# AND-PD - Patient Information Sheet

- Please take time to read the following information carefully. Discuss it with friends and relatives if you wish. Take time to decide whether you wish to take part.
- You are free to decide whether or not to take part in this research study. If you choose not to take part, this will not affect the care you get from your own doctors in any way. You can stop taking part in the study at any time, without giving a reason.
- Ask us if there is anything that is not clear or if you would like more information.

  Thank you for reading this information. If you decide to take part, you will be asked to sign a consent form either electronically or on paper. You will be provided with a copy of both this patient information sheet and the signed consent form.

## Important things that you need to know

- We want to find out how and where anxiety with or without depressive symptoms originates in patients with Parkinson's disease, and why some people with Parkinson's disease are more prone to anxiety than others.
- 150 patients with Parkinson's (both with or without anxiety or depression) and 50 volunteers (both with and without anxiety) will be recruited to this study across 5 hospitals/neurology centres in and around London, UK.
- The study includes an assessment at baseline, with follow-up assessments at 6 and 12 months. These will either be held online or one of the participating clinical centres, including the Royal Free Hospital, London, UK, or King's College Hospital, whichever one is closest to you. There is one optional MRI scan either at the Wellcome Centre for Human Neuroimaging (WCHN, UCL) or at the Centre for Neuroimaging Sciences, again whichever is nearest to you.

## Contents

## 1 Why are we doing this study?

Anxiety has been listed as the second most important issue by people with Parkinson's and depression is also common in Parkinson's, affecting approximately 40% of patients. There is currently little information about how and where anxiety with or without depressive symptoms originates in patients with Parkinson's, how to be best treat it or why some patients with Parkinson's are more prone to anxiety than others.

### What are we trying to find out?

We want to find out what the risk factors and associated clinical features are for anxiety in people with Parkinson's, and to identify the underlying biological changes associated with emotional dysfunction in the disease. The eventual aim will be to identify targets to help design therapies to improve anxiety in Parkinson's. We also would like to see if patterns of anxiety and depression, which is often associated with anxiety, differ in people with and without Parkinson's. Finally, we would like to see if there are structural or functional brain differences between people who have anxiety in Parkinson's and those who do not.

## 2 Why am I being asked to take part?

You are being asked to take part in the AND-PD study for these reasons:

- You have a confirmed diagnosis of Parkinson's disease.
- You are aged between 18 and 89 years old.

## 3 What will I need to do if I take part?

### Can I definitely take part?

Not everyone will be able to take part in this study. Only patients that meet the study entry requirements and are willing to participate may take part.

You have been given this information sheet because your nurse or doctor feels you may be suitable to take part. The research staff will go through this information sheet with you and you

can ask questions about the study. You may also share this information sheet with family, friends or GP.

If you decide you would like to take part, you will be invited to attend a screening visit. At this screening visit, you will have the opportunity to ask any questions you may have regarding the study. You will be asked to sign a consent form, either electronically or handwritten, should you wish to continue.

If you are a woman of childbearing potential you will also be asked to use adequate contraception throughout the study and to have a pregnancy test before the start of the study, as you cannot have a research MRI scan if you are pregnant.

You will be asked to complete study assessments and questionnaires.

The results from all assessments, urine pregnancy test and questionnaires will be analysed by the research staff to determine if you are suitable for inclusion in this study.

With your permission we will inform your GP once you join the AND-PD study.

## What if the tests show I can take part?

If you meet all the entry requirements for the AND-PD study, you may be enrolled onto the study on the same day. If you need time to discuss your participation in the study with family, friends or GP then a member of the research team will contact you at a later date to answer any questions you may have and to arrange a convenient time for you to return to the hospital/clinic to be enrolled onto the study. The research staff will go through the next key steps with you.

## What will happen to me during the study?

You will be asked to attend three (3) study appointments over a 12-month period: the screening visit (visit 1), baseline (visit 2) and follow-up at 6 months (visit 3) and follow-up at 12 months (visit4/final visit). Visit 1 can be combined with visit 2.

You will have a physical examination, psychology testing and computer-based tasks. Participants can also have (optional) brain scans (MRI) to measure brain responses correlating with measures of anxiety in different regions of the brain. The assessments for the current study will include medical history, physical tests, neuropsychological assessment, clinical questionnaires, behavioural testing, and a structural and functional MRI scan. Many of these tests and questionnaires can be carried out online except for the MRI scan. We will give you the option to be video recorded in order to help us standardised the marking and analysis of these tests.

The computer-based tasks will be piloted (tested) at the beginning of the study and refined as the study progresses. Pilot studies are small-scale, preliminary studies which aim to investigate whether all components of a study will be feasible. They may be used to improve upon various aspects of the study design. We will be looking at the ease of administering the different tasks, and any feedback participants might have about them across both sites (UCL and KCL).

The tests will include tasks such as naming colours, calculation or selecting cards to gain reward points

At each study visit, you will be asked to complete several study assessments including questionnaires. These questionnaires will contain questions asking about your anxiety symptoms, depression, and your movement symptoms. There will also be general questions asking about your quality of life. Your doctor will complete some scales also asking about your movement skills and your mental capabilities. The various assessments and questionnaires performed at each study visit are shown in the Summary of Assessments at the end of this patient information sheet.

The study visits will either be online or at the clinical centre where you were recruit to the study.

The MRI scans will be carried out either at Wellcome Centre for Human Neuroimaging, Queen Square (or if you are being seen at KCH, then your scan will be at the Centre for Neuroimaging Sciences). The scans will be carried out by a radiographer and one of the researchers. Heart rate and skin-conductance measurements will be carried out during your MRI appointment.

You will be assessed at baseline and then invited back for reassessment after 6 months (visit 3) and one further follow-up visit at 12 months.

### What checks and tests will be done?

We estimate the screening/baseline visit assessments and questionnaires will take between two and three hours (and another two to three hours if you have an MRI scan). We anticipate that the assessments and questionnaires at follow up visits will be completed in under three hours. Each testing session can be done over two days, if preferred.

Many of the assessments and tests can be carried out securely online (see accompany COVID information sheets). Some of the questionnaires can be emailed or posted prior to the study days, answered at home and either completed online, emailed, or brought to the assessment on the day.

## 4 What are the possible benefits of taking part in this study?

Although there is no promise that this study will benefit you personally, the results generated may help to improve the treatment options of people with anxiety in Parkinson's disease in the future.

## 5 What are the possible disadvantages and risks of taking part?

The risks of taking part in the observational study are very low as this does not involve a drug or device other than your own computer. The main potential risk is discomfort or increased anxiety at the time of the assessments. We will take careful measures during the assessments, considering physical and emotional issues, and will break up assessments as desired by you.
In case you have any worries about having the study procedures, please contact us (and-pd@ucl.ac.uk) for advice and we will discuss this with you.

If you would like some support with your anxiety, Anxiety UK is a charity providing support for people with an anxiety condition. Phone: 03444 775 774 (Monday to Friday, 9.30am to 5.30pm). Website: www.anxietyuk.org.uk. You can also speak to your doctor for advice.

**What happens if something suspicious is seen on my MRI?**
The brain scans we do are not designed to diagnose disease; however, abnormalities are occasionally detected during the scanning process. Most of these are no cause for concern. In some cases, identification of a major abnormality that requires action will be reported to the doctor you specify on your MRI consent form and to the study investigators.

It is important to understand that we will not notice all potentially serious abnormalities. If you do not receive any feedback from us, you should not regard this as reassurance about your health, and it should not stop you from seeing your doctor about health concerns you might have.

If you suffer from claustrophobia, you should notify a member of the study team before you have the MRI scan in case you become anxious while in the magnetic resonance scanner. There may be loud noises such as knocking or hammering that occur while the MRI is being conducted. You should also inform the study doctor if you have a pacemaker or metal implants (screws, plates, or clips) because this may preclude MR evaluation; a radiographer will undertake a final check that there is nothing that makes is unsafe for you to be scanned on the day of your scan, but please discuss any potential issues with the study team before your visit if at all possible.

Please let the study team know as soon as possible if you are suffering from COVID symptoms or may have come into contact with someone with COVID, and if so, please **DO NOT** come to the scanning centre.

# 6 More information about taking part

## Do I have to take part in the AND-PD study?

No, 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 you will be asked to sign a consent form.

If you decide not to take part in this study, will not affect the standard of care you receive.

## Will I get back any travel costs?

You may be able to claim money to cover additional travel expenses incurred for study visits (up to a maximum of £10 per visit). Please speak to your study doctor/nurse.

## Can I stop taking part after I've joined the study?

You can stop taking part in the study at any time and without giving a reason. A decision to stop taking part at any time will not affect the standard of care you receive. You can withdraw from the study at any point. If you do withdraw, the study team will keep data already collected but will not collect any additional data.

## What will happen to information about me collected during the study?

If you consent to take part, the records obtained while you are in this study, as well as related health records, will remain strictly confidential at all times. The information will be held securely on paper and electronically under the provisions of the 2018 General Data Protection Regulation (GDPR). To safeguard your rights, we will only collect the details that identify you, for example your name and contact details, that are needed for the study. These details will not be passed to anyone else outside the research team or the Sponsor (UCL), who is not involved in the study.

When you enrol in the study you will be allocated a unique number, which will be used as a code to identify you on all study forms. This means your data is pseudoanonymised.
Your records will be available to people authorised to work on the study but may also need to be made available to people authorized by the Sponsor, which is the organization responsible for ensuring that the study is carried out properly. All will have a duty of confidentiality to you as a research participant.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

**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/, UCL website or https://www.ucl.ac.uk/legal-services/privacy

· our leaflet available from Sponsor Data Protection Officer data-protection@ucl.ac.uk

· by asking one of the research team · by sending an email to and-pd@ucl.ac.uk or Sponsor Data Protection Officer data-protection@ucl.ac.uk

· by ringing us on 020 8016 8181

Data will be stored on manual paper files, on a secure database (REDCAP), NHS computers, university computers and laptop computers.

If the study research team are unable to contact you at any time during the study, with your permission, they will access the relevant sections of your medical records on NHS Digital (Spine) to obtain your contact details.

You can find out more about how we use your information at www.ucl.ac.uk/cctu/use-of-data.

## What will happen to the results of the AND-PD study?

We will publish the results in a medical journal, so that other doctors and researchers can see them. Your identity and any personal details will be kept confidential. No named information about you will be published in any report of this study.

## Who is organising and funding the study?

This study is organised by University College London (UCL).

University College London has overall responsibility for the conduct of the study. They are responsible for ensuring the study is carried out ethically and in the best interests of the study participants.

Funding for this research has come from an EU Commission grant Horizon202 grant 848002.

## What if new information becomes available during the study?

Your doctor might also suggest that it is in your best interests to stop taking part in the study. Your doctor will explain the reasons and arrange for your care to continue outside the study.

## What happens if the AND-PD study stops early?

Very occasionally a study is stopped early. If it happens, the reasons will be explained to you and your doctor will arrange for your care to continue outside of the study.

## What if something goes wrong for me?

Every care will be taken during this AND-PD study to ensure that your well-being is not compromised. If, however you have a concern about any aspect of this study, please feel free to

contact a member of the research team (see contact details below). We will do our best to answer your questions or concerns. If you are not satisfied with this, you can make a formal complaint using the normal NHS (National Health Service) procedures. Details can be obtained from the Department of Health website: http://www.dh.gov.uk. You can do this within 12 months of the events concerned, or within 12 months of becoming aware of the problem. Your complaint will be recorded as part of our formal complaints policy. You can contact the confidential patient advice and liaison service (PALS). PALS was set up to support patients, their families and visitors who need advice or have problems and concerns. The contact details for PALS at the Royal Free Hospital are:

Tel: 020 7472 6446 or 020 7472 6447 (open from 10am to 4pm, Monday to Friday).
24-hour answer phone: 020 7472 6445
Fax: 020 7472 6463
SMS: 447860023323 (Deaf and hearing-impaired patients only)
Email: rf.pals@nhs.net

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 study doctor, please make the claim in writing to Prof Anette Schrag who is the Chief Investigator for the study and is based at The Royal Free Hospital. 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. Participants may be able to claim compensation for injury caused by participation in this study without the need to prove negligence on the part of University College London or another party. You should discuss this possibility with your study doctor in the same way as above.

**Who has reviewed this study?**

All research in the NHS is reviewed by an independent group of people, called a Research Ethics Committee (REC) which is there to protect your safety, rights, wellbeing, and dignity. This study has been reviewed and given a favourable ethical opinion by the Research Ethics Committee (REC) and the Health Research Authority (HRA) in accordance with UK regulations.

## 7 Contacts for further information

You are encouraged to ask any questions you wish, before, during or after your study participation. If you have any questions about the study, please speak to a member of the study team or doctor, who will be able to provide you with up-to-date information about the procedures involved.

If you decide to take part, then please read, and sign the consent form. You will be given a copy of this information sheet and the signed consent form to keep.

Thank you for taking the time to read this information sheet and to consider this study.

**Your Research team:**

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## AND-PD - Summary of Assessments