

CoCoA v4; 22.12.14

PARTICIPANT INFORMATION SHEET: PATIENT

## **Computerised Cognitive Assessments in Neurodegenerative Disorders**

### **Contact details for principal investigator:**

Dr. Rupert Noad, Consultant  
Neuropsychologist  
NeuroCoRe  
Clinical Neurology Research Group  
N13, ITTC Building  
Tamar Science Park  
PL6 8BX

Tel. 01752 439829

### Invitation for Research Participation

Thank you for taking the time to consider participating in our research study.

Please read the attached information sheet before deciding whether to take part.

If you are interested in participating, and have not already provided your contact details, please complete the contact form attached at the end of this information pack.

The study is voluntary and deciding not to participate will not affect your treatment in any way.

## **Participant information sheet for patients**

### **Investigating computerised cognitive assessments in neurodegenerative disorders**

We would like to invite you to participate in a research project. Before you decide whether you want to take part, it is important for you to understand why the research is being conducted 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.

#### **What is the study about?**

Neurodegenerative diseases, such as Parkinson's disease, Alzheimer's disease or Huntington's disease affect a large number of people in the UK, the majority of patients developing disease in middle to later life. As the population as a whole ages, these diseases will become more common. Neurodegenerative diseases can cause problems with thinking and memory, and also problems with movement. We want to learn more about the way that thinking and memory problems can be assessed in these diseases, and whether using a computer might give more accurate information and make it easier for patients to complete the tests.

#### **Why have you been asked to take part?**

You have been invited to take part in this study as you are someone with a neurodegenerative condition.

#### **Do I have to take part?**

No. Participation in this study is entirely voluntary and it is up to you to decide whether or not to take part. If you do decide to take part you will be asked to sign a consent form, but you are still free to withdraw at any time in the future without giving a reason. You will be given a copy of this information sheet to keep and you will also keep a copy of your signed consent form. If you decide not to take part, or you withdraw from the study at any point, your usual medical care will not be affected in any way.

#### **Is this a medical assessment?**

This is a research project not a medical assessment. You will not be told the scores of your assessments. All data collected during the study will be anonymous. If you feel that you are developing problems with your thinking/memory please contact your GP to discuss this further. We will send a letter to your GP informing them of your participation, but we will not send them any details of the assessments.

### **What will I have to do?**

If you are interested in taking part in the study, you can contact us, either by completing a contact details form (attached to the back of the flyer that you may have received, or the back of this information sheet) or by telephoning the study team on 01752 315264. We will then contact you by telephone to discuss the study with you, ask you a couple of questions and see if you want to take part. If you are happy to take part we will arrange a time to do the assessment, either in a study clinic or at a location to suit you. During the assessment we will ask you for some brief details about yourself. You will then be asked to complete a series of tests of memory and thinking. Some of these tests will involve you being asked questions by the researcher. Some tests will be paper and pencil based. Some tests will be using a computer which the researcher will bring with them. You will then be asked for some feedback on how you found the computer-based tests. The assessment will take 2 hours in total including a 15 minute break. You can ask for a break at any point during the assessment. You will also be asked whether you would be willing to complete another assessment in the future, looking at a different computer-based test or the same test in more detail.

### **Will the information collected during the study be kept confidential?**

The study will be conducted in accordance with the Data Protection Act (1998). All information collected about you during the study will remain strictly confidential.

Your personal details will be stored securely on a computer in the Peninsula Medical School in Plymouth, accessible only by members of the study team. Your name and address will not appear on any study forms or questionnaires so that you cannot be recognised from them. All other information collected about you during this study will be entered onto a separate, secure database and will only be identifiable by a study number and initials. Only members of the study team will have direct access to these data.

If you consent to take part in the study, your medical records may be inspected by the doctors looking after you.

If you agree to take part we will inform your general practitioner, unless you specifically ask us not to.

### **What are the benefits to me of taking part in this study?**

There are no direct benefits to you from taking part in this study. By completing the study you are helping us design tests that will help in

future studies of these symptoms.

### **What are the risks to me?**

You should not experience any adverse effects from taking part in the study. Some people may find some of the questions difficult or upsetting, for example questions about thinking and memory. However, the data collected will be held anonymously as the forms will have only your study number (not your name or date of birth), and you are free to withdraw from the study at any point. If you would like to discuss any aspect of the study then please call a member of the study team on: 01752 315264.

### **Will I have to pay for travel?**

If your assessment is taking place at a study clinic, then your travel expenses will be reimbursed.

### **What if I have more questions or do not understand something?**

If you have further questions please contact Dr Noad (contact details on page 1) or other members of the study team on 01752 315264 who will try to answer your queries.

### **What happens now if I decide to take part?**

If we already have your contact details, a member of the research team will contact you to see if you want to take part. If you are happy to take part in the study they will arrange a time for your assessment. If we do not have your contact details, please complete the form at the back of this information sheet and return to us in the freepost envelope provided, and a member of the study team will be in touch to arrange a time for your assessment.

### **What happens if I do not wish to take part?**

Your participation in this study is entirely voluntary. You do not have to take part, or give a reason if you choose not to. If you do not wish to take part it will not affect your future treatment or care.

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

You are free to withdraw from the study at any time. You do not have to give a reason. If you do not wish to continue in the study it will not affect your future treatment or care.

### **What to do if something goes wrong?**

We do not expect any harm to come to you as a result of taking part, thus special compensation arrangements do not arise. If you have any

concerns about the way that you have been approached or treated during this study, you are free to follow the usual NHS complaints procedure. If you are harmed due to someone's negligence then you may have grounds for legal action but you may have to pay for this yourself. Your right to claim for compensation for injury where you can prove negligence is not affected. If you do have any complaints about your experiences with us, please address them to PALS Plymouth: **08451558121**

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

We intend to publish the study results in a medical journal within a year of completion of the study and also to present the results at medical and scientific meetings. Each participant will receive a summary of the results at the time of publication. We will also publish the results of the study in patient newsletters.

### **Contact for further information**

If you require any further information about this project, or have any questions please contact the research team on 01752 315264 during office hours and a member of the project team will be able to help you.

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

The project is being organised by the Neuropsychology and Clinical Neurology Research teams at the Peninsula Medical School in Plymouth. It is being led by Dr Rupert Noad.

**Thank you for considering taking part in this study.**

## **Computerised Cognitive Assessments in Neurodegenerative Disorders**

### **CONTACT FORM**

**Please fill in this form if you have not already provided us with your telephone number and you would like to discuss participating in this study. We will aim to contact you within 1 week.**

**Please Return the form to the Research Group:**

NeuroCoRe  
Clinical Neurology Research Group  
N13, ITTC Building  
Tamar Science Park  
PL6 8BX

Tel. 01752 315264

**Contact details:**

*Name:*

Mr./Mrs./Miss .....

Please tick one of the following:

- |                    |                      |                          |
|--------------------|----------------------|--------------------------|
| I am someone with: | Alzheimer's disease  | <input type="checkbox"/> |
|                    | Huntington's disease | <input type="checkbox"/> |
|                    | Parkinson's disease  | <input type="checkbox"/> |
|                    | Other                | <input type="checkbox"/> |

(Please specify: .....)

*Telephone number:* .....

*Address:*

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*Best times to call you (days/ times):*

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