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## PARTICIPANT INFORMATION SHEET

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### *Principal Study: "Neuropsychological investigation of visuo-perceptual, visuo-spatial and literacy skills in posterior cortical atrophy"*

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You are being invited to take part in a research study. This study is funded by Alzheimer's Research UK/ Economic and Social Research Council/ National Institute for Health Research/ Alzheimer's Society and is based at University College London (UCL) with involvement from UCL and Brunel University researchers. Before you decide whether to take part 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. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

#### **1. What is the purpose of the study?**

To examine the range, type and impact of visual problems experienced by individuals with Posterior Cortical Atrophy. The purpose of the study is find out how much of a link there is between difficulties with everyday activities such as reading, writing and finding a way around a room and being able to see things clearly and judge distances. Observing a link between these different abilities will then allow us to better understand how our reading, writing, navigation and other skills are affected by dementia and under what conditions any problems can be minimised (e.g. what size and type of written words are most easy to read; what lighting is optimal to navigate a room).

#### **2. Why have I been asked to participate in this study?**

We are seeking the help of up to 200 people with a diagnosis of Posterior Cortical Atrophy, 200 people with typical sporadic Alzheimer's disease who have prominent memory problems, and 200 people who do not have a neurological disease. We are approaching people attending the Specialist Cognitive Disorders clinics at the National Hospital, people being cared for within Brighton and Sussex University Hospitals NHS Trust, people who have taken part in research before, and carers of those with a diagnosis of Posterior Cortical Atrophy or Alzheimer's disease.

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

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you

are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect your current or future medical care.

#### **4. What will be involved if I decide to take part?**

Taking part will require a series of testing sessions lasting up to two hours. The number and timing of the sessions would be arranged by agreement between you and the researcher. A maximum of 10 sessions might be involved though in many cases fewer sessions would be needed. You may want to consider attending multiple testing sessions on the same or different days depending on what is most convenient for you. You will also be asked to have yearly follow-up assessments. In addition, if you are not already having regular brain scans as part of another project here at the Dementia Research Centre, you will also be asked to have a scan once at the beginning of the study and then again at your yearly follow-up assessment. You will also be asked to have a neurological examination by a trained physician and to answer questions about any symptoms you/ someone you know may experience.

The research will take place at the National Hospital for Neurology and Neurosurgery. Some visits may take place at your home if this is more convenient for you. The study involves answering spoken and written questions, completing paper-and-pencil and computerized tasks. We will record only your answers to the test questions, your eye movements, your brain scan and some basic personal information (name, age, gender, years of education, main profession). We will record the audio responses to some questions on a digital voice recorder so we can make anonymised transcripts to assist researchers to analyse data after the research visit. We would also like to consult your medical notes for other information which may be relevant to the study. Where participating in the project will involve visits to the hospital which you would not otherwise be making, reasonable travel expenses will be reimbursed.

Should you be unable to travel to London for the annual visit but remain willing to be involved in the study, we would conduct clinical interviews by telephone at a time convenient to you.

#### **5. What do I have to do?**

You will be asked to complete a short set of standard psychology tests of general abilities such as memory and language, and visual tasks including viewing and making judgements about a variety of shapes, colours, objects and words. You will also be asked to provide a verbal description of, and complete questionnaires about, any unusual visual experiences you/ someone you know may have had, such as washes of colour or double vision; these descriptions may be recorded and listened to by researchers. You may also be asked to have a brain scan and neurological examination once per year. In addition to the annual psychology tests, questionnaires and brain scan, you may also be asked to participate in one or more sub-studies involving further examination of reading, navigation, the impact of visual problems on everyday life, vision testing, everyday tasks, or balance. As with the principal study, participation in each of these sub-studies is entirely voluntary; if you do decide to take part in these additional studies, information about your psychology tests, questionnaires and

brain scans gathered in this study will be re-used so that you don't have to complete these assessments again.

#### **6. What is the procedure that is being tested?**

We are trying to establish how important different visual problems affect one another, how they develop, their impact on everyday activities, and how damage to the brain can result in unusual visual experiences.

#### **7. What are the possible disadvantages and risks of taking part?**

There are no risks involved in the psychology tests. No experimental treatment will be given. You will be assessed to see whether you can have a brain scan safely. Anybody who is not suitable for a brain scan (e.g. those with pacemakers) will not be asked to take part in that section of the study. You may feel claustrophobic or uncomfortable lying in the scanner. You will hear loud knocking noises but we will provide you with earplugs to wear during the MRI. You can ask to stop the MRI at any time if it becomes too uncomfortable. The brain scans we perform are designed for research rather than clinical examination. However, if an unexpected finding is seen on your scan, your GP will be informed and the finding will be discussed with you.

#### **8. What are the possible benefits of taking part?**

The benefits will be helping to understand the brain and to develop aids and strategies which help one to better cope with problems reading or navigating a room. However, it will not help directly with any problems you may have.

#### **9. What if there is a problem?**

If you, your relatives or your informant have any concerns about the research study you can speak to a member of the research team who will do their best to answer any questions. Contact details are at the end of this information sheet.

If you wish to complain, or have any concerns about any aspect of the way you have been approached or treated by members of staff you may have experienced due to your participation in the research, National Health Service or UCL complaints mechanisms are available to you. Please ask your research doctor if you would like more information on this. You, your relatives or your informant can also contact the UCLH Patient Advice and Liaison Service at the following address; PALS, Box 25, National Hospital for Neurology and Neurosurgery, Queen Square, London WC1N 3BG or you can email: [PALS@uclh.nhs.uk](mailto:PALS@uclh.nhs.uk).

In the unlikely event that you are harmed by taking part in this study, compensation may be available. If you suspect that the harm 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 research doctor, please make the claim in writing to Professor Sebastian Crutch who is the Principal Investigator for the research and is based at The Dementia Research Centre, Box 16, The National Hospital for Neurology and Neurosurgery, London WC1N 3BG. 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.

#### **10. Will my taking part in this study be kept confidential?**

All information which is collected about you during the course of the research will be managed in accordance with the Data Protection Act. Your GP will be informed of your participation in the study. Any recordings made during the assessment and information on physical activity will be kept on a secure computer system at UCL or Brunel University and only accessed by research staff involved specifically on this project. Any information about you which leaves the research unit will have your name and address removed so that you cannot be recognised from it. Information about you and your involvement in the study will be handled by the lead researchers (Professor Sebastian Crutch at University College London, Professor Nick Tyler of University College London and Professor Mary Gilhooly of Brunel University) and their team members. This information, including audio recordings and transcripts, will be held for at least 10 years so that further ethically approved research may be conducted in the future.

#### **11. What will happen to the results of the research study?**

The results will be presented to the scientific and medical community to improve further research. You will be very welcome to request a copy of any resulting publications, however, it will not be possible for you to know individual test results. If you would like you may receive a copy of the Dementia Research Centre newsletter which describes this and other work taking part in this department.

#### **12. Involvement of your General Practitioner (GP)**

With your consent, we will notify your GP by letter that you are taking part in this study, and will contact your GP for a health update in the event we lose touch with you during the course of the study. Whilst you will not receive individual results of the different assessments, if your test results are unusual the Chief Investigator of this study (Sebastian Crutch) will discuss with you the implications of your results, and any need to inform your GP. Your GP will only be notified with your consent.

#### **13. Identifying a consultee**

If you are participating in this study as a person living with dementia, we will ask you to choose someone (either a close relative/ friend or carer if applicable) to act as a personal consultee. The person you nominate would act in your best interests and decide whether or not you should continue in the study if you were finding it difficult to make a decision about taking part in this study in the future. They would only be asked to take on this role if we are unsure in the future as to whether you are able to continue to understand what taking part in the project would involve.

If we need to appoint your consultee to act on your behalf (a 'nominated consultee') to decide whether or not you were able to continue taking part in the study, two things might happen:

1. If your nominated consultee agrees for you to continue taking part in the study, you would be able to continue being a participant in this study. We would keep consulting your consultee and checking that they continue to agree for you to take part in ongoing sessions.
2. If your nominated consultee does not agree that you should take part, or continue to take part in the study, then you would be withdrawn from the study. Any data collected as part of the project up to that point with your consent would be retained by us. We would not collect further data or undertake any other research procedures with you going forward.

**14. Who is organising and funding the research?**

This study is being organised and funded by the Alzheimer's Research UK, Economic and Social Research Council and National Institute for Health Research.

**15. Who has reviewed the study?**

This study has been reviewed by the London Queen Square Research Ethics Committee.

**16. Contact for further information**

You may contact Professor Sebastian Crutch during office hours on 020 3448 3113.

Thank you for considering taking part in this study. You will be given a copy of the information sheet and a signed consent form to keep.