

Participant Information Sheet

You are invited to take part in a research study

Before you decide whether or not you would like to take part in this study, it is important that you have a good understanding of why the research is being done, and what it will involve.

Please read the following information carefully and take your time to decide. You may want to talk to others about the study before taking part. And, it's important to understand that if you do decide to take part, you can change your mind and withdraw without consequence.

About us: ieso is a company that provides mental health services to the NHS across England and Scotland. We are funding and running this study to explore the use of computer/mobile-based tools to provide information to people with mental health concerns.

Speak to us: If you have any questions about this study you can contact a member of the research team at research.participant@iesohealth.com, or on 0800 074 5560.

Overview of the study

Title of Project: Investigating design, usability, and acceptability of conversation in a digital tool for common mental health concerns

This study aims to explore the use of computer/mobile-based digital therapy tools to provide information to people with mental health concerns. Computerised approaches are already used elsewhere, but evidence suggests that many people have not found these engaging. We are trialling our tools with members of the general public to gain feedback about the design and experience of using them. We will use this feedback to improve the digital tools so we can offer them to people concerned about their mental health. It is important to understand that this study is designed to gain feedback about the usability and acceptability of these tools: it does not provide a course of medical treatment.

Who can take part in this study?

This study is open to anyone over the age of 18 who:

- has no recent (within the last 2 years) diagnosis of a mental health condition,
- has not previously attempted suicide,
- is not currently prescribed medication for symptoms of a mental health condition
- is not undergoing-, or on a waiting list for-, a psychological therapy.

What happens 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. After you

have given your consent, you will be asked to test up to two of our digital tools. This will involve interacting with a computer or a person by typing into a chat window on a mobile phone app or a web browser. In most cases you will be interacting with a computer, however sometimes you may be interacting with a human who will be following a pre-defined script.

IMPORTANT: The written exchange between you and the chatbot will NOT be reviewed or monitored by a clinician, regardless of whether you are interacting with a computer or a person. However, the research team will have full access to this written exchange for research and development purposes only. Therefore, you should not share anything that you feel you would not want another person to read. The written exchange may also be used to train machine learning models to help us to learn how to make our tools more effective. These data will not be linked to any other data or contain any directly identifiable data, so that the research team will not know who the written exchange belongs to.

Sometimes we may ask you to use the tools by yourself, or we may arrange a time to set up a live online session with you, so we can ask you questions while you use the tool in order to understand what you are thinking, feeling and doing as you use it. In these cases, a screen recording and audio transcription of the session will be collected to help us analyse how you interacted with the tool. When you've finished interacting with the digital tools, we will ask you a series of questions and/or ask you to complete feedback questionnaires to assess your views on the design and experience of using the tools. You will not need to come into our office in person to take part as we can gather this information remotely.

Once you've submitted your feedback, we will provide you with a full debrief detailing the purpose of the research. Your involvement in the study ends after you have been debriefed (and had any/all questions answered satisfactorily) or after you request to withdraw. Depending on the element/tool you are using, the test should take around 90 minutes to complete in most cases, with a maximum duration of two hours.

Will I be paid for taking part in this study?

For your participation, you will be rewarded a payment of £10 per hour (pro rata) in the form of a voucher. This will be credited to you after your participation in the trial has ended, as a thank you for your contribution.

What are the benefits of taking part in this study?

By taking part in this research, you will be contributing to the development of tools that we aim to be effective for individuals with concerns about their mental health.

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

We do not anticipate that taking part in this study will pose a significant risk to you. However, it is important to note that the digital tools will ask questions about your thoughts and feelings. You are not under any obligation to answer these based on your own personal experience, especially if that might lead to making you feel distressed.

ieso does not provide a crisis service and your interaction with the digital tools will not be monitored or reviewed by a clinician. It is important to know that this study does not provide a treatment for any mental health problems.

If you are struggling with your mental health, please contact the below support services and if needed read through the 'Managing suicidal thoughts' leaflet provided:

- your GP / doctor
- the Samaritans (call: 116 123)
- NHS 111 (call: 111)
- or the emergency services (call: 999).

What data will be collected as part of this study?

If you decide to take part in this study you will be asked to test up to two of our digital tools. Your written exchanges when interacting with the tools will be recorded. Sometimes we may ask you to set up an online live session so we can ask you questions while you use the tools. In this case, screen recordings and an audio transcription of the session will be collected to help us analyse how you interacted with the tool. When you've finished interacting with the digital tools, we will ask you to complete a questionnaire to assess your views on the design and experience of using the tools.

How will my information be kept confidential?

We take great care to protect your information to ensure data security, privacy, and confidentiality. In all study-specific data and documents, other than the signed consent, your data will be identified by a unique study-specific number and/or code, *not* by your name. The research team will have access to information such as your age, but not to your name or any other directly identifying details. These personal details will not be included in any study data electronic files. Your personal information is strictly confidential and will not be published, shared or discussed with anyone. Audio recordings (voice only) of you interacting with the digital tool will be securely kept in a password protected directory separate from any personal information, and only researchers analysing your responses during the interaction will have access to these.

Your 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 ISO 27001, <https://www.iesogroup.com/ieso-certificates>).

As researchers, we have a responsibility to protect participants and others from risks to physical and/or psychological distress. Confidentiality of any sensitive information that is disclosed or witnessed during a research session will be broken only if the researcher believes there is imminent danger to you or someone else, or there is a safeguarding concern. In these extremely rare situations, the researcher will discuss all courses of action with you first before breaking confidentiality.

What will happen to my data at the end of the study?

Any screen recordings or transcripts of interviews will be deleted as soon as analysis is complete or within six months of collection at the latest. All other research data will be held for a minimum of 20 years: <https://www.iesogroup.com/trustcentre/privacy-policy>

What will happen with the results of this study?

At the end of the study, the data 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. The feedback we collect as part of this study will help inform us about what improvements we can make in order to design the most effective digital tools for mental health concerns.

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

You can change your mind about participating in this study. If you wish to withdraw from this study please contact the Study Team: research.participant@iesohealth.com or phone 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. For example, if the findings of this research are already published, it may not be possible to delete the data or remove it from the analyses.

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.

What if I have any concerns?

If you have any concerns about this study you can contact ieso's Research Governance Board at RGB@iesohealth.com, or by phone on 0800 074 5560.

If you wish to make a formal complaint, please submit to RGB@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