ieso

Do you have worries or concerns about *anxiety*?

Would you like to participate in our user research study?

‘Formative usability evaluation of a digital 6-week wellness programme for people with mental health concerns’

conducted by ieso

Let us introduce ourselves

We, ieso, are a company that provides mental health services to the NHS across England and Scotland. We are funding and running this study to test the usability and experience of an end-to-end 6-week wellness programme that involves using a digital app.

We invite you to take part in a research study

Before you decide whether to take part in this study, it is important to understand why we are conducting this research, and what is involved. This leaflet will provide you with this information.

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. If you decide to take part, you can change your mind and stop participating at any time with no consequence.

! If anything is not clear on this information sheet or you have questions about the study please contact the research team at: **clinicalstudies@iesohealth.com**

Overview

This study tests an entire 6-week programme using a digital tool (an app), which is still in development, that provides information about mental health. We know that mental health apps are being widely used, but evidence shows that many people do not find these usable or engaging. In this study, we are testing our new program with members of the public to understand the end-to-end experience over the course of 6-weeks. This will help us improve the developing programme using the tool, so in future we can offer it to people concerned about their mental health. Importantly, this study is only designed to gain understanding about the use and experience of the end-to-end programme.

This study does not provide a course of medical treatment.

Who can take part in this *study?*

You can take part in this study if:

- You are over 18 years of age and located in the UK or the USA.
- You speak and are literate in the English Language (this app is still in development and only available in English).
- You have access to an iPhone with a reliable internet connection.
- You have the capacity to decide for yourself whether to participate in this study.
- You self-identify as having worries or concerns about anxiety.
- You will be asked about personal experiences during your use of the app. Please consider whether you are happy to go ahead on this basis or if this may be distressing and you would prefer not to take part.
- **You have not** previously participated in a study with ieso using the digital tool.
- **You do not** have an impairment that would prevent you from being able to use a phone app (this app is still in development and has not yet undergone accessibility evaluation).
- **You are not** currently receiving or waiting for treatment, including psychological therapy or medication, for symptoms of a mental health condition, (for example, anxiety or depression).
- Excluding Generalised Anxiety Disorder or Depression, **you have never** been diagnosed with a mental health condition (including substance misuse).

What happens if I decide to take part in this *study*?

You will be able to sign up for the study via a study management website called 'userinterviews.com'.

Here you will provide your contact details, fill out a screening questionnaire and we will ask you to sign a consent form. It is important that we obtain your written consent before you participate. A sample form is shown on the last page.

After you sign the form, you will be invited to schedule an initial introductory phone call that will begin your 6-week programme. **This call is necessary for you to take part in the study.** The whole study is remote: you do not need to travel to take part.

If you have any questions about the study, please ask the research team before you sign the consent form. You can ask more questions during the testing session, and you can change your mind and stop taking part in the study at any time without giving a reason.

What happens in this *study*?

You will interact with a digital mobile phone app, which is under development, for 6 weeks. Each week has up to 3 sessions where you will have a typed, text-based conversation with a chatbot. You will be typing into a chat window on a mobile phone app (like a WhatsApp conversation) and navigating through the app and its various features.

At the start and end of the 6-week programme you will be required to complete some additional questionnaires. The activities each week will involve completing questionnaire measures that will ask you about your mood, or experience of the app, and interacting with the digital app via typed conversations with a chatbot. These conversations will teach you about worry and anxiety in any accessible and personalised way.

More about the *sessions*

A researcher will not be present during this study or while you are interacting with the app.

Members of the research team will be in contact with you between sessions through email and/or phone calls for reminders and routine check-ins.

When you finish using the app, we will ask you to fill out questionnaires to get your feedback on the experience of using the app.

Something important for you to note:
The written exchange between you and the app will NOT be reviewed or monitored by a clinician. However, our researchers will be able to read the text as part of their research and development work. **Do not share anything that you do not want another person to read.** The written exchange will also be used to train machine learning models to help make conversations more engaging. These data will not be linked to any other data about you or contain any directly identifiable information. When researchers analyse the data, they will not know who wrote the text.

How *long* does it take?

We estimate that this study will take **13 hours over 6-weeks**, and you will need to spend **up to 2-hours per week** to complete all of the activities.

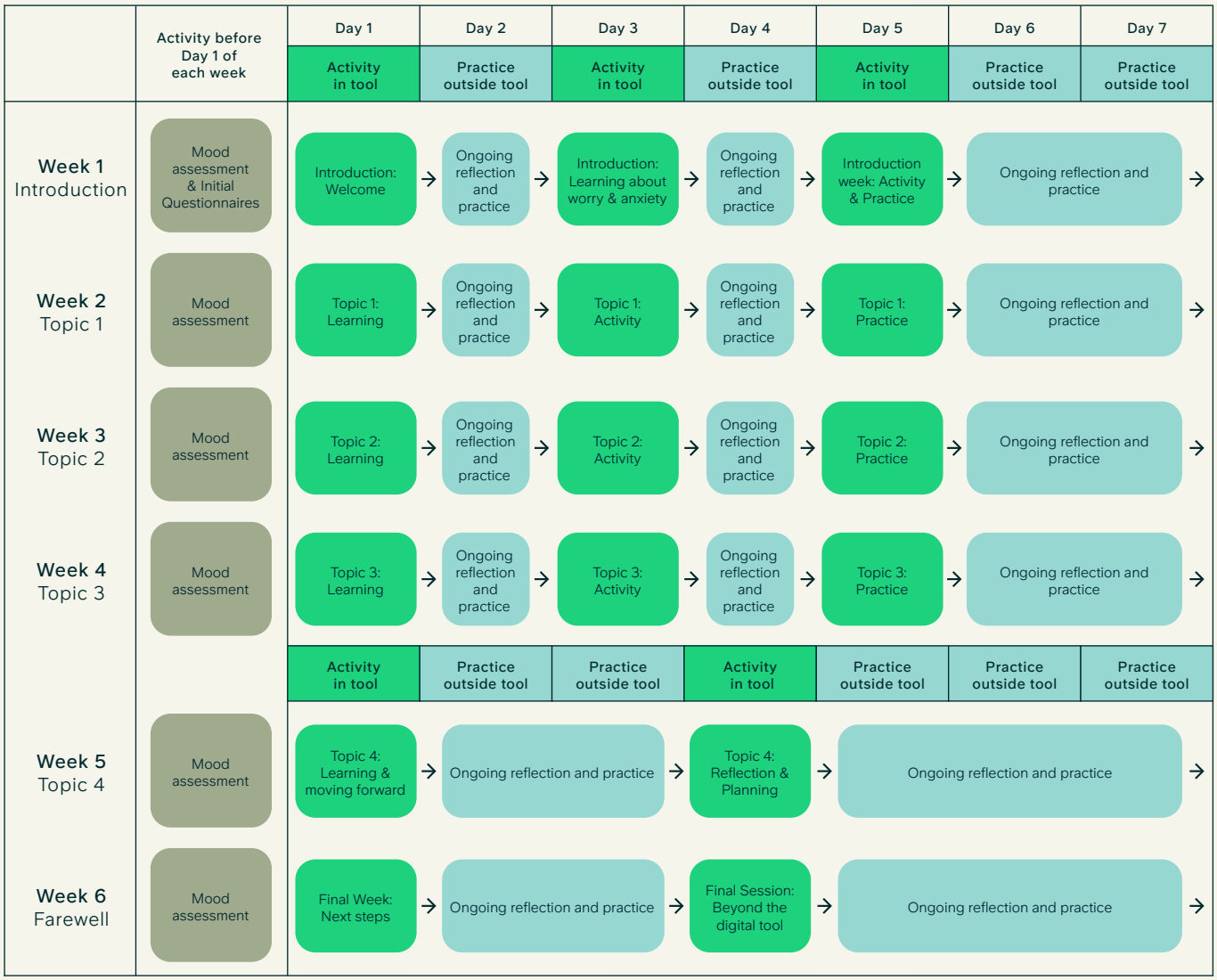
Individual activities in the app are provided at pre-defined timings, that are “unlocked”, and this is based on completion of the previous session. We ask that you complete all of the activities on time. Because you will be doing this in your own time, it is possible to fall behind schedule. You can take up to a maximum of 9 weeks, but after this you will not be allowed to complete any sessions that have not yet been unlocked.

It is important to note that because of the pre-defined schedule and the allotted maximum number of weeks for the programme, if you fall too far behind, then it will be impossible to catch-up and complete all sessions.

To fully adhere to this study, complete all sessions, and be paid in full you must adhere to the predefined schedule provided on the next page.

At the end of the programme, we will send you another information sheet to debrief you and ask if you have any more questions about the study. Your involvement in the study will end after you have been debriefed or after you stop participating.

Schedule of *participation*



Will I be paid for taking part in this study?

You will be given a payment per week in the form of Amazon vouchers as a thank you for your contribution with a total compensation of £260. The payment will vary depending on the number of activities required per week and the rate is £20 per hour.

Payments are outlined on a weekly basis, however **payment will be dependent the completion of that week's activities**. For example, the payment for week 1 will only be given once all of the activities for week 1 have been completed even if that takes slightly longer than 1 week.

	Payment (£) in the form of Amazon vouchers
Week 1	70
Week 2	30
Week 3	30
Week 4	30
Week 5	30
Week 6	70
TOTAL	**260**

What are the possible disadvantages to 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 understand that the app that is used in this 6-week protocol will ask questions about your thoughts and feelings, and you will be asked to complete questionnaires that ask about your mood.

If you do not think you will be able to keep yourself safe while engaging in this study then please do not take part.

What are the benefits of taking part in this study?

Your participation will help us develop tools that help people with mental health concerns, such as anxiety or depression.

Our mission is improve access to mental healthcare for as many people as possible.

If you are struggling with your mental health, please use the below *resources*

SUPPORT HELPLINES

- ✓ Ring or text a **friend or family** member
- ✓ Talk to your **GP**
- ✓ Contact **Samaritans** on 116 123 - they offer a listening service
- ✓ **SHOUT** offers text support any time, text SHOUT to 85258
- ✓ Telephone **NHS 111** by dialling 111
- ✓ **If you need urgent help, call 999**

USEFUL WEBSITES

- **MIND get help resources**
  https://www.mind.org.uk/need-urgent-help/using-this-tool/
- **Mental Health Foundation support**
  https://www.mentalhealth.org.uk/explore-mental-health/get-help
- **Royal College of Psychiatrists Information about mental health**
  https://www.rcpsych.ac.uk/mental-health

! ieso does not provide a crisis service. A clinician will not monitor or review your interaction with the app. This study does not provide a treatment for any mental health problems.

What data will we collect as part of this study?

- Demographic information: age, gender, and education. These will be linked to your other research data in order to understand how engagement and usability of our app might be different based on these demographic factors. This will help us build an app that works equally well for everyone.
- Your written exchanges when interacting with our app.
- Passive metrics about usage of the app. For example, measures of when and how long you are in the app, and what features are used.
- Questionnaires asking about mood, thoughts, feels, and symptoms of anxiety and depression.
- Questionnaires about the usability, engagement and experience of the programme and app.
- Your verbal feedback and comments during check-in calls about the digital app, 6-week programme, and adherence will be noted, but not audio-recorded.
- Some optional demographic questions for diversity monitoring. These will not be linked to you or any other data you provide. We collect comprehensive demographic information to summarise who has provided feedback on our tool, and to make sure we are recruiting diverse participants so that our app is inclusive.

How will we use *information* about you?

We take great care to protect your information to keep your data safe and secure. We comply with all UK data protection legislation and have provided you with our privacy notices. The only directly identifiable information we will obtain about you is your:

- Name;
- Email address;
- Phone number;
- Postcode (diversity monitoring questionnaire only; we will use this to produce a summary measure about where you live and delete your postcode from our records as soon as we have done this - we will not link this to your other data collected for this study).

Only a small group of our employees running this study will have access to this information. Any other ieso researchers that use your data will only see a unique code that does not provide identifiable information. **Your personal information is strictly confidential and will not be published, shared, or discussed with anyone. We will store your conversations with the digital tool securely in a password protected directory separate from any personal information.**

In line with current best-practice recommendations, we will hold all other research data for up to 20 years (outlined in our privacy notice).

What are my data protection *rights*?

We have assessed all of your information rights in relation to this research and have made some restrictions based on when these rights would no longer be possible.

If you wish to withdraw your data, you are free to do so until a data report is generated, which may occur any time after participation or up to 2 weeks following the end of the study, whichever occurs first. Passive measures of app usage will be monitored in real-time, and so it is not feasible to withdraw these data.

If you wish to withdraw your data speak to the Research Team:
clinicalstudies@iesohealth.com

Withdrawing your data is different from stopping participation in the study, details of which can be found below in the section "What happens if I don't want to carry on with the study?"

We will store your data 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).

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

Your participation in this study is voluntary.

It is important to discuss any concerns you may have with a member of the Research Team before you agree to participate.

You can stop participating in this study at any time and without giving a reason. If you do stop taking part, a standardised email will be sent to ask for any feedback about your participation in the study, but it is not mandatory for you to complete this.

Stopping participation in the study is different from withdrawing data that has already been collected. Due to the de-personalised and on-going way in which we report data, the time to withdraw data is limited and these limitations are specified above in the section "What are my data protection rights?".

What will happen with the results of this study?

We will analyse the data and 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 de-personalised data and feedback that we collect as part of this study will help us improve the 6-week programme and our app.

I have more questions... What should I do?

If you would like to ask any questions about the study or find out more information, please contact the Research Team:
clinicalstudies@iesohealth.com

Participant *confidentiality*

Our researchers have a responsibility to protect participants and others from risks to physical and/or psychological distress. If any sensitive information is disclosed or witnessed during a research session and the researcher believes there is imminent danger to you or someone else, then confidentiality will be broken. In these extremely rare situations, the researcher will discuss all courses of action with you.

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

Who has reviewed this study?

All ieso research studies are reviewed to protect your safety, rights, well-being, and dignity by our Research Governance Board and the ieso Ethics Panel.

Does this study have any commercial benefit?

This study may have commercial benefit for ieso. Participants will not benefit financially in any way if commercialization of any research findings are successful.

! This is the end of the participant information sheet. From us at ieso, thank you for taking the time to read it and to consider taking part in our study.

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Sample *Consent* Form

Title of study: Formative usability evaluation of a digital 6-week wellness programme for people with mental health concerns

Names of Lead Investigators:
Sylwia Dzula, Design Researcher, ieso
Elisa Cooper, PhD, Senior Engagement Scientist, ieso

I confirm that I have read the information sheet V1.1 dated 23/12/2022 for this study, have had the opportunity to consider the information, ask questions, and have had these answered satisfactorily.

I understand that my participation is voluntary and that I am free to stop taking part at any time without giving any reason, without my legal rights being affected, and I understand that this is separate to data withdrawal.

I understand that withdrawing my data can only occur within a limited time-window due to the way data is reported: Specifically, I understand that I am are free to withdraw my data until a data report has been generated or up to 2 weeks following the end of study, whichever occurs first. I understand that passive usage metrics will be monitored in real-time, therefore it will not be feasible to withdraw these data.

I understand that this study involves the use of digital tools, conversational agents and questionnaires that address common concerns about mental health.

I understand that I will be asked about personal experiences during my use of the app. I have considered this and confirm that I am happy to take part in this study.

I understand that taking part in this study by using these tools is not intended to provide me with medical treatment.

I understand that typed digital conversations will be stored for research purposes.

I understand the payment schedule that has been outlined in the information sheet, and that I will receive payment in the form of vouchers based upon the completion of all activities assigned in a given week, and that at the end of this programme, adherence to the protocol means these payments will add up to £260 in Amazon Vouchers.

I agree to take part in the above study.

Signature
A. N. Sample

Date
23 December 2022

Name of person seeking consent
Researcher

Date
23 December 2022