Participant Information Sheet

UCL Research Ethics Committee Approval ID Number: 6198/002

YOU WILL BE GIVEN A COPY OF THIS INFORMATION SHEET

Title of Study: The effect of SSRIs on threat of shock potentiated neural circuitry

Department: UCL Institute of Cognitive Neuroscience
Name and Contact Details of the Researcher(s): Millie Lowther; millie.lowther@ucl.ac.uk; Alexandra Pike; alex.pike@ucl.ac.uk
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 us 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 administering Escitalopram affects how the brain processes emotional information. Escitalopram is an antidepressant which increases serotonin levels in parts of the brain and is commonly prescribed for the treatment of depression and anxiety disorders. In order to study its effects, we will be giving half of the participants in our study Escitalopram. The other half will receive a sugar tablet (a placebo).

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 200 participants over a period of 2 years. We are looking for 100 people who have been experiencing persistent anxiety and/or low mood, and 100 people who have never experienced any mental health problems. 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. Participants are chosen from the in-depth screening form that is completed via the REDcap online service.

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. You can withdraw at any time without giving a reason and without it affecting any benefits that you are entitled to. If you decide to withdraw you will be asked what you wish to happen to the data you have provided up that point.

5. 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. We will also require you to take Escitalopram or placebo tablets for up to 21 days. Please see below for more information on these tablets. Before you start, we will send a letter to your GP informing them of your participation in the study.

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
- Complete an ECG (electrocardiogram) to ensure it is safe for you to take the drug (see the Escitalopram information sheet for more information).

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). This session, which will last around 2 hour 30 minutes, will take place at The Institute of Cognitive Neuroscience, 17–19 Queen Square and 26 Bedford Way, WC1H 0DS. After this you will be provided with a study information booklet that contains all the information you require in order to complete the medication course. During this phase, you will be required to take one tablet per day for the next 14 to 21 days (depending on your availability for the third visit) and complete some very short daily measures.

Third visit:

Around two 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 hour 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.

6. What is the drug or procedure that is being tested?

The drug used in this study is called Escitalopram, a commonly used treatment for depression and anxiety disorders. It is a selective serotonin reuptake inhibitor, believed to work by changing the levels of a brain chemical called serotonin. We have put together an Escitalopram Information sheet which we will go through with you when you are given the drugs, but do let us know if you would like to receive it in advance.

In this study you may receive 10mg of Escitalopram to take daily for up to 21 days. In a previous study an equivalent dosage of Citalopram (20mg), another Selective Serotonin Reuptake Inhibitor, was given to participants for 28 days without participants experiencing any adverse side effects. Neither you nor the experimenter will know whether you are receiving the antidepressant or placebo pills. As the experiment is randomised this means there is a 50% chance of you being in the drug group.

PLEASE NOTE: As various drugs of misuse can interact with antidepressants in a dangerous way, it is important that you avoid taking any illicit drugs for the duration of the study. Please DO NOT start any medication during the course of the trial without informing your GP as it may be contraindicated with Escitalopram. Please also inform us of any medication you start whilst taking part in the trial. Please try to maintain a relatively steady diet and sleep routine throughout the study.

Sometimes during the course of a research project, new information becomes available about the treatment/drug that is being studied. If this happens, your doctor will tell you about it and discuss whether you want to continue in the study. If you decide to withdraw arrangements will be made for your care to continue. If you decide to continue in the study you will be asked to sign an updated consent form.

7. What are the side effects of Escitalopram?

During clinical treatment with Escitalopram, the most common side-effects that have been found are: sleepiness, difficulty in sleeping, increased sweating, dry mouth, feeling sick, decreased appetite, nervousness/agitation and decreased sex drive. While it is unlikely that such side effects will occur from the tablets, we strongly recommend that you do not drive if you experience any drowsiness or dizziness, or any other side effects which might impair your ability to do so safely. Contact details of a Psychiatrist will be provided along with the medication so that you can ask questions or discuss any negative side effects you may be experiencing. We will also contact you during the study to check how you are feeling. You are free to withdraw from the study at any point, should you so wish.

8. 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.

9. 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.

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). Please copy in the study researchers to all communications. Should you come to any harm as a result of your participation in this study, the University College London and University College Hospital no-fault compensation scheme is in place.

If you wish to raise a complaint or have any issues regarding any aspect of the study, please contact the Principal Researcher of the study (o.robinson@ucl.ac.uk) in the first instance. If your issues are not resolved or handled to your satisfaction, you can make a formal complaint to the Chair of the UCL Research Ethics Committee (ethics@ucl.ac.uk), who is completely independent of the study team.

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.

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. If you are participating in a project run by a student, the data may be included in the final submitted report, for example an undergraduate or Masters dissertation, or a PhD thesis.

Your 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 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. Local Data Protection Privacy Notice

The data controller for this project 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. UCL’s Data Protection Officer can also be contacted at 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, address, age, gender, health information including mental health, neuroimaging scan data

Your personal data will be processed for the purposes outlined in this notice.

The legal basis used to process your personal data will be for performance of a task in the public interest. The legal basis used to process your ‘special category’ (sensitive) personal data will be for scientific and historical research or statistical purposes.

Your personal data will be processed so long as it is required for the research project. If we are able to anonymise or pseudonymise the personal data you provide we will undertake 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. If you remain unsatisfied you may wish to contact the Information Commissioner’s Office (ICO). Contact details, and details of data subject rights, are available on the ICO website at: https://ico.org.uk/for-organisations/data-protection-reform/overview-of-the-gdpr/individuals-rights/

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 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 the Wellcome Trust

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.