

Mood Awareness Psychotherapy Support (MAPS) Participant Information Sheet

Key Points

We would like to invite you to participate in this research study. This first page gives you a 'key points' summary about the aims of the study and what your participation would involve. The pages that follow give you more detailed information.

- We are carrying out this study to try and develop more effective and accessible treatments for people who are experiencing symptoms of depression and anxiety.
- This study will be testing an adapted version of an internet-based treatment package developed and tested in Sweden and the UK.
- The treatment is a self-guided programme called Internet-Based Psychodynamic Therapy (iPDT), containing 8 'chapters' available weekly, with text, videos and short worksheets that you access through the treatment website. You will also have your own Therapeutic Support Worker who will send you a message each week through the website, and you can respond by message.
- To check whether you are eligible to participate we will ask you to fill in some questionnaires. This will help us all be sure that this treatment is right for you.
- You get as much out of the programme as you put into it! It is important that you understand that participating in a programme like this requires time and commitment. Even though you will receive support from your Therapeutic Support Worker, it is your responsibility to read the chapters and complete the exercises.
- As part of the study we will ask you to fill in questionnaires weekly, once the study is finished, and after 3 months of completion.
- We may also invite you to participate in a brief interview to explore your experiences, once you have finished the programme.
- Your participation is completely voluntary, and you can exit the programme and the study whenever you want.
- This study is being carried out by researchers at UCL. All your data will be kept confidential and securely stored. Only the research team, and the website technicians, will have access to it. No one else will know that you are taking part. Taking part will not impact your studies in any way.

Now here is the more detailed explanation – it isn't just 'the fine print' – it contains some important information and if you read it you'll get a much clearer understanding of the study and what taking part would involve.

UCL Ethics Project ID number: 26049/001

We would like to invite you to participate in this research project. Before you decide whether you want to take part, it is important for you to understand why the research is being done and what participation will involve. You can ask any questions you wish before deciding whether to take part.

What is the purpose of this project?

Research suggests that internet-based treatment can provide good and long-lasting effects for many people experiencing mental health difficulties. This study will be testing an adapted version of a relatively new treatment package, which has been developed and tested in Sweden and the UK. The treatment we use in this research study is called iPDT, which stands for Internet-Based Psychotherapy. We are carrying out this study to try and develop more accessible treatments for people who are experiencing symptoms of low mood and anxiety.

Is this suitable for me?

This study is for UCL students who are experiencing symptoms of low mood and anxiety. You do not need a diagnosis of anxiety or depression to participate. To check if the study is suitable for you, you will first fill out some questionnaires to ensure that you meet the study criteria (see below).

The format of this treatment is not suitable for everyone. Internet-administered treatment is not suitable for people with complex needs who might need more intensive support or who might be at greater risk of harming themselves. This is not a suitable treatment for you if you suffer from bipolar disorder, personality disorder, PTSD, or psychosis. It is also not a suitable treatment for you if you have previously tried to end your life, or if you have started new medication less than three months ago or use medication irregularly. If you have a learning difficulty or intellectual disability, this treatment may not be best for you, as it involves quite a lot of reading and some writing. If those descriptions fit with your situation, then we recommend that you book an appointment with your GP to discuss a possible referral to a specialist service, or if the situation is urgent, go directly to your local A&E department.

What is internet-based psychotherapy?

The treatment consists of 8 "chapters" that you will get access to weekly, with text, video and short exercises that you read on your smartphone, tablet or computer. The treatment lasts for 10 weeks so you have a little extra time if needed.

If you are allocated to the treatment starting in January then you will have your own Therapeutic Support Worker who provides feedback and who sends you a message each week, through the treatment website. You can also send messages to your Therapeutic Support Worker (TSW).

If you are allocated to the treatment starting in April you will be able to request a message from a Therapeutic Support Worker each week – you do this by sending a message, and a TSW will reply. So, you initiate the conversation; if you don't send the TSW a message, then they won't contact you.

You can choose the name that TSWs use to refer to you. All therapeutic support workers will be trained and supervised by appropriately experienced clinicians, and overall clinical risk is managed by an experienced clinical psychologist. The TSWs will be masters students working and studying at UCL on the MSc in Early Child Development and Clinical Applications.

What happens if I'm interested to take part?

To begin with, we will ask you to fill in a questionnaire to help see whether iPDT is something that seems suitable for you. This is done via an online form. You do not have to experience all the problems we ask about to be able to participate in the study! If the questionnaire shows that the treatment may suit you, you will be invited to provide consent via another online form.

If your questionnaire responses indicate that that a different support service might be more appropriate for you, we will advise that you discuss this with your GP. You may also wish to access local talking therapies services (IAPT), which can be found here: <https://www.nhs.uk/service-search/mental-health/find-an-nhs-talking-therapies-service>

If you are eligible to take part and have provided consent, we will let you know and we will then contact you again in January 2024 to ensure that you are still happy to take part. If you are, you will

be asked to complete some questionnaires on an online platform called Iterapi, before starting the treatment.

Participating in a program like this requires time and commitment. A Therapeutic Support Worker can give you support, but you will need to prioritize engaging with the programme online and completing the weekly exercises. This is because we want you to learn strategies and techniques that are useful even after the study is over. If you do not have time for this in your life right now, it may be better not to sign up, as completing the programme will take some commitment on your part.

What does my participation in this study involve?

You will be asked to fill in some questionnaires about yourself and how you're feeling before starting treatment. These questionnaires will take around 30 minutes to complete, however you do not have to do it all in one go and hopefully you will find it interesting. There are also a smaller number of questionnaires that you'll be asked to fill in each week, so we can keep track of how you're doing

It is up to you how much time you spend on each of the 8 chapters on Iterapi. You will receive access to a 'new' chapter of the intervention for the first 8 weeks. You will then have 2 extra weeks to review or catch up on any of the previous chapters. Reading and engaging with the chapters will take approximately 30 minutes at minimum, but you are welcome to take your time and revisit the information. If you find the information to be helpful, you will be able to download a PDF of this from Iterapi to keep for as long as you like after the 10 weeks of the intervention are finished.

After completion of the treatment, you will be asked to fill in the questionnaires again, to help us to estimate the results of the treatment. These questionnaires will also be filled in 3 months after the end of treatment to evaluate any long-term improvement. As you can see, there are quite a lot of questionnaires to fill in, but in previous studies, participants have shared that the questionnaires are quite interesting as they help you to reflect on yourself and how you're feeling. The information you provide will also help you to get the most from your messages with your therapeutic support worker.

Once treatment is finished, you may be contacted through the Iterapi platform to ask whether you would like to participate in an online interview with one of the researchers to help us understand your experience of Iterapi and to provide further feedback. You can decide if you would like to take part in the interview, you don't have to do so.

There is no payment for taking part, however, the treatment itself is free of charge.

Is it possible to keep my participation confidential?

When you provide consent to take part in the study, we will collect some identifiable information from you – your name, email address, and phone number. The document with this personal data will then be stored in a secure manner on the Iterapi platform (the treatment website). It can only be viewed by the research team, or in theory by the IT technicians who run the website. These technicians are based in Sweden, and in practice they would be extremely unlikely to access this data, and would only do so if it was necessary to ensure the continued secure running of the platform.

During treatment your data will be kept confidential through automatically generated study codes that are given to each participant. The identification key that connects the participant's study code to the actual personal identifiable information (name, mobile number, and email address) is only accessible to the research team. All your personal information stays between you and the research team. Your information is confidential. That means we cannot share your information with anyone

unauthorized. Although this study has received ethics approval from University College London, this information will not be shared with the university and students' participation will not impact their studies in any way. Other participants will not know that you are participating in this research.

You will receive reminders from the online platform if you need to log on and complete activities. These notifications will be sent by email or SMS to the address and number you provide us with. Therefore, it's important to make sure that no one else can access your emails or messages, otherwise they might be able to read these notifications.

Do I have to take part?

It is up to you to decide whether or not to take part in the study. If you do decide to take part and the study is suitable for you, you will be asked to complete an online consent form that we will keep as a record. You will have an opportunity to ask any questions by email. We want to make sure you understand what your participation involves. It is completely voluntary to participate and you can end your participation in the programme and/or the study whenever you want. Although it is helpful for us to know why anyone decides to stop taking part in the study, you can do so without giving any reason.

You can also stop the treatment whenever you want. We hope of course that you can be part of the whole treatment, as continuing until the end means you have the opportunity to access all of the treatment materials. If you decide to stop, you can let us know via the platform where you communicate with your Therapeutic Support Worker. If you do not say anything, as part of the programme your Therapeutic Support Worker will try to contact you to check that you are ok, and encourage you to continue with the programme.

You will be able to withdraw your data from the research by contacting the research team at any time. We will delete your data unless it has already been included in group level analysis. This means that your data would have been combined with the data of other participants, and in that case it will not be possible to identify and remove data from one person specifically. Therefore, you can withdraw your data any time up to 10 weeks after you begin the first week of intervention.

What happens if my mental health becomes worse?

There is no indication that taking part in iPDT will make you feel worse, but for all kinds of reasons, this can sometimes happen. Your therapeutic support worker or a member of the research team will keep track of your well-being by looking at the questionnaires you fill in every week and paying attention to what you say in your messages. If your low mood becomes worse while you are part of the project, your therapeutic support worker, or a member of the research team, will discuss this with you, and if necessary, think together about what other kinds of support you may need to access. If we are concerned that your mood has worsened so much that it is a danger to your life or that of others, then we will need to think about how we can keep you safe. In this case, we will try to contact you by telephone to discuss how best to help you. If you choose not to respond to our telephone calls, we will share resources with you by message on the Iterapi platform.

It is important to know that we cannot access any information about you that you have provided to UCL as part of your studies. Therefore, we only have your name, phone number, and email address. We do not know where you live, and we do not know the contact details of your family or course tutor. Therefore, in an emergency we cannot help you unless you speak with us. If you stop replying to our messages or do not answer our phone calls, we will not be able to take any further steps to keep you safe.

Our priority is always to keep you safe, but we also want to respect your confidentiality and work collaboratively with you. If you stop replying to our messages, we will send you information about where you can access alternative support. We will advise you to call 999, go to your local A&E, or call the Samaritans for free by calling 116 123 (the Samaritans phone line is available 24 hours a day). We will also advise you to locate your local NHS crisis line if it is needed

(<https://www.nhs.uk/service-search/mental-health/find-an-urgent-mental-health-helpline>). The research team will not be able to take any further action if you choose to stop participating or do not respond to our messages.

How will communication work and is it secure?

We will send notifications and reminders to fill in questionnaires through text messages or email. Should there be any more sensitive information, such as feedback on your answers to the questionnaires and exercises, you will have to log into the platform to be able to read them. You may receive a message by email saying that you have a pending message on the platform, but the email will not reveal what the message says. You can use your regular UCL email address to register and log into the platform.

Contact with the Therapeutic Support Worker and those responsible for the study will take place via the Iterapi website. You will be assigned a username that you will use to login and read these messages.

To ensure your participation in the study, and all correspondence, remains confidential, please ensure that no one else has access to your email. Please also be careful to log out of the platform if you are using a shared device.

Are there risks in taking part?

We do not know of any risks that are specific to the Internet-based psychological treatment. The study has been approved by UCL ethics committee. Some may experience iPDT as challenging or uncomfortable at times, as it can be difficult to reflect on one's mood and start exploring emotions which have previously been avoided. However, we hope this will lead to feeling better in the long run. Your Therapeutic Support Worker will keep track of your progress. Should there be a deterioration in your mood, your Therapeutic Support Worker and the research team in the study will think with you what other steps might need to be taken.

What do you do with my data?

We are very careful to securely store your data and maintain confidentiality, so that no unauthorized person will know that you have participated in this study or be able to see your data. Your information will not be used for commercial purposes.

All information you provide – including your questionnaire responses and messages with your Therapeutic Support Worker – will be stored securely on the Iterapi platform. All identifiable information about you will be deleted once the trial is finished.

Your questionnaire responses will be analysed statistically using your participant code and presented only as an average of all participants, so that individual responses cannot be traced. The reason we ask you to fill in information about yourself and your mood is that we want to evaluate how effective the treatment is. In this way, we can further develop the treatment so that it can help more people with symptoms of low mood and anxiety.

The treatment includes contact with your Therapeutic Support Worker via messages. Quotes or sentences from these messages may be presented in research presentations and in scientific publications, and in the future we may want to go back and study what has been said in the messages, to help us improve the way the treatment works. We always delete names and any other personal information that can be traced to an individual. No one will be able to see who wrote a message. The reason why we may come to analyse these messages is to describe to other researchers how the treatment is done and evaluate the effectiveness of messages in the treatment. If you have given consent, we may ask if we can interview you by video-call after you have been in the treatment. It is entirely voluntary, and you have the right to say no without it affecting your participation in the study in any way. You can have your camera turned off, if you prefer. This is to

help us understand more about your experience of iPDT and your involvement in the study. Quotations from these interviews may be presented in research, but all personal information, such as names, will be changed so you cannot be identified.

How long will the data be kept before being securely destroyed?

We process personal data following the General Data Protection Regulation (GDPR). All data containing personal information (full name, email address, mobile number), your responses to the questionnaires, and transcripts (written copies) of your messages with your Therapeutic Support Worker will be kept in the Iterapi platform, only accessible to the research team and the IT technicians. This data will only be looked at by the research team. You can request that information about you be deleted at any point; however, if we have already analyzed your data alongside data from other participants, we will not be able to remove your data from the overall analysis. At the end of the study, we will securely destroy all identifiable information about you. However, anonymised data (i.e. data that does not include any identifiable information about you) is stored for ten years after the study has ended. During this time, anonymised copies of data that cannot be linked to you may be used by researchers who want to continue to understand the results of this project or develop future research studies. These future researchers will not know who you are or that you participated in the study.

What will happen to the results of the research project?

The information you provide will be anonymised and used as part of two doctoral theses, and also as part of research papers which will be submitted for publication in one or more academic journals. We also intend to present results at one or more conferences. Anyone reading the research will not be able to identify you. If you have any questions about the study, or if any questions arise after you have participated, you are welcome to contact us. Furthermore, if you would like to receive a copy of the two doctoral theses or a brief summary of findings you are welcome to contact us by email, and we'll be very pleased to share the research findings with you.

An Ethics Committee has checked the research project

All research projects are looked at by an independent group of people, called a Research Ethics Committee, to protect your rights. This research has been reviewed and agreed by the UCL Research Ethics Committee (Project ID Number: 26049/001).

What happens if something goes wrong?

If you wish to complain, or have any concerns about any aspect of the way that you have been approached or treated by members of staff, please contact Henry Clements:

henry.clements@ucl.ac.uk.

If you then feel that your complaint has not been handled to your satisfaction, you can also contact the Chair of the UCL Research Ethics Committee at ethics@ucl.ac.uk.

You can also contact the Data Protection Officer at UCL: data-protection@ucl.ac.uk

What happens next?

Please feel free to discuss the information above with others, if that would help you to decide whether to take part. You can keep this information sheet to look at whenever you need to. If you decide to take part, you will need to give consent (on the online form). Once you have completed the questionnaires a member from the research team will contact you when the treatment is ready to begin.

Researcher contact details :

Henry Clements (Principal Investigator)
Henry.clements@ucl.ac.uk

Rose Mortimer
Rose.mortimer@ucl.ac.uk

Dominika Iluczyk
dominika.iluczyk.22@ucl.ac.uk

If you have concerns about how your data will be used in this study, you can contact the UCL data protection officer: Alexandra Potts data-protection@ucl.ac.uk

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

Privacy Notice

This notice is to outline what we do with the information that you share with us as part of this project and your rights about our use of that information. For a full statement visit [UCL General Privacy Notice for Participants](#). These rights are as set out in the [General Data Protection Regulation](#) (GDPR), which takes over from the Data Protection Act in May 2018

1. Introduction

The research team, in the Division of Psychology and Language Sciences (“we” “us”, or “our”) respects your privacy and is committed to protecting your personal data.

Please read this Privacy Notice carefully – it describes why and how we collect and use personal data and provides information about your rights. It applies to personal data provided to us, both by individuals themselves or by third parties and supplements the following wider [UCL privacy notice\(s\)](#):

- [General privacy notice](#) when you visit UCL’s website
- [Student privacy notice](#)
- [Staff privacy notice](#)
- [Research participants for health and care purposes privacy notice](#)

We keep this Privacy Notice under regular review. It was last updated on 13th July 2023.

2. About us

The Division of Psychology and Language Sciences is part of the Faculty of Brain Sciences at University College London (**UCL**).

UCL, a company incorporated by Royal Charter (number RC 000631), is the entity that determines how and why your personal data is processed. This means that UCL is the ‘controller’ of your personal data for the purposes of data protection law.

3. Personal data that we collect about you

This research project will hold the following data on you:

1. Personal data and special category data: full name, age group, email address, telephone number, ethnicity, medication, diagnoses, mental health care
2. Consent forms
3. Responses to questionnaires and worksheets completed on the Iterapi platform
4. Weekly message exchanges with your therapeutic support worker
5. Interview about your experiences during the treatment.

4. How we use your personal data:

We will only use your personal data when the law allows us to. We will use your personal data in the following circumstances:

- **To register you as a research participant and to manage our relationship with you.**
- **To support you to access and engage with the therapeutic intervention and the research study.** For example, we use your email address to send you reminders about tasks to complete on the research study website.

For the purposes of data protection legislation, the legal basis for processing these data for the research project is public interest (Article 6 (1)(e) and Article 9(2)(j) of the General Data Protection Regulation). This means that personal data can be processed where necessary for the performance of a task carried out in the public interest. In this case it is to carry out research and inform future health provision.

When processing 'special category personal data' for research purposes the legal basis is 'for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes.' In addition to these legal bases, we also collect your ethical informed consent.

Where the processing is based on your consent, you have the right to withdraw your consent at any time by contacting us using the details set out below. Please note that this will not affect the lawfulness of processing based on consent before its withdrawal.

We may also use anonymised data, meaning data from which you cannot be identified, for the purposes of:

- Service evaluation;
- Education and research

Anonymised data may also be used in published reports or journals and at conferences.

5. Who we share your personal data with

Your personal data will be collected and processed primarily by our staff and UCL. Access to your personal information is limited to staff who have a legitimate need to see it for the purpose of carrying out the research study.

The therapy platform is hosted in Sweden, and run by a team of IT technicians who work at Linköping University. These IT technicians could access your personal data as part of their work, however, they

have signed confidentiality agreements and agreed not to view participant data unless this is necessary for the purposes of maintaining the safety, security, and functionality of the therapy platform. We require all third parties to respect the security of your personal data and to treat it in accordance with the law. We do not allow our third party service providers to use your personal data for their own purposes – we only permit them to process your personal data for specified purposes and in accordance with our instructions.

The data management procedures adhere to GDPR, with University College London (UCL) as the data controller and Linköping University as the data processor. For analysis, anonymized data will be stored in encrypted files on secure drives at University College London. No data transfer outside of the EU/EEA will occur.

You are free to withdraw your participation from the intervention at any time without giving a reason. You will be able to withdraw your data from the research by contacting the research team at any time. Your data will be deleted, unless it has already been included in group level analysis. This means that your data would have been combined with the data of other participants which will mean it will not be possible to identify and remove data from one person specifically. Therefore, it will not be possible to identify you from the anonymised data.

Lawful Basis for Processing

All data will be collected and stored in accordance with the General Data Protection Regulation (GDPR), which takes over from the Data Protection Act in May 2018. Your personal data will be processed for the purposes outlined in the attached information sheet. The legal basis for processing these data for the research project is public interest (Article 6 (1)(e) and Article 9(2)(j) of the General Data Protection Regulation). This means that personal data can be processed where necessary for the performance of a task carried out in the public interest. In this case it is to carry out research and inform future health provision.

6. International transfers

We do not transfer your personal data outside the European Economic Area (EEA).

7. Information security

We have put in place appropriate security measures to prevent your personal data from being accidentally lost, used or accessed in an unauthorised way, altered or disclosed. We have established procedures to deal with any suspected personal data breach and will notify you and any applicable regulator of a breach where we are legally required to do so.

8. Data retention

We will only retain your personal data for as long as necessary to fulfil the purposes we collected it for, including for the purposes of satisfying any legal, accounting, or reporting requirements.

We will keep your personal data according to the [Records Retention Schedule](#).

9. Your rights

Under certain circumstances, you may have the following rights under data protection legislation in relation to your personal data:

- Right to request access to your personal data;
- Right to request correction of your personal data;

- Right to request erasure of your personal data;
- Right to object to processing of your personal data;
- Right to request restriction of the processing your personal data;
- Right to request the transfer of your personal data; and
- Right to withdraw consent.

If you wish to exercise any of these rights, please contact the [Data Protection Officer](#).

Contacting us

You can contact UCL by telephoning +44 (0)20 7679 2000 or by writing to: University College London, Gower Street, London WC1E 6BT.

Please note that UCL has appointed a Data Protection Officer. If you have any questions about this Privacy Notice, including any requests to exercise your legal rights, please contact our Data Protection Officer using the details set out below:

Alexandra Potts data-protection@ucl.ac.uk

10. Complaints

If you wish to complain about our use of personal data, please send an email with the details of your complaint to the [Data Protection Officer](#) (Alexandra Potts, data-protection@ucl.ac.uk) so that we can look into the issue and respond to you.

You also have the right to lodge a complaint with the Information Commissioner's Office (**ICO**) (the UK data protection regulator). For further information on your rights and how to complain to the ICO, please refer to the [ICO website](#).

If you have any concerns or questions about this research, the data processing, and/or your involvement in the project please contact:

Principal researcher: Dr Henry Clements

E-mail: henry.clements@ucl.ac.uk

Phone: 07877 127 863

Address: Research Department of Clinical, Educational and Health Psychology
University College London
Gower Street
London WC1E 6BT