Oxford University Hospitals NHS
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NUFFIELD DEPARTMENT OF CLINICAL NEUROSCIENCES

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# PARTICIPANT INFORMATION SHEET (Patients)

## Study title: Oxford study of Quantification in Parkinsonism

We would like to invite you to take part in our research study. Before you decide whether you would like to do so it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish.

There is no obligation to take part in this research study and choosing not to will not affect your care in any way.

Part 1 tells you the purpose of this study and why we have asked you to help us.

Part 2 gives you more detailed information about what will happen to you if you decide to take part. If there is anything that is not clear, or if you would like more information, please ask us.

Thank you for reading this information sheet.

## PART 1

### What is the purpose of the study?

Parkinson's disease (PD) is a common neurodegenerative disease that affects one in every hundred people over the age of 55. It is estimated that there are seven to ten million people with PD worldwide. It is disabling, incurable and gradually progressive. Progressive Supranuclear Palsy (PSP) is a related condition that presents initially with very similar features to PD. Eventually other features appear that are not part of idiopathic PD, such as paralysis of voluntary upgaze. Currently available treatments for both PD and PSP are symptomatic only, and while they may be effective for a number of years, they do not have any preventive or disease-slowing effect.

One of the problems with these conditions is that we presently lack a completely reliable means of measuring their severity. We use "clinical rating scales" which are points-based systems in which a doctor or nurse has to score how badly the person with PD or PSP is affected by various aspects of their condition. This is a subjective process, in other words it depends on the impression of the person making the assessment, and two doctors may sometimes disagree about the score. The scale is also sometimes difficult to interpret, for example the difference between scores of 20 and 30 may not be the same size as the difference between scores of 30 and 40. In contrast, most medical conditions nowadays can be very accurately and reliably measured using special equipment, for example the level of your blood pressure, or the difficulty of breathing in asthma.

The need for accurate measures is particularly great when conducting trials of new drugs. Accurate evaluation of whether they work or not depends on precise measures of disease symptoms for each patient both before and after treatment. Drug trials may take years, and an accurate early measure of effect would allow interim results to guide decisions at which point resources can be focussed on those drugs that look most promising.

The aim of this study is to develop and validate sensitive tests to measure the symptoms of PD and PSP.

**Why have I been invited?**

You have been chosen to consider taking part in this study because you either have Parkinson's Disease or Progressive Supranuclear Palsy. We are also asking people without Parkinsons Disease or Progressive Supranuclear Palsy to take part in this study in order to understand accurately what the test results are in the absence of any neurological disease.

**Do I have to take part?**

It is up to you to decide whether or not to take part. We have provided you with information in this sheet, which we hope will enable you to make a decision. We are very happy to discuss this further in person or over the phone if you have any questions or concerns. If you do decide to take part, you are free to withdraw at any time, without giving a reason. A decision to withdraw will not affect the standard of care you receive.

## PART 2

**What will happen to me if I decide to take part?**

We will firstly go through with you once more the information in this form and give you another opportunity to ask questions. If you still wish to proceed we will complete a study consent form with you.

The tests we ask you to do will be the same for all of the participants in this study. For most patients, we will ask to see you once every three months for two years (total of nine visits). A small group of participants will be chosen because they are having, or have had, deep brain stimulation for Parkinson's disease. If you are a deep brain stimulation patient we will see you a maximum of two times, as described further below.

Each appointment will last between an hour and a half and two hours. At the first appointment we will ask about your medical history and what tablets you are taking (it may help to bring a list of any repeat prescriptions). This information is important because other medical conditions or medications may affect the results of some of our tests. In order to ensure that this information remains accurate, on subsequent visits we will ask you whether you have had any new medical problems or changes in medication since the last visit.

On each visit we will go through the same sequence of tests, which will include:

- **Standard clinical rating scales** including the Movement Disorders Society Unified Parkinson's Disease Rating Scale (MDS-UPDRS) or the PSP Rating Scale (PSPRS) as appropriate, the Hoehn and Yahr scale, 3 metre timed get up and go test, the Schwab and England score, the EQ-5D health questionnaire, and the PDQ-39 questionnaire. The standard movement tests in the MDS-UPDRS or PSPRS will be performed while wearing accelerometer devices that quantify the movements being performed.

- **Walking and balance** testing using "wearable" accelerometer/gyroscope sensors. These are in form of bracelets/anklets or adhesive skin patches and will be comfortable to wear.

- **A cognitive assessment** including conventional pen and paper style tests and some newly developed tests that run on a tablet computer.

- **Eye movement tests** in which we record your eye movements while you perform various tasks, for example following the movements of a dot of light on a screen. Some eye movement data will be captured by a device that rests on the bridge of your nose and is held in place with an elastic strap around your head, and in other tests we will use a device mounted on a table that you sit in front of and look through.

- **Finger-tapping tests** in which you will be asked to tap touch sensitive pads on a tabletop device with your fingers, while we record the rate and rhythm of your tapping.

- **Reaction time tests** in which you will be asked to respond to the appearance of a visual stimulus by pressing an appropriate button on a control box. The stimulus may be in the form of a light on the control box or an image on a display screen.

- **Muscle activity tests (EMG)** in which we record electrical activity in muscles using sticky pad electrodes attached to your skin.

On one occasion, if you are happy for us to do so we will record brain signals from the scalp (known as the "electroencephalogram" or EEG) whilst performing the cognitive and eye movement tests. This is a non-invasive procedure which simply involves wearing a cap during the testing, that records signals from the skin surface.

If you have mild to moderate (but not advanced) PD we will ask you to come to one of your visits (usually the second or third) without having taken your medication that morning, but only if you are happy to do this. On that occasion only, we will do the tests twice, once on arrival and then you can take your medication and we will repeat the tests half an hour later. This gives us valuable information about how the test results are affected by the medication itself (as opposed to the PD).

At the end of each clinic appointment, if you are willing we may give you bracelets/anklets or adhesive skin patches to wear that will record body movements at home over a longer unsupervised period (maximum 3 days). They will be comfortable to wear and not interfere with normal activity. In order to avoid additional inconvenience, at the end of the monitoring period the devices may in some cases be returned by mail (we will provide a prepaid envelope) or we will offer to collect them from you.

If you are a deep brain stimulation patient we will see you on a maximum of two occasions, once (visit 1) during your assessment for deep brain stimulation, and/or once (visit 2) some months after your surgery once your stimulation has been optimised. During assessment for deep brain stimulation there is always a short (one or two days) planned inpatient stay in hospital, in order for the clinical team to conduct a detailed evaluation of your symptoms both on and off medication. Visit 1 for this study will be during that time, when you are in hospital anyway. We will test you while you are off your medication and then again when you are on your medication. At visit 2, we will test you once with your stimulator turned on and once with it turned off (we will not stop or change any of your medication for this). This may require an extra clinic visit but we will try to coincide it with a routine clinic visit if possible.

Some patients will be seen only once, either because they do not go on to have DBS after their assessment (hence visit 1 only), or because they are recruited to this study subsequent to having DBS surgery (hence visit 2 only).

**Are there any possible disadvantages or risks from taking part?**

All the tasks in this study are entirely non-invasive and pain free. On one occasion, if you are happy to do so, we may ask you to come to your appointment without taking your Parkinson's medication that morning, so that we can see how your symptoms are when off medication. If you do not wish to do this, you can still take part in the rest of the study. Testing on and off medication has been extensively performed in many research studies without any reported detrimental effects. We will only ask patients with mild to moderate PD to do this, not those with advanced PD. Patients will be asked to take their medication immediately after testing and before they head home.

If you have a Deep Brain Stimulation (DBS) system we will briefly switch it off (for a period of not more than one hour). This may lead to a temporary worsening of movement related symptoms. This is routinely done during follow up assessments to assess how well the DBS system is working, and in our experience it is well tolerated, but if the symptoms are at all

distressing we can turn the stimulation back on rapidly. The switching on and off of DBS systems would be performed only by personnel trained in the use of the DBS equipment.

**What are the possible benefits of taking part?**

There is no direct benefit to you from taking part in this research study. We hope that the information we get from this study may help us understand Parkinsonism better, and in particular to find ways to accurately quantify its symptoms, which will greatly help in running clinical trials of potential new treatments.

**Will my General Practitioner/family doctor (GP) be informed of my participation?**

We will inform your GP about your participation in this study. If you do not wish your GP to be contacted please do not initial the box on the consent form.

**Will my taking part in the study be kept confidential?**

All the information that is collected about you during the course of the research will be kept strictly confidential.

Each participant will be assigned a unique participant ID and all data and results will be stored using this, instead of your name or any other identifiable personal information, and under password protection. A document linking participant names to ID codes will be stored separately, password-protected on a secure NHS computer system accessible only by the study team. It will not be possible for anyone else to identify the results as yours.

Responsible members of the University of Oxford and Oxford University Hospitals NHS Foundation 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.

With your consent, anonymised data collected during the course of the study may be shared with researchers to be used in other studies in the department or to other organisations which may include commercial organisations.

**Will I be reimbursed for taking part?**

All of your travel expenses will be fully reimbursed using standard business mileage costs for car travel and any parking costs. The costs are refunded directly into your bank account within one month of each visit via our Finance Department.

**What will happen if I don't want to carry on with the study?**

You are 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 your future care in any way. We will ask whether you are still happy for us to use data that we have collected up to the point when you decided to withdraw. If you are not happy for us to use this data it will be destroyed.

In addition, we may discontinue your participation in some circumstances, including:

- if you develop another medical condition that might make the test results difficult to interpret accurately
- if we become unable to contact you

**What will happen to the results of this study?**

We hope that the results of this study will be suitable for scientific publications in biomedical journals as well in presentations at national and international conferences. We will also send you a newsletter at the end of each year to update you on the study progress and any analysis that we might have carried out by that time. At the end of the study we will send you the final summary of our results.

Please note that it will never be possible to identify you or your individual data from any report or publication placed in the public domain.

Data will be kept **in anonymous form** after this study is complete in case it proves useful in future studies. The standard period for retention for studies at the University of Oxford is 20 years.

**What if you find something unexpected?**

It is important to understand that the tests in this research study cannot be regarded as accepted clinical tests for Parkinsonism at present. We will only know if they work well once the study has been completed and all the data has been analysed. For this reason, we do not intend to discuss individual results with participants but we will keep all participants informed about overall group-level findings and inform the wider international scientific community.

The tests we will use are not intended to diagnose any other conditions. If by coincidence members of the study team see anything that leads us to think you might have an unrelated medical condition, you will be informed of this and we will advise you to discuss it with your General Practitioner (GP).

**What if there is a problem?**

If there are any problems or you have any complaints during the course of this study, you should contact either Dr James FitzGerald (PA Vicky Ford 01865 234605) or Dr Chrystalina Antoniades on 01865 234728.

If you are still unhappy you can contact your local hospital's Patient Liaison Service (Oxford University Hospitals NHS Foundation Trust PALS Department on 01865 221473) or the Head of the University of Oxford Clinical Trials and Research Governance office (01865 572224 / e-mail: ctrg@admin.ox.ac.uk).

The University of Oxford, as Sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this trial.

**How have patients and the public been involved in this study?**

We believe that involving people affected by Parkinson's at all stages of research produces higher quality, more relevant research and ensures that the benefits are felt by the people who need it most.

We have set up a study committee which will always include at least two patients and two lay people together with members of the research team, who will be consulted about any changes to protocol or other significant issues that arise as the study progresses.

If you would like to read some further general information about taking part in research please visit

- www.crn.nihr.ac.uk/can-help/patients-carers-public/how-to-take-part-in-a-study/
- www.nhs.uk/Conditions/Clinical-trials/Pages/Introduction.aspx

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

The study is being run from within the Nuffield Department of Clinical Neurosciences (NeuroMetrology research group), part of the University of Oxford, based at the John Radcliffe Hospital Oxford. It has been funded by a grant from UCB Biopharma SPRL.

**Who has reviewed the study?**

The study has been reviewed by the following bodies

- Scientific committee of UCB's early drug development unit
- Clinical Trials and Research Governance, University of Oxford

*This study has been reviewed and given favourable opinion by the* South West - Cornwall & Plymouth Research Ethics Committe*.*

**Further information and contact details:**

Please contact Dr James FitzGerald (Principal Investigator) by telephone on 01865 234728 or email james.fitzgerald@nds.ox.ac.uk, or Prof Chrystalina Antoniades on 01865 234728 or email chrystalina.antoniades@ndcn.ox.ac.uk.

*Thank you for considering taking part.*