 (SD 2.2, range 3-12). Furthermore, about 40% of the participants showed mild to severe depression (mild: $n=5862$, 24.6%; moderate or severe: $n=3464$, 14.5%). The mean of the PHQ-9 score was 4.6 (SD 5.5, range 0-27; see Table 2).

Table 1. Background variables of the participants (N=23,863).

Variables	Participants, n (%)
Sociodemographics	
Sex	
Male	7605 (31.9)
Female	16,258 (68.1)
School-related information	
Grade	
First year	9017 (37.8)
Second year	6425 (26.9)
Third year	5061 (21.2)
Fourth year	2281 (9.6)
Fifth year	542 (2.3)
Master's or above	537 (2.3)
Faculty	
Medicine	10,850 (45.5)
Arts	4232 (17.7)
Science	3901 (16.4)
Engineering	1809 (7.6)
Social science	846 (3.6)
Others	2225 (9.3)
Living arrangement during CNY^a	
Staying in the university's city	
No	11,116 (46.6)
Yes	12,747 (53.4)
Staying with family	
No	1559 (6.5)
Yes	22,304 (93.5)
Self-reported physical health status	
Moderate/poor/very poor	4926 (20.6)
Good/very good	18,937 (79.4)
Information about participants' localities of stay at the time of survey	
Local entry/exit control during CNY (shutdown)	
No	7018 (29.4)
Yes	16,845 (70.6)
Confirmed COVID-19 cases^b in the province participant was in	
0-50	4965 (20.8)
51-150	8385 (35.1)
151-300	5581 (23.4)
>300	4932 (20.6)

^aCNY: Chinese Lunar New Year.^bThe number of cumulative confirmed COVID-19 cases refers to the national data reported by the launch day of this study (February 1, 2020).

Table 2. Descriptive statistics of the independent variables, the mediator, and the dependent variable (N=23,863).

Variables	Participants
Cognitive factors, n (%)	
Perceived airborne transmission	
No/do not know	18,273 (76.6)
Yes	5590 (23.4)
Perceived Infection Risk Indicator^a	
0	18,779 (78.7)
1	1846 (7.7)
2	1707 (7.2)
3	1531 (6.4)
Perceived permanent bodily damage	
Disagree/do not know	15,340 (64.3)
Agree	8523 (35.7)
Perceived chance of controlling the epidemic within 6 months	
Else	7149 (30.0)
Definitely yes/very high	16,714 (70.0)
Behavioral factors, n (%)	
Time spent going out during CNY^b (hours)	
≥15	1295 (5.4)
11-14	1233 (5.2)
5-10	4156 (17.4)
1-4	5422 (22.7)
0	11,757 (49.3)
Close contacts with people who had visited Wuhan 2 weeks before CNY	
No or do not know	22,704 (95.1)
Yes	1159 (4.9)
Psychosocial factors, n (%)	
Perceived discrimination due to COVID-19	
Very low	9989 (41.9)
Low	8750 (36.7)
High	3690 (15.5)
Very high	1434 (6.0)
Mental distress to COVID-19, mean (SD)	6.9 (2.2)
0, n (%)	12,628 (52.9)
1, n (%)	2892 (12.1)
2, n (%)	1910 (8.0)
3, n (%)	6433 (27.0)
Depression (PHQ-9^c), mean (SD)	4.6 (5.5)
Normal, n (%)	14,537 (60.9)
Mild, n (%)	5862 (24.6)
Moderate, moderately severe, or severe, n (%)	3464 (14.5)

^aThe Perceived Infection Risk Indicator counted the number of endorsements of “high/very high” for three items about perceived risk of infection for

oneself, family members, and classmates; the indicator counted the number of endorsements of “high/very high” for three items measuring negative psychological responses to COVID-19; details are described in the Methods section.

^bCNY: Chinese Lunar New Year.

^cPHQ-9: Patient Health Questionnaire-9.

Associations Between Background Variables and Depression

The associations between background variables and depression are presented in Table 3. Females showed more depressive symptoms than males, but the difference did not reach statistical significance ($P=.07$). Several contextual factors were significantly associated with lower risks of depression, including

staying in the city of the university, staying with family, and self-perceived physical health, while the number of confirmed cases (>300 cases) detected in the province where the participants were staying at the time of the survey was positively associated with depression symptoms (ie, higher scores of PHQ-9). Whether the city had been *shut down* was, however, not associated with depression. The background variables were adjusted for in the SEM analysis.

Table 3. Linear regression analyses on the associations between background variables and depression (n=23,863).

Variables	Depression	
	β	<i>P</i> value
Sociodemographics		
Sex		
Male	— ^a	—
Female	-.01	.07
School-related information		
Grade		
First year	—	—
Second year	.02	.005
Third year	-.01	.11
Fourth year	-.01	.51
Fifth year	-.01	.41
Master's or above	.01	.40
Faculty		
Medicine	—	—
Arts	.04	<.001
Science	.01	.04
Engineering	.01	.16
Social science	.02	.009
Others	-.01	.27
Living arrangement during CNY^b		
Staying in the university's city		
No	—	—
Yes	-.02	.02
Staying with family		
No	—	—
Yes	-.04	<.001
Self-reported physical health status		
Moderate/poor/very poor	—	—
Good/very good	-.28	<.001
Information about participants' localities of stay at the time of survey		
Local entry/exit control during CNY (shutdown)		
No	—	—
Yes	-.01	.85
Confirmed COVID-19 cases^c in the province participant was in		
0-50	—	—
51-150	.01	.48
151-300	.01	.04
>300	.03	<.001

^aReference variable.^bCNY: Chinese Lunar New Year.

^cThe number of cumulative confirmed COVID-19 cases refers to the national data reported on the launch day of this study (February 1, 2020).

The Mediation Analysis

Correlations Among Variables

A number of variables were positively correlated with depression, including the Perceived Infection Risk Indicator ($r=0.11$, $P<.001$), having close contacts with people who had visited Wuhan 2 weeks prior to the CNY ($r=0.05$, $P<.001$), perceived discrimination due to COVID-19 ($r=0.14$, $P<.001$),

and mental distress due to COVID-19 ($r=0.25$, $P<.001$). Some variables were negatively correlated with depression, including perceived chance of getting the epidemic under control in China within 6 months ($r=-0.13$, $P<.001$) and staying at home ($r=-0.08$, $P<.001$). Perceived airborne transmission ($r=-0.01$, $P=.29$) and perceived permanent bodily damage ($r=.01$, $P=.44$) were *not* significantly associated with depression; mediation analyses were hence not performed for these two associations (see Table 4).

Table 4. Spearman correlations among the independent variables, the mediator, and depression (N=23,863).

Variables	Depression	
	<i>r</i>	<i>P</i> value
Cognitive factors		
Perceived airborne transmission	−0.01	.29
Perceived Infection Risk Indicator ^a	0.11	<.001
Perceived permanent bodily damage	0.01	.44
Perceived chance of controlling the epidemic within 6 months	−0.13	<.001
Behavioral factors		
Staying at home	−0.08	<.001
Close contacts with people who had visited Wuhan 2 weeks before CNY ^b	0.05	<.001
Psychosocial factors		
Perceived discrimination due to COVID-19	0.14	<.001
Mediating variables		
Mental distress due to COVID-19 (the summative score)	0.25	<.001

^aThe Perceived Infection Risk Indicator counted the number of endorsements of “high/very high” for three items about perceived risk of infection for oneself, family members, and classmates; the indicator counted the number of endorsements of “high/very high” for three items measuring negative psychological responses to COVID-19; details are described in the Methods section.

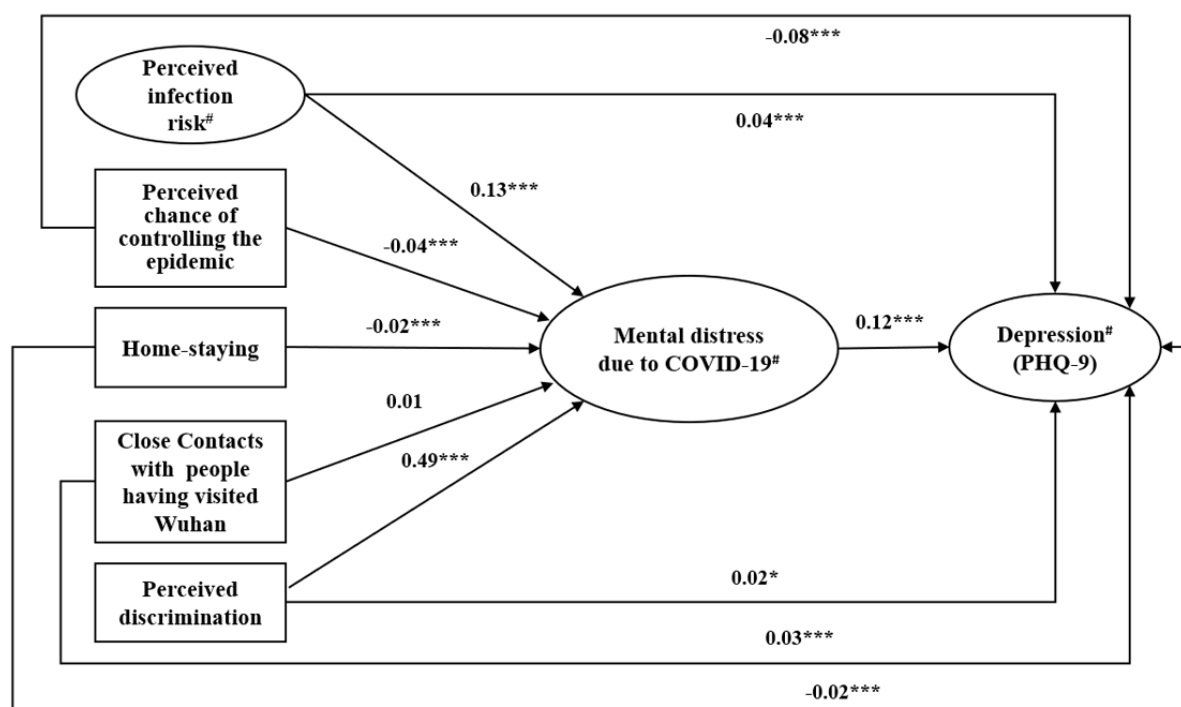
^bCNY: Chinese Lunar New Year.

Testing Mediation and Suppression Effects of Negative Psychological Responses Between the Studied Factors and Depression

The SEM model's fit index was satisfactory (comparative fit index 0.95, normed-fit index 0.94, Tucker-Lewis index 0.94, and root mean square error of approximation 0.04); the range of factor loadings for the three latent variables was 0.70–0.97 (all $P<.001$). No collinearity was detected with the VIF values of all studied variables ranging from 1.00 to 1.37 (VIF>5 indicates the existence of collinearity). In Figure 1, mental

distress due to COVID-19 partially mediated or suppressed the association between perceived infection risk and depression (mediation effect size 27.4%, Sobel test $P<.001$), between perceived discrimination and depression (mediation effect size 79.5%, Sobel test $P<.001$), between perceived chance of epidemic control and depression (suppression effect size 6.0%, Sobel test $P<.001$), and between staying at home behavior and depression (suppression effect size 9.8%, Sobel test $P<.001$). The nonsignificant mediator was close contacts with people who had visited Wuhan (Sobel test $P=.32$). The beta values are shown in Figure 1.

Figure 1. The mediation effect of mental distress due to COVID-19 on the associations between the independent variables and depression. The structural equation model was adjusted for background variables, including sex, school-related information, living arrangement during the Chinese Lunar New Year, self-reported physical health status, and information about localities of stay at the time of the survey. # indicates latent variables; details are described in the Methods of the text. PHQ-9: Patient Health Questionnaire-9. * $P<.05$; ** $P<.01$; *** $P<.001$.



Discussion

This population-based study, which covers 26 universities of 16 cities in 13 provinces of China, revealed a relatively high level of depressive symptoms among university students during the initial phase of the COVID-19 outbreak in China (10–20 days since the official recognition of the person-to-person transmission property of COVID-19). This study identifies a number of significant COVID-19-related cognitive (ie, perceived infection risk and perceived controllability of the epidemic), behavioral (ie, staying at home behavior and close contacts with people from Wuhan), and psychosocial (ie, perceived discrimination) factors of both mental distress due to COVID-19 and depressive symptoms; nonsignificant factors included perceived airborne transmission and perceived permanent bodily damage. As expected, mental distress due to COVID-19 was significantly and positively associated with depressive symptoms; it further mediated the associations between some of the cognitive/behavioral/psychosocial factors and depressive symptoms. The findings present a rough snapshot of what happened in the country and shed light on how people may react emotionally to new emerging infectious diseases and how various types of responses (eg, cognitive and behavioral responses) would be associated with such emotional responses.

The COVID-19 pandemic has affected people's mental health. The findings of this study reveal prevalent mild to severe depression in 40% (9326/23,863) of university students in China, according to the PHQ-9. The prevalence obtained from studies among university students in China prior to the COVID-19 period seemed lower (eg, 23.8% among Chinese university

students reported in a meta-analysis [40] and 29.5% reported during the SARS outbreak among Chinese university students [41]), but such prevalence was not exactly comparable, as different tools and sampling methods were used. Three of the four studies on Chinese university students conducted during a similar time period also used the PHQ-9. Two of the studies, which were conducted in Guangzhou [11] and 29 Chinese provinces [14], presented prevalence of moderate to severe depression (PHQ-9 \geq 10) of 7.7% and 23.3%, respectively, compared to the 14.5% (3464/23,863) of this study, denoting geographical variations in addition to differences in sampling methods. This study has the strength that it was population-based and had a class-based sampling frame, while the others were distributed conveniently online.

Depressive symptoms were prevalent among university students at the initial phase of the COVID-19 outbreak in China; this can be seen from the high levels of self-reported mental distress directly attributed to COVID-19, which is understandable, as uncertainties and the Wuhan lockdown were alarming and worrisome. Furthermore, mental distress due to COVID-19 was positively associated with depressive symptoms. Thus, the mental distress directly attributed to COVID-19 might have increased the already high level of depression among university students during the initial phase of the epidemic in China. As mental distress and depression affect preventive behaviors [9] and individual well-being [42], and acute stress may turn into chronic depression [43,44], health care workers need to integrate mental health promotion with prevention of COVID-19 at the initial stages of outbreaks for new emerging infectious diseases.

The context of this study was unique and relevant, as it was conducted during the CNY and soon after the first outbreak and lockdown in Wuhan. It can be seen that students who stayed in the *university's city* or with family members were less likely than others to be depressed. They might have received better support from their significant others, and social support and coping resources are protective against mental health problems [45,46]. The perceived number of confirmed cases in the *province they were located in* was positively associated with depression; it is plausible that the perception might increase perceived susceptibility and perceived severity of the epidemic and thus depression. It is interesting that travel restrictions on entering and exiting from the city of stay, which was then a *new* preventive measure, was not significantly associated with depression. The findings suggest that such drastic restriction, if implemented orderly and with good support, does not necessarily cause substantial panic or negative impacts on mental distress. A number of countries implemented even more severe lockdowns such as bans on going out soon after the completion of this study (eg, Italy), which was followed by many other countries (eg, parts of the United Kingdom, France, and Australia). In some countries, the strict social distancing measures were associated with depression [27,47]. Future studies should review this *new* measure and identify ways to minimize its adverse mental health effects. This study hence documents the initial responses to preliminary lockdown measures in the COVID-19 pandemic.

This study has interesting findings that involve interpretations in the context of the initial outbreak and in comparison with other studies. Spearman analysis and the SEM showed that some COVID-19–related cognitions (perceived chance of controlling COVID-19 and perceived risks of infection) were significantly associated with both mental distress due to COVID-19 and depressive symptoms; such findings corroborate with other studies [15,20–23]. However, it is unexpected that perceived bodily damages (a reflection of perceived severity) and perceived airborne transmission (possibly a misconception) were not significantly correlated with mental distress due to COVID-19 and depression, while such correlations were significant in similar H1N1 research [7,8]. It is plausible that this study was conducted in the early prepandemic phase of COVID-19 when no clear information was given about long-term harms and modes of transmission.

The behavioral factors of self-reported mental distress due to COVID-19 and depressive symptoms also illustrated the uniqueness of this study. The duration of staying at home during the CNY was protective against depression, which has not been reported in the global literature (except one general population study that found a nonsignificant result [15]). However, other studies have reported positive associations between social distancing and isolation and depression [27,47]. It has some special implications, as there were then no clear and strict social distancing policies in China (except in Wuhan), and people could leave home without facing penalties. The government, however, pledged for national support to contain COVID-19; staying at home during the CNY hence might have involved altruism and social responsibility, which were negatively associated with depression [48]. People may also feel safer at

home. Thus, a short period of staying at home (for the 7-day holiday) during the initial outbreak period of a new emerging infectious disease may not cause mental distress but was instead protective. It seems that social distancing policies need to be exercised as early as possible during new outbreaks of important emerging infectious diseases to increase effectiveness and minimize distress. In addition, we found that close contacts with people coming from Wuhan was a risk factor of depression. To our knowledge, no study has looked at this variable, although other studies looked at visits to Wuhan (eg, [13]). This finding has important implications, as Wuhan was the epicenter where the first outbreak occurred, and the virus was spread to other regions. The variable became nonsignificant in the SEM, possibly because of controlling for a potential confounder of perceived discrimination.

This study also investigated the psychosocial factor of perceived discrimination. Over half (13,874/23,863, 58.1%) of the participants perceived discrimination related to COVID-19, possibly because of their traveler status. Associations between perceived discrimination and depression were similarly reported in previous studies related to SARS and H1N1 [7,8,49]. In fact, the association with depression was the strongest one among all the factors of this study. Thus, university students may feel more depressed during the COVID-19 epidemic, not only because of related perceived susceptibility and severity but also the way they are treated by others. To our knowledge, only one Canadian general population study had looked at such an association but found a nonsignificant finding [16]. The situation in China was unique. The country faced strong international pressure during the study period; Wuhan was accused of spreading the disease to other regions. Indeed, COVID-19 was initially labelled as the *Wuhan virus*. Travelers might be regarded as potential carriers of the virus; discrimination found a fertile ground to grow and might have a powerful negative effect on mental distress. It is imperative to investigate whether perceived discrimination related to epicenters has caused mental distress in the later phase of the pandemic. For instance, there were over 22 million detected cases in the United States as of January 10, 2021, and a new viral strain of higher infectivity was found in the United Kingdom where the incidence of COVID-19 is soaring. The level of perceived discrimination and its association with depression might be country specific due to politicization. When facing outbreaks of new emerging infectious diseases in the future, stigma needs to be removed from the location of the outbreak. The effects of the generalized perceived discrimination need to be investigated.

This is one of the few studies that looked at the mechanisms behind the associations between COVID-19–related factors and depression during the COVID-19 period. The findings suggest that COVID-19–related cognitive, behavioral, and psychosocial factors, and mental distress directly attributed to COVID-19 were all associated with depression, while the relationships between some of the COVID-19 cognitive, behavioral, and psychosocial factors, and depression may be partially mediated and suppressed through mental distress due to COVID-19. Specifically, perceived risk and perceived discrimination may have an indirect effect on depression via mental distress due to COVID-19; such risk factors might have increased mental

distress due to COVID-19, which would in turn increase risk of depression. In addition, confidence in controlling the epidemic and staying at home could potentially be protective against depression via reduction of mental distress due to COVID-19, which was in turn positively associated with depression. Interventions to improve these cognitions or preventive behaviors may thus reduce depression directly or via reduction of mental distress due to COVID-19. Moreover, the mediation and suppression model presented in Figure 1 are supported by the common sense model [36], which suggests that diseases (COVID-19 in this case) as stimuli trigger cognitive representations (perceptions related to COVID-19) and emotional representations (negative psychological responses to COVID-19). The two types of responses would in parallel determine the coping process and health outcomes (depression in this case). In addition, the theory postulates that the cognitive responses would have an effect on the emotional responses. The findings and the model suggest that both cognitive and emotional outcomes are important in jointly determining mental distress during the COVID-19 period. No study has tested this contention. Future longitudinal studies are warranted to test the full common sense model in the context of the COVID-19 epidemic.

This study has the strength of covering a large number of university students who were staying in most of the provinces in China. The data thus presents a crude *national* scenario. This study has some limitations. First, it did not have national coverage. Selection bias may exist, as classes and departments

were not randomly selected. Second, we did not cover important interpersonal factors (eg, subjective norms and social support), which were associated with many health-related behaviors [50,51]. Third, the relatively mild magnitudes of some mediation and suppression effects of mental distress due to COVID-19 imply existence of other unstudied mechanisms. Last, the cross-sectional study design does not allow for causal inferences, as depression may also change perceptions. Longitudinal studies are needed to confirm these contentions.

The findings suggest that mental distress due to COVID-19 and depression were prevalent among university students in China during the initial COVID-19 outbreak period. The former may have further increased the prevalence of the latter. Various cognitive, behavioral, and psychosocial responses to COVID-19 showed both direct and indirect effects (via mental distress due to COVID-19) on depression. Thus, interventions to improve such multidimensional factors might reduce mental distress during the initial COVID-19 outbreak period. The associations between some of the studied factors and depression may change over time as more information and experiences were obtained by the public, signifying early investigation of community responses to avoid mental distress, which would carry over to later phases and affect prevention behaviors. Some of the findings may shed light on handling new emerging infectious diseases that occur in the future. It is important to validate the findings in general and specific populations in China and in other countries.

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Authors' Contributions

JTFL conceived the research questions, designed the study, assembled the team of collaborators, and supervised the project's implementation; JTFL, YY, and RS conducted the statistical analysis and drafted the manuscript; JTFL and YY finalized the manuscript. All authors assisted in the questionnaire design, data collection, and data interpretation, and gave comments to the intellectual content of the manuscript. JTFL, YY, MX, RS, and SL have full access to all the data of the study and are responsible for the integrity of the data and the accuracy of the data analysis.

Conflicts of Interest

None declared.

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Abbreviations

CNY: Chinese Lunar New Year

H1N1: novel influenza A

PHQ-9: Patient Health Questionnaire-9

QR: Quick Response

SARS: severe acute respiratory syndrome

VIF: variance inflation factor

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Original Paper

Improving Mood Through Community Connection and Resources Using an Interactive Digital Platform: Development and Usability Study

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Abstract

Background: COVID-19 continues to disrupt global health and well-being. In April-May 2020, we generated a digital, remote interactive tool to provide health and well-being resources and foster connectivity among community members through a text messaging platform.

Objective: This study aimed to prospectively investigate the ability of a health system-based digital, remote, interactive tool to provide health and well-being resources to local community participants and to foster connectivity among them during the early phases of COVID-19.

Methods: We performed descriptive and nonparametric longitudinal statistical analyses to describe and compare the participants' mood ratings over time and thematic analysis of their responses to text messages to further assess mood.

Results: From among 393 individuals seeking care in an urban emergency department in an academic setting, engaged in a two-way text messaging platform, we recorded 287 mood ratings and 368 qualitative responses. We observed no difference in the initial mood rating by week of enrollment [Kruskal-Wallis chi-square $H(5)=1.34$; $P=.93$], and the average mood rating did not change for participants taken together [Friedman chi-square $Q(3)=0.32$; $P=.96$]. However, of participants providing mood ratings at baseline, mood improved significantly among participants who reported a low mood rating at baseline [$n=25$, 14.97%; $Q(3)=20.68$; $P<.001$] but remained stable among those who reported a high mood rating at baseline [$n=142$, 85.03%; $Q(3)=2.84$; $P=.42$]. Positive mood elaborations most frequently included words related to sentiments of thankfulness and gratitude, mostly for a sense of connection and communication; in contrast, negative mood elaborations most frequently included words related to anxiety.

Conclusions: Our findings suggest the feasibility of engaging individuals in a digital community with an emergency department facilitation. Specifically, for those who opt to engage in a text messaging platform during COVID-19, it is feasible to assess and respond to mood-related queries with vetted health and well-being resources.

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KEYWORDS

community; COVID-19; digital health; digital tool; mental health; mood; prospective; thematic analysis; virtual support; well-being

Introduction

Background

Since January 2020, COVID-19 has continuously disrupted global health and well-being. The World Health Organization (WHO) declared a state of global public health emergency, which is the highest level of alarm under international legislation. The WHO reported that COVID-19 induces and exacerbates fear, worry, anxiety, loneliness, and stress, especially among vulnerable populations and those with chronic and underlying health conditions [1].

Previous studies have reported that connecting individuals to community resources and providing ongoing support can decrease loneliness, thereby potentially improving well-being in the context of the trauma associated with COVID-19 [2,3]. Additionally, during the pandemic it is especially critical for individuals to be directed to trusted community and health information resources [4]. Given the concerns regarding the mental health impacts of COVID-19, the need for community interventions to address these potential consequences has arisen [5].

Despite the current need to address mental health through community-based interventions, the implementation of such interventions has been difficult owing to public health constraints such as social distancing. This is particularly concerning for vulnerable population (eg, homeless individuals, older individuals, those with substance abuse, or those with mental health issues) who may not have access to traditional support networks or resources because many physical locations are nonoperational, operating through drastically reduced hours, or operating at limit capacity. Digital platforms and technology and their utility have received increasing attention in bridging the gaps between individuals and community-based support [4]. The rapid expansion of digital platforms that offer connection are critical for supporting individuals and their networks to foster access to credible health information and support mental health and well-being during social distancing and shelter-in-place orders [6].

Objective

This study aimed to prospectively investigate the ability of a health system-based digital, remote, interactive tool to provide health and well-being resources to individuals and facilitate a sense of connection during the early phases of COVID-19. We investigated self-reported individual mood ratings of the study participants and hypothesized that digital engagement and community resources would improve their mood. Additionally, we investigated user-generated comments to identify themes in areas of need.

Hypotheses

We first hypothesized that texting individuals is feasible and acceptable to disseminate the tool as we continually attempt to define and improve mental health and well-being. Second, given that participants received differential text-based follow-up depending on their initial mood rating with the aim to improve their self-reported mood rating by providing continuous support, we hypothesized that participants beginning the intervention with low self-reported mood ratings would experience mood improvement through the 4-week intervention, while those with initial high self-reported mood ratings would retain such a rating.

Methods

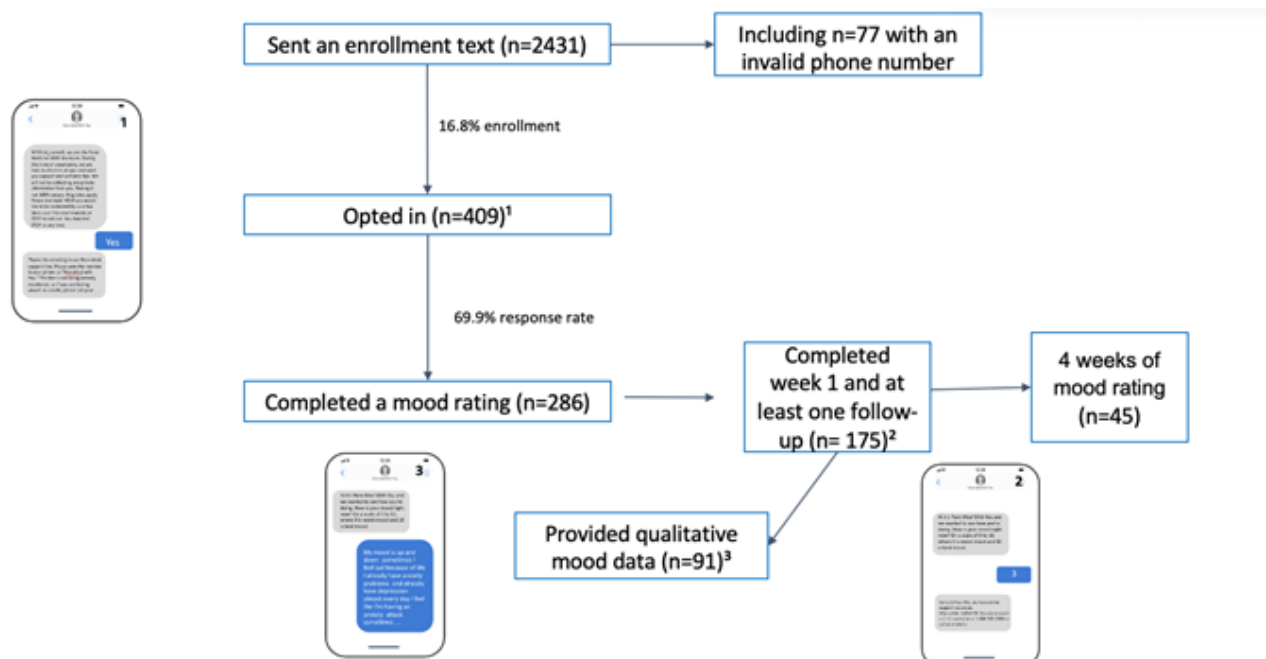
Intervention and Participants

In March 2020, we built a digital platform that deployed automated texting to assess well-being and provide the responders with access to community-based health and well-being resources. The platform provided participants with institution-supported health information, COVID-19 updates, virtual support, well-being tips, and additional resources. We used Mosio, a platform complying with the Health Insurance Portability and Accountability Act of 1996, to invite eligible participants and communicate with them through two-way texting. This study was approved by the institutional review board and quality improvement unit of the University of Pennsylvania.

Eligible participants, including adults aged >18 years and with SMS-capable phone numbers were identified from the electronic health record and approached for enrollment through text message after being discharged from one of two emergency departments (ED) (including a university medical center ED with a high patient capacity, and a second community-based university-affiliated hospital ED with a comparatively lower patient capacity) in the Philadelphia area between April 13 and May 8, 2020. Eligible subjects needed to opt into the follow-up text messages and the 4-week program after enrollment (Figure 1).

Upon enrollment, participants received weekly text messages asking them to rate their mood from 0 to 10 [7]. Individuals could voluntarily provide qualitative descriptors of their mood along with their rating. Tiers of mood rating by the participants trigger the receipt of differential content (Multimedia Appendix 1). Participants reporting a “high” mood rating of 7-10 would always receive a link to an uplifting resource, whereas those reporting a “low” mood rating of 0-3 always received links to mental health and well-being resources. Those reporting a “medium” mood rating of 4-6 received links to either an uplifting resource or to the resource homepage to view all featured resources, alternating each week.

Figure 1. Schematic representation of the study design. A total of 2431 individuals were sent an enrollment text after being discharged from the emergency department at one of two academic medical centers emergency. Of them, 409 (17%) individuals opted in and were asked to self-report well-being, of whom 286 (70%) responded. Of them, 236 (83%) individuals provided a mood rating at week 1 and 175 (60%) responded during week 1 and at least one follow-up, including 101 (35%) individuals who responded at weeks 1 and 4. Furthermore, 45 (16%) participants responded at all 4 weeks.



Statistical Analysis

Quantitative Analysis

We used summary statistics to describe the participant demographics. We performed the two-sample Student *t* test and Fisher exact test to compare the demographics of responders and nonresponders. We conducted a quantitative and qualitative analysis of the mood rating data and a descriptive analysis for all mood ratings.

Changes in Mood Rating Stratified by Low and High Initial Mood Ratings

We used a Kruskal-Wallis rank test to assess weekly mood ratings of the cohort through the study period (7 weeks) and differences in δ mood (difference in mood rating between weeks 1 and 4) across the three groups of initial mood rating (low, medium, high) and further assessed these differences using the Dunn post hoc test. We performed nonparametric longitudinal statistical analysis using the Friedman test to compare mood ratings by participant over the course of their enrollment in the intervention (4 weeks). To test our hypothesis that participants with an initial “low” mood rating upon initial participation in the intervention would experience mood improvement over the 4-week intervention, we stratified the aforementioned analysis by “low” (rating 0-3) and “high” (rating 7-10) mood.

Qualitative Overall Themes

We used a qualitative thematic analysis approach and applied the five stages of framework analysis (familiarization, identification of a thematic framework, indexing, charting, mapping, and interpretation) [8]. We performed thematic coding of the data through an iterative open coding process. An initial

set of codes was generated after open review of a subset of responses by the authors (RO and LS), which yielded a codebook (Multimedia Appendix 2). The author (LS) then coded and independently reviewed qualitative responses ($n=368$) for consistency and agreement.

Qualitative Mood Themes

After two authors (RO and LS) applied the initial codes to the main content and reviewed them, we observed that the codes were reproducible and in themselves represented themes from among the main content messages. However, considering our aim to assess mood in this study, we conducted a subanalysis of the content in the text messages specifically under the main theme (code) of “mood” to form subthemes (LS). Word clouds were generated to capture the raw counts of most frequently used words in the open-ended responses for messages identified under the theme of “mood” and subthemes of “positive mood elaborations” and “negative mood elaborations.”

Data Exclusion

Over the study period, a total of 2431 individuals were discharged from the ED of one of two urban academic medical centers and approached with an enrollment text. Of them, 409 (17%) opted into the “With You” program, and 383 participants provided demographic ($n=374$) or mood rating ($n=286$) data. For completeness, all data available from the 383 samples were used for all statistical analyses.

Results

Intervention and Participants

The 409 individuals who opted in the “With You” program were asked to self-report well-being. Almost two-third ($n=286$,

70%) participants responded (Figure 1). Of them, 236 (83%) responded with a mood rating at week 1, and 175 (60%) responded during week 1 and to the follow-up text during week 4, including 101 (35%) who responded during weeks 1 and 4. Furthermore, 45 (16%) participants responded during all 4 weeks. The majority of participants were Black (n=275, 73.5%),

were female (n=264, 70.1%), and had a mean age of 46.9 (SD 16.8) years (Table 1). Most participants (n=225, 60.2%) were recruited from the ED of the hospital with a high overall patient capacity (hospital A). We observed no difference in demographics between mood-rating responders and nonresponders.

Table 1. Participant demographics (N=374).

Characteristics	Total population ^a	Responders (n=280)	Nonresponders (n=94)	P value
Age (years), mean (SD)	46.9 (16.8)	47.1 (16.9)	44.1 (17.2)	.06
Females, n (%)	264 (70.1)	202 (54.0)	62 (16.6)	.26
Race, n (%)				.51
Black	275 (73.5)	204 (72.9)	71 (75.5)	
White	69 (18.4)	55 (19.6)	14 (14.9)	
Asian	14 (3.7)	11 (3.9)	3 (3.2)	
Other	16 (4.3)	10 (3.6)	6 (6.4)	
Hispanic ethnicity, n (%)	14 (3.7)	10 (3.6)	4 (4.3)	.65
Emergency department, n (%)				.91
Hospital A	225 (60.2)	168 (60.0)	57 (54.3)	
Hospital B	149 (39.8)	112 (40.0)	37 (39.4)	

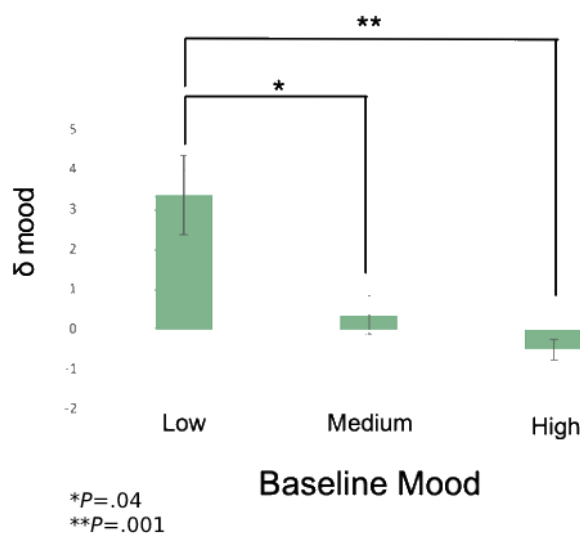
^aOf the total study sample (n=383), all demographic data were missing for 9 (2.3%) participants.

Statistical Analysis: Quantitative

Mood ratings did not significantly change through the course of the study [7 weeks; $H(5)=1.34$; $P=.93$] or by participant when all participant mood ratings were cumulated [$Q(3)=0.32$; $P=.96$]. However, on comparing mood changes between weeks 1 and 4 of enrollment (δ) by grouping participants on the basis of their initial mood rating (low, medium, and high), δ was significantly higher for participants who initially reported a low mood rating

[$H(2)=14.85$; $P<.001$] (Figure 2). The Dunn post hoc test revealed significant pairwise differences in δ between low and medium mood tiers ($P=.004$) and between low and high mood tiers ($P=.001$) but not between medium and high mood tiers ($P=.11$). A sensitivity analysis stratified by initial mood, using a dichotomous variable for a low mood rating (0-5, n=69) and a high mood rating (6-10, n=167), did not impact our findings ($z=2.6$; $P=.009$).

Figure 2. Change in mood from week 1 to week 4 of the intervention (δ) for participants varied significantly across mood tiers [$H(2)=14.85$; $P<.001$]. Pairwise comparisons revealed significant differences between low and medium mood tiers ($P=.04$) and between low and high mood tiers ($P=.001$). * $P=.04$, ** $P=.001$.

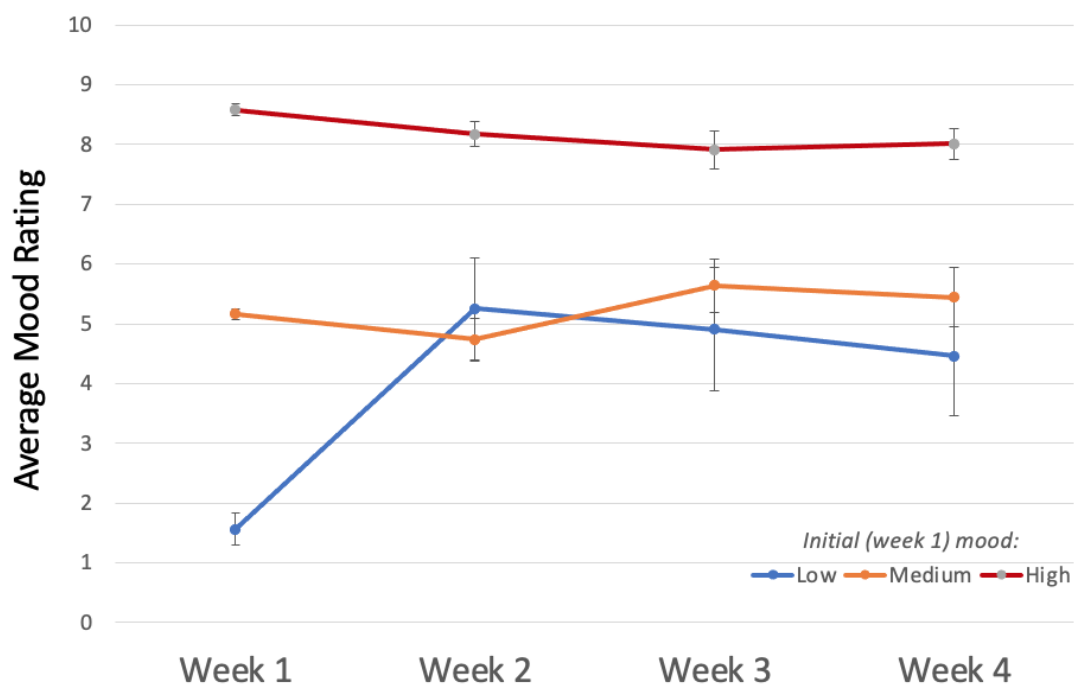


Changes in Mood Rating Stratified by Low and High Initial Mood Rating

The remaining quantitative analysis was stratified by a low initial mood rating (0-3) and a high initial mood rating (7-10). Among participants who provided mood ratings at baseline, for those with a low mood rating at baseline ($n=25$, 14.97%), mood significantly improved through the 4-week intervention [$Q(3)=20.68$; $P<.001$] (Figure 3). Post hoc analysis revealed a

significant increase in mood ratings at week 1 and those at weeks 2, 3, and 4 ($P<.001$ for all three pairwise comparisons) but no change in mood rating between weeks 2 and 3 ($P=.46$), 3 and 4 ($P=.48$), and 2 and 4 ($P=.49$). However, among participants who provided mood ratings at baseline, those who reported initial high mood ratings ($n=142$, 85.03%) retained their high mood rating (showing no longitudinal change) across the 4-week intervention [$Q(3)=2.84$; $P=.42$] (Figure 3).

Figure 3. Change in mood from week 1 to week 4 of the intervention (δ) for participants varied significantly across mood tiers [$H(2)=14.85$; $P<.001$]. Pairwise comparisons revealed significant differences between low and medium mood tiers ($P=.004$) and between low and high mood tiers ($P=.001$).



Statistical Analysis: Qualitative Overall Themes

Qualitative analysis revealed the main content themes based on 368 qualitative responses to the text messages through the platform (Table 2 and Multimedia Appendix 2), including administrative references, health-related responses or questions, mood elaborations, and brief statements of sentiments or

pleasantries. Of these main themes, most ($n=135$, 36.6%) were related to mood. In total, 125 (34.0%) participants simply reported “pleasantries,” where participants responded with comments such as “have a blessed day” [Participant #1, female, aged 62 years]. Health-related responses were recorded from among 53 (14.4%) responses, including, for example, asking for assistance with health insurance.

Table 2. Qualitative elaborations on mood (N=135^a).

Themes (codes)	Operational definition	Frequency, n (%)	Illustrative examples
Positive mood elaborations	Elaborates on how or why they are in a good or positive mood	71 (52.6)	<ul style="list-style-type: none"> “I am in a good space. Praying for this attack on America to end so that we can get back to a normal existence. On a scale from 1-10 my mood is a 10. I'm grateful to be alive and I'm trusting God to restore your lives the way that is best for us and pleasing to Him.” [Participant #2, female, aged 58 years] “Should be a 10 later cause of the beautiful weather” [Participant #3, male, aged 39 years] “My mood is much better. I am working with my therapist” [Participant #4, female, aged 43 years]
Somatic	Discusses somatic symptoms	32 (23.7)	<ul style="list-style-type: none"> “My mood is an 8 right now just came from dialysis and is cramping a little” [Participant #5, male, aged 62 years]
Negative mood elaborations	Elaborates on how or why they are in a bad or negative mood	17 (12.6)	<ul style="list-style-type: none"> “Thanks still at 3 I am going to call after I talk to my doctor” [Participant #6, male, aged 65 years] “My mood is up and down sometimes I feel sad because of life I already have anxiety problems and already have depression almost every day I feel like I'm having an anxiety attack sometimes ...” [Participant #7, female, aged 38 years]
Medical or scheduling concerns	Asks about medical appointments or scheduling related to mental health or mood	5 (3.7)	<ul style="list-style-type: none"> “I'm going to reach out to my PCP and see if there is anything he can do/let him know what's going on” [Participant #8, female, aged 35 years]

^aThe sample of qualitative responses coded for the overall theme of “mood,” which was used for subanalysis of mood elaborations, including 10 (7.4%) responses that were noncodable through subtheme analysis.

Qualitative Mood Themes

Given our interest in understanding mental health, further subanalysis of these 135 responses coded under the main theme of “mood” revealed 7 subthemes among those listed in Table 2. Most subthemes were positive mood elaborations, with a frequently observed association between mood and health-related topics. For example, somatic health concerns included citing pain impacting mood as, “my knees are bothering me this morning but otherwise I am okay” [Participant #2, female, aged 24 years]. Medical health concerns included the need for the participants to reach out to their health care providers (eg, primary care providers or psychiatrists) for medical assistance with their mood:

I really don't know like I said I do have a psych therapist he calls me once a week there is nothing more that can be done for me ... I take my psych meds everyday they help somewhat ... [Participant #3, female, aged 46 years]

Analysis of the subthemes for positive and negative mood elaborations provided us a nuanced understanding of how participants reflect and elaborate on their current level of

well-being (Figure 4). Among negative mood elaborations, the words “anxiety,” “still,” and “feel” were most commonly used. We did not observe any theme or the use of the word “loneliness,” although 2 participants with negative mood elaborations alluded to isolation from “friends” and “contact,” with one stating, “I miss the personal contact and conversation.” [Participant #11, female, aged 35 years]

Among the positive mood elaborations, the words “thank” and “good” were most commonly used. For instance, several participants sent responses to the text messages, which were similar to the following representative responses:

Thank you for your help tips I also meant to tell you that I'm over 60 years old I also am a diabetic and asthma so it really is taking a toll on me but I do have a in home health care person he helps me out a whole lot but when I am by myself that's when I feel the worst so I will keep up with the tips and keep up with your team thank you. [Participant #4, female, aged 63 years]

I [am] feeling a lot better thank you so much for being here for me. [Participant #5, female, aged 57 years]

Table 2 provides additional examples of mood elaborations.

Figure 4. For the respondents who provided qualitative text responses related to mood (n=136), positive mood elaborations were most common (n=71, 52.6%) and frequently referenced sentiments of “good mood” secondary to “thanks.” Negative mood elaborations (n=17, 12.6%) often referencing statements of “anxiety,” “feel,” and “still.”



Discussion

Principal Findings

Our study demonstrates the feasibility of using a novel digital texting platform to assess mood early during COVID-19 and the ability to acutely identify and address trends specifically supporting mental health and well-being among individuals recruited from the EDs of two hospitals. First, we demonstrate the feasibility of enrolling individuals to the digital platform in an otherwise less accessible population for consistent communication with the health system. The ED is a unique recruitment site with varying medical conditions, chief complaints, and a patient population often without access to or engagement in consistent preventive care. Nonetheless, individuals discharged from the ED, who opted into this study, were highly engaged. Our overall response rate of 70% demonstrates the feasibility and acceptability of this platform in this cohort. Through the intervention, we obtained preliminary results suggestive of a high efficacy of this platform for our enrollees with low mood ratings at baseline, whose mood improved over the enrollment period, while a high mood rating was retained among those enrollees who reported high mood ratings at baseline. Second, we identified common themes of gratitude and positive mood elaborations in participant communication through qualitative text messages. These findings suggest that for those who opt to engage in communication through the platform, a text intervention for resource delivery may benefit users by improving mood and maintaining a positive mood. Further, our study reports preliminary findings that support the need for a larger randomized controlled trial of our digital mood support platform.

Prior to COVID-19, many health systems enacted clinical remote monitoring lines; however, given the current practices of

quarantining and social distancing, real-time digital platforms are indispensable to patient care [9]. When designing novel well-being and mental health digital tools, it is crucial for such interventions to provide support to individuals with a low or negative mood and to those with a high or positive mood. Our study revealed an improvement in low mood ratings and the stabilization of high mood ratings among participants enrolled over 4 weeks. Although we cannot definitively conclude the cause of the observed changes in mood ratings without a comparison group, our mixed methods analysis potentially provides some valuable insights into digital patient care and mood support. Our resources, including the social engagement aspect of an interactive platform or the combination, may have led to improvements among individuals with a low mood rating and to stability for those with a high mood rating. However, our qualitative findings may provide preliminary insights into a tool for mood enhancement and well-being during the pandemic. Our intervention may have effectively supported well-being and a positive mood through “gratitude” by fostering a sense of connection and through positive reinforcement with our resources. In particular, the interactive nature of the automated text messages to the participants when asking questions, making directed statements of thanks, and offering pleasantries to the receiver may indicate that the participants found the platform interpersonal. Of note, the theme of “loneliness” was lacking, but the theme of “gratitude” was markedly apparent during communication through the platform. Lateef [10] reported that for, “EDs to make meaningful progress in enhancing patient care, safety, satisfaction, and quality, staff must listen and respond to patients and customers.” Many participants responded to the platform’s text messages as though they were responding to a peer and would ask how about our mood was and how we were doing through the pandemic. Having elicited sentiments of gratitude and connection, our

intervention may serve as a digital modality for ensuring that patients and users feel heard. This pilot study shows how digital platforms and technology can bridge the gaps between individuals and community-based support.

Further large-scale randomized controlled trials are required to understand the variables involved in interpersonal communication, compared to resource delivery; nonetheless, our findings provide preliminary evidence to show that the combination of these elements may effectively enhance mood. Further, since social media exposure is reportedly associated with the exacerbation of anxiety and depression in China, which is hypothesized to be related to the “infodemic” of misinformation classified by the WHO [11], our results—suggesting the possibility that accurate, virtual resources and information can potentially benefit individuals—provide a potential means to mitigate such misinformation.

Future Directions

To understand the effect of the COVID-19 pandemic on mental health and prepare for future public health crises, health systems and community organizations should be equipped to implement population-level efforts to address and support well-being through virtual means. The need for evidence-based mental health platforms that provide reliable information to participants was expressed even before the pandemic [12]. This study provides insights into health systems and community centers, among other stakeholders, which are faced with challenges to devise solutions to address the immediate and long-term impact of the COVID-19 pandemic on mental health issues across communities [13]. Since individual needs would likely vary through periods of social distancing, phases of lockdown, or reopening of facilities, this platform offers a promising tool to engage local community members with credible, relevant information and provide social support. Future randomized controlled trials aiming to assess and enhance the applications of this platform need to compare the present intervention group with a control group and assess the participants’ readiness to engage in support and change their mood, as this may improve subject engagement and reach.

Limitations

This study has several limitations. First, it did not have a comparison or control group, thus limiting conclusions that can be drawn from mood improvements among participants with a low self-reported mood rating. It is possible for these participants to have improved their mood without the resources provided here, although the finding that overall mood did not change over the 7-week study period suggests otherwise. Nonetheless, these preliminary data may potentially facilitate the development of platforms focused on well-being, considering an increase in individuals experiencing mental health issues as an aftermath of the pandemic, and further highlight the need for a randomized controlled trial to assess differential mood changes between individuals who receive the intervention and those who do not. Second, this study is limited by its enrollment and retention rates. Specifically, since this study used an opt-in approach for participant enrollment, only a small subset of individuals discharged from the EDs of two hospitals were

enrolled. This may have resulted in a selection bias for those who were more motivated to accept the intervention, and that mood improvement among these participants might have resulted from their readiness to change their mood rather than from the actual intervention itself. However, among the individuals who opted into this study, we observed a relatively high response rate (70%) to at least one mood rating despite limited follow-up for all four ratings. Accordingly, since recruitment essentially involved “cold” texting to most individuals discharged from the ED in a specific period, the response rate may be considered high given the pragmatic nature of the approach. Future studies are required to address the barriers to and improvements in participant retention and in engaging participants who may potentially change their mind to opt into the intervention or seek mood support. Lastly, our study used a simplified rating scale for mood, and though our results provide qualitative insights into the participants’ mood states, future studies could explore the interplay of mood ratings with depressive and anxiety symptoms. With the 70% response rate, this study highlights the feasibility of a pragmatic and completely remote mood intervention.

Comparison With Previous Studies

The “With You” digital platform delivered real-time social or mood support, consistent with the broader goal of a digital microintervention [14]. Accordingly, our study reports on assessment parameters suggested for digital microinterventions such as user engagement, with 60% of subjects providing at least two responses to mood ratings and quantitative and qualitative data. In particular, data related to our primary outcome of interest (ie, mood) and qualitative data including the identification of users with general medical and health care concerns demonstrate the potential future implications of our example of a digital microintervention aimed toward care delivery and social engagement. Our specific results reveal a generally positive and stable mood early during the pandemic, concurrent with previous reports [15]. This explains why our findings of improved mood in our study population particularly during the pandemic are promising. Furthermore, we found that anxiety was a frequently reported negative mood elaboration in our qualitative data, concurrent with previous reports. Early during COVID-19, the Census Bureau and Centers for Disease Control and Prevention in the United States reported that one-third of Americans experienced anxiety in May 2020, the prevalence rate being almost 2-fold that reported in the 2014 census [16]. However, previous studies have reported that interventions delivered through app-based platforms effectively decreased the prevalence of depression and anxiety, with particular improvements in anxiety when the app involved interactive coaching, as is the case for apps contained in the IntelliCare platform [17]. Indeed, our study suggests the potential for digital interventions for depression and anxiety to particularly meet the needs of individuals with low mood amid the pandemic.

Conclusions

Our findings suggest that a text messaging platform offering brief social engagement and vetted resources addressing mood support can assess and improve mood and potentially benefit

end users, specifically for a likely vulnerable population—those accessing an ED during the pandemic and may otherwise not initiate their own digital engagement. This pilot study suggests that individuals with low mood, who opt to engage with the texting platform, may experience mood improvement over a 4-week period. Finally, our qualitative data may clarify the role

of future interventions in supporting mood, more specifically in the context of physical health, anxiety, and gratitude. Given the current need of digital interventions and data acquisition with social distancing, these findings have implications in future measures to address community engagement and mental health support.

Conflicts of Interest

RO is a consultant for the Aurrera Health Group on the ACEs Aware Initiative, which is beyond the scope of our study.

Multimedia Appendix 1

Opted in participants were texted weekly to assess mood and well-being using simple numeric scale (0-10, 0 representing worst mood and 10 as best mood) (Panel A). For participants who reported a low mood, (0-3), they received follow-up message to assess their mood compared to the previous day. If participants reported consistent low well-being scores (up to 3 days) or responded with an urgent individual need (e.g. mental health issue) they were contacted by our team and connected to a trained CHW. Mood scores four and greater received curated resources (Panel B). Panel C represents sample weekly featured resources. [\[PNG File , 523 KB - mental_v8i2e25834_app1.png\]](#)

Multimedia Appendix 2

Supplemental Table 1.

[\[PNG File , 218 KB - mental_v8i2e25834_app2.png\]](#)

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Abbreviations

WHO: World Health Organization

ED: emergency department

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