DEPARTMENT OF PSYCHIATRY

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The effects of medication on learning and memory in Parkinson's Disease

PARTICIPANT INFORMATION SHEET

Ethics Approval Reference: R61310/RE001

We'd like to invite you to take part in our research study. This information sheet provides some information to help you decide whether to do so. Please take time to consider the following information carefully and discuss it with friends, family or your GP if you wish. If there is anything you do not understand, or you would like more information, please ask us.

1. *What is the purpose of this research?*

People with Parkinson's Disease (PD) can have changes in their learning and memory. Because these changes are often subtle, they are difficult to measure. We have developed a set of computer based tasks measuring memory and learning that we think are more sensitive to the changes seen in people with PD. The aim of this study is to test the extent to which performance on these tasks is affected by PD medication. If our tasks are sensitive to the effects of medication, they may be used to test the effects of new drug treatment for PD.

2. *Why have I been invited to take part?*

You have been invited because you are aged between 50 and 75 and have been diagnosed with PD within the last six years.

3. *Do I have to take part?*

No. It is entirely your decision whether to participate. If you do agree to participate, you may withdraw yourself from the study at any time, without giving a reason, by advising the researchers of this decision.

4. *What will happen to me if I take part in the research?*

If you are happy to take part in the research, you will be invited to attend a preliminary screening visit at the Department of Psychiatry, Warneford Hospital. This visit will involve us asking a series of questions about your health and lifestyle to determine whether you meet our eligibility criteria for the study. This screening visit will last a maximum of 2 hours. You will be asked to bring your own prescription with you so that we can see what medication you are taking.

Eligible participants will then be invited for two further study visits approximately 2-3 weeks apart.
These visits are identical in terms of what you will need to do. On one visit ("on-medication") we will test you after you have taken your first morning dose of regular PD medication. On the other visit, we will test you in an "off medication" state. The exact procedure for this

depends on the type of medication you are taking. If you are on a levodopa medication (e.g. Sinemet or Madopar), we will ask you to not take your usual dose in the morning of the test session. If you are on a dopamine agonist (e.g. pramipexole, ropinerole, rotigotine) that you take once a day, we will ask you to not take your usual dose in the morning of the test session. If you are on a dopamine agonist that you take twice a day, we will ask you to not take your medication the night before and on the morning of the test session. If you are on a combination of medications we will give you specific instructions for what to do. We will go through the medication procedure with you before the visits and you will also be given written instructions to take away with you. Both visits will last between 2-3 hours and will take place at the Department of Psychiatry, Warneford Hospital.

Prior to the study visit, you will be sent a pack of questionnaires to fill in and bring in for the study visit. During the visit, you will be asked to complete a set of computer-based tasks. All tasks will be presented on touch screen devices that have previously been used by Parkinson's patients with little difficulty. These tasks will involve measuring reaction time and accuracy to different stimuli, mostly shapes, displayed on-screen. These cognitive tasks will almost feel like playing simplified touch-screen video games. Regular breaks will be offered throughout the Study Visits.

At the end of the "off-medication" visit, you will be advised to take the usual dose of your delayed medication that you will have brought with you to the study visit.

5. Are there any potential risks in taking part?

Withdrawal from your PD medication may cause a temporary worsening of symptoms, e.g. increase in tremor, stiffness or slowness. This procedure has been used safely in previous studies and has been developed with the help of a consultant neurologist. Since you will be using your own medication, and the withdrawal period for the 'off' medication visit is short, the risks are considered minimal. However, should any procedure throughout the study cause distress, such as the withdrawal symptoms resulting from the delayed medication intake, support will be provided by a member of the research team, under the supervision of the senior members of the team. Should the medication withdrawal cause considerable worsening of symptoms or distress, the visit will be discontinued and you will be advised to take your missed dose at that point in time. You will be free to discontinue the study at any time and for any reason.

6. Are there any benefits in taking part?

You will be paid £100 upon completion of your participation in the research. If you do not complete the study, you will be given a pro-rata amount to recompense the time you did spend in the study. Reasonable travel expenses for any visits will be reimbursed on the production of receipts, or a mileage allowance provided as appropriate.

7. What happens to the data provided?

Any research data from which you can be identified (eg. your name, date of birth, contact details, medical and psychiatric history), is known as **personal data.** All personal data will be stored securely in a locked filing cabinet in a room that is locked when unoccupied. All research data, i.e. from tasks and questionnaires will be anonymised and identified only by a participant ID number. Your identity will be related to a randomized participant ID number through a link key system, the details of which will be stored in the trial folder which will also be stored securely in a locked filing cabinet within a locked room. Completed paper questionnaires will also be stored securely in a locked filing cabinet in a locked room. Anonymised electronic and paper-based data will be stored on University computers (which are firewall and password protected) or in a locked filing cabinet in a secured building.

Consent forms and research data will be kept securely for 10 years before being destroyed. All other personal data and the link key will be destroyed 6 months after the last study visit.

8. Will the research be published?

Some of the results of this study may be published in a scientific journal. However, no information which could be used to identify any individual participant will be published. If you are interested in finding out about the overall results of this research, please let us know, and we will make arrangements to inform you once the study is completed.

In addition, the University of Oxford has established an online archive of research materials. This archive includes digital copies of student theses successfully submitted as part of a University of Oxford postgraduate degree programme. Student theses submitted as part of this study will be published here.

9. Who is organising and funding the research?

This study will be funded through the alliance between Oxford University and the pharmaceutical company Union Chimique Belge (UCB). Through this alliance, UCB funds academic work at the University of Oxford which might be useful in the future development of drug treatments. The study is conducted by the Department of Psychiatry within the Medical Science Division of Oxford University.

10. Who has reviewed this study?

This study has been reviewed by, and received ethics clearance through, the University of Oxford Central University Research Ethics Committee (Reference number: R61310/RE001).

11. *Who do I contact if I have a concern about the study or I wish to complain?*

If you have a concern about any aspect of this study, please speak to the relevant researcher Dr Susannah Murphy (+44 (0)1865 618313) or the Principal Investigator Catherine Harmer (+44 (0)1865 618326) who will do their best to answer your query. The researcher should acknowledge your concern within 10 working days and give you an indication of how they intend to deal with it. If you remain unhappy or wish to make a formal complaint, please contact the relevant chair of the Research Ethics Committee at the University of Oxford who will seek to resolve the matter in a reasonably expeditious manner:

Chair, **Medical Sciences Inter-Divisional Research Ethics Committee**; Email: ethics@medsci.ox.ac.uk; Address: Research Services, University of Oxford, Wellington Square, Oxford OX1 2JD

12. Data Protection

The University of Oxford is the data controller with respect to your personal data, and as such will determine how your personal data is used in the study. In the interest of auditing this study, the research data collected during the study may be looked at by designated individuals from the University of Oxford where it is relevant to my taking part in this study.

The University will process your personal data for the purpose of the research outlined above by fully anonymising it. Research is a task that we perform in the public interest. In addition, you may agree to your research data being shared with researchers, including

those working outside of the EU, to be used in other research studies. If you choose to consent to this, any data that will leave the research group will be fully anonymised so that you cannot be identified. This is an optional part of the study.

Further information about your rights with respect to your personal data is available from http://www.admin.ox.ac.uk/councilsec/compliance/gdpr/individualrights/.

13. *Further Information and Contact Details*

If you would like to discuss the research with someone beforehand (or if you have questions afterwards), please contact:

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