**LONDON’S GLOBAL UNIVERSITY**

**Participant Information Sheet**

**Title of Study: Effort-based decision-making, reward and dopamine in depression in Parkinson’s disease.**

**Department:** UCL Institute of Cognitive Neuroscience  
**Name and Contact Details of the Principal Researcher:** Dr Harry Costello, Clinical PhD fellow to Professor Jonathan Roiser (Chief Investigator).

Contact: email - [harry.costello@ucl.ac.uk](mailto:harry.costello@ucl.ac.uk), tel - 02031082269, Institute of Cognitive Neuroscience, Alexandra House, 17-19 Queen Square, London WC1N 3AZ

**1. Invitation Paragraph**

You are being invited to take part in a research project conducted as part of a PhD student study. Before you decide it is important for you to understand why the research is being done and what your 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 the psychological processes and role of the chemical messenger dopamine in depression and Parkinson’s disease.

Depression in Parkinson’s disease is common and poorly understood. We want to know whether the amount of effort we are prepared to make to get a potential reward is impaired in people with Parkinson’s disease and depression, and if the chemical messenger dopamine is involved in this process. In our study, people with Parkinson’s disease and some people who don’t have Parkinson’s disease will complete a computerised task that investigates this. We will ask participants to complete the task while on their Parkinson’s medications and again when having delayed taking them for 10 hours.

Using magnetic resonance imaging (MRI), we will also look at your brain activity when you repeat the computerised psychological task. We will again ask people to do this twice, while on and off their Parkinson’s medications. We hope that these findings will improve the understanding of processes involved in depression and Parkinson’s and potentially inform the development of new treatments.

**3. Why have I been invited?**

You have been invited because you have a diagnosis of Parkinson’s disease. Your participation would allow us to investigate key differences in behaviours and brain changes in people with and without depression and Parkinson’s disease. We hope to recruit a maximum of 180 participants over a period of 24 months. We are looking for people who have a diagnosis of Parkinson’s disease aged 50 or over. 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 (implants, medical devices, etc).

**4. Do I have to take part?**

No. 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 treatment that you are entitled to or would normally receive. If you withdraw from the study any data collected will be removed and destroyed.

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

This study will involve up to four testing sessions (in most cases two sessions) with the study researchers based in Queen Square, London. You will be paid £7.50 per hour for your time participating in the study, we will reimburse your travel expenses (up to £40 per trip) and up to £20 will be able to be won by each participant as the reward for completing the behavioural task during each session.

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.

You will initially have a telephone conversation with Dr Costello, where he will make sure that you are suitable to take part in the study. Following this conversation we will ask you to arrive for your first testing session either:

1. **Having taken your Parkinson’s medication as usual.**

**OR**

1. **Having not taken your Parkinson’s medication for a minimum of 10 hours.**

***First visit***

The first visit (which will take place at The Institute of Cognitive Neuroscience, Alexandra House, 17-19 Queen Square) and 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 four questionnaires about your mood and Parkinson’s symptoms. You will also have your memory tested and have a physical examination of your Parkinson’s symptoms.
* Complete a computerised task where you will be asked to exert physical effort via grip force for a potential reward.
* If able you will be asked to repeat the task while undergoing a brain scan. If you would prefer to do this at another time further (third & fourth visits) will be offered.

If you are ineligible for the study after this first visit, you will be reimbursed for your time (at £7.50 per hour) and no further procedures will follow.

***Second visit***

The second visit (again this will take place at The Institute of Cognitive Neuroscience, Alexandra House, 17-19 Queen Square) will last around 1 hour.

During this visit if you were asked prior to the first visit to arrive having not taken your Parkinson’s medication, you will now be asked to take your medication as usual prior to arrival, and vice versa. You will then complete the following:

* - Further questionnaires about your mood and physical examination of your Parkinson’s symptoms.
* - You will then repeat the computerised task where you will be asked to exert physical effort via grip force for a potential reward.
* - If able you will be asked to repeat the task while undergoing a brain scan. If you would prefer to do this at another time further (third & fourth visits) will be offered.

***Third & Fourth visit***

If you are suitable and had not undergone brain imaging during your first two visits, you will be invited in to repeat the computerised task inside the MRI scanner (see below for more information on MRI). These visits are optional and each session, which will last around 2 hours, will take place at The Wellcome Centre for Human Neuroimaging 12 Queen Square, WC1N 3AR.

During these visits you will be asked to complete the computerised task while having an MRI brain scan. We will again ask you to arrive either:

1. Having taken your Parkinson’s medication as usual.

OR

1. Having not taken your Parkinson’s medication for a minimum of 10 hours i.e not taking your morning medication prior to testing.

Total time commitment for all visits will be a minimum of 3 hours and a maximum of 7 hours.

**MRI brain scan**

We use functional magnetic resonance imaging (fMRI) to take images of 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 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 could be risks associated with taking magnetic metal into the scanner, so you will be screened thoroughly to ensure you have no such metal on your person or in your body.

The brain scan may reveal abnormalities or unusual findings that are unaware of and which may require further investigation. In the event of such findings you will be informed, they will be discussed with an onsite neuroradiologist and we will then inform your GP with view to local clinical services taking further action if needed.

Delaying your Parkinson’s medications may cause your symptoms to worsen for a few hours during this period. During testing a clinician (Dr Costello) will be with you throughout to monitor your symptoms, and if at any point symptoms become distressing we will ensure you can take your medication and discontinue testing.

As testing will be in person there is an ongoing risk of COVID-19 infection. To avoid this during testing social distancing and mask wearing will be mandatory, and government guidance regarding ventilation and decontamination followed. All researchers will be double vaccinated and to minimise risk of infection we request participants are double vaccinated.

**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, and potentially inform future treatments of depression.

**9. Payment**You will be paid £7.50 per hour for your time participating in the study, we will reimburse your travel expenses (up to £40 per trip) and up to £20 will be able to be won by each participant as the reward for completing the behavioural task during each session.

**10. What if something goes wrong?**

If you experience any adverse side effects relating to any aspect of this study, please contact the Chief Investigator of the study (harry.costello@ucl.ac.uk) in the first instance. Dr Costello is a trained psychiatrist and can also be contacted for any medical concerns.

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 Professor Jonathan Roiser (j.roiser@ucl.ac.uk), who is the Principal Investigator for the research who is based at the UCL Institute of Cognitive Neuroscience. The Principal 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**.**

UCLH patient and advice liaison service (PALS) can also be contacted via by telephone (020 3447 3042) or email: [uclh.pals@nhs.net](mailto:uclh.pals@nhs.net) .

**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 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. If you have consented you may be contacted by researchers to be involved in future research.

**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, the UCL Data Protection Officer is Alexandra Potts ([data-protection@ucl.ac.uk](mailto:data-protection@ucl.ac.uk)). 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 or University College London Hospital 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 or University College London Hospital 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 and or University College London Hospital 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 UCLH 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.

**Who has reviewed this study?**

This study has been reviewed and approved by the North of Scotland Research Ethics Committee. It has undergone peer review by the UCL Wellcome Trust Clinical Research Fellowship panel, the Medical Research Council Clinical Research Fellowship panel and by the Neuroscience & Mental Health group at the UCL Institute of Cognitive Neuroscience.

**Who is organising and funding this study?**

Professor Jonathan Roiser in Chief Investigator on the study and Dr Harry Costello is Principal Investigator. Dr Costello and the study is funded by a grant from The Wellcome Trust (grant award number: 175479)

**Contact details**

**If you are interested in potentially taking part in this study or would like to discuss this information further please email:-** [**harry.costello@ucl.ac.uk**](mailto:harry.costello@ucl.ac.uk) **or Phone*:* 02031082269**