Acceptability of a Conversational Agent-led Digital Program for Anxiety: A Mixed-Methods Study of Patient Perspectives

Pearla Papiernik[1], Sylwia Dzula[1], Marta Zimanyi[1], Edward Millgate[1], Malika Bouazzaoui[1], Jessica Buttimer[1], Graham Warren[1], Elisa Cooper[1], Ana Catarino[1], Shaun Mehew[1], Emily Marshall[1], Valentin Tablan[1], Andrew Blackwell[1] & Clare E Palmer[1]

[1] *Ieso Digital Health, The Jeffrey's Building, Cowley Road, Cambridge, CB4 0DS, UK*

Paper type: Original Article

Corresponding Author: Pearla Papiernik

ieso Digital Health
The Jeffrey's Building
Cowley Road
Cambridge
CB4 0DS
United Kingdom

pearla.papiernik@iesohealth.com

Abstract

Background. Prevalence rates for anxiety and depression are increasing globally, outpacing the capacity of traditional mental health services. Digital Mental Health Interventions (DMHIs) offer a cost-effective solution, but user engagement is poor. Integrating AI-powered conversational agents could enhance engagement and the user experience, though AI technology is rapidly evolving, and the acceptability of these solutions remains uncertain.

Objective. This study aims to understand the acceptability, engagement and usability of a conversational agent-led DMHI with human support for generalized anxiety by exploring patient expectations and experiences using mixed methods.

Methods. Participants (N=299) were offered a DMHI for up to 9 weeks and completed self-report validated measures of engagement (User Engagement Scale, UES, N=190), usability (System Usability Scale, SUS, N=203) and acceptability (Service User Technology Acceptability Questionnaire, SUTAQ, N=203) post-intervention. To explore patients' expectations and experiences with the digital program, a sub-sample of participants completed qualitative semi-structured interviews before the intervention (N=21) and after the intervention (N=16), analyzed using inductive Thematic Analysis.

Results. Participants found the digital program engaging (mean UES total score = 3.7, 95%CI [3.5,3.8]), rewarding (mean UES rewarding subscale = 4.1; 95%CI [4.0-4.2]) and easy to use (SUS total score = 78.6, 95%CI [76.5, 80.7]). Participants were satisfied with the program and found it increased access to and enhanced their care (mean SUTAQ subscales = 4.3-4.9, 95% CI [4.1-5.1]). Insights from both pre and post-intervention qualitative interviews highlighted four key themes important for the acceptability of this digital program: 1) easy access to practical and effective solutions leading to tangible mental health improvements ("Accessing Effective Solutions"); 2) a personalized and tailored experience ("Personal Experience"); 3) being guided with a clear structure yet control over their journey ("Guided but in Control"); 4) fostering a sense of support facilitated by humans ("Feeling Supported"). Overall, the DMHI met expectations for theme 1, 3 and 4 yet participants wanted more personalization and felt frustrated when the conversational agent misunderstood them.

Conclusions. Incorporating factors important for patient acceptability into DMHIs is essential to maximize their global impact on mental healthcare. This study provides quantitative and qualitative evidence for the acceptability of a structured, conversational agent-driven digital program with human support for adults with generalized anxiety. Findings emphasize the role of design, clinical and implementation factors in enhancing engagement, highlighting opportunities for continued optimization and innovation. Scalable models with stratified human support and the safe integration of generative AI are poised to transform patient experience and enhance the real-world impact of conversational agent-led DMHIs.

Keywords: mental health; anxiety; digital intervention; conversational agent; artificial intelligence; user experience; acceptability; engagement; thematic analysis

Introduction

Demand for mental healthcare is increasing, with one in eight individuals globally living with a mental health condition[1]. Despite this growing need, there are only four psychiatrists per 100,000 people worldwide[2], leading to long waiting lists and lack of care[3–5]. The traditional one-to-one mental healthcare model is proving insufficient to meet the rising demand.

Digital mental health interventions (DMHIs) provide a cost-effective way to increase access to care worldwide[6], but face challenges with user engagement and adherence[7–9]. Key factors impacting engagement include available guidance, perceived fit and personalization[10]. Artificial Intelligence (AI) powered conversational agents, typically using tree-based dialogue systems, have shown potential to enhance DMHI engagement by offering more interactive and personalized experiences compared to self-guided activities[11]. Meta-analytic evidence suggests these agents reduce attrition rates[12], and show promising efficacy[13–16]. However, the agent misunderstanding user input can be frustrating[17]. Advances in generative AI, like Open AI's ChatGPT (released November 2022), are rapidly evolving and enable more fluid and naturalistic interactions that have the potential to transform DMHIs. However, currently, most DMHIs rely on tree-based dialogues systems with templated responses to ensure a patient's experience is safe, evidence-based and deterministic. It is unclear how user familiarity with generative AI applications will impact perceived effectiveness and engagement with conversational-agent DMHIs reliant on tree-based dialogue systems.

Acceptability is central to developing and evaluating DMHIs as it is linked to engagement, effectiveness and adoption[18]. It is a multi-dimensional construct that reflects how people think and feel about an intervention and whether they view it as appropriate, either before, during or after using it[19]. Qualitative studies suggest conversational agent-led DMHIs are perceived positively by users[20], in part by providing easily accessible and judgment-free environments[21]. However, uptake of such interventions is impacted by mixed expectations on their effectiveness[22,23]. Presence or absence of empathy, personalization and ability of the agent to understand user messages also impact the user experience[17,24]. Our current understanding of conversational agent-led DMHI acceptability relies on limited qualitative data (e.g. app store reviews, answers to in-app free-text questions about positive and negative experiences)[13,25–28]. A deeper understanding of the many factors contributing to user perception and experience with conversational agent-led DMHIs is important to maximize their impact. The person-based approach to intervention development highlights the importance of using mixed methods to systematically investigate user perspectives and experiences, providing a deeper understanding of factors shaping intervention acceptability[29].

The current study reports additional patient-reported endpoints from a propensity-matched study evaluating the effectiveness, acceptability, engagement and safety of a digital program for adults with mild to severe symptoms of generalized anxiety[16]. Participants engaged with the program for up to 9 weeks via a smartphone app. The intervention consisted of a structured program using traditional and third-wave Cognitive Behavioral Therapy (CBT) approaches delivered through multimedia content and text-based interactions with an AI-powered conversational agent. The conversational agent followed a tree-based dialogue system, using natural language processing to deliver appropriate clinician pre-written responses. The program was combined with human support, aimed to enhance user experience and adherence with the program, addressing documented barriers to engagement[10]. The digital program showed a mean reduction in anxiety symptoms comparable to traditional human-delivered therapy[16]. This sub-study aimed to understand the acceptability, engagement and usability of the digital program by combining quantitative and qualitative methods to explore patient expectations and experiences with the intervention and examine the extent to which the program met their needs. Self-report measures for subjective engagement, usability

and acceptability were collected post-intervention to quantify the user experience, and qualitative semi-structured interviews were conducted with a sub-sample of participants both prior to and following the intervention to provide deeper insights into user needs and experiences.

Methods

Study design

This mixed methods sub-study explored the perspectives and experiences of individuals with mild, moderate and severe symptoms of generalized anxiety before and after engaging with a DMHI. It was conducted within a wider pragmatic, single-intervention arm study with a sample of 299 participants from the UK[16].

Potentially eligible individuals completed a clinical assessment with a qualified clinician to determine eligibility. At the point of consent, participants were asked if they wanted to participate in qualitative interviews. A sub-sample of participants (n=21) attended a semi-structured interview pre-intervention. All participants were asked to download the software on their smartphone and engage with the six-module program in their own time, over a nine-week period. Participants from the interviewed sub-sample were invited to attend a second semi-structured interview after using the program. All outcomes collected at different time points are reported in Palmer et al. (2024)[16]. For the present study, engagement, usability and acceptability measures, collected with validated questionnaires post-intervention, were analyzed, as well as qualitative analysis of the pre and post intervention semi-structured interviews.

The study was pre-registered (ISRCTN ID: 52546704) and obtained ethical approval prior to recruitment (IRAS ID: 327897, NHS Research Ethics Committee: West of Scotland REC 4). The participant CONSORT flowchart for the whole sample and the interviewed sub-sample are summarized in Figure 1. For more details on participant flow prior to enrolment, please refer to Palmer et al. (2024)[16]. In line with the Declaration of Helsinki, all participants provided signed informed consent and were debriefed following the study.

Description of digital intervention

The intervention consisted of a six-module digital program delivered via a smartphone app ('ieso Digital Program'; software name: IDH-DP2-001), developed by ieso Digital Health (https://www.iesogroup.com), a mental health technology company and provider within NHS Talking Therapies (TT) delivering 1:1 human-delivered CBT via a typed modality to treat patients with common mental health disorders. The ieso digital program used a conversational agent to guide users through activities, with clinical oversight and user support provided by non-clinical research coordinators. The program was designed for people primarily presenting with symptoms of generalized anxiety and was based on principles from traditional CBT and third wave approaches such as Acceptance Commitment Therapy (ACT). Sessions were released on a timed schedule, subject to completing the prior session, allowing space for practice and reflection between sessions. Each session included videos, educational content, conversations, and worksheets written by accredited clinicians. To ensure safety and clinical quality of the messages delivered to the user, the conversational agent used in this version of the program followed a tree-based dialogue system, using natural language processing to understand user input and deliver appropriate pre-written responses. The program complied with ISO 13485 and was registered as a UKCA marked Class 1 medical device. For more details, see Palmer et al. (2024)[16].

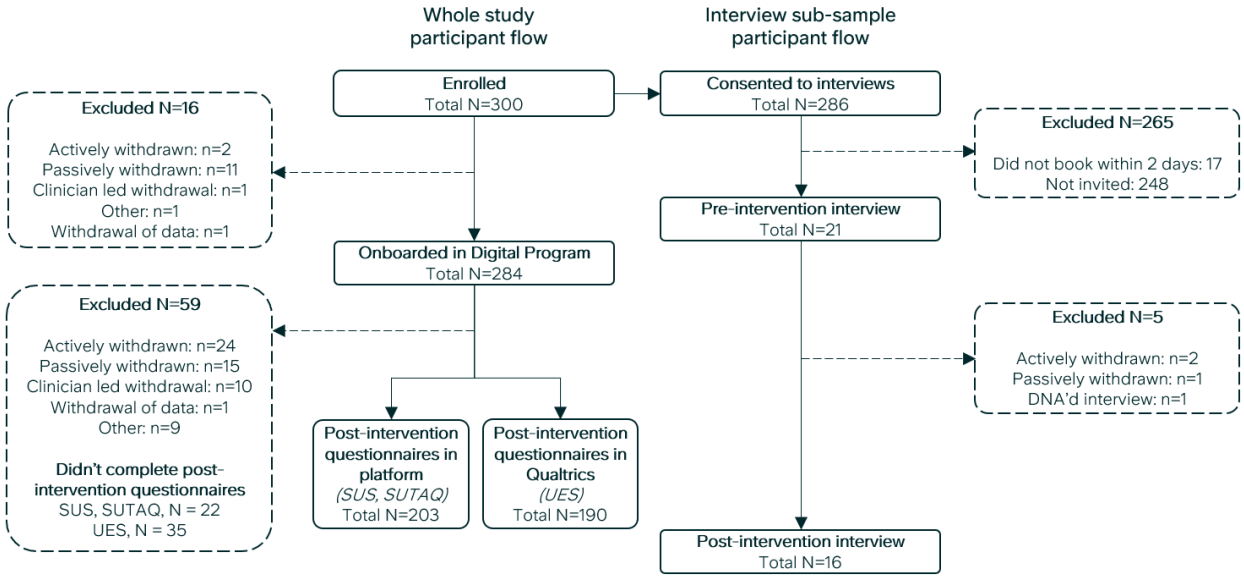

Figure 1 – Participant flow for study sample and interviewed sub-sample. Details of recruitment sources and participant flow prior to enrolment are detailed in Palmer et al. (2024). Participants were withdrawn either actively (requested to withdraw), passively (dropped-out or disengaged from study procedures), clinician-led (withdrawn based on clinician recommendation), or other (due to reasons such as technical issues). Participants who consented to be interviewed were invited to book an interview slot on a first-come first-served basis. Participants were given two days to respond to the invitation. Interview invitations were stopped once a sufficient sample had attended a pre-intervention interview. Participants completed some post-intervention questionnaires in ieso's validated clinical delivery platform developed to collect patient outcomes as part of routine care in NHS TT (System Usability Scale, SUS; Service User Technology Acceptance Questionnaire, SUTAQ), and one on Qualtrics (User Engagement Scale, UES).

Participants

Adults with mild to severe anxiety symptoms were recruited between 10th October 2023 and 2nd February 2024, through three streams: i. referrals to ieso's typed therapy service (self-referral or via their NHS Provider) (https://www.iesohealth.com/); ii. responses to online advertisements; and iii. responses to email invitations through the NIHR BioResource (https://bioresource.nihr.ac.uk/). Only participants with a main presentation of Generalized Anxiety Disorder (GAD) were eligible, as established through a clinician assessment following the NHS TT manual[30].

Participants had to meet the following eligibility criteria:

- > 18 years at point of recruitment
- GAD-7 total score > 7
- PHQ-9 total score < 16
- Access to a smartphone and internet connection
- Registered with a General Practitioner in the UK
- Not currently receiving psychological therapy
- Suitable for CBT (excludes individuals with diagnosis of multiple disorders, psychotic or personality disorder, autism spectrum condition or intellectual disability)
- No diagnosis of an untreated mental health condition including substance misuse, except GAD or Major Depressive Disorder (MDD)
- Not have Post-Traumatic Stress Disorder (PTSD), Obsessive-Compulsive Disorder (OCD) or Panic Disorder
- Not have a change in psychiatric medication in the past 1 month
- Not display significant risk of harm to self, to others or from others (established with the clinical assessment)
- Not previously participated in user research for the digital program

Considering the study's aims and design, participant specificity, and experienced user researchers collecting data, a moderate sample size between 15 to 30 participants was estimated to provide sufficient informational power[31]. We aimed to enroll up to 30 participants to account for an estimated 50% attrition rate with the goal of having at least 15 post-intervention interviews. Those who consented to interviews self-selected into the interviewed sub-sample by signing up for a pre-intervention interview slot on a first-come-first-served basis. If they didn't sign-up within two days of receiving the invitation they were sent the information to continue with the app download to avoid delays. Interview invitations were sent out from December 2023, two months into the enrolment period. Interview invitations were stopped once a sufficient sample had attended a pre-intervention interview.

Vouchers up to a total of £60 were provided for participating in the study based on study assessments and completion of modules. An additional £15 voucher per interview was provided to those who attended an interview.

Patient Public Involvement (PPI)

Experts-by-lived experience were involved as members of a PPI panel. PPI members took part in study conceptualization and supported recruitment through co-designing marketing campaigns and participant facing documents. PPI members were also involved in the thematic analysis process through a workshop aimed to discuss the coherence of thematic groupings and the relevance of theme names, providing insights to improve the analysis. Prior to the workshop, PPI members were introduced to thematic analysis and qualitative methods.

Data collection and analysis

Self-report measures of user experience

Validated self-report measures of user experience were collected at post intervention between January and April 2024 (after completion or after nine-weeks), either via ieso's validated clinical delivery platform (System Usability Scale; Service User Technology Acceptability Questionnaire) or Qualtrics™ (User Engagement Scale). Demographic data were collected at enrolment and are summarized in Table 1.

Engagement

Engagement was evaluated with the User Engagement Scale (short form) (UES)[32], a validated scale to measure user engagement with digital systems. This scale consisted of 12 items across 4 subscales: i. "*Focused Attention*" - how absorbed the individual was in the intervention, ii. "*Perceived Usability*" - whether the intervention was taxing or frustrating to use, iii. "*Aesthetic Appeal*" - how visually appealing the intervention was, and iv. "*Rewarding*" – whether using the intervention was worthwhile. The 12 items were rated on a 5-point scale (strongly disagree = 1; strongly agree = 5). A high score can be interpreted as positive perceived engagement. Items were presented in a random order for each participant. Three items on the "Perceived usability" sub-scale were reverse scored, such that a lower value on each item was associated with greater perceived engagement. Individual items are reported as the number and percentage of participants that selected each Likert rating. These were averaged across items within each subscale to estimate the distribution of participants that on average agreed or disagreed with the items within each subscale. Average percentage agreement or disagreement to subscales across participants are also reported, calculated by regrouping all levels of agreement (agree, strongly agree) or disagreement (disagree, strongly disagree).

Usability

Usability was evaluated with the System Usability Scale (SUS)[33]. The SUS consisted of 10 items relating to the overall usability of the intervention. Items were rated on a 5-point scale (strongly disagree = 1; strongly agree = 5). An overall SUS score was calculated as a sum across all items after reverse coding certain items and scaling to produce a score from 0 to 100[33]. A high score can be interpreted as positive perceived usability. Individual items are reported as the number and percentage of participants that selected each Likert rating. These were averaged across all items to estimate the proportion of participants that on average agreed or disagreed with items across the questionnaire. Average percentage agreement or disagreement per item and for the whole questionnaire across participants are also reported, calculated by regrouping all levels of agreement (agree, strongly agree) or disagreement (disagree, strongly disagree).

Acceptability

Acceptability was quantitatively evaluated with the Service User Technology Acceptability Questionnaire (SUTAQ)[34]. It consisted of 22 items across 6 sub-scales: i. "*Care personnel concerns*" – concerns about the skills and continuity of the personnel looking after them, ii. "*Enhanced care*" - beliefs that the intervention can improve care, iii. "*Increased accessibility*" - beliefs that the intervention enhanced access to care, iv. "*Kit as substitution*" - beliefs that the intervention may be an alternative to regular care, v. "*Privacy & discomfort*" – concerns privacy and the intervention interfering with their daily life or making them feel uncomfortable, and vi. "*Satisfaction*" – beliefs indicating acceptance and satisfaction with the kit and service provided. Participants rated their level of agreement with each item on a 6-point Likert scale (strongly disagree = 1; strongly agree = 6). High scores can be interpreted as positive user perception, except for sub-scales "*Care personnel concerns*" and "*Privacy & discomfort*" that are inverted, therefore a low score is interpreted as a positive user perception. The intermediate value 3.5 is interpreted as a point of neutrality. Reverse coding was carried out on one item in the *"Kit as substitution"* subscale[34] (item 18, see Supplementary Table 3, Multimedia Appendix 2). Individual items are reported as the number and percentage of participants that selected each Likert rating. These were averaged across items within each subscale to estimate the distribution of participants agreeing or disagreeing with the items within each subscale. Average percentage agreement or disagreement to subscales across participants are also reported in text, calculated by regrouping all levels of agreement (mildly, moderately and strongly agree) or disagreement (mildly, moderately and strongly disagree).

Qualitative data

Semi-structured interviews pre- and post-intervention provided qualitative data about user expectations and experiences with the program, to assess the acceptability of the ieso Digital Program in meeting the needs of patients. Pre-intervention interviews, conducted by two researchers between December 2023 and February 2024 (S.D., M.Z.), lasted 16-38 minutes (mean: 23 minutes). Post-intervention interviews, conducted by one researcher between February and April 2024 (MZ), lasted 30-47 minutes (mean: 39 minutes). Pre-intervention interviews explored participants' motivations to take part, their experience and views of using technology for mental health, and their expectations for the intervention. Post-intervention interviews explored participants' overall experience with the intervention, engagement barriers and facilitators, perceived usefulness and effectiveness, and perceived safety and support. Refer to supplementary materials for detailed interview schedules (Multimedia Appendix 1). Interviews were conducted on Microsoft Teams and were automatically transcribed on Dovetail (https://dovetailapp.com) and reviewed and anonymized by researchers.

Pre- and post-intervention interviews were analyzed with Thematic Analysis[35]. One researcher trained in qualitative research methods (P.P.) familiarized with the data by reading transcripts multiple times and did line-by-line inductive coding at the semantic and latent level on Dovetail. Codes were then grouped into candidate themes, which were then reviewed by returning to the underlying data. Analysis was regularly discussed between researchers (P.P., C.E.P., M.B., M.Z.) and lived experience partners to refine themes, and authors met to agree on final themes and names. Final themes grouped both pre- and post- interview data that was linked by the common underlying concept of the theme. Results describe expectations and experiences in each theme.

The Framework Method[36,37] was used to explore patterns between pre-intervention expectations and post-intervention experiences. Inductive themes from the thematic analysis were used to create an analytical framework, and coded extracts were categorized within it. A framework matrix summarized data for each participant and theme by interview time (pre-, post-), with illustrative quotes. The framework matrix was interpreted by exploring patterns within and between participants, before and after the intervention, and relevant nuances and insights were added to our description of themes developed through thematic analysis.

Results

Self-report measures of user experience

The final sample for analysis included 203 participants who completed the SUS and the SUTAQ, and 190 participants who completed the UES. Table 1 provides an overview of the demographic and clinical characteristics of participants enrolled in the intervention that completed the questionnaires (N=203). 80% were female, with a mean age of 41 years (SD=12.0; range: [19–75]), and 83% completed a significant proportion of the program (minimum meaningful clinical dose as defined in Palmer et al, 2024)[16]. UES and SUTAQ subscale scores are reported in Figure 2, and average agreement or disagreement across scale items are reported in Table 2 (UES, SUS) and Table 3 (SUTAQ). Item level data for each scale can be found in Supplementary Tables 1 to 3 (Multimedia Appendix 2).

Engagement

Overall, the mean total score for the UES was 3.7 (95%CIs [3.5;3.8]) indicating agreement that the program was engaging. On average across the intervention sample, 84% (n=159) agreed that the program was rewarding and worthwhile (Rewarding subscale mean=4.1, 95%CIs [4.0;4.2]), 68% perceived the app not to be frustrating or taxing (Perceived Usability subscale mean=3.7; 95%CIs [3.6;3.9]) and 70% found the app aesthetically pleasing (Aesthetic Appeal subscale mean=3.8; 95%CIs [3.7;3.9]). There were mixed views on whether participants were fully focused on the experience (Focused Attention subscale mean=3.1; 95%CIs [2.9;3.2]). Item-level scores indicated participants generally disagreed that they were “getting lost” in the experience, and there were mixed views on whether participants were fully absorbed in the app (Supplementary Table 1, Multimedia Appendix 2).

Table 1. Sample characteristics of all study samples

Demographic	Category	Questionnaire sample (N=203)	Interview sub-sample (N=21)	
			Pre-intervention sample (N=21)	Post-intervention sample (N=16)
Baseline GAD-7[a] score, mean (SD)		12.4 (3.4)	11.8 (3.2)	11.6 (3.6)
Baseline PHQ-9[b] score, mean (SD)		7.9 (3.8)	7.7 (2.4)	7.7 (2.5)
Age, mean (SD)		41.0 (12.0)	46.0 (13.4)	44.0 (13.3)
Gender, n (%)	Female (F)	163 (80.3)	17 (81.0%)	13 (81.3%)
	Male (M)	34 (16.7)	3 (14.3%)	2 (12.5%)
	Other	2 (1.0)	1 (4.8%)	1 (6.3%)
	Not Known	4 (2.0)	0 (-)	0 (-)
Ethnicity, n (%)	White	185 (91.1)	19 (90.5%)	15 (93.8%)
	Mixed	3 (1.5)	0 (-)	0 (-)
	Asian	9 (4.4)	2 (9.5%)	1 (6.3%)
	Black/African/Caribbean/Black British	1 (0.5)	0 (-)	0 (-)
	Other	1 (0.5)	0 (-)	0 (-)
	Prefer not to say	4 (2.0)	0 (-)	0 (-)
Long Term Condition (LTC), n (%)	LTC	83 (40.9)	9 (42.9%)	6 (37.5%)
	No LTC	112 (55.2)	10 (47.6%)	9 (56.3%)
	Not Known	8 (3.9)	2 (9.5%)	1 (6.3%)

[a] GAD-7 categories: mild (scores 5 – 9), moderate (scores 10 – 14), severe (scores ≥ 15).
[b] PHQ-9 categories: mild (scores 5 – 9), moderate (scores 10 – 14), moderately severe (scores 15 – 19), severe (scores ≥ 20)

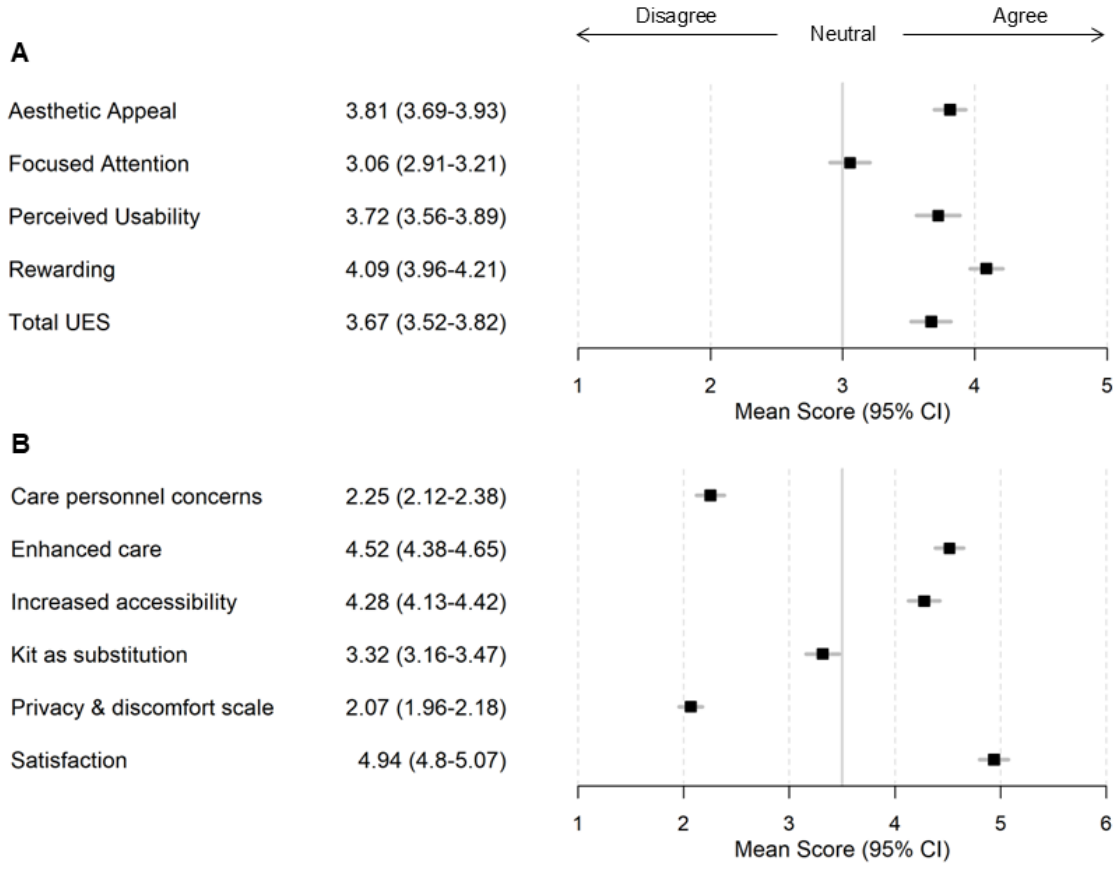

Figure 2. Self-reported user experience mean scores and 95% confidence intervals. A) User Engagement Scale (UES) subscales and total score. B) Service User Technology Acceptability Questionnaire (SUTAQ) subscale scores. Higher mean scores on all subscales indicate positive user sentiment, except for the SUTAQ "Care personnel concerns" and "Privacy & discomfort" subscales where a lower score indicates a more positive sentiment.

Table 2. Agreement and disagreement to self-reported measures of engagement (UES) and usability (SUS)

	Mean proportion agreement across all items or items within each subscale				
	(1) Strongly Disagree	(2) Disagree	(3) Neither agree nor disagree	(4) Agree	(5) Strongly agree
UES (N = 190)					
Aesthetic appeal	1.2%	4.6%	24.2%	51.8%	18.3%
Focused Attention	6.5%	26.3%	29.3%	30.9%	7.0%
Perceived usability	4.4%	14.2%	13.5%	40.5%	27.4%
Rewarding	1.9%	3.7%	10.5%	51.4%	32.5%
Total	3.5%	12.2%	19.4%	43.6%	21.3%
SUS (N = 203)					
Total	1.4%	5.3%	9.7%	44.6%	39.0%

Usability

Self-reported usability scores were high with a mean total score for the SUS of 78.6 (N=203; 95%CIs [76.5; 80.7]). Item-level data (Supplementary Table 3, Multimedia Appendix 2) shows that on average most participants agreed that the system was quick to learn to use (91%), without the support of a technical person (93%). On average the majority, 89%, felt confident using the app and 88% found it easy to use. The item participants agreed the least strongly with was whether they would like to use the system frequently (67% average agreement).

Acceptability

Across the intervention sample (N=203), on average 88.5% of participants were satisfied with the intervention ("Satisfaction": Mean=4.9, 95%CIs [4.8;5.1]). On average, 81% of participants found that the app could improve care ("Enhanced care": Mean=4.5, 95%CIs [4.4;4.7]) and 75% found that it increase access to care ("Increased accessibility": Mean=4.3, 95%CIs [4.1;4.4]), without interfering with their daily life or making them feel uncomfortable ("Privacy & Discomfort": Mean(reverse scored)=2.1, 95%CIs [2.0;2.2]), and without concern about the skills and continuity of the personnel looking after them ("Care personnel concerns": Mean(reverse scored)=2.3, 95%CIs [2.1;2.4]). There were mixed responses about whether the program could be used as a substitution for their regular mental health care ("Kit as substitution": Mean=3.3, 95%CIs [3.2;3.5])

Table 3. Agreement and disagreement to self-reported measure of acceptability (SUTAQ)

	Mean proportion agreement across all items or items within each subscale					
	(1) Strongly disagree	(2) Moderately disagree	(3) Mildly disagree	(4) Mildly agree	(5) Moderately agree	(6) Strongly agree
SUTAQ (N = 203)						
Care personnel concerns	36.1%	27.4%	19.1%	11.2%	4.9%	1.3%
Enhanced care	4.8%	5.2%	9.1%	25.3%	25.5%	30.1%
Increased accessibility	5.8%	6.4%	12.8%	28.1%	23.2%	23.8%
Kit as substitution	14.8%	16.9%	21.0%	24.1%	15.6%	7.6%
Privacy & discomfort	45.2%	23.8%	15.8%	10.8%	3. 3%	1.1%
Satisfaction	2.6%	2.8%	6.1%	16.3%	31.4%	40.9%

Qualitative Results

Table 1 provides an overview of the demographic and clinical characteristics of participants enrolled in the interview sub-sample (N=21). Participants in the interview sub-sample were mostly white (91%) women (81%), with a mean age of 46 years (SD=13.1; range: 19-72). Half of the sample had moderate anxiety (48%), followed by mild (33%) and severe (19%) anxiety. Five participants did pre-intervention interviews only: four were withdrawn from the study; and one did not attend their post-intervention interview. Participants were highly engaged with 67% of the pre-intervention and 75% of the post-intervention interview sub-samples completing a minimum meaningful clinical dose of the program.

Figure 3 shows a map of the themes developed through thematic analysis of the pre- and post-intervention interviews. Four themes represent patient needs for conversational agent-led DMHIs and describe to what extent they were met, based on their expectations and experiences with the ieso digital program: 1) Accessing Effective Solutions, 2) Personal Experience, 3) Guided but in Control, 4) Feeling Supported. Quotes are provided with participant gender, age, and anxiety severity at baseline (GAD-7).

Figure 3. Thematic Map. Factors influencing the acceptability of conversational agent-led DMHIs, through users' expectations and experiences of the program.

Theme 1 – Accessing effective solutions

This primary theme describes participants' motivation to access effective solutions for managing anxiety and highlights the program's usefulness in helping participants engage in therapeutic content and processes.

Participants expressed three main motivations to use the digital program. First, to access mental health support that was otherwise difficult to obtain through the NHS. Participants appreciated that the program was a faster, easier and more affordable way to access support. For some, the digital program served as an initial point of call for addressing their mental health concerns.

> *"It's always easy to get an appointment but then from there the support is pretty much nonexistent. (…) Basically, the advice is you could probably do with some more talking therapy, you can go on the waiting list and that will be up to a year, otherwise you can pay. So that's why the program is such a positive thing, because otherwise there's nothing." Post, P14 (F, 53, severe anxiety)*

A second motivation was to access the specific advantages provided by a digital approach to mental health support. Participants wanted to reflect about their experiences and understand their triggers, thoughts, and feelings, and believed that a digital program was better suited for them to do this work. Indeed, several participants expected and found it easier to express their feelings to an app compared to a human therapist, feeling less judged or embarrassed to open-up, or feeling that it may be less biased than a human therapist. Participants also valued having more time to understand information and to reflect before answering, and being able to revisit and reflect on past content and discussions, saved and centralized on an app.

> *"Hopefully I can sort of go back and revisit things that really resonate with me in a way that you can't with a spoken conversation." Pre, P12 (F, 48, moderate anxiety)*

Finally, a third motivation expressed in pre- and post- intervention interviews was to access a solution-focused intervention to effectively manage or reduce anxiety. Participants differentiated the need to "*offload,*" from their current need to "*change behavior*" and receive "*tools*" and "*solutions*". Most wanted to learn techniques to manage their anxiety long-term, while some sought momentary support or both. Accessing helpful content and learning new information and techniques was crucial to participants and was for many a key motivator, even for participants who experienced frustration when the conversational agent misunderstood them. Nearly all participants interviewed found the program useful and effective. Seeing improvements and perceiving the program as beneficial was an important motivator for continued engagement with the program and continued application of techniques learned.

> *"I was motivated to continue because each module had something which helped me. I felt that it was helping me reduce my anxiety right from the beginning. So, you wanted to do the next module" Post, P5 (F, 68, mild anxiety)*

Participants practiced and applied techniques in everyday life, particularly when anxious or when facing a stressful situation. Time between sessions was seen as crucial to practice, and several participants wanted more time to do so. Many wanted continued app access post-study to further engage and review content.

> *"If I could go back into the app to see how I wrote down what I was feeling, that would be, that would really reinforce it all." Post, P9 (F, 57, mild anxiety)*

Participants noted the program's time and effort demands but emphasized the importance of engaging to see benefits. For many, this was acceptable as they began the program highly motivated and ready to

engage, however one participant was surprised by the program's workload and another shared that they couldn't have engaged similarly at another time in their mental health journey.

> *"If you can stick with it and really commit to trying the things it suggests you try, you'll definitely find it helpful. (…) But you have got to be willing to kind of commit to it and put in the time and do what it's asking you to do. So, you've got to be in the right headspace." Post, P14 (F, 53, severe anxiety)*

Theme 2 – Personal experience

The second theme describes how participants wanted the program to be tailored and feel personal, but sometimes found the conversational agent to be generic, and often felt misunderstood by it.

Pre-intervention, several expected personalized strategies for anxiety, tailored advice, and pathways or exercises based on their input or assessments. Half of the participants viewed technology and an AI guide as an opportunity for tailored and accurate support.

> *"I would assume that based on my answer to questions or how I'm responding to things, that machine learning will tell the digital guide move things to get onto the right journey." Pre, P7 (F, 53, moderate anxiety)*

Post-intervention, some found the conversational agent impersonal or generic, and desired more context-specific advice, historical knowledge use, and the ability to ask questions.

> *"I didn't quite enjoy that I was talking to a robot that didn't tell me things tailored to my needs, only generic things. So many times it didn't really matter what I said, the robot only repeated what I said" Post, P2 (M, 33, moderate anxiety)*

Feeling heard and understood was crucial to participants. In pre-intervention interviews, interacting with a conversational agent was viewed as acceptable if it was well trained, lacked bias, and was able to understand them and offer thoughtful answers.

> *"As long as it's been well trained, it will be interesting to see what it comes back with. That it's not just a sort of trite responses you get when you're trying to get customer service out" Pre, P12 (F, 48, moderate anxiety)*

Post-intervention, some participants explained that the downside of a conversational agent was that they could not receive empathy and be understood like they would with a therapist. Nearly all users reported instances where the conversational agent wrongly paraphrased messages or misunderstood complex thoughts and feelings. This often led to frustration or confusion. Safety messages that appeared when the user did not feel they were needed could lead to frustration and distraction from the session.

> *"I think there was a lot of instances where it was clear that whatever I typed it hadn't understood. In a way that's like sitting in a room with a therapist and you tell them something and they just look blank." Post, P15 (non-binary, 42, severe anxiety)*

Some participants found the conversational agent's understanding abilities were less bothersome and less present over time, and some explained that they learned to communicate more effectively with it.

> *"I think as the program went on, I got to know the program and I got maybe a bit better myself at finding ways to word things." Post, P14 (F, 53, severe anxiety)*

However, others explained that simplifying their answers to ensure the conversational agent would understand impacted their ability to express their emotions.

> *"And so you learn to keep it really simple. But that sometimes didn't help, I couldn't really express how I was feeling because the chatbot didn't understand." Post, P5 (F, 68, mild anxiety)*

Several participants were not too impacted by these limitations, finding them expected and acceptable for a conversational agent, and not interfering with the overall program's usefulness.

> *"You could tell it was looking for specific responses, but that's fine. That's what they do." Post, P2 (M, 33, moderate anxiety)*

Post-intervention, participants had mixed views on the conversational agent's human-likeness, some finding it human-like and others robotic. Notably, two participants valued its neutrality and "*ambiguity*", neither distinctly human nor robotic, and neither male nor female.

Theme 3 – Guided but in control

The third theme highlights participants desire to have autonomy and control over how they engaged with the program while also wanting structure and guidance throughout.

Being self-directed within a flexible yet structured intervention was valued by participants and was a motivation to participate in the study. Accessing a time-bound and structured program through an app was seen by participants as useful for personal accountability to help them regularly engage in the work they wanted to do to feel better.

> *"I think this would be helpful because I can tap in and out of it as and when. And it's something that's available, the app is always there for you to use. And at the same time there's time frames on it. So, you have to do things by certain dates. So there's a bit of a routine, but also a bit of flexibility. Pre, P1 (F, 35, mild anxiety)*

Reminders were also seen as important to support adherence to the program particularly considering reported engagement challenges such as their mental health, forgetfulness, or external obligations.

> *"The reminders did serve, as a prompt to say, OK, just reminding you that you got your next session and you'll be on track to complete the study." Post, P8 (M, 32, mild anxiety)*

Accessing a program that is easy to navigate, with a "*logical pathway*" to follow was important. Participants also wanted to be guided towards what they should practice and reflect on, through conversational agent prompts and exercises. One participant viewed conversational agents as acceptable only if used within a structured program.

> *"The other app I used, I would say something and then the chatbot would reflect that back to me. I'm assuming there is a structured program in the ieso app. So, it's not just going to be stuff I say being reflected back, there would be ideas for me and something for me to follow." Pre, P13 (F, 55, moderate anxiety)*

In post-intervention interviews, some participants expressed that having more in-app features and sessions to support with practice and reviewing content would be helpful, or guided support when experiencing symptoms of anxiety, such as meditation or breathing exercises.

> *"I think to actually have some, a few recorded meditations that people could turn to relax breathing techniques or relaxation, especially if you're having a bit of a crisis and you need to calm down" Post, P13 (F, 55, moderate anxiety)*

In parallel to wanting guidance and structure, autonomy was important to participants.

> *"Nothing feels forced upon you. Even the reminders I think are gentle, they're like a little nudge rather than a big old slap" Post, P16 (F, 44, severe anxiety).*

Many participants expressed high satisfaction with the intervention's flexibility and ability to fit into their life, allowing engagement at their own pace, when in the right headspace, and in various settings. Several participants therefore saw the program as particularly adapted for people with demanding jobs or caregiving responsibilities.

> *"I don't have a lot of time to attend scheduled appointments. So being able to pick something up to help my own mental health in my own time is more likely to be something I would use in the future than in-person therapy." Post, P6 (F, 44, moderate anxiety)*

Many participants desired more control over session timing, duration, and frequency, and several participants disliked time-locks between sessions, feeling it slowed their progress. Agency in interactions with the conversational agent was also crucial, as pre-formatted answers were seen as restrictive and frustrating, making users feel "*forced out of [their] own voice*".

Theme 4 – Feeling Supported

The final theme describes how participants found the program to be supportive and safe, facilitated by human support. Clinician involvement in the design of the program provided credibility. Participants were willing to engage as the content was clinically backed and written by humans.

> *"I think if it's controlled, it's preprogramed responses written by an expert then, I have a lot of confidence in that system." Pre, P3 (F, 31, severe anxiety)*

Nearly all participants reported not feeling worse during the study. If users experienced increased anxiety, it was attributed to external stressors and users were able to speak to a clinician. Some users said that negative emotions could sometimes arise, but this was viewed as expected when engaging in such exercises.

> *"There were a few moments where it would ask you to think of something negative to practice. But I think that's how those sessions work. And at the end of it, I always felt better. But yeah, there was the odd moment, when it was getting you to think something, but I can't see a way for it to get you to practice and explain it without that." Post, P10 (F, 30, mild anxiety)*

Participants valued human support throughout the program.

> *"I think it was good that you can just pick it up and do it as and when, while also having some support from real people if and when you needed that." Post, P1 (F, 35, mild anxiety)*

Regular calls with research coordinators were beneficial for adherence and engagement with the program, providing gentle reminders or deadlines in addition to app reminders.

> *"It helped with accountability knowing that someone was going to call because then if I hadn't done it, that wouldn't be good." Post, P10 (F, 30, mild anxiety)*

Importantly, regular check-ins with research coordinators and the option to consult a clinician provided users with a sense of safety and reassurance during the program, and knowing about this human element was a motivating factor to take part in the study. Knowing they could talk to a human was important even when participants didn't experience the need for it. Several participants suggested integrating easy ways to contact a human within the app.

"That was the good thing about those calls [with the research coordinator], you did know there was actually somebody there. I never had to contact a clinician or anything, but it was always very clear that that is an option if that is necessary." Post, P4 (F, 19, mild anxiety)

While most felt supported by the human contact provided, a few desired more frequent clinician interaction and guidance. Some accessed the human support they needed outside of the program, through friends and family, and one participant explained that the program itself encouraged and helped them seek social support.

While the presence of human support was important, several participants pre-intervention were drawn to using a DMHI because they hoped it would provide a non-judgmental space and found it easier to approach a digital program than seeing someone in person. Post-intervention, participants expressed that the program's design and content created a supportive and encouraging environment. Several participants described the program as "*calming*", "*relaxing*", "*gentle*", the content as "*lovely*" and "*therapeutic*", and the conversational agent as "*friendly*" and "*reassuring*".

"And the acknowledgment at the end, 'Let's acknowledge that this may be hard for you', 'Are you willing to commit to it?'. At that level of acknowledgement, you feel heard. It was like having a cheerleader on your side, you know? That was nice I thought." Post, P12 (F, 48, moderate anxiety)

Discussion

This mixed-methods study demonstrates the overall acceptability of a digital program driven by an AI conversational agent with human support, for adults with generalized anxiety symptoms. Quantitative self-reported measures showed that participants found the digital program to be rewarding, easy to use, and both increased access to and enhanced their mental healthcare. Qualitative interviews provided in-depth understanding of factors important for DMHI acceptability that underlie the quantitative findings, such as guiding users, fostering a sense of support, and seeing tangible mental health improvements. However, a lack of personalization and frustrations with the conversational agent misunderstanding them were frequently reported, and there were mixed views as to whether this could be a substitution for standard care. Using mixed methods allowed for a deeper understanding of patient acceptability, and a new perspective on previously reported outcomes[16], capturing participants' affective and cognitive investment beyond usage metrics[38]. These findings pinpoint opportunities to optimize and innovate DMHIs to enhance their acceptability and impact on mental healthcare.

In this study, many participants sought a self-directed and autonomous solution while also wanting to feel supported, emphasizing the need to balance structure and guidance with personal agency in DMHIs. Indeed, users appreciated the structured program and wanted more in-app support, such as prompts or worksheets to facilitate reflection and practice. In contrast, some participants wanted increased control over their pace through the program echoing findings from other conversational agent DMHIs[39]. For example, time-locked sessions were designed to encourage practice between sessions, but many participants wanted more control over this. Most participants found the program easy to use, as shown by a high mean SUS score of 78.6, greater than other conversational agent DMHIs reporting scores from 63.6 to 66.2 [17], and that the program met their expectations around access and flexibility (74% agreed the program increased access to care; SUTAQ increased accessibility subscale).

Despite wanting a self-led digital solution, perceived by some participants as providing a judgment-free and less intimidating way to access mental health support by not talking with a therapist, human support remained crucial for participants to trust the program, feel safe, and stay engaged. Non-clinical research coordinators, providing motivational support through emails and phone calls, were perceived as helpful by

fostering a sense of accountability. Participants also valued the option to talk to a clinician if needed. This aligns with patient perceptions that DMHIs should facilitate access to mental health professionals[23], and is consistent with findings that DMHIs with human support have lower drop-out rates [12] and better outcomes[40], especially at higher symptom severity[41]. Most participants had minimal concerns about the program's personnel skills and care continuity (SUTAQ care personnel concerns subscale; mean score = 2.3; range 1-6), highlighting the acceptability of this support model for real-world implementation. Despite this, there were mixed views on the acceptability of the digital program as a replacement to regular mental healthcare (SUTAQ kit as substitution subscale; mean score = 3.3; range 1-6). Individual needs and preferences will impact the acceptability of DMHIs; therefore, it is essential to ensure patients have an informed choice around how to receive their care. Moreover, although human support can enhance acceptability, implementations must remain scalable to meet the rising demand for mental healthcare. With the current program, comparable outcomes to human-delivered care were found with up to 8x fewer clinician hours[16]. Innovative implementation approaches should be explored to further optimize scalability, acceptability and engagement with DMHIs using human support[41,42].

Acceptability can be further enhanced through improvements to the conversational agent. Being misunderstood by the conversational agent was a significant frustration in this study and is a common issue with tree-based dialogue systems[13,14,39,43,44]. Recent advances in generative AI have revolutionized how humans interact with technology by enabling dialogue systems that can emulate fluent human conversation making users feel heard and understood[45]. Users have reported finding rule-based mental health apps less satisfying than generative conversations[46], and recent findings suggest generative conversational agents can provide a larger ameliorative impact on psychological distress than retrieval-based ones[47]. While needing further research, these preliminary findings suggest that employing generative AI could improve engagement and effectiveness in DMHIs. However, using generative AI technology introduces new patient risks[48,49]. The integration of generative AI in DMHIs should be shaped by mental health professionals[50], and rigorous frameworks for evaluating clinical risk and quality in mental health contexts will be essential[51].

Interestingly, despite the conversational agent's limitations, many participants remained engaged due to the content's usefulness. This aligns with prior research linking perceived usefulness to greater engagement[10], and value users place on insights learned from DMHIs[13,44]. In the current study, 89% found the intervention to be satisfactory (SUTAQ satisfaction subscale), 81% found that it enhanced care (SUTAQ enhanced care subscale), and 83% found it to be rewarding and worthwhile (UES rewarding subscale). Post-intervention interviews indicated that perceiving benefits was key to staying engaged, in line with theory placing perceived efficacy as a core construct influencing acceptability[18,19]. Therefore, while prior research on conversational agent-led DMHIs emphasizes the importance of factors such as empathy and human-likeness to develop engaging programs[17], our findings highlight that expected outcomes and perceived efficacy remain of central importance to patients.

Limitations to the current study include a lack of sample diversity and biases in the sub-samples. Considering mental health inequities[52] and varying attitudes towards AI across groups[53], research on DMHI acceptability in diverse populations is essential, yet currently lacking[17,54]. Quantitative data are biased by those who adhered to the full study protocol. Those who completed questionnaires post-intervention were more likely to reach the minimum meaningful program dose in 9 weeks (83%) than the full enrolled sample (60%). The interviewed sub-sample, selected pre-intervention, showed similar engagement to the full enrolled sample (67%), and those who completed post-intervention interviews had higher engagement (75%). Exploring participants' expectations before the study helped mitigate this limitation and provided insights into factors important for acceptability, regardless of engagement. However, this is an important limitation. Findings therefore reflect acceptability for the most engaged, however actionable guidance for the development of DMHIs aims to enhance engagement across the whole population. Further research on those who did not engage is essential to understand barriers to acceptability of DMHIs. Moreover, there

are limitations to the validity of the self-reported measures (UES, SUS, and SUTAQ) in this context. Engaging in DMHIs encompasses differential motivations and behavioral process from users experiencing mental ill health compared to general digital systems or telehealth services that were used to develop and validate these measures, therefore interpretability in this context is challenging[7]. For example, the UES "Focused Attention" subscale (representing feeling absorbed in the experience), might not be as applicable in the context of a DMHI compared to a non-interventional system, as highlighted in the qualitative analysis (perceptions of a demanding but rewarding program). Additionally, the interpretability of the scales was limited by the scarcity of suitable benchmarks. To address these limitations, we provided item-level response data to enhance understanding of the scales, and qualitative findings offer deeper contextual insights.

In conclusion, this study provides evidence for the acceptability of a structured, conversational agent-driven digital program with human support for adults with symptoms of generalized anxiety. Understanding patient acceptability using multiple methods is crucial for enhancing engagement with DMHIs, a critical problem limiting their real-world impact. This study underscores the importance of design, clinical and implementation factors in maintaining adherence. Importantly, patient expectations of conversational agents are rapidly shifting due to ubiquitous access to generative conversational agents, such as ChatGPT. Generative AI has the potential to radically transform the user experience with DMHIs by enabling dynamic, empathetic and personalized interactions across multiple modalities and languages. However, rigorous evaluation of this technology is crucial to ensure patient safety and equitable health outcomes, alongside education and research into its acceptability. If integrated safely within structured, evidence-based, effective DMHIs, shown here to be acceptable to patients, then this technology could revolutionize the delivery of mental health care and impact patient outcomes globally.

Acknowledgements

We extend our gratitude to the patients who participated in the study and to the dedicated clinicians and support staff involved. We would like to thank Gerald Chan, Stephen Bruso, Andy Richards, Ann Hayes, David Icke, Michael Black, Clare Hurley, Florian Erber, Richard Marsh, Sam Williams, Jo Parfrey for their support and encouragement. We are grateful to Prof Thalia Eley for introducing us to NIHR BioResource. We thank NIHR BioResource volunteers for their participation, and gratefully acknowledge NIHR BioResource centers, NHS Trusts and staff for their contribution. We thank the National Institute for Health and Care Research, NHS Blood and Transplant, and Health Data Research UK as part of the Digital Innovation Hub Program. The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health and Social Care.

Funding

This research was funded by ieso Digital Health Ltd.

Competing Interests

All investigators are employees of ieso Digital Health Limited (the company funding this research) or its subsidiaries. None of these authors had a direct financial incentive related to the results of this study or the publication of the manuscript

Author contributions

CEP, EMa & AB conceptualized the study. CEP and PP drafted the paper. PP, CEP, EMi, MB, MZ, GW, AC, JB contributed to data analyses and interpretation. SD, MZ, CEP, EMa conducted the study. All authors contributed to the interpretation of results and paper revision and approved the final version.

Data availability

Owing to the potential risk of patient identification, and following data privacy policies at ieso, individual-level data are not available. Aggregated data are available upon request, subject to a data-sharing agreement with ieso. Data requests should be sent to the corresponding author and will be responded to within 30 days.

Abbreviations

ACT: acceptance commitment therapy
AI: artificial intelligence
CBT: cognitive behavioral therapy
CI: confidence interval
DMHI: digital mental health intervention
GAD: generalized anxiety disorder
PPI: patient and public involvement
NHS: National Health Service
NHS TT: NHS Talking Therapies
SD: standard deviation
SUS: system usability scale
SUTAQ: service user technology acceptance questionnaire
UES: user engagement scale

References

1. World Health Organisation. *Mental Health and COVID-19: Early Evidence of the Pandemic's Impact*.; 2022.
2. Our World in Data. Psychiatrists per 100,000 people. 2024. Accessed July 3, 2024. https://ourworldindata.org/grapher/psychiatrists-working-in- the-mental-health-sector
3. British Association for Counselling and Psychotherapy. *BACP Mindometer 2023*.; 2023. Accessed July 8, 2024. https://www.bacp.co.uk/about-us/home/
4. Alonso J, Liu Z, Evans-Lacko S, et al. Treatment gap for anxiety disorders is global: Results of the World Mental Health Surveys in 21 countries. *Depress Anxiety*. 2018;35(3):195-208. doi:10.1002/da.22711
5. American Psychological Association. 2022 COVID-19 Practitioner Impact Survey. Accessed January 2, 2025. https://www.apa.org/pubs/reports/practitioner/2022-covid-psychologist-workload
6. Roland J, Lawrance E, Insel T, Christensen H. *The Digital Mental Health Revolution. Transforming Care through Innovation and Scale-Up*.; 2020.

7. Ng MM, Firth J, Minen M, Torous J. User Engagement in Mental Health Apps: a Review of Measurement, Reporting and Validity HHS Public Access. *Psychiatr Serv*. 2019;70(7):538-544. doi:10.1176/appi.ps.201800519
8. Torous J, Nicholas J, Larsen ME, Firth J, Christensen H. Clinical review of user engagement with mental health smartphone apps: evidence, theory and improvements. 2018;21(3). doi:10.1136/eb-2018-102891
9. Baumel A, Muench F, Edan S, Kane JM. Objective user engagement with mental health apps: Systematic search and panel-based usage analysis. *J Med Internet Res*. 2019;21(9). doi:10.2196/14567
10. Borghouts J, Eikey E, Mark G, et al. Barriers to and facilitators of user engagement with digital mental health interventions: Systematic review. *J Med Internet Res*. 2021;23(3). doi:10.2196/24387
11. Boucher EM, Harake NR, Ward HE, et al. Artificially intelligent chatbots in digital mental health interventions: a review. *Expert Rev Med Devices*. 2021;18(sup1):37-49. doi:10.1080/17434440.2021.2013200
12. Jabir AI, Lin X, Martinengo L, Sharp G, Theng YL, Car LT. Attrition in Conversational Agent-Delivered Mental Health Interventions: Systematic Review and Meta-Analysis. *J Med Internet Res*. 2024;26(1). doi:10.2196/48168
13. Fitzpatrick KK, Darcy A, Vierhile M. Delivering cognitive behavior therapy to young adults with symptoms of depression and anxiety using a fully automated conversational agent (Woebot): A randomized controlled trial. *JMIR Ment Health*. 2017;4(2). doi:10.2196/mental.7785
14. Inkster B, Sarda S, Subramanian V. An empathy-driven, conversational artificial intelligence agent (Wysa) for digital mental well-being: Real-world data evaluation mixed-methods study. *JMIR Mhealth Uhealth*. 2018;6(11). doi:10.2196/12106
15. Linardon J, Torous J, Firth J, Cuijpers P, Messer M, Fuller-Tyszkiewicz M. *Current Evidence on the Efficacy of Mental Health Smartphone Apps for Symptoms of Depression and Anxiety. A Meta-Analysis of 176 Randomized Controlled Trials*. Vol 23.; 2024.
16. Palmer CE, Marshall E, Millgate E, et al. Combining AI and human support in mental health: a digital intervention with comparable effectiveness to human-delivered care. *medRxiv*. Published online December 20, 2024:2024.07.17.24310551. doi:10.1101/2024.07.17.24310551
17. Limpanopparat S, Gibson E, Harris DA. User engagement, attitudes, and the effectiveness of chatbots as a mental health intervention: A systematic review. *Computers in Human Behavior: Artificial Humans*. 2024;2(2):100081. doi:10.1016/j.chbah.2024.100081
18. Perski O, Short CE. Acceptability of digital health interventions: embracing the complexity. *Transl Behav Med*. 2021;11(7):1473-1480. doi:10.1093/tbm/ibab048
19. Sekhon M, Cartwright M, Francis JJ. Acceptability of healthcare interventions: An overview of reviews and development of a theoretical framework. *BMC Health Serv Res*. 2017;17(1). doi:10.1186/s12913-017-2031-8
20. Abd-Alrazaq AA, Alajlani M, Ali N, Denecke K, Bewick BM, Househ M. Perceptions and Opinions of Patients about Mental Health Chatbots: Scoping Review. *J Med Internet Res*. 2021;23(1). doi:10.2196/17828
21. Haque MDR, Rubya S. An Overview of Chatbot-Based Mobile Mental Health Apps: Insights From App Description and User Reviews. *JMIR Mhealth Uhealth*. 2023;11. doi:10.2196/44838
22. Benda NC, Desai PM, Reza Z, et al. Patient Perspectives on AI for Mental Health: With Great [Computing] Power, Comes Great Responsibility. Published online 2024. doi:10.21203/rs.3.rs-3793389/v1
23. Humphreys J, Gill M, Rooney S, Ahmad Z. *Digital Mental Health Technology: User and Public Perspectives Research Report from Woodnewton April 2024*.; 2024.
24. Ahmed A, Aziz S, Khalifa M, et al. Thematic Analysis on User Reviews for Depression and Anxiety Chatbot Apps: Machine Learning Approach. *JMIR Form Res*. 2022;6(3). doi:10.2196/27654

25. Fulmer R, Joerin A, Gentile B, Lakerink L, Rauws M. Using Psychological Artificial Intelligence (Tess) to Relieve Symptoms of Depression and Anxiety: Randomized Controlled Trial. *JMIR Ment Health*. 2018;5(4):e64. doi:10.2196/mental.9782
26. He Y, Yang L, Zhu X, et al. Mental Health Chatbot for Young Adults With Depressive Symptoms During the COVID-19 Pandemic: Single-Blind, Three-Arm Randomized Controlled Trial. *J Med Internet Res*. 2022;24(11). doi:10.2196/40719
27. Liu H, Peng H, Song X, Xu C, Zhang M. Using AI chatbots to provide self-help depression interventions for university students: A randomized trial of effectiveness. *Internet Interv*. 2022;27. doi:10.1016/j.invent.2022.100495
28. Oh J, Jang S, Kim H, Kim JJ. Efficacy of mobile app-based interactive cognitive behavioral therapy using a chatbot for panic disorder. *Int J Med Inform*. 2020;140:104171. doi:10.1016/j.ijmedinf.2020.104171
29. Yardley L, Morrison ; Leanne, Bradbury K, Muller I. The Person-Based Approach to Intervention Development: Application to Digital Health-Related Behavior Change Interventions. *J Med Internet Res*. 2015;17(1):30. doi:10.2196/jmir.4055
30. *NHS England. NHS Talking Therapies for Anxiety and Depression Manual*.; 2018. Accessed January 2, 2025. https://www.england.nhs.uk/publication/the-improving-access-to-psychological-therapies-manual/
31. Malterud K, Siersma VD, Guassora AD. Sample Size in Qualitative Interview Studies: Guided by Information Power. *Qual Health Res*. 2016;26(13):1753-1760. doi:10.1177/1049732315617444
32. O'Brien HL, Cairns P, Hall M. A practical approach to measuring user engagement with the refined user engagement scale (UES) and new UES short form. *Int J Hum Comput Stud*. 2018;112:28-39. doi:10.1016/J.IJHCS.2018.01.004
33. Brooke J. SUS: A "Quick and Dirty" Usability Scale. In: Jordan P, Thomas B, Lyall McClelland I, Weerdmeester B, eds. *Usability Evaluation in Industry*. 1st Edition. ; 1996:207-2012. doi:10.1201/9781498710411
34. Hirani SP, Rixon L, Beynon M, et al. Quantifying beliefs regarding telehealth: Development of the Whole Systems Demonstrator Service User Technology Acceptability Questionnaire. *J Telemed Telecare*. 2017;23(4):460-469. doi:10.1177/1357633X16649531
35. Braun V, Clarke V. Using thematic analysis in psychology. *Qual Res Psychol*. 2006;3(2):77-101. doi:10.1191/1478088706qp063oa
36. Gale NK, Heath G, Cameron E, Rashid S, Redwood S. *Using the Framework Method for the Analysis of Qualitative Data in Multi-Disciplinary Health Research*.; 2013. doi:10.1186/1471-2288-13-117
37. Ritchie J, Spencer L. Qualitative data analysis for applied policy research. In: Bryman A, Burgess R, eds. *Analyzing Qualitative Data*. Routledge; 1994:173-194. doi:10.4324/9780203413081
38. Torous J, Michalak EE, O'Brien HL. Digital Health and Engagement - Looking behind the Measures and Methods. *JAMA Netw Open*. 2020;3(7). doi:10.1001/jamanetworkopen.2020.10918
39. Gaffney H, Mansell W, Tai S. Conversational Agents in the Treatment of Mental Health Problems: Mixed-Method Systematic Review. *JMIR Ment Health*. 2019;6(10):e14166. doi:10.2196/14166
40. Gilbody S, Brabyn S, Lovell K, et al. Telephone-supported computerised cognitive-behavioural therapy: REEACT-2 large-scale pragmatic randomised controlled trial. *British Journal of Psychiatry*. 2017;210(5):362-367. doi:10.1192/bjp.bp.116.192435
41. Werntz A, Amado S, Jasman M, Ervin A, Rhodes JE. Providing Human Support for the Use of Digital Mental Health Interventions: Systematic Meta-review. *J Med Internet Res*. 2023;25. doi:10.2196/42864
42. Bernstein EE, Weingarden H, Wolfe EC, Hall MD, Snorrason I, Wilhelm S. Human Support in App-Based Cognitive Behavioral Therapies for Emotional Disorders: Scoping Review. *J Med Internet Res*. 2022;24(4). doi:10.2196/33307

43. Beatty C, Malik T, Meheli S, Sinha C. Evaluating the Therapeutic Alliance With a Free-Text CBT Conversational Agent (Wysa): A Mixed-Methods Study. *Front Digit Health*. 2022;4. doi:10.3389/fdgth.2022.847991
44. Malik T, Ambrose AJ, Sinha C. Evaluating User Feedback for an Artificial Intelligence–Enabled, Cognitive Behavioral Therapy–Based Mental Health App (Wysa): Qualitative Thematic Analysis. *JMIR Hum Factors*. 2022;9(2). doi:10.2196/35668
45. Yin Y, Jia N, Wakslak CJ. AI can help people feel heard, but an AI label diminishes this impact. *Proc Natl Acad Sci U S A*. 2024;121(14):e2319112121. doi:10.1073/pnas.2319112121
46. Siddals S, Coxon A, Torous J, Israel B. "It just happened to be the perfect thing": Real-life experiences of generative AI chatbots for mental health. Published online 2024. doi:10.21203/rs.3.rs-4612612/v1
47. Li H, Zhang R, Lee YC, Kraut RE, Mohr DC. Systematic review and meta-analysis of AI-based conversational agents for promoting mental health and well-being. *NPJ Digit Med*. 2023;6(1). doi:10.1038/s41746-023-00979-5
48. Weidinger L, Mellor J, Rauh M, et al. Ethical and social risks of harm from Language Models. Published online December 8, 2021. http://arxiv.org/abs/2112.04359
49. Blease C, Torous J. ChatGPT and mental healthcare: balancing benefits with risks of harms. *BMJ Mental Health*. 2023;26(1). doi:10.1136/bmjment-2023-300884
50. Elyoseph Z, Gur T, Haber Y, et al. An Ethical Perspective on The Democratization of Mental Health with Generative Artificial Intelligence (Preprint). *JMIR Ment Health*. Published online October 17, 2024. doi:10.2196/58011
51. Stade EC, Stirman SW, Ungar LH, et al. Large language models could change the future of behavioral healthcare: a proposal for responsible development and evaluation. *npj Mental Health Research*. 2024;3(1). doi:10.1038/s44184-024-00056-z
52. Dawes DE, Amador CM, Jha M, et al. *The Economic Burden of Mental Health Inequities in the United States Report*. Accessed January 2, 2025. https://satcherinstitute.org/research/ebmhi/
53. Gillespie N, Lockey S, Curtis C, Pool J, Ali Akbari. *Trust in Artificial Intelligence: A Global Study*.; 2023. doi:10.14264/00d3c94
54. Khosravi M, Azar G. Factors influencing patient engagement in mental health chatbots: A thematic analysis of findings from a systematic review of reviews. *Digit Health*. 2024;10. doi:10.1177/20552076241247983

Supplementary Materials

Table of Contents

Supplementary Methods (Semi-structured interview schedules)

Pre-intervention interviews

Section 1 – Motivation

1. What was your motivation to sign up to the study?
2. Do you think that this program is the right solution for you at this time?

Section 2 – Views and previous experiences with different mental health support

3. How do you think technology can help you improve your mental health?
4. Have you tried any other digital tools for your mental health before? *If yes:*
    a. How did you find it? What was helpful and what was not helpful?
    b. How different do you think the ieso Digital Program will be from the tools you used?
5. Is it your first time accessing any type of mental health support? *If no:*
    a. What support / therapy have you accessed before? (e.g. face-to-face therapy, CBT, counselling, etc.)
    b. How different do you think the ieso Digital Program will be from what you have done before?
6. What was your journey in seeking mental health support?
    a. Did you have any setbacks?

Section 3 – Expectations for the program

7. Based on what you know of the ieso Digital Program, how do you imagine it to be?
8. Can you tell me about any doubts you might have about doing this program?
9. Do you believe that this program can reduce your symptoms of anxiety? Why or why not?
10. How do you think this program will fit into your lifestyle?
11. What do you think will be the main benefits of using the ieso Digital Program?
12. Can you tell me about any concerns you might have about the ieso Digital Program?
13. Which of your needs do you think the ieso Digital Program will meet?
14. Which of your needs do you think the ieso Digital Program will not meet?
15. What are your expectations about interacting with a digital guide in the app?
16. What are your views on using an AI-powered digital guide in mental health care?
17. What are your expectations about human contact during the program?

Post-intervention interviews

Section 1 – Overall experience of the ieso Digital Program

1. Tell me about your experience with the program, how was it for you?
2. How did the program meet your expectation? How did it not meet your expectations?
3. What did you find most valuable or impactful in addressing your anxiety?
4. What did you find most frustrating about the program?

Section 2 – Perceived Fit

5. Do you feel that this program is well suited for people in your situation? (prompt: e.g. your age, gender, lifestyle, mental health experience, etc.)
6. Are there any specific groups of people that you think this program would be well-suited or most helpful for?

Section 3 – Perceived support and safety

7. How supported did you feel while using the program?
8. How safe did you feel while using the program? Was the support enough to help you feel safe?
9. Tell me about your experience with the fortnightly calls with the research coordinators? *Prompts*:
    a. How helpful or unhelpful were they?
    b. How often do you think these should be?
    c. How long do you think these should be?
10. Was there any point during the study where you felt worse? *If yes:*
    a. Did you think this was related to using the app?
    b. Did you think this was related to other parts of the study outside of the app? (e.g. assessments, calls, messages with your clinician…)
    c. Did you know what to do or who to contact in this situation?

Section 4 – Program and app design

11. What did you think of the length of sessions and of the overall program?
12. What did you think of the frequency of sessions and activities?
13. How did this program fit into your schedule?
14. What helped you or made you want to continue with the program? E.g. the app, the program, other…
15. What did you think of the reminders in the app?
16. How did you find the interaction with the digital guide through the sessions? *Prompts:*
    a. How well or poorly did you feel the digital guide listened and responded to your entries?
    b. Tell me some instances where you felt the digital guide could be more helpful?
17. Can you reflect on if and how you practiced the tools and techniques you learned in the sessions?
    a. Did you practice them during your personal time between sessions?
    b. What helped you practice these techniques?
    c. What were the barriers to practicing these techniques?
    d. What do you think the app could do to encourage and better support you in engaging between sessions in your own time?

Section 5 – Perceived effectiveness

18. Can you share any specific examples of techniques you found beneficial in your daily life>
19. How motivated did you feel to make changes after using the program?
20. How effective do you believe this program is?

   a. How effective do you think it is relative to in-person therapy (or other treatments or support you received in the past)

Section 6 – Closing questions

21. If you had a magic wand and could build your own program to help individuals with anxiety and/or depression, what is the one thing you would be sure to include?
22. Is there anything else you would like to share or ask?

Supplementary tables (Self-reported measures of user experience)

User Engagement Scale (UES) item-level results

Supplementary table 1 – Raw UES item level agreement data in the whole sample (N=190)

Subscale	Items	Proportion agreement N (%)				
		Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
Focused attention	I lost myself in this experience.	24 (13)	69 (36)	59 (31)	33 (17)	5 (3)
	The time I spent using ieso's digital programme just slipped away.	9 (5)	40 (21)	58 (31)	66 (35)	17 (9)
	I was absorbed in this experience.	4 (2)	41 (22)	50 (26)	77 (41)	18 (9)
Perceived Usability [a]	I felt frustrated while using ieso's digital programme.	33 (17)	64 (34)	26 (14)	49 (26)	18 (9)
	I found ieso's digital programme confusing to use.	86 (45)	80 (42)	16 (8)	6 (3)	2 (1)
	Using ieso's digital programme was taxing.	37 (19)	87 (46)	35 (18)	26 (14)	5 (3)
Aesthetic Appeal	ieso's digital programme was attractive.	2 (1)	6 (3)	60 (32)	90 (47)	32 (17)
	ieso's digital programme was aesthetically appealing.	2 (1)	8 (4)	31 (16)	108 (57)	41 (22)
	ieso's digital programme appealed to my senses.	3 (2)	12 (6)	47 (25)	97 (51)	31 (16)
Rewarding	ieso's digital programme was worthwhile.	4 (2)	5 (3)	18 (9)	93 (49)	70 (37)
	My experience was rewarding.	5 (3)	10 (5)	32 (17)	92 (48)	51 (27)
	I felt interested in this experience.	2 (1)	6 (3)	10 (5)	108 (57)	64 (34)

[a] Items are reverse scored to produce the subscale scores in table 2

System Usability Scale (SUS) item-level results

Supplementary table 2 – Raw SUS item level agreement data in the whole sample (N=203)

Items	Proportion agreement N (%)				
	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
I think that I would like to use this system frequently	9 (4.4)	31 (15.3)	28 (13.8)	97 (47. 8)	38 (18.7)
I found the system unnecessarily complex	84 (41.4)	94 (46.3)	15 (7.4)	8 (3.9)	2 (1.0)
I thought the system was easy to use	1 (0.5)	11 (5.4)	12 (5.9)	97 (47. 8)	82 (40.4)
I think that I would need the support of a technical person to be able to use this system	125 (61.6)	63 (31.0)	11 (5.4)	2 (1.0)	2 (1.0)
I found the various functions in this system were well integrated	5 (2.5)	12 (5.9)	30 (14. 8)	110 (54.2)	46 (22.7)
I thought there was too much inconsistency in this system	64 (31.5)	80 (39.4)	34 (16.8)	21 (10.3)	4 (2.0)
I would imagine that most people would learn to use this system very quickly	0 (0)	4 (2.0)	14 (6.9)	113 (55.7)	72 (35.5)
I found the system very cumbersome to use	74 (36. 5)	89 (43.8)	26 (12.8)	9 (4.4)	5 (2.5)
I felt very confident using the system	1 (0.5)	3 (1.5)	19 (9.4)	93 (45.8)	87 (42.9)
I needed to learn a lot of things before I could get going with this system	120 (59.1)	69 (34.0)	8 (3.9)	6 (3.0)	0 (0)

Service User Technology Acceptability Questionnaire (SUTAQ) item-level results

Supplementary table 3 – Raw SUTAQ item level agreement data in the whole sample (N=203)

Subscale	Items [a]		Proportion agreement N (%)					
			Strongly disagree	Moderately disagree	Mildly disagree	Mildly agree	Moderately agree	Strongly agree
Care personnel concerns	*9*	I am concerned about the level of expertise of the individuals who monitor my status via the digital programme.	98 (48.3)	62 (30.5)	22 (10.8)	12 (5.9)	7 (3.5)	2 (1.0)
	20	The digital programme interferes with the continuity of the care I receive (i.e. I do not see the same care professional each time).	76 (37.4)	53 (26.1)	52 (25.6)	18 (8.9)	3 (1.5)	1 (0.5)
	21	I am concerned that the person who monitors my status, through the digital programme, does not know my personal health/social care history.	46 (22.7)	52 (25.6)	42 (20.7)	38 (18.7)	20 (9.9)	5 (2.5)
Enhanced care	*10*	The digital programme has allowed me to be less concerned about my health and/or social care.	15 (7.4)	19 (9.4)	38 (18.7)	61 (30.1)	51 (25.1)	19 (9.4)
	11	The digital programme has made me more actively involved in my health.	5 (2.5)	7 (3.5)	5 (2.5)	58 (28.6)	70 (34.5)	58 (28.6)
	13	The digital programme allows the people looking after me, to better monitor me and my condition.	19 (9.4)	15 (7.4)	27 (13.3)	70 (34.5)	42 (20.7)	30 (14.8)
	15	The digital programme can be/should be recommended to people in a similar condition to mine.	6 (3.0)	9 (4.4)	16 (7.9)	36 (17.7)	48 (23.7)	88 (43.4)
	17	The digital programme can certainly be a good addition to my regular health or social care.	4 (2.0)	3 (1.5)	6 (3.0)	32 (15.8)	48 (23.7)	110 (54.2)
Increased accessibility	*1*	The digital programme has saved me time in that I did not have to visit my GP clinic or other health/social care professional as often.	16 (7.9)	11 (5.4)	21 (10.3)	44 (21. 7)	34 (16.8)	77 (37.9)
	3	The digital programme has increased my access to care (health and/or social care professionals).	14 (6.9)	18 (8.9)	27 (13.3)	68 (33.5)	45 (22.2)	31 (15.3)
	4	The digital programme has helped me to improve my health.	6 (3.0)	3 (1.5)	12 (5.9)	62 (30.5)	67 (33.0)	53 (26.1)
	19	The digital programme has made it easier to get in touch with health and social care professionals.	11 (5.4)	20 (9.9)	44 (21.7)	54 (26.6)	42 (20.7)	32 (15.8)
Kit as substitution	*16*	The digital programme can be a replacement for my regular health or social care.	33 (16.3)	44 (21.7)	42 (20.7)	43 (21.2)	31 (15.3)	10 (4.9)
	18	The digital programme is not as suitable as regular face to face consultations with the people looking after me. [b]	12 (5.9)	22 (10.8)	36 (17.7)	51 (25.1)	40 (19.7)	42 (20.7)
	22	The digital programme has allowed me to be less concerned about my health status.	15 (7.4)	19 (9.4)	35 (17.2)	68 (33.5)	42 (20.7)	24 (11.8)
Privacy & discomfort	*2*	The digital programme has interfered with my everyday routine.	62 (30.5)	47 (23.2)	44 (21.7)	41 (20.2)	7 (3.5)	2 (1.0)
	5	The digital programme has invaded my privacy.	125 (61.6)	51 (25.1)	19 (9.4)	5 (2.5)	3 (1.5)	0 (0)
	8	The digital programme has made me feel uncomfortable, e.g. physically or emotionally.	82 (40.4)	43 (21.2)	36 (17.7)	29 (14.3)	8 (3.9)	5 (2.5)
	12	The digital programme makes me worried about the confidentiality of the private information being exchanged through it.	98 (48.3)	52 (25.6)	29 (14.3)	13 (6.4)	9 (4.4)	2 (1.0)
Satisfaction	*6*	The digital programme has been explained to me sufficiently.	1 (0.5)	2 (1.0)	5 (2.5)	17 (8.4)	47 (23.2)	131 (64.5)
	7	The digital programme can be trusted to work appropriately.	8 (3.9)	6 (3.0)	19 (9.4)	44 (21.7)	79 (38.9)	47 (23.2)
	14	I am satisfied with the digital programme I received.	7 (3.5)	9 (4.4)	13 (6.4)	38 (18.7)	65 (32.0)	71 (35.0)

[a] Items are preceded by a number representing the order in which the item was presented to participants.
[b] Items are reverse scored to produce the subscale scores in table 2