PARTICIPANT INFORMATION SHEET

CAN-PDP mechanistic MRI Control Study

We would like to invite you to take part in our research study. Before you decide, it is important for you to understand why the research is being done and what it will involve for you. Please take time to read the following information and discuss it with others if you wish. Please ask a member of the study team if there is anything that is not clear or if you would like more information.

What is the purpose of the study?

People with Parkinson's often suffer from unusual experiences such as hallucinations (e.g. seeing things or hearing voices that are not there) or develop delusions (i.e. false beliefs, for example, that someone may be trying to harm them) as part of their illness. These experiences are also known as psychotic symptoms and are distressing both to patients and those caring for them.

More than half of all patients with Parkinson' eventually develop these symptoms over the course of their disorder. These problems can be difficult to manage and can impact quality of life. Currently, existing medications to treat these symptoms are either not very effective or have significant side effects.

This MRI control study will be an add onto the clinical trial, Cannabidiol for Parkinson's Disease Psychosis (CAN-PDP). CAN-PDP aims to test a novel treatment called cannabidiol (CBD) and look at how safe and well CBD works in Parkinson's patients with psychosis, and how well it is tolerated.

Another important aspect of the CAN-PDP trial will be to investigate the effect of CBD on the brain function of Parkinson's patients with psychosis. To do this, we would like to compare the brains of people from the CAN-PDP trial to the brains of people with Parkinson's, but without psychosis, and healthy volunteers without Parkinson's using magnetic resonance imaging (MRI). Hence this mechanistic MRI control study.

Why have I been approached?

We are looking for 40 volunteers: 20 people who have Parkinson's but no psychosis and 20 healthy older adults without Parkinson's.

You have been invited to take part in this study because you do not have Parkinson's and have showed interest in participating and requested further information.

Do I have to take part?

It is up to you to decide whether or not to take part. If you decide to take part, you will be given this information sheet to keep and will be asked to sign a consent form. If you decide to take part, you are still free to withdraw at any time, without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the future medical care that you receive.

What will happen to me if I take part?

If you agree to participate, you will undergo a clinical assessment and a brain scan on one occasion.

➢ Screening

The screening visit will last approximately 2 hours and will take place either at the Clinical Research Facility, King's College Hospital or in your own home, whichever is most convenient for you. You will be asked some questions to review your eligibility to take part in this research project and, if eligible, be asked to read and sign a consent form.

We will ask questions to get basic background information about you and your past medical history. We will ask you to fill in three questionnaires and rating scales relating to your memory and to ensure that you do not have any symptoms of psychosis. We would also like to ask an informant (someone that knows you well) to answer some questions relating to any behavioural or psychological symptoms that you may be experiencing.

To minimise the length of time taken for face-to-face visits, we will aim to conduct some of the activities such as taking consent and completing questionnaires virtually (i.e. email, videocall, over the telephone) where this is feasible. Remote visits will be conducted through Microsoft Teams. If you have any questions about Microsoft Teams and how we will conduct these remote visits, please feel free to ask us.

➢ MRI

You will undergo an MRI scanning session that will last approximately 60 minutes at King's College London, Denmark Hill.

The MRI scan involves lying on a bed, which would then be moved into the middle of a long tube. Below there is a picture of how an MRI scanner looks. We would help you on to the bed if mobility is difficult and ensure that you are comfortable prior to starting.

The scanner is noisy (a bit like a road drill) but we will provide earplugs and ear-defenders, and you would able to speak to the radiographer at all times. If you get tired or need to have a break, we can bring you out of the scanner as needed. There is a 'panic button' you can press at any time if you want to stop the scan and be taken out. We would remove you immediately if you felt uncomfortable in any way.

You can find more information about the MRI scan and what it involves at the following websites:

https://www.kch.nhs.uk/service/cancer/tests-and-investigations/mri-scan

https://www.nhs.uk/conditions/mri-scan/

During the scan, you will be asked to lie flat on your back with your head inside the scanner. We will ask you to perform some simple tests while you are having the scan, which will be fully explained to you beforehand. During these tests, you will be asked to respond to different pictures appearing on a screen displayed in the MRI scanner by pressing a button or saying a word. We will also perform further brain scans during which you will only be required to lie still and not perform any tasks.

What are the possible benefits of taking part?

There will not be any direct benefits for you from taking part in this study. The information we obtain may help us to understand the brain functioning in people with

Parkinson's and treat them more effectively in the future, reducing both patient and caregiver distress.

What are the possible disadvantages and risks of taking part?

1) MRI can sometimes feel discomforting because of the noise, but you will be provided with ear protection when lying in the scanner. Sometimes MRI can cause temporary dizziness. Some people can also become claustrophobic in the scanner. If you are worried about becoming claustrophobic, please let a member of staff know before coming to your appointment. This way we can show you the scanner and ensure that you are comfortable to go ahead, prior to being scanned.

We appreciate that 60 minutes is a long time for anyone to remain still. Time will therefore be allowed in-between scans for adjustment of position to reduce any discomfort.

People who have any metallic foreign bodies in the body or eyes, or metal implants in the body, such as intra-cranial aneurysm clips, pacemakers or defibrillators cannot take part in this study. If you are not sure whether you are able to participate in the MRI scan due to the presence of metal in your body, please ask the study team.

Prior to the MRI scan you will be asked to complete a questionnaire and will be screened by the radiographer to make sure that you can safely complete a scan. The radiographer will also be able to answer any questions or concerns that you have about the scan.

2) Some of the questionnaires and rating scales may involve you and your informant answering questions that are sensitive and of a personal nature. You should only answer those questions that you are comfortable with. You do not need to answer any questions you do not wish to.

What will we do if we notice something abnormal on the scan?

The scans taken for this study are not the same as the one we would acquire for clinical diagnostic purposes. However, in the unlikely event that we would notice a potentially medically relevant abnormality on your scan, we will inform you directly and your GP if you wish us to do so. Your GP will then arrange for any further investigation or treatment if needed.

How will we use information about you?

Members of the research team will use information from you and from your medical records as needed for this research project. The identifiable information will include:

- your name and contact details
- your date of birth
- your NHS number

All information collected about you during the course of the research will be kept strictly confidential. Any information about you on the database will be assigned a randomly generated ID number and any identifying details such as name, contact details will be removed so that you cannot be recognized from it.

If you consent to take part in the research, with your permission we will write to your GP to inform him/her that you are participating in this study.

KCL/ SLaM is the sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller. This means that we are responsible for looking after your information and using it properly. KCL/ SLaM will keep identifiable information about you for 10 years after the study has finished.

Individuals from KCL/ SLaM, regulatory authorities or NHS Trust may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

People who do not need to know who you are (for example, the people who analyse the information) will not be able to see your name or contact details. Your data will have a code number instead.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.
- If you agree to take part in this study, you will have the option to take part in future research using your data that is saved from this study on the KCL database.

Where can you find out more about how your information is used?

You can find out more about how we use your information:

- at www.hra.nhs.uk/information-about-patients/
- by ringing a member of the study team on 07936545178
- by contacting King's College London's Data Protection Officer, Mr Albert Chan at info-compliance@kcl.ac.uk

Will I be reimbursed for taking part?

As a thank you, we would like to give you a £25 gift voucher at the end of the MRI visit. This should help to cover any reasonable costs of participating in the study. If preferred, we are happy to refund any travel or other reasonable expenses you incur in order to attend the research visits. We simply ask that you keep your receipts.

What will happen if I do not want to carry on with this study?

Your decision to participate in this study is voluntary. You may choose not to participate, or you may withdraw from the study for any reason, without penalty or loss of benefits to which you are otherwise entitled and without any effect on your future medical care. If you withdraw from the study, unless you state otherwise, data which have been collected whilst you have been in the study will be used for research as detailed in this participant information sheet.

What will happen to the results of the research?

We will publish the results in international scientific journals and present the findings at scientific conferences. You will not be identified in any publications or presentations.

What if there is a problem?

If you wish to complain or have concerns about any aspect of the way you have been approached or treated during the course of this study, please contact the Study Manager on 07936545178 or by email at canpdp.trialoffice@kcl.ac.uk.

You may also contact the NHS Patient Advice and Liaison Service (PALS) for independent advice. South London and Maudsley (SLaM) NHS Foundation Trust PALS can be contacted on free-phone 0800 731 2864 or by email at pals@slam.nhs.uk. Alternatively, you can dial NHS 111 to find the nearest PALS.

Regarding insurance cover, King's College London (KCL)/ SLaM will maintain adequate insurance in relation to the study, KCL through its own professional indemnity and no-fault compensation, and the Trust having a duty of care to patients via NHS indemnity cover.

King's College London will provide compensation for claims in respect of non-negligent harm and there is insurance for negligent action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the study we would encourage you to discuss this with us as soon as possible and we will do our best to rectify matters or change procedures as appropriate.

Who is funding the study?

Parkinson's UK is funding this research.

Who has reviewed the study?

This study has been reviewed and given favourable opinion by London Hampstead Research Ethics Committee.

Further information and contact details:

Thank you for reading this information and for your interest in the CAN-PDP mechanistic MRI control study. For further information, please contact the CAN-PDP Study Manager:

Address: Department of Psychosis Studies, Institute of Psychiatry, Psychology & Neuroscience (6th Floor), 16 De Crespigny Park, London, SE5 8AF

Tel: 07936545178

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