Participant Information Sheet

You are invited to take part in a research study

TITLE OF THE STUDY: DIGITAL THERAPEUTIC TOOLS IN THE TREATMENT OF MILD TO MODERATE DEPRESSION AND ANXIETY DISORDERS.

ieso are running a study to explore the use of computer/mobile-based therapy tools to enhance the effectiveness of cognitive behavioural therapy (CBT) for the treatment of depression and anxiety disorders.

You are free to decide whether or not to take part in this study. Before you make your decision, it is important for you to understand why the research is being done, and what it will involve. You may want to talk to others about the study before taking part. If you decide to participate you may change your mind at any time and it will not affect any treatment/care you receive.

Overview of the study

The current study aims to explore the use of computer/mobile-based digital therapy tools to enhance the effectiveness of CBT for the treatment of depression and anxiety disorders. Computerised approaches are already a recommended treatment option for those with depression and anxiety, but evidence suggests 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 increase access therapies like CBT, both in developed countries, but particularly in areas of the world which have little or no access currently.

Anyone referred to ieso for the treatment of mild to moderate depression or anxiety is eligible to take part in the study. If you chose to take part, you 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.

Why am I being invited to participate in this study?

You are being invited to participate because you have self-referred or were referred to ieso for cognitive behavioural therapy (CBT). Anyone over the age of 18, who has experienced any symptoms of low mood or anxiety is invited to participate in this study. People who are not suitable for this study will still be offered online CBT. We are planning to have a total of 300 people take part in this study.

What will happen if I decide to take part in this study?

If you decide to take part in this study, you will need to provide us with your written consent to take part. A consent form will be provided to you for you to sign electronically.

At the outset of the study, you 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, you will receive a course of online CBT enhanced by up to six digital tools. These tools, which have been newly developed at ieso, are for use during the period in between therapy sessions. Your therapist will explain which tools to use but you are free to use as many as you like.

- Standard group: If allocated to this group, you will receive a standard course of online CBT, but you will be given standard non-interactive therapy tools, delivered through from the platform as pdf documents.

What are the benefits of taking part in this study?

Those receiving treatment (regardless of which group they are assigned to) may experience improvement of symptoms of depression and anxiety, whilst also gaining easy access to transcripts of therapy sessions and useful tools to help manage their own condition going forward. This will help us learn whether many more people with depression and anxiety could benefit from this way of delivering CBT. Further to this, if our results show that our digital tools can be as effective in providing support for CBT, this will provide a starting point for the continued development of autonomous digital therapy tools.

By taking part in this research, you will potentially be contributing to the development of tools that can not only be more effective in reducing a person's symptoms but may also be further developed to the stage where digital therapy can be mostly autonomous, with minimal oversight from a therapist. This would increase access to therapies like CBT, both in developed countries, but particularly in areas of the world which currently have little or no access. For the avoidance of doubt, all of your therapy will be delivered by one of our therapists or PWPs and not an automated agent.

What are the possible disadvantages and risks of taking part in this study?

We anticipate taking part in this study will pose no significant risk to your mental health. All study participants will receive a course of online CBT, delivered by a qualified clinician.

In the event where a high level of clinical risk (of harm to yourself or others) is identified, and the level of risk increases to such a point that requires a further level of support than

CBT can provide, then appropriate actions will be taken to ensure a referral onwards is facilitated for a participant to receive the most suitable level of care.

Who can I talk to about this study?

This study is funded by ieso. If you have any questions about this study, please contact the Study Team: dtx-trial-support@iesohealth.com

What will happen with the results of this study?

At the end of the study, results will be analysed and we will produce a report with our findings. These findings may be published in academic and scientific peer-reviewed journals. Your name or directly identifiable data will never be included in any publication.

If the study results show that that our digital tools can be as effective in providing support for CBT as those that are used currently, we may explore the opportunity to roll out this service to a larger number of patients.

How will my information be kept confidential?

All study specific data and data duplicated for our research database will be stored separately from medical case files, be identified by a unique identification number and not contain directly identifiable information. These data will be stored confidentially and securely within the Microsoft Azure cloud environment, in the UK. ieso follows nationally and internationally recognised standards for information security (Cyber Essentials Plus and ISO 27001, https://www.iesohealth.com/en-gb/legal/iso-certificates), and completes the NHS Data Security and Protection Toolkit annually.

In all study-specific data and documents, other than the signed consent, the patients will be identified by a unique study-specific number and/or code, not by name. The research team will have access to information such as patient age, gender and symptom scores but not to patients' names and any other directly identifying details will not be included in any study data electronic files. However, to facilitate patient invitation and enrolment in the study, one member of the research team must be given temporary access to the patient's case file, which includes directly identifiable information such as their name and email address. This member of the research team will only access the messaging section and email address to send information about the trial, and the questionnaire section to retrieve patient consent. Once a therapist has been allocated to the patient, the researcher will only access the patient's case file if technical support is requested by the patient or therapist. In this situation, the researcher may need to access the case file to retrieve the unique study-specific number. This member of the research team has received specialist training on how to handle patient data and adheres to strict privacy policies.

As part of the research project, it is also likely that a member of the research team will need to access transcripts from homework tasks as well as session transcripts (e.g. to evaluate how the homework task is performed). Where this is required the transcripts will be extracted removing the names of the patient and therapist and in a way that disconnects them from the rest of the patient file. Your personal information is strictly confidential and will not be published, shared or discussed with anyone for the purposes of this study. All research data including personal data held separately from your patient file will be held for a minimum of 20 years in accordance with Medical Research Council guidance. Personally identifiable data collected as part of routine practice (standard of care) shall be retained for reference by you during your lifetime as explained in our therapy site privacy notices https://www.iesohealth.com/en-gb/therapy/legal/privacy.

Informing your GP

Your treatment is confidential and your GP will not be informed that you are taking part in the trial. However, during registration you are asked whether or not you are happy for your therapist to share information with your GP, and if you consent we will make them aware of your entering and leaving treatment, with related questionnaire scores. Outside of this, there are two main reasons when we would be required to contact your GP. One would be if the therapist assesses that the participant would be at risk of harm to themselves or pose a risk to others. The other reason would be if a participant became distressed during the course of treatment and the therapist assessed that there was a need for a referral to a more specialist service. In these rare instances the therapist would at first seek to gain consent from the participant to share information with the GP and the specialist service. Decisions to break confidentiality are rare, however when they do happen we have robust processes to ensure that the decision to share information follows accepted best practice/ regulations and is in the participants best interest. This decision will not be made by the therapist alone but will be made by the clinical team and overseen by the Senior Clinician.

What will happen if I don't want to carry on with the study?

You can change your mind about participating in this study at any time. If you no longer wish to participate in this study please contact the Study Team: dtx-trial-support@iesohealth.com or by phone on 0800 074 5560.

If you change your mind your data will be removed from this study, up to and until the point where removing the data would seriously impair the research or render it impossible. However, your therapy case file will be retained as a resource that you can return to at any time you wish. This can help you remember coping strategies, techniques or processes that you learnt in therapy. We retain your clinical record by reference to the IGA Records Management Code of Practice for Health and Social Care guidance for managing health records https://digital.nhs.uk/information-governance-alliance and to support our legal obligations to be accountable for your care. The Code is based on current legal

requirements and professional best practice. Our data retention practices are reviewed at least annually in conjunction with industry standards and best practice.

Who has reviewed this study?

All research studies are reviewed by an independent group of people, called a Research Ethics Committee, to protect your safety, rights, well-being and dignity. This study has been reviewed and has been given a favourable opinion.

How have patients and the public been involved in this study?

Study progress will be overseen and monitored by a study steering committee and patient panel. The steering committee will be formed by representatives of the sponsor, who will ensure the study is progressing according to plan and following relevant regulations and operating procedures. In addition to the steering committee, a patient panel was be set up for this study, composed of former internet enabled-CBT patients. These former patients will provide insight from a patient perspective and help steer the project.

What if something goes wrong?

If you have any complaints about this study, you can contact the Chief Investigator Michael Ewbank at m.ewbank@iesohealth.com or by phone on 0800 074 5560.

If you wish to make a formal complaint, please submit to:

Email address: info@iesohealth.com

Postal address: ieso, Jeffreys Building, St Johns Innovation Park, Cowley Road, Cambridge, CB4 1DS

If you are unhappy with the outcome of your complaint, you can contact the Independent Sector Complaints Adjudication Service (ISCAS):

70 Fleet Street London

EC4Y 1EU

Tel: 020 7536 6091

Email: info@iscas.org.uk