

## Participant information sheet for adults in research studies

UCL Research Ethics Committee Approval ID Number: 1338/010

Title of Study: **The effectiveness of a smartphone application in reducing symptoms of depression and anxiety in a university student population**

Department: UCL Division of Psychiatry

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### Invitation to participate

You have been invited to participate in this research project. You should only participate if you want to; choosing not to take part will not disadvantage you in any way. Before you decide whether you want to take part, it is important for you to read the following information carefully and discuss it with others if you wish. Please ask one of the researchers if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

### What is the project's purpose?

We are interested in how a smartphone application might be used to improve mental wellbeing and reduce symptoms of depression and anxiety. The My Online Therapy self-care smartphone app is designed to help mental health difficulties and wellbeing by using techniques that are known to work when used in a face-to-face therapy session. We believe the application will enable the person to reduce negative symptoms and improve mental wellbeing themselves without direct contact with a therapist. If this is true, individuals who are suffering with feelings of depression and anxiety would be able to recover without needing to go through their general practitioner (GP) and without needing to wait for treatment or pay to receive it privately. The primary aim of the study is to understand the effectiveness of therapy apps and should not be seen as a direct endorsement of the My Online Therapy self-care application by UCL.

### Why have I been chosen?

We would like to invite any students aged over 18 who are experiencing feelings of depression and/or anxiety to participate in the study. To participate, you will need to own either an iPhone or Android phone. Exclusion criteria for this study include a current psychiatric diagnosis, current use of psychiatric medication, any past or current major medical condition, or any previous bad experiences with psychological therapy.

### Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep (and be asked to sign a consent form). After completing the study, you will be able to withdraw your data up to 4 weeks after the end of participation. If you decide to take part you are still free to withdraw at any time and without giving a reason. If you decide to withdraw you will be asked what you wish to happen to the data you have provided up to that point.

### What will happen if you take part?

If you agree to take part in this study you will be asked to fill out a brief questionnaire involving some personal information such as your age and gender. We will also ask you to complete questionnaires that will tell us about your mental wellbeing and the symptoms of depression and anxiety you are experiencing currently. You will then be randomised to one of two groups in which you will be given access to the application immediately or be put on a waiting list. Those who download the application immediately will be asked to use it at least once per week for 8-weeks, and answer questions about their mental wellbeing and feelings of anxiety and depression once a week. A group of those on the waiting list will also be asked to answer these questions each week. If you are in either of these groups, at the end of the 8 weeks we will ask you to complete similar questionnaires to record your mental wellbeing and feelings.

Depending on personal usage, we estimate the application will take approximately 3-4 hours to complete in total, during the 8 weeks of the trial. We also estimate that the questionnaires will take 15-20 minutes to complete each week. We expect that every week you will need about 30 minutes in total to participate in the trial. However, there is no need to spend all this time in one sitting. All of this can be done in your own time, alone, wherever you prefer, as long as you have access to the internet and the device needed for the application.

### **Possible disadvantages and risks of taking part**

You should be aware that using the app may not improve your mental wellbeing or reduce your feelings of depression and/or anxiety. You should carefully consider this when deciding whether to take part. If at any time during the experiment you are experiencing any negative effects or you feel your symptoms are getting worse, you can discuss this with a clinician (Dr Joseph Hayes). If you would rather not speak to one of the research team, we would recommend directly contacting UCL Student Psychological and Counselling services (<https://www.ucl.ac.uk/students/support-and-wellbeing/student-psychological-and-counselling-services>). If you are experiencing distress and need urgent support, you can call the Samaritans (tel: 116 123) to speak to someone any time, or call Nightline overnight – a listening service run by students for students (+44 (0)207 631 0101).

### **What are the possible benefits from taking part?**

As the app is designed and based on therapeutic approaches, there is a potential immediate benefit of reducing any feelings of depression and/or anxiety. It is also hoped that this work will inform our understanding in the use of digital interventions in the treatment of mental health issues.

### **What if something goes wrong?**

If you have further questions or concerns regarding participation in this research study you may contact one of the researchers detailed on this form. If you are unhappy with how you have been treated or if you have been injured whilst participating in this study please contact the Principal Investigator (James Bisby). If you feel your complaint has not been handled in a satisfactory way (by a researcher or Principal Investigator), you should contact the Chair of the UCL Ethics Committee ([ethics@ucl.ac.uk](mailto:ethics@ucl.ac.uk)).

### **Will my taking part in the project be kept confidential?**

All the information that we collect during the research study will be kept strictly confidential. All data collected will be pseudonymised and stored on UCL password protected computers. You will not be able to be identified in any ensuing reports or publications.

### **Limits of confidentiality**

Confidentiality will be respected unless there are compelling and legitimate reasons for this to be breached. If this were the case, we would inform you of any decisions that might limit your confidentiality.

### **What will happen to the data collected for this study?**

The data will be used only for the purpose of informing the research questions in this study and will only be accessed by the research team. The results may be published in scientific journals, but you will in no way be identifiable. Findings from the study will be disseminated via academic journals, through the My Online Therapy website and through academic conferences. The study will also be written up by Olivia McGowan and Ernesta Motouzaite as their dissertation research project for completion of an MSc in Clinical Mental Health Sciences awarded by the UCL Division of Psychiatry. We would be happy to send you a copy of any publications arising from the research or a layperson summary of the main findings. The data will be retained for 10 years and may be accessed in the future by the research team for comparison with future data. Dr James Bisby is custodian of the data.

### **Data Protection Privacy Notice**

The data controller for this study will be University College London (UCL). The UCL Data Protection Office provides oversight of UCL activities involving the processing of personal data, and can be contacted at [data-protection@ucl.ac.uk](mailto:data-protection@ucl.ac.uk). This 'local' privacy notice sets out the information that applies to this particular study. Further information on how UCL uses participant information can be found in our 'general' privacy notice: <https://www.ucl.ac.uk/legal-services/privacy/ucl-general-research-participant-privacy-notice>

The information that is required to be provided to participants under data protection legislation (GDPR and DPA 2018) is provided across both the 'local' and 'general' privacy notices.

The categories of personal data used will be as follows:

- Name (consent form only)
- Age
- Gender
- Email address (only during the period of the trial)

The lawful basis that would be used to process your *personal data* will be performance of a task in the public interest. The lawful basis used to process *special category personal data* will be for scientific and historical research or statistical purposes. Your personal data will be processed as long as it is required for the research project. If we are able to anonymise or pseudonymise the personal data you provide we will do this, and will endeavour to minimise the processing of personal data wherever possible. If you are concerned about how your personal data is being processed, please contact UCL in the first instance at [data-protection@ucl.ac.uk](mailto:data-protection@ucl.ac.uk).

**Who is organising and funding the research?**

This research project is funded by University College London.

**Contact for further information**

Please feel free to contact Dr James Bisby, Olivia McGowan, or Ernesta Motouzaite (emails at the top of this form) at UCL Division of Psychiatry, Maple House, 149 Tottenham Court, London, W1T 7NF

**You will be provided with a copy of this information sheet.**

**Thank you for reading this information sheet and for considering taking part in this research study. research study.**