Understanding the Social Brain in Healthy Volunteers and People with Psychological Difficulties – Part II.

This study has been approved by the Research Ethics Committee for Wales (Project ID Number): 12/WA/0283

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 how the social brain works of adults suffering psychological difficulties and compare them with healthy control participants. For instance, only little is known about the brain functioning in Borderline and Antisocial Personality Disorders. Our study design will address some of these open questions. This will hopefully allow us to gain a better understanding of the disorders and to develop 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 previously took part in our study **Understanding to Social Brain in Healthy Volunteers and People with Psychological Difficulties** and stated you were happy to be contacted about further research studies being undertaken by the PD-CPA research group.

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. 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. 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 agree to participate in this study you will be asked to come to the Welcome Trust Centre for Neuroimaging on one occasion. You will play five different interactive computerised tasks on a laptop and complete 4 task-related short questionnaires. These tasks further explore different types of social interaction and interpersonal behaviours, and you will receive full explanation of the task instructions before you perform each task. Together, this testing session will last no longer than 3 hours including breaks.

What are the possible disadvantages and risks of taking part?

There are no major risks in participating. Some people may find some of the task components upsetting or stress-inducing. In any case, 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 a handout on emotional regulation skills, and crisis phone numbers and details of clinical services to contact. Your personal therapist or probation officer 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 Personality Disorders, 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 with additional compensation depending on your performance on some of the tasks.

Who will know 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 USA. 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 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. Janet Feigenbaum or Dr Tobias Nolte on behalf of the Chief Investigators (Profs Read Montague and Read 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 **REC for Wales 12/WA/0283**..

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 my supervisor Dr. Janet Feigenbaum (Strategic and Clinical Lead for Personality Disorder Services, North East London NHS Foundation Trust and Senior Lecturer, Research Department of Clinical, Educational and Health Psychology, UCL) on 07957 919 961or by email at janet.feigenbaum@nhs.net.

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