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[Information Sheet for Sub-Study; Clinical Services]

MDD – CPA

Major Depressive Disorder – a Computational Psychiatry Approach

Understanding the Social Brain in Healthy Volunteers and People with Psychological Difficulties – Reduced Sub-Study

We would like to invite you to participate in this research project.

You are being invited to take part in a research study. You should only participate if you want to. Before you decide whether to take part, this sheet will give you some more information about why the study is being carried out, what you would be asked to do if you decide to take part, and how the study will be conducted. Please take some time to read this sheet, and to discuss it with other people if you wish. You are also very welcome to ask any further questions about the study, or if you find anything on this sheet unclear.

Why is this study being done?

With the proposed project we plan to investigate social interaction styles/behaviours and personality/character traits in people suffering from Major Depressive Disorder and compare them with healthy control participants. Our study design will aim to address some of the gaps in current knowledge and investigate whether there is a relationship and if so, whether social behaviours can be predicted or modelled using personality/character traits. This will hopefully allow us to gain a better understanding of the disorder and contribute toward developing more informed and effective treatments from which clients will benefit.

Why have you been invited to take part?

You have been invited to take part in the study because you have recently been assessed by a clinician at one of the clinical services currently in collaboration with the research team.

Do I have to take part?

No. Taking part in the study is entirely voluntary. It is your choice whether or not you would like to participate. Deciding not to take part in the study will not affect the care you receive from services either now or in the future. If you do decide to participate, you will be given this information sheet to keep, and you will later be asked to sign a consent form stating that you wish to take part. If you do give consent to take part in the study, you are still free to leave the study at any point, without giving a reason. This will not affect the care you are currently receiving, or will receive in the future. If you leave, any information that we have already collected from you will be destroyed.

What will happen if I decide to take part?

If you wish to take part in the study, then you can get in touch with the research team or provide your contact details so that we can arrange a time to discuss the study in more detail. The researcher you will speak to will also explain that the study can be completed online via the Internet and they will explain the use of the online platform(s) which host the study components (described in more detail below). You can ask any questions or address any concerns you may have. If you decide to take part, you will be given access to the online platform(s). Once you have accessed the online platform(s), we will ask you to provide written consent that you agree to take part in this research study.

There are two main components in this study: computerised, cognitive game(s) investigating social interaction/behaviour and a series of self-report questionnaires assessing personality/character traits, developmental history and symptomatology. Some questionnaires are sensitive in nature and include questions regarding childhood experiences. You will also be asked to provide some demographic information about yourself. The self-report questionnaires usually takes ca. 1-2 hours to complete and you can save your progress in order to take breaks in between questionnaires if required.

The computerised, cognitive task(s) will involve responding to written cues using different keyboard buttons to estimate or compare different events or conditions (similar to simple computer games). In some of them, you will play another person who is also playing the game in a different location. We will make sure that you understand all aspects of the task(s) before you are asked to play them, and we will provide you with reminders of the instructions immediately prior to the task beginning. There will also be opportunities for you to ask any questions if you are uncertain about the instructions or task(s) in general. This component will take between 30 and 45 minutes. Most people find the test(s) quite straightforward and interesting to do.

All identifiable information will be removed prior to you completing the study.

No part of the study is compulsory and there will be separate consent sections for each part of the study.

We do encourage you to discuss these details with the research team when they contact you over the phone in order to make sure that you fully understand them and that your concerns and questions can be addressed.

What are the possible disadvantages and risks of taking part?

Some people can find it upsetting to answer questions about their personal experiences. We will support you if you become upset. A specific Risk and Safety protocol for this study has been developed. You will be given time at the end of the study to be fully debriefed with a member of the research team and provided with information on emotional regulation skills, and crisis phone numbers and details of clinical services to contact. Your personal therapist will also be aware of your participation in the study and able to support you should you find discussing your experiences difficult. Should you feel overwhelmed or acutely distressed during or at the end of the assessments, you will be appropriately looked after by an experienced clinician.

What are the possible benefits of taking part?

You may find it interesting to complete these tasks and the information gathered during this study will also help to inform our understanding of treatment for Depression, which will hopefully be a step towards helping improve interventions in the future.

Will I be paid for taking part in the study?

As an acknowledgement of your time, we will be offering you a flat rate of £10 per hour for your participation. There is also the possibility to earn a small additional compensation on the computerised task(s) depending on your performance in these games.

Who will know you are taking part in the study?

We will inform your personal therapist that you are taking part in the study. We will inform your GP of your participation in this study, but information collected during all stages of the study will be kept strictly confidential. All information will only be viewed by members of the research teams at University College London and Virginia Tech University in the US (this is the

Principle Investigator's second office). **However, if through the course of the study it was found that you are at immediate risk of harm to yourself or others, this information will be shared with your therapist or GP and, if necessary, emergency services.**

Your consent form will be kept in a separate location from all your other data, ensuring that this remains anonymous. All data will be stored in secure locations whereby a participant ID will be assigned to your data. Non-identifiable personal information and the results of your tasks will be recorded on computers or flash drives which are password protected. Any published data will also be entirely anonymous meaning individuals cannot be identified.

The data from this study will be stored in accordance with the UCL and NHS Data Protection and Records Management policies.

All data will be collected and stored in accordance with the Data Protection Act 1998.

What will happen to the results of the research study?

The results will be written up in the form of reports to be submitted to scientific journals or presented at conferences. As mentioned, you will not be identifiable from these results. On completion and if you request it you will be sent a report of the study.

What if there is a problem?

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) negligence then you may be able to claim compensation. After discussing with your research doctor, please make the claim in writing to Dr. Steven Pilling or Dr Tobias Nolte on behalf of the Chief Investigators (Profs Read Montague and Peter Fonagy) who are based at University College London. 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.

If you wish to complain, or have any concerns about any aspect of the way you have been approached or treated by members of staff you may have experienced due to your participation in the research, National Health Service or UCL complaints mechanisms are available to you. Please ask your research doctor if you would like more information on this. In the unlikely event that you are harmed by taking part in this study, compensation may be available to you. If you suspect that the harm 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 the Prof Fonagy who is the Chief Investigator for the research and is based at UCL, Research Department of Clinical, Educational and Health Psychology, 1-19 Torrington Place, London, WC1E 7HB. 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

Who has reviewed this study?

This study has been reviewed by the **Queen Square REC (16/LO/0077).** Insurance/Indemnity for this study is provided by UCL.

Contact Details

If you wish to contact the research team to discuss any of the information further or any concerns you have about the study, then please do so by getting in touch with the members of the research team listed below:

If you feel that we have not addressed your questions adequately or if you have any concerns about the conduct of the research team, then please contact myself or the clinical supervisor Dr. Steven Pilling (s.pilling@ucl.ac.uk, Professor of Clinical Psychology and Clinical Effectiveness, Div of Psychology & Language Sciences, Faculty of Brain Sciences at UCL).

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Thank you very much for taking the time to read this information sheet.