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Engagement and acceptability of a digital programme for anxiety

Submission date
28/04/2023

Recruitment status
No longer recruiting

Registration date
20/09/2023

Overall study status
Completed

Last Edited
23/05/2025

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
This study tests a 6-week digital programme, delivered via a smartphone app, designed to help people develop skills to cope with stress, worry, or anxiety. Mental health apps are being widely used, but evidence shows that many people do not find these very engaging. In this study, the researchers are testing their new programme to understand whether people find it useful for them and how it makes them feel. The programme also contains a digital guide that is powered by machine learning. In this study the researchers are also testing our machine-learning models to help make the conversations more engaging. The programme has been developed by a team of accredited clinicians. It is a smartphone app with a combination of therapist videos, educational content, and worksheets developed based on research and evidence, such as principles underlying cognitive behavioural therapy (CBT).

Who can participate?
Patients aged over 18 years primarily presenting with anxiety symptoms

What does the study involve?
Participants are either referred to ieso's internet-enabled cognitive behavioural therapy (IECBT) service through an NHS trust, self-refer via ieso's website or respond to an online advert for the study. Participants will be asked to download the app on their own smartphone in order to complete the activities in their own time. A clinician will assess eligibility, obtain informed consent, and monitor the participant's progress throughout. If participants stay on schedule the programme will take 6 weeks, but if they fall behind it could take longer. They will have a maximum of 9 weeks to complete the programme.
Participants complete the digital programme using a smartphone at home on their own. At the start, middle and end of the programme they will be asked to complete some questionnaires about how they are feeling and their experience with the app. Participants will be invited to have a typed conversation with one of our study clinicians before and after completing the programme. The programme takes around 6 weeks to complete. Each week there are up to three sessions, which on average take 20 minutes, though some will be longer and some shorter than this. These sessions will have a typed, text-based conversation with the digital guide.

Participants will be talking to the guide by typing into a chat window, like a WhatsApp conversation. Sometimes the guide will respond with text and other times they will respond with videos or activities to complete.

What are the possible benefits and risks of participating?
Whilst the researchers cannot guarantee any clinical benefits from taking part in this study, it is hoped that people find this programme beneficial. Taking part in this study will help the researchers to improve their digital programme in order to improve access to mental healthcare for as many people as possible.
It is not anticipated that taking part in this study will pose a significant risk. Participants will be using a smartphone app for up to 2 hours per week. Although unlikely, they may experience common side effects of using apps, like headaches, but the researchers don't think there is anything different about their app compared to other ones.
It is important to understand that the app will ask questions about people's thoughts and feelings, and they will be asked to complete questionnaires that ask about their anxiety and mood symptoms. This can be distressing for some people. Throughout the study they will be able to contact one of the research team via email if their anxiety or mood symptoms get worse. In addition, the research coordinators will check the anxiety and mood questionnaire scores weekly and will notify the participant's allocated clinician if deemed necessary.

Where is the study run from?
ieso Digital Health (UK)

When is the study starting and how long is it expected to run for?
February 2023 to May 2024

Who is funding the study?
ieso Digital Health (UK)

Who is the main contact?
1. Dr Clare Palmer, c.palmer@iesohealth.com
2. Ms Emily Marshall, e.marshall@iesohealth.com

Contact information

Type(s)
Principal investigator

Contact name
Miss Emily Marshall

Contact details
ieso Digital Health
The Jeffreys Building
Cowley Road
Cambridge
United Kingdom
CB4 0DS
+44 (0)8000745560
e.marshall@iesohealth.com

Type(s)
Public

Contact name
Dr Clare Palmer

Contact details
ieso Digital Health
The Jeffreys Building
Cowley Road
Cambridge
United Kingdom
CB4 0DS
+44 (0)8000745560
c.palmer@iesohealth.com

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
327897

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 327897

Study information

Scientific Title
Evaluating engagement and acceptability of ieso's 6-week digital programme for adults experiencing symptoms of anxiety

Acronym
Nil known

Study objectives
The primary objective is to evaluate the engagement and acceptability of ieso's digital programme with clinical support for adults with anxiety symptoms. The aim is to understand:
1. How users engage with the programme
2. Whether participants use the programme as intended and complete all the modules along the schedule provided
3. Whether the programme meets their needs

The secondary objectives are to determine the feasibility of this study protocol for future clinical trial design and generate preliminary safety data.

The exploratory objectives are to generate preliminary effectiveness data for anxiety symptoms and understand the effect of the programme on additional outcomes, such as mood, work and social adjustment and psychological flexibility, in order to inform the design of future clinical trials.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 14/07/2023, West of Scotland REC 4 (Research Ethics, Ward 11, Dykebar Hospital, Grahamston Road, Paisley, PA2 7DE, UK; +44 (0)141 314 0213; WoSREC4@ggc.scot.nhs.uk), ref: 23/WS/0081

Study design
Single-centre single intervention arm prospective observational study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Anxiety symptoms in adults

Interventions
The intervention consists of a 6-week digital programme that follows a pre-defined set of psychoeducational activities with a clinical oversight wrap-around model. These activities will be made available at specific time points throughout the 6-week programme to enable time between sessions for reflection and practice of activities. Each week, three new activities will be made available on a specific timed schedule throughout the week. Participants will be able to interact with all of the available content in their own time over the course of each week.

Each week participants will be asked to complete the Generalised Anxiety Disorder Assessment (GAD-7) and Patient Health Questionnaire-9 (PHQ-9) within the device as part of the programme to measure changes in anxiety/mood. Participants will also complete a set of validated questionnaires to measure other behavioural outcomes (prior to the intervention, at the mid-point and after completing the intervention.

For a sub-sample of participants, the researchers will collect additional data about the user experience, acceptability and safety of the digital programme in the form of semi-structured interviews.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
ieso’s digital programme

Primary outcome(s)

Current primary outcome measures as of 26/04/2024:
1. Passive usage metrics are measured throughout the programme and during the follow-up period:
1.1. Mean and distribution of time spent in the device across participants
1.2. Proportion of participants successfully engaged with the programme (defined as completing session 1 of week 2 in the device)
1.3. Proportion of participants completing the 6-week digital programme
1.4. Number of activities completed per week vs expected number of activities per week (defined weekly dose)
2. How likely a participant is to recommend the programme to a friend is measured by the Net Promoter Score post intervention
3. User engagement is measured using the User Engagement Scale (UES) post intervention
4. Proportion of participants requiring technical support recorded during the programme
5. Usability of the device is measured using the System Usability Scale (SUS) post intervention
6. Acceptability of the programme is measured using the Service User Technology Acceptability Questionnaire (SUTAQ) post intervention
7. Qualitative analysis of acceptability of the programme for participants as assessed using a semi-structured interview in sub-sample
8. Sub-group analysis of quantitative primary engagement and adherence endpoints across anxiety severity at baseline (measured by GAD-7 questionnaire)

Previous primary outcome measures:
1. Passive usage metrics are measured throughout the programme and during the follow-up period:
1.1. Mean and distribution of time spent in the device across participants
1.2. Proportion of screens in the programme not accessed
1.3. Proportion of participants successfully engaged with the programme (defined as completing 2 full weeks worth of activities in the device)
1.4. Proportion of participants completing the 6-week digital programme
1.5. Number of activities completed per week vs expected number of activities per week (defined weekly dose)
2. How likely a participant is to recommend the programme to a friend is measured by the Net Promoter Score post intervention
3. User engagement is measured using the User Engagement Scale (UES) post intervention
4. Proportion of participants requiring technical support recorded during the programme
5. Usability of the device is measured using the System Usability Scale (SUS) post intervention
6. Acceptability of the programme is measured using the Service User Technology Acceptability Questionnaire (SUTAQ) post intervention
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Key secondary outcome(s))

1. Recruitment rate across different recruitment methods and referral avenues
2. Clinician and research coordinator total time spent and cost recorded across the study period
3. Number of off-schedule check-ins required recorded across the study period
4. Overall attrition rate and attrition rate recorded at follow-up assessment
5. Adverse event reporting across the study period
6. Number of cases withdrawn and referred on due to safety concerns (compared with expected

number receiving first-line intervention in TTAD) recorded across the study period
7. Number of times clinical risk escalation protocols were initiated and time spent by clinician responding recorded across the study period
8. Qualitative analysis of safety assessment from a semi-structured interview in sub-sample post intervention

Exploratory endpoints:
Clinical effectiveness determined by:
1. Symptoms of anxiety measured using the GAD-7 questionnaire from baseline to programme completion
2. Symptoms of anxiety measured using the GAD-7 questionnaire across all time points (baseline, weekly during the intervention, at programme completion and 1-month follow-up)
3. Sub-group analysis stratified by symptom severity at baseline measuring symptoms of anxiety using the GAD-7 questionnaire in severity from baseline to follow-up and across all time points (baseline, weekly during intervention, at programme completion and 1-month follow-up)

Additional outcomes:
1. Symptoms of depression measured using the PHQ-9 from baseline and to programme completion
2. Impairment in functioning measured using the Work and Social Adjustment Scale (WSAS) at baseline and programme completion
3. Psychological flexibility measured using the Multidimensional Psychological Flexibility Inventory (MPFI) at baseline and programme completion

Completion date
31/05/2024

Eligibility

Key inclusion criteria
Current inclusion criteria as of 26/04/2024:
1. Individuals must be over 18 years old at the time of recruitment
2. Anxiety must be the primary presenting issue that individuals are seeking help for (i.e. with a GAD-7 score >7), with symptoms of anxiety and worry typically associated with Generalised Anxiety Disorder (GAD)
3. If depressive symptoms are present at screening, these are not within the severe range (i.e., participants must have a PHQ-9 score <16)
4. Individuals must be able and willing to sign a consent form prior to the study
5. Individuals must be registered with a GP in the UK
6. Individuals must have access to a smartphone with an internet connection

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4. Individuals must be able and willing to sign a consent form prior to the study
5. Individuals must be registered with a GP in the UK
6. Individuals must have access to a smartphone with an internet connection

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
300

Key exclusion criteria
1. Individuals currently receiving psychological therapy
2. Individuals who are not suitable for CBT, this includes individuals with a comorbid diagnosis (a diagnosis of multiple disorders) of psychotic or personality disorder, autism spectrum condition or intellectual disability
3. Individuals who have a formal diagnosis of an untreated mental health condition including substance misuse (except for GAD, MDD or Mixed Anxiety and Depression)
4. Individuals who have Post Traumatic Stress Disorder (PTSD), Obsessive Compulsive Disorder (OCD) or Panic Disorder
5. Individuals who have had a change in psychiatric medication in the past 3 months
6. Individuals who display a significant risk of harm to self, to others or from others
7. Individuals who do not have access to an Internet-enabled device or an Internet connection
8. Individuals who have a low level of literacy in the English language. People who cannot write or read emails or texts will be excluded from this study because they will be unable to utilise the intervention
9. Individuals who have an impairment that will prevent them from using a phone app and/or who usually rely on accessibility features (note: this app has not yet gone through accessibility evaluation)
10. Individuals who become unsuitable for treatment within an NHS primary care mental health service. The normal NHS Talking Therapies for Anxiety and Depression (TTAD) exclusion criteria will be applied whereby people who become actively suicidal or present as a risk to or from others require a referral on to a more specialised, secondary care service. In addition, people who are experiencing symptoms of psychosis, hyper-mania, severe cognitive impairment, severe personality disorder or severe learning disability are also deemed as being unsuitable for a TTAD service. These people will be excluded from this study and referred on to more specialised services.
11. People who are already involved in or who have previously participated in our user research relating to this digital programme

Date of first enrolment
09/10/2023

Date of final enrolment
02/02/2024

Locations

Countries of recruitment
United Kingdom

England

Scotland

Study participating centre
Ieso Digital Health
Jeffrey Building
St. Johns Innovation Park
Cowley Road
Cambridge
United Kingdom
CB4 0DS

Sponsor information

Organisation
ieso Digital Health

Funder(s)

Funder type
Industry

Funder Name
ieso Digital Health

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		13/05/2025	23/05/2025	Yes	No
Basic results			23/05/2025	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes