The Newcastle upon Tyne Hospitals
NHS Foundation Trust

Newcastle University

PARTICIPANT INFORMATION SHEET

A PET- MR study of occipital connectivity in LBD (ALLSPICE)

Principal Investigator: Professor John-Paul Taylor

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take the 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.

Thank you for reading this.

What is the purpose of the study?

People with Lewy body disease (LBD), including dementia with Lewy bodies and Parkinson's disease, often have visual disturbances such as vivid hallucinations. The exact reason these occur remains unclear but they can be very distressing. Brain scans have found reduced activity in the vision part of the brain (at the very back of the brain) in people with LBD and this may relate to the problems that some people with LBD experience with their vision. It is currently unclear what the cause of this low activity is, but one possibility is that there are changes to other areas in the brain that help with vision.

A recently developed method, using a **P**ositron **E**mission **T**omography (PET) magnetic resonance (MR) scanner, allows us to investigate both the strength and direction of brain signals between different regions in the brain. This study intends to use this to see whether the signals between the vision part of the brain and other parts of the brain are altered, and whether these alterations may be related to things like visual hallucinations or other visual problems that can occur in people with LBD. This will help us to better understand whether reduced activity in the visual part of the brain is a cause or consequence of the hallucinations, helping us to understand the origins of these symptoms better so that we can develop more effective treatments for LBD.

Why have I been invited?

You have been invited to take part in this study because you have either been diagnosed with dementia with Lewy bodies or Parkinson's disease and have been experiencing visual disturbances such as visual hallucinations. By looking at differences in brain activity between people with LBD and people without, we hope to better understand why certain symptoms, such as visual hallucinations, arise in LBD.

Do I have to take part?

It is up to you whether you decide to participate. If you decide to participate you will be given this information sheet to keep and will be asked to sign a consent form. Participants are free to withdraw from the study at any time and do not have to provide a reason. However, the research team would find it useful to know the reason for your withdrawal, as this will help us to improve the study. Any personal information collected during participation in the study can also be withdrawn should you request it. This will not have any influence upon the treatment or standard of care that you receive in the future.

What will happen to me if I take part?

If you agree to take part, we will first arrange to visit you at home. At the start of this visit, the researcher will discuss the study with you and answer any questions you may have. You will then be asked to sign a consent form to show your willingness to

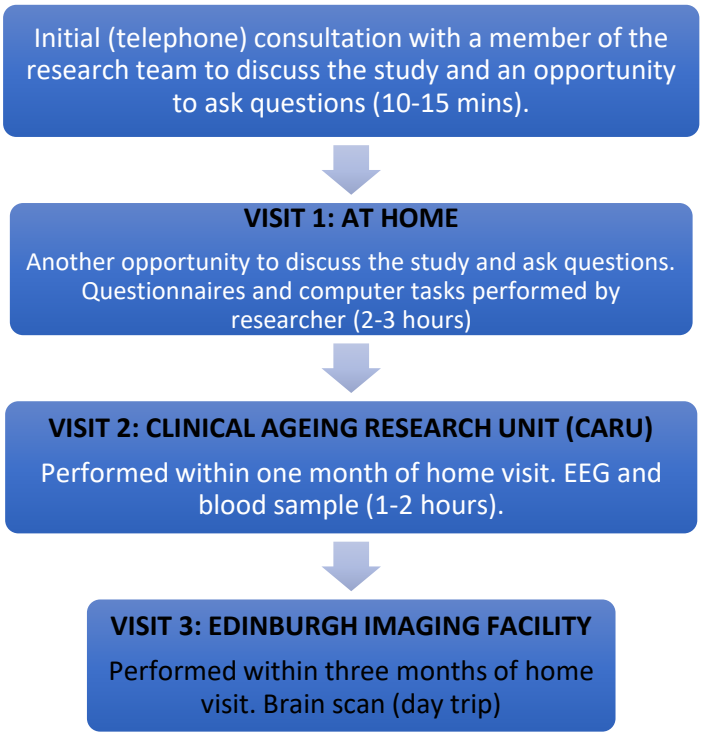
participate. Following this, you will be asked some questions about your general health and demographics (e.g., age, years of education, occupation).

We will then ask you to complete a set of assessments which measure thinking skills such as memory, language, and problem solving, followed by some tasks on a laptop to assess your attention and visual perception. We will also ask you questions about any visual hallucinations you have experienced and perform an assessment of your movements. We will also ask a close family member or carer to be present and answer some questionnaires about you. This visit is usually expected to last between 2-3 hours.

Within one month of this visit, we will then ask you to attend the Clinical Ageing Research Unit (CARU) at the Campus for Ageing and Vitality for a single visit. We will cover the costs of your travel to and from CARU (e.g. reimburse fuel costs or arrange and pay for taxis). We expect this visit to last between 1-2 hours. During this visit we will perform something called an electroencephalography (EEG) and take a small blood sample (around 4 teaspoons of blood).

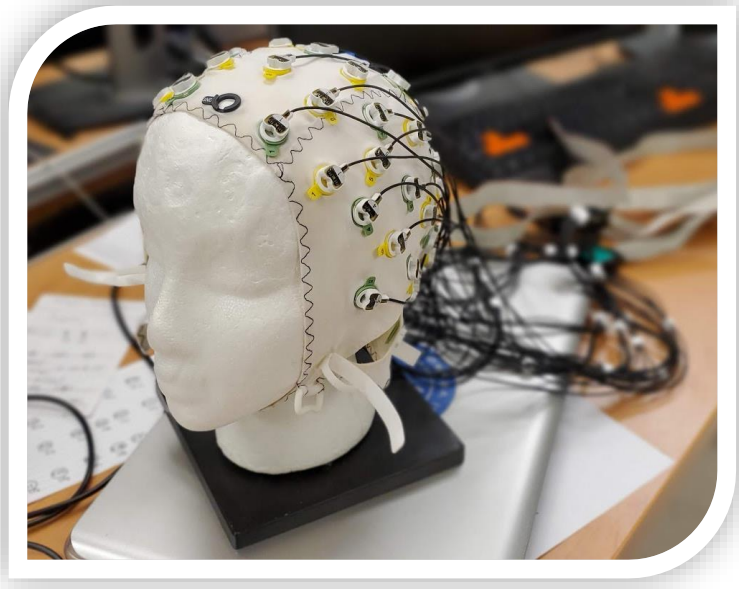
A separate visit will also be arranged for you to receive a brain scan. This will take place at the Edinburgh Imaging Facility, so will require a day trip to Edinburgh. We will arrange and cover all travel costs to and from the facility for you and a friend/family member (trains and taxis). A member of the Newcastle research team will also accompany you on this visit.

During all study visits you will be given the opportunity to take frequent breaks. Where necessary, or should you request it, the study can also be divided into separate, shorter visits. A summary of each visit and what is involved is pictured below:



Electroencephalography (EEG)

EEG is a technique which uses a set of small cups placed on your scalp using a cap to measure your brain activity (pictured). These cups are filled with a gel like material to allow us to measure the tiny electrical signals being made by your brain. The procedure is not painful and doesn't involve anything going through your skin. This technique will allow us to look at which areas of your brain show over- or under-activity. At the start of the EEG you will be prompted by the researcher to open and close your eyes at 5-minute intervals. Following this, you will be asked to look at a computer screen whilst doing a visual task while we continue to record the EEG. This will take around 60 minutes.



Pictured: EEG cap and electrodes (cups)

Brain Imaging

Your third study visit will involve a day trip to Edinburgh to attend the University of Edinburgh imaging facility for a brain scan. At the imaging facility, you will be asked to lie on your back on a scanner bed (pictured below). The scanning team will help you to get as comfortable as possible. A qualified technician/nurse will then insert a small cannula into a vein in your arm so that we can administer a special dye called fluorodeoxyglucose (FDG) into your blood stream during the scan. This allows us to look at which areas of the brain are active at different times. You will be given ear protection so that the scanner isn't so loud. A scanner head-coil will then be positioned around your head to minimize head movements. Once you are comfortable, you will be moved into the scanner for the main scan. A mirror system will be adjusted to ensure that you can see clearly outside of the scanner while the scan is being completed. You will receive five different scans of your brain while in the scanner, with a total scan time of approximately 60 minutes. For the majority of the scan, you will be asked to relax and remain still. Approximately halfway through the scan the special dye will be administered through the cannula in your arm by the nurse. Following this, you will be asked to perform a simple 10-minute visual task and look at some images in the scanner. While in the scanner a radiographer will keep in contact with you through a communication system in the scanner and will be able to tell you about each stage of the scan. You will also be provided with a squeeze bulb connected to an alarm system should you need to alert the radiographers if you experience any concerns or anxieties during the scans, and the scan can be ended at any time should you wish.

Pictured: Example of the MRI scanner used in the study to collect images of the brain.

Blood Samples

A small blood sample (approximately 4 teaspoons) will be taken prior to the scan. With your permission, this sample will be used for future studies. We are finding that certain blood components may associate with how the disease progresses as well as being useful for future diagnosis. Another key area that we will be investigating with colleagues internationally is how genetics may influence how people get LBD and what symptoms they experience. In addition, as we have learned from studies in the past, sometimes there is the development of a new analysis approach which gives powerful insights into the causes of the disease. Therefore, we would like your permission to store your blood longer term (25 years) in case future technologies are developed that we can test on the blood samples. The blood samples will be stored at the Newcastle Brain Tissue Resource (NBTR), which is a bank used to store samples (such as blood) collected for use in research. Samples will be anonymised (so it will not be linked to any of your personal information) and securely stored in freezers only accessible to authorised researchers.

Will a family member need to be in attendance?

We ask that you attend with a family member or carer. This should be the same person at both the home visit and visit to CARU.

Are there any risks?

EEG is a very safe technique and very few people report any side effects. However, some people may experience temporary redness under electrode pads on the scalp or mild discomfort during electrode set-up. On rare occasions people may experience a headache from the EEG cap or may have an allergic reaction to electrode pads or gel.

As part of the brain scan you will receive a single FDG injection. This procedure uses ionising radiation to form images of your brain. Ionising radiation can cause cell damage that may, after many years or decades, turn cancerous.

We are all at risk of developing cancer during our lifetime. The normal risk that this will happen is about 50% of people at some point in their life. Taking part in this study will only increase the chances of this happening to you from 50% to 50.01%. However, due to the radiation exposure, we advise that you avoid close contact with babies or pregnant women for a few hours after the visit as a precaution.

As the scans use MRI, there is a risk to people who have implanted medical devices such as cardiac pacemakers. For safety reasons, at the beginning of the study you will be thoroughly screened for any contraindications to MRI, such as metal implants.

Some people may feel claustrophobic in the scanner, or may experience some discomfort from lying still or flat for a long period of time. A radiographer performing the scan will communicate with you throughout to check that you are comfortable and you can request to leave the scanner at any time.

How does this study benefit me?

While there will be no direct benefits to you in taking part, this study will help us to better understand how certain symptoms in LBD arise which may help us to develop more effective treatments in the future.

What happens at the end of the study?

We will keep you informed of any findings and send you, with your permission, a newsletter to update you after the study has been completed.

What if there are any problems?

This is an observational study and therefore does not involve any interventions, like new treatments, which may cause unpredictable problems. Sometimes, previously unrecognised medical issues may be identified during the assessments that require further attention. In the unlikely event that an abnormality is identified, such as during a scan, we will seek the advice of a radiologist who will examine the scans and take appropriate action. This will usually mean discussing the matter with you and writing to your General Practitioner (GP).

The NHS will provide indemnity for the study. If you have any concerns about any aspect of the way you have been approached or treated during the course of the study, the normal National Health Service complaints mechanisms will be available to you.

If you wish to raise any concerns with someone not involved in your care, you can contact the Patient Advice and Liaison Service (PALS). This is a confidential service and can be contacted on Freephone: 0800 032 0202.

Personal Information Policy

If you decide to take part in this study, all information you provide to us and the results of the study will be treated confidentially. Data will be assigned a unique, anonymous, study number and will be stored securely in locked cabinets or on password protected computer systems at Newcastle University. We may retain anonymised data for use in future and similar studies. Any personal data (e.g. name, address, contact telephone number), will be kept to a minimum and secured so that it is only accessible to researchers directly involved in the study. This information will only be used to contact you about the study (e.g. arranging visits), to give you feedback on the results (e.g. newsletters) or to contact you about future research studies should you agree.

We will write to your GP and any specialists involved in your care to inform them of your agreement to take part in this study, with your permission.

Data Protection (General Data Protection Regulation)

The Newcastle upon Tyne Hospitals NHS Foundation Trust is the sponsor for this

study based in the United Kingdom. We will be using information from you and 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. The Newcastle upon Tyne Hospitals NHS Foundation Trust 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.

You can find out more about how we use your information at https://www.hra.nhs.uk/information-about-patients/.

The research team will collect information from you and your medical records for this research study in accordance with our instructions. Individuals from The Newcastle upon Tyne Hospitals NHS Foundation Trust and regulatory organisations may look at your medical and research records to check the accuracy of the research study.

Who is organising and paying for the study?

The study is funded by the Lewy Body Society. The research team are based at the Translational and Clinical research institute at Newcastle University.

Further Information

If you would like further information please contact Professor John-Paul Taylor (in charge of the study) or any member of the research team at the Biomedical Research Building, Translational and Clinical Research Institute, Newcastle University, Campus for Ageing and Vitality, Newcastle Upon Tyne, NE4 5PL (Telephone: 0191 248 1310).

A study management group, comprised both of researchers directly involved with and independent of the present study, will meet regularly to review the ongoing progress and conduct of the study and address any problems should they arise.

What happens next?

A member of the research team will be in touch with you shortly. If you are interested in taking part in the study, they will arrange to visit you at home. You will also be given the chance to ask any questions about taking part before making a decision. If you decide to take part, the researcher will discuss a consent form with you and ask you to sign it. It is up to you whether or not you wish to take part. If you do not wish to participate, you do not have to give a reason and this will have no effect on the care you receive now or in the future. If you change your mind, you can withdraw from the study at any time without giving a reason. You will be given a copy of this leaflet and a signed consent form to keep.

Thank you for taking the time to read this.

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