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# Digital therapeutic tools in the treatment of mild to moderate depression and anxiety disorders

**Submission date**
21/04/2020

**Recruitment status**
Stopped

**Registration date**
12/05/2020

**Overall study status**
Stopped

**Last Edited**
13/02/2024

**Condition category**
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

## Plain English summary of protocol

Background and aims
Mental health disorders constitute an enormous healthcare concern, with one in four people estimated to be affected. Despite their commonness, in the UK, only 1 in 5 adults with a mental health disorder have access to psychological therapy like cognitive behavioural therapy (CBT). However, delivery of therapy by computers and mobile phones is helping to improve access. The current study aims to explore the use of computer/mobile-based therapy tools to enhance the effectiveness of CBT for the treatment of depression and anxiety disorders. Evidence suggests that other existing computerised approaches are already a recommended treatment option for those with depression and anxiety, but that acceptance of these so far has been poor. It is hoped that, ultimately, the tools we develop can not only be also more effective in reducing a person's symptoms, but also be further developed to the stage where digital therapy can be largely autonomous, with minimal or no oversight from a therapist. This would dramatically increase access therapies like CBT, both in developed countries, but particularly in areas of the world which have little or no access currently.

Who can participate?
Adult patients (aged over 18) who experience low mood or anxiety and have registered to receive IECBT with Ieso Digital Health

What does the study involve?
At the outset of the study, participants will be allocated at random to one of two groups. One group will receive digitally-enhanced therapy, and the other group will receive standard online therapy. Digitally enhanced group: If allocated to this group, participants will receive a course of online CBT enhanced by one of six possible digital tools. These tools, which have been newly developed at Ieso, are for use during the period in between therapy sessions. Standard group: If allocated to this group, participants will receive a standard course of CBT without the support of these digital tools; but they will be given standard non-interactive therapy tools, delivered through from the platform as pdf documents. CBT will be delivered by a qualified Psychological Wellbeing Practitioner (PWP) or a high-intensity CBT therapist (see http://www.babcp.com for further details of accreditation). CBT will be delivered individually, online, using synchronous

written communication (similar to instant messaging) via the web-based platform developed and provided by the company Ieso Digital Health (see www.iesohealth.com). All participants will receive an evidence-based treatment which will consist of weekly therapy appointments lasting 60 minutes, with the same therapist. Average treatment durations are seven treatments sessions over a period of two months, although patients who require more sessions (in order to gain benefit) will be provided with more sessions.

What are the possible benefits and risks of participating?
Participants for this study are invited to take part once they have already registered for IECBT and thus receive CBT treatment as appropriate regardless of whether they choose to participate in the study or not. Patients who respond well to treatment may experience improvement of their symptoms of depression or anxiety, whilst also gaining easy access to transcripts of therapy sessions and useful tools to help manage their own condition going forward. There will be no further benefit to patients other than the knowledge that they are helping to develop an understanding about methods of therapy that have the potential to help future patients.During the course of treatment it may be identified that there is significant risk of harm to a patient or other individual. Ieso Digital Health has procedures in place to safeguard patients. Patients at risk will be counselled by their therapists and signposted to specialist services as appropriate. Because of the online nature of the therapy and data storage to be used in this study, there may be concerns regarding potential breaches of confidential information. Ieso Digital Health, routinely treats patients through the NHS, and must comply with NHS information governance, data security and confidentiality legislation. The only time when patient information might be given out without the patient's consent would be if the patient is considered to be at risk to themselves or others, in which case the patients would be referred to appropriate services. Ieso Digital Health has infrastructure and cybersecurity technology in place that adheres to Cyber Essentials Plus and NHS information governance regulations. Anonymised patient data will be stored in a secure environment.

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

When is the study starting and how long is it expected to run for?
January 2020 to January 2024

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

Who is the main contact?
Dr Michael Ewbank
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# Contact information

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Scientific

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Public

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## Additional identifiers

### Clinical Trials Information System (CTIS)
Nil known

### Integrated Research Application System (IRAS)
275982

### ClinicalTrials.gov (NCT)
Nil known

### Protocol serial number
IRAS 275982

## Study information

### Scientific Title
Digitising paper-based tools in common use for the treatment of mild to moderate depression and anxiety disorders: an investigation of efficacy and acceptability

### Acronym
DTx4DepAnx

### Study objectives

In this study the researchers are interested in exploring whether digital tools are efficacious in reducing the severity of patients' depression and anxiety symptoms. The primary hypothesis to be tested in this study is that digital therapeutic tools, developed by Ieso Digital Health are more effective in improving outcomes in therapist-delivered internet-enabled CBT (IECBT) compared to the paper-based tools on which they are based.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Approved 18/06/2020, West of Scotland REC 5 (West of Scotland Research Ethics Service, Ward 11, Dykebar Hospital, Grahamston Road, Paisley, PA2 7DE, UK; +44 (0)141 314 0213; WoSREC5@ggc.scot.nhs.uk), REC ref: 20/WS/0076

## Study design
Single-centre interventional randomized controlled trial

## Primary study design
Interventional

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Common mental health disorders including depression and anxiety disorders (including generalized anxiety disorder, obsessive-compulsive disorder, phobias, post-traumatic stress disorder, and social anxiety)

## Interventions
This is an interventional study involving patients entering into treatment with Ieso Digital Health, a provider of Internet-enabled cognitive behavioural therapy (IECBT), where patients communicate with a qualified CBT therapist using a real-time text-based system. Patients entering into the IECBT service who fulfil eligibility criteria will be invited to participate in the research study.

Before commencing their course of IECBT treatment, consenting patients will be randomised to one of two groups by the patient services team.

The active group will be given digitally enhanced therapy. Patients allocated to this group will receive a course of human-delivered IECBT for mild to moderate depression or an anxiety disorder, enhanced by one of six possible digital therapeutic tools, delivered under the supervision of a clinician and used by the patient alone during the period in between therapy sessions.

The control group will be given standard therapy. Patients allocated to this group will receive a standard course of human-delivered IECBT for mild to moderate depression or an anxiety disorder, without the support of digital tools; but they will be given standard non-interactive therapy tools, delivered through from the platform as pdf documents.

Patients' clinical outcomes and response to therapy will be monitored. Therefore, patients will be involved in the study for the duration of a course of therapy, which is typically between 8 and 12 weeks.

Due to the nature of the study, it is not possible to blind therapists or patients to study group. Nevertheless, therapists will be especially trained in the study procedures and will aim to deliver the same standard of care across both groups.

### Intervention Type
Behavioural

### Primary outcome(s)
1. Symptoms of depression measured using the Patient Health Questionnaire (PHQ-9), completed by the participant at initial assessment and before every treatment session
2. Symptoms of anxiety measured using the Generalised Anxiety Disorder Questionnaire (GAD-7), completed by the participant at initial assessment and before every treatment session

### Key secondary outcome(s))
1. Drop-out rates measured by observing the number of patients who cease therapy either before clinical recovery or before being discharged by the therapist
2. Engagement rates measured by observing the number of patients who fail to attend at least two treatment sessions (after completing an initial assessment session)
3. Acceptability of digital tools measured by responses to an acceptability questionnaire devised at Ieso Digital Health (only to be given to the active group) which patients will complete once, after completion of the homework task
4. Treatment duration measured by the number of treatment sessions needed to reduce symptoms of anxiety and depression, measured from the first treatment session to the last

### Completion date
01/01/2024

### Reason abandoned (if study stopped)
Participant recruitment issue

## Eligibility

### Key inclusion criteria
Current participant inclusion criteria as of 11/02/2022:
Patients referred to the IECBT service for the treatment of depression or an anxiety disorder, who meet the eligibility criteria, will be invited to participate in the study. These criteria are as follows:
1. Patients must be over 18 years old at the time of recruitment and registered with a general practitioner in the geographical region where the service is commissioned (over 50 CCGs in the UK)
2. Patients must have a diagnosis of an anxiety disorder or depression in the mild to moderate range, i.e. GAD-7 score at assessment between 8 and 17 points, PHQ-9 scores at assessment below 14 points
3. Patients must be able and willing to sign a consent form prior to the study

Previous participant inclusion criteria:
Patients referred to the IECBT service for the treatment of depression or an anxiety disorder,

who meet the eligibility criteria, will be invited to participate in the study. These criteria are as follows:
1. Patients must be over 18 years old at the time of recruitment and registered with a general practitioner in the geographical region where the service is commissioned (over 50 CCGs in the UK)
2. Patients must have a diagnosis of an anxiety disorder or depression in the mild to moderate range, i.e. GAD-7 score at assessment between 8 and 14 points, PHQ-9 scores at assessment between 10 and 14 points, inclusive
3. Patients must be able and willing to sign a consent form prior to the study

## Participant type(s)
Patient

## Healthy volunteers allowed
No

## Age group
Adult

## Lower age limit
18 years

## Sex
All

## Total final enrolment
269

## Key exclusion criteria
It is important that this study only seeks to recruit patients who are suitable for a primary care psychological therapy intervention and that these patients are suitable for CBT. It is also essential that patients recruited to the study are able to access and use a computer or other Internet enabled device. Therefore, the following groups of patients will be excluded from the study:
1. Patients who are not suitable for CBT, this includes patients with a comorbid diagnosis (a diagnosis of multiple disorders) of psychotic or personality disorder, autism spectrum condition or intellectual disability
2. Patients who have started a course of psychotropic medication or changed medication within the last 3 months (currently being prescribed medication is not an exclusion criteria)
3. Patients at a significant risk of self-harm, as assessed by item 9 of the PHQ-9 questionnaire and ongoing assessment by their assigned clinician.
4. Patients undergoing any other psychological therapy
5. People who do not have access to an internet-enabled device or have access to internet connection
6. People who have a low level of literacy; those who cannot write or read emails or texts will be excluded from this study because they will be unable to utilise the intervention
7. People who are visually impaired and are unable to write on or read from a computer and do not have access to appropriate assistive technology for the visually impaired
8. People who are not suitable for CBT, e.g. patients with cognitive deficits from brain damage

or dementia, and patients who do not wish to engage with the process e.g. by completing homework
9. Patients who do not speak English

**Date of first enrolment**
03/12/2021

**Date of final enrolment**
01/09/2023

# Locations

**Countries of recruitment**
United Kingdom

England

**Study participating centre**
**Ieso Digital Health**
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# 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

Participant level data will not be made available as there is a privacy risk associated with sharing data at this level. It would be possible for individual participants to be identifiable by 'triangulation'. To mitigate this risk, it is the researchers' general policy to never share participant-level data for any of the patients that they treat. The data is stored securely within their own computing environment and can be made available to researchers who apply for it, pass the internal review process, and are able to visit their premises to access the data from terminals within their firewall.

## IPD sharing plan summary

Not expected to be made available

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| HRA research summary | | | 28/06/2023 | No | No |
| Participant information sheet | Participant information sheet version V1 | 11/11/2025 | 11/11/2025 | No | Yes |
| Protocol file | | | 18/05/2020 | No | No |
| Protocol file | version 1.3 | 23/02/2022 | 23/02/2022 | No | No |