PARTICIPANT INFORMATION SHEET

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. If there is anything that is not clear or if you would like more information, then please contact us using the contact details located on the front of the booklet.

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 develop these diseases in their middle to later life, and as the population as a whole ages, these diseases will become more common. Neurodegenerative diseases can cause problems with thinking and memory, and we want to learn more about the way these types of symptoms can be measured. Therefore, we are investigating whether a computer might give more accurate and sensitive 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. Taking part in this study is entirely voluntary and it is up to you to decide whether or not you will take part. If you do decide to take part you will be asked to sign a consent form, but you are still free to stop the study at any point 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 want to stop the study at any point, your usual medical care will not be affected in any way.

Is this a medical assessment?
This is a not a medical assessment. You will not be told the scores of your assessments as this is a research project. All data collected during the study will be anonymous. If you feel you are developing problems with your thinking and 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), by completing the expression of interest form or by telephoning the study team on 01752 438122. We will contact you by telephone to discuss the study with you and 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 that suits you best.

During the assessment we will ask you for some brief details about yourself and we will ask you 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. Sometimes we will ask you to do the tests at home using your own computer. You will then be asked for some feedback on how you found the computer-based tests. The assessment will take a maximum of 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 other assessments in the future, either looking at a different computer-based test or the same test in more detail or using a different administration method.

At times it may be necessary to make an audio or video recording in order to ensure accurate scoring of the cognitive assessments. We will ask for your consent prior to any recording taking place. You are still free to withdraw at any point or time in the future without giving a reason. If you are invited to a face-to-face assessment, you will be asked to follow COVID-19 procedures which may include having to social distance and wearing personal protective equipment (PPE) for example, face masks, gloves and aprons. You will be provided all PPE necessary to adhere to these guidelines upon arrival to your appointment.

Will the information collected during the study be kept confidential?

The study will be conducted in accordance with the Data Protection Act (2018). All information collected about you during the study will remain strictly confidential.

Your personal details will be stored securely on a computer in the Research and Development Office 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 any identifiable information.

If you consent to take part in the study, your medical records may be reviewed by the research team. Where relevant, data collected during this study may be shared with individuals from academic institutions, regulatory authorities or from the NHS Trust.

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

University Hospitals Plymouth NHS Trust (UHPNT) is the sponsor for this study based in the United Kingdom. We will be using information from you and/or your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. UPHNT will keep identifiable information about you for 5 years after the study has finished.

Your rights to access change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

UHPNT will use your name, NHS number and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from UHPNT and regulatory organisations may look at your medical and research records to check the accuracy of the research study. The NHS site / Social Enterprise will pass these details to UHPNT, along with the information collected from you and/or your medical records. The only people in UHPNT who will have access to information that identifies you will be people who need to contact you to discuss this study, or audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number or contact details.

You can find out more about how we use your information at **https://www.plymouthhospitals.nhs.uk/your-personal-info.**

If you have any questions or concerns about how we manage your Information then please contact the Data Protection Officer for the Trust.

Data Protection Officer
University Hospitals Plymouth NHS Trust
Information Governance Team
1st Floor Bircham House
William Prance Road, Derriford
Plymouth, PL6 5WR
Tel: 01752 437284
Email: informationgovernancepht@nhs.net

The UK regulator for Data Protection Legislation can be contacted as follows:

Information Commissioner's Office (ICO)
Information Commissioner's Office
Wycliffe House Water Lane
Wilmslow
SK9 5AF

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 assessments and measurements of these symptoms in patients with Neurodegenerative Disorders.

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 438122

Some assessments require the researcher to be in the same room as you. During this time, we are taking every precaution to limit transmission of COVID-19. This includes following government guidance and the local policies set out by the NHS, individual councils and the location in which the assessment is planned to take place. In order for you to make an informed decision about whether you wish to participate, before your appointment, you will be told about what is required of you during your visit including whether you are required to wear a face mask, gloves, aprons etc.

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 any further questions please contact Dr Noad, or a member of his research team on 01752 438122 who will attempt 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: **01752 439884**

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 to present the results at medical and scientific meetings.

Each participant will receive an end of year CoCoA Research Update, which will outline our recruitment progress, preliminary findings in ongoing studies, and a summary of the results from completed studies.

Contact for further information
If you require any further information about this project, or have any questions please contact the research team on 01752 438122 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 Research and Development Office 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 Co-ordinator:

CoCoA Coordinator
Department of Neuropsychology
Level 7, Derriford Hospital
PL6 8DH

Tel:01752 438122

Email: plh-tr.cocoaplymouth@nhs.net

Contact details:

Name:
Mr./Mrs./Miss …….....

Please tick one of the following:

I am someone with: Alzheimer's disease ☐

Huntington's disease ☐

Parkinson's disease ☐

Other ☐

(Please specify: ……..……..)

Telephone number: …….....

Address:

…….....

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…….....

Best times to call you (days/ times):

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