



Participant Information Sheet

NHS Research Ethics Committee Approval ID Number: 19/LO/1149

YOU WILL BE GIVEN A COPY OF THIS INFORMATION SHEET

Title of Study: The impact of CBT on shock-potentiated neural circuitry

Department: UCL Institute of Cognitive Neuroscience

Name and Contact Details of the Principal Researcher: Oliver Robinson (o.robinson@ucl.ac.uk)

1. Invitation Paragraph

You are being invited to take part in a research project. Before you decide it is important for you to understand why the research is being done and what participation will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us 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. Thank you for reading this information sheet.

2. What is the project's purpose?

The aim of this project is to increase our knowledge about psychological processes which may contribute to mental health problems such as depression and anxiety.

We want to know if undergoing cognitive behavioural therapies (CBT) affects how the brain processes emotional information. In our study, half of our participants will be investigated whilst undergoing CBT, and the other half will be investigated whilst in a waiting list for CBT. Which group you will fall into will be randomly determined, however, this will not affect the length of your waiting times to receive CBT.

Using magnetic resonance imaging (MRI), we will look at your performance and brain activity whilst you complete computerised psychological tests. Some of these will be performed under threat of unpredictable electrical shock (to induce temporary anxiety). It is hoped that these findings will improve the understanding of processes involved in mental health disorders and potentially inform the development of new treatments for depression and anxiety.

3. Why have I been chosen?

We hope to recruit a total of 174 participants over a period of 4 years. We are looking for people who have been experiencing persistent anxiety and/or low mood. All participants must be between 18 and 64 years old. Participants will need to be safe to go into the MRI scanner, meaning they must have no metal in their body that cannot be removed (piercings, implants, medical devices, etc). We unfortunately cannot accept participants who have taken antidepressant medication in the past six months.

4. 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.

5. What happens if I do not want to carry on with the study?

You can withdraw at any time without giving a reason and without it affecting any benefits that you are entitled to.

6. What will happen to me if I take part?

This study will involve three testing sessions with the study researchers in Bloomsbury, London. Unfortunately we cannot reimburse travel expenses.

It is important for the success of our study that you attend any scheduled appointments with us and follow the instructions given to you carefully. It is also important that you do not drink any alcohol for 24 hours before the second and third appointments. We would also ask that you try to be well-rested before these appointments.

First visit:

The first visit (which will take place at The Institute of Cognitive Neuroscience, Alexandra House, 17-19 Queen Square) will make sure that it is safe for you to take part and that you are suitable for this study. This session will last around 1 hour 20 minutes – 2 hours. During this visit you will:

- Have the opportunity to ask any questions in person
- Be asked to sign a consent form on paper
- Complete standardised structured interviews that will ask about your mood and some experiences you may have had
- Complete a number of psychological questionnaires and screening forms

After this visit, you will be randomly assigned to either the 'CBT' or 'waiting list' conditions. Randomisation is a standard research procedure that involves dividing participants into groups on a random basis to avoid bias in group formation. Please note that your participation in this study will not affect your waiting times to receive CBT – assignment to these conditions will determine when you attend your testing sessions over the course of your care (either early/during the waiting period, or later around the time of CBT). To reiterate – participation in this study WILL NOT increase or decrease the duration of waiting times for CBT, and should treatment become available during your participation in the study, this would not be delayed due to participation.

If you are ineligible for the study after this first visit, you will be reimbursed for your time and no further procedures will follow.

Second visit:

If you are suitable and decide you would like to proceed with the study, you will be invited in to complete several computerised tasks both outside and inside the MRI scanner (see below for more information on MRI). Some of the tasks will involve mild and harmless electrical shocks which will be sent via electrodes attached to the wrist or ankle (please see section 7 below for more details about these shocks). This session, which will last around 2 hours 30 minutes, will take place at The Institute of Cognitive Neuroscience, 17–19 Queen Square and 26 Bedford Way, WC1H 0DS.

Third visit:

Several weeks after your second visit, you will be invited back to your final appointment where you will complete the computerised tasks again, both inside and outside the MRI scanner. This will also take place at The Institute of Cognitive Neuroscience, 17–19 Queen Square and 26 Bedford Way, WC1H 0DS and last around 2 hours 30 minutes.

MRI brain scan

We use functional magnetic resonance imaging (fMRI) to scan the brain. Functional MRI allows us to see changes in the brain's activity when you are doing a task and making responses.

If you've never had a scan before, you may find the following section useful as it gives an idea of what you can expect and reassures you about some of the measures that are in place. If you are afraid of small spaces and loud noise, the scanner environment may not be suitable for you. If you have any concerns after reading this section, please ask any member of the research team for more information. Remember, you will be able to communicate with the research team at all times throughout the scan.

Before the brain scan, you will be asked to remove any metal objects, as there is a strong magnetic field in the scanner. We will double check that there is no metal on your body. The scanner is quite noisy and so you will be given earplugs to protect your ears, but you will still be able to communicate with the research team (through speakers and a microphone which are present in the scanner). Whilst the general sound level is fairly noisy, if you have not had a scan before the nature of the sounds themselves can perhaps be a little odd. If you let us know, we can play you recordings of the types of noises you are likely to hear in the scanner, so you know what to expect during the scanning session. The inside of the MRI scanner is quite small, so it can feel a little claustrophobic, but you will be moved in slowly at the beginning so you can get used to your environment.

Before the scan starts we will make sure you are comfortable by providing cushions around your head and under your legs and a blanket if you feel cold. You will be given a bell to hold in your hand when you are inside the scanner. If at any time you feel uncomfortable you can squeeze this to communicate with the research team who will be on the other side of a window just outside the scanner room. It is very important you keep still during the scans and try not to move your head.

If you have any concerns or want to find out more after reading this, please do not hesitate to contact a member of the research team.

7. What are the possible disadvantages and risks of taking part?

There are no serious risks from performing the computerised tasks, receiving mild electrical shocks or from going in the MRI scanner. There is a risk associated with taking magnetic metal into the scanner, so you will be screened thoroughly to insure you have no such metal on your person or in your body. The electric shocks may be slightly painful, and you will likely feel anxious anticipating them, but they should not cause any long-term effects. The pain is comparable to that of a rubber band snapping against the skin. These techniques have successfully and safely been used in numerous prior studies without incident. The electrodes used to send the shocks will be attached to the wrist or ankle.

8. What are the possible benefits of taking part?

Whilst there are no immediate benefits for those people participating in the project, it is hoped that you will find the study interesting and that it will contribute to our understanding of the mind and brain.

9. Payment

You will be reimbursed £50 for full participation in this study. Partial participation, due to exclusion or withdrawal, will be reimbursed at a rate of £7.50 per hour.

10. What if something goes wrong?

If you experience any adverse side effects relating to any aspect of this study, please contact the Principal Researcher of the study (o.robinson@ucl.ac.uk) in the first instance. For any medical concerns, you can contact the research group psychiatrist Dr Rick Adams (rick.adams@ucl.ac.uk), or alternatively Dr Oliver Robinson (o.robinson@ucl.ac.uk) or Dr John Cape (j.cape@ucl.ac.uk). Please copy in the study researchers to all communications.

Every care will be taken in the course of this study. However, in the unlikely event that you are injured by taking part, compensation may be available. If you suspect that the injury is the result of the Sponsor's (University College London) or the hospital's negligence then you may be able to claim compensation. After discussing with your research doctor, please make the claim in writing to Dr Oliver Robinson, who is the Chief Investigator for the research who is based at the UCL Institute of Cognitive Neuroscience. The Chief Investigator will then pass the claim to the Sponsor's Insurers, via the Sponsor's office. You may have to bear the costs of the legal action initially, and you should consult a lawyer about this.

11. Will my taking part in this project be kept confidential?

All the information that we collect about you during the course of the research will be kept strictly confidential. You will not be able to be identified in any ensuing reports or publications. As part of routine research practice we may collect personal data, including: name, address, telephone number, email address and date of birth. It is a necessary procedure in a clinical trial for us to inform your GP that you will be participating in this study, and in the event of an incident or incidental clinical finding during the study, your GP may be informed.

12. Limits to confidentiality

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

13. What will happen to the results of the research project?

The data from this research project will be disseminated through standard scientific outlets, for example in peer-reviewed papers, talks and conference posters. Some of the data you provide may be included in a student thesis, for example an undergraduate or Masters dissertation, or a PhD thesis. If this is the case, all data protection principles will apply (please see below for details). You may also request the results of the study from researchers following completion of data analysis.

Your study data may be stored indefinitely, and shared with others outside the research group for the purposes of further scientific research. Any personal data you provide will be kept securely, and would not be included in any data shared with other research groups. If it is no longer necessary to keep your personal data, it will be deleted.

The study data you provide through participating in the study may be archived online as “open data” following publication of any resulting papers, in a de-identified form. Any such data could be downloaded by anyone with an internet connection, and used for any purpose. Any data that could identify you personally would be removed before online archiving.

14. Data Protection Information

University College London (UCL) is the sponsor for this study based in the United Kingdom. We will be using information from you and your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. UCL will keep identifiable information about you for 20 years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

The Camden and Islington NHS Foundation Trust will collect information from you and/or your medical records for this research study in accordance with our instructions. They will use your name, NHS number and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from UCL and regulatory organisations may look at your medical and research records to check the accuracy of the research study. The Camden and Islington NHS Foundation Trust will pass these details to UCL along with the information collected from you and your medical records. The only people in UCL who will have access to information that identifies you will be people who need to contact you to regarding this study or audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number or contact details.

The Camden and Islington NHS Foundation Trust will keep identifiable information about you from this study for the duration of your care under their services.

UCL will collect information about you for this research study from the Camden and Islington NHS Foundation Trust. This information will include your name, NHS number, contact details and health information, which is regarded as a special category of information. We will use this information as part of follow-up clinical data for our research analyses.

When you agree to take part in a research study, the information about your health and care may be provided to researchers running other research studies in this organisation and in other organisations. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research (<https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/>). This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of health and care research, and cannot be used to contact you or to affect your care. It will not be used to make decisions about future services available to you, such as insurance.

The Birkbeck/UCL Centre for NeuroImaging's (BUCNI – where the MRI scanning will take place) local procedures which follow these principles:

- Using 'technical and organizational measures' to ensure data minimisation, e.g. pseudonymisation
- Using anonymised data where possible
- Not processing in ways that are likely to cause substantial damage or distress to individuals
- Not supporting measures or decisions with respect to individuals
- Having the assurance that research ethics committee approval is in place where needed

15. Who has reviewed the research?

The NHS Research Ethics Committee have reviewed and approved this research.

16. Who is organising and funding the research?

This research is being organised by the Neuroscience and Mental Health group at the Institute of Cognitive Neuroscience. The research is being funded by the Medical Research Council, and is sponsored by University College London (UCL).

If you would like any further information on this study or if you have any concerns, please do not hesitate to contact: Dr Oliver Robinson, Institute of Cognitive Neuroscience, Alexandra House, 17-19 Queen Square, London, WC1N 3AZ; email: o.robinson@ucl.ac.uk

You will be given a copy of the information sheet and a signed consent form to keep. Thank you for reading this information sheet and for considering taking part in this research study.