Bristol Medical School
Faculty of Health Sciences

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Participant Information Sheet

Study Title

Feasibility of measuring sleep-dependent brain activity at home in people with Mild Cognitive Impairment and mild Alzheimer's disease to help delay symptoms (SleepAD) Substudy 2

Summary

We are inviting you to take part in a study that will compare a blood test for Alzheimer's disease with the lumbar puncture that you are having as part of your clinical care. Your decision to take part is entirely voluntary. Should you not wish to participate, this will not affect the healthcare you receive in any way.

Purpose of Study

Sleep problems are common in dementia and research now suggests that poor sleep may increase the chance of developing Alzheimer's disease. We need to improve our understanding of how sleep might affect development of Alzheimer's disease. To do this, we need to develop a good way to identify people with very early Alzheimer's – so we can stop them progressing to full blown dementia. The current best tests for Alzheimer's disease are either very expensive scans or lumbar punctures. Very recently, blood tests have been developed that might be as good as scans and lumbar punctures at detecting Alzheimer's. But they have not yet been tested in people who are attending clinic for diagnosis. Our aim is to test whether state-of-the-art blood tests are as accurate as a lumbar puncture to diagnose Alzheimer's disease.

Why am I being asked to take part?

You are being invited to this study because you have recently attended the Cognitive Disorders Clinic at Southmead and you have agreed with your doctor that a lumbar puncture would be a useful diagnostic test to understand the cause of your memory and thinking symptoms.

What does the study involve?

If you agree to take part, you will have your lumbar puncture in the normal way. We always take blood tests at the same visit as lumbar puncture as we need to compare blood and spinal fluid results for some tests. At the time of your routine blood test, we will take another 2 tubes of blood – a maximum of 20ml (4 teaspoons full). As an optional addition to the study, we will also take an extra < 5 ml (1 teaspoon full) of cerebrospinal fluid for testing and storage as long as it does not prolong the procedure by more than 1 minute.

What are the possible benefits of taking part?

There are no direct benefits from participating in this study except perhaps the satisfaction in contributing to research that helps us improve our understanding of dementia. We will not give feedback on the results as they are being collected purely for research purposes and will not affect the healthcare you receive.

What are the possible risks of taking part?

The risks are few and very low. Occasionally blood tests can make people feel faint or leave a bruise. We will stay with you for at least 10 minutes after blood testing to make sure you do not feel faint. You would have been having the blood test anyway, but it may last 30-60s longer due to our research. We will only take CSF if flowing freely during the procedure. You produce 500ml of CSF per day and so will very quickly replace the sample that is taken. We do not expect that taking an extra 5ml of CSF will cause any side effects, but there is a tiny risk it could worsen headache afterwards and so this part of the study is optional.

Will my GP be informed?

No, we will not inform your GP unless you request us to do so.

How will we use information about you?

The University of Bristol is the Sponsor for this study. We (the University of Bristol) will need to use information from you and your medical records for this research project.

This information will include your full name, contact details, NHS number. People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have (please see below for more details).
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.
- If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study. After the study has ended, the data will be deposited in the University of Bristol Research Data Storage Facility and held for 20 years, and will then be securely disposed of. This is a secure set of disks and servers for the long-term storage of data. Your anonymised data may be made available to approved reputable researchers only and their research institution would need to complete a request form and sign a Data Access Agreement. In addition, your anonymised data may be securely uploaded, and held in perpetuity, on the Dementia Platforms UK Data Portal, for approved reputable researchers to use in future ethically-approved research.

Where can you find out more about how your information is used?

You can find out more about how we use your information:

- at www.hra.nhs.uk/information-about-patients/
- the Health Research Authority leaflet available from: www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team
- by sending an email to Henry Stuart (Information Governance Manager and Data Protection Officer, University of Bristol: henry.stuart@bristol.ac.uk

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

Your decision to take part is entirely voluntary and you may change your mind at a later stage for any reason at all. Should you not wish to continue participating in the study you can withdraw, and this will not affect the healthcare you receive in any way. In order to withdraw from the study, you can speak to a member of the research team. You do not have to give a reason but if you do feel comfortable to do so this information will help us to plan future research.

If you do withdraw from the study, provided that you are happy for us to do so, and if in the opinion of the research team the reason for withdrawal is not likely to affect the data gathered, we will keep the data already collected. However, you are free to request that all your information and samples are withdrawn from the study and these will safely be disposed of, provided that your anonymised data has not already been analysed.

Who do I contact if I am unhappy about something or have a complaint?

We hope that taking part in this study will be a positive experience but if you have any concerns or have a complaint we would much rather hear about it. If appropriate, in the first instance, please contact the study team using the contact information contained within the 'Further Information' section below. Alternatively, or if you feel that the matter has not been resolved to your satisfaction, please contact the sponsor of the study (Research and Enterprise Development - University of Bristol) via the Research Governance Team. Email : research-governance@bristol.ac.uk.

Further Information

The Chief Investigator for SleepAD is Dr Elizabeth Coulthard, Associate Professor in Dementia Neurology. Before commencing this study will have approved formal approval from a Research Ethics Committee. Arrangements have been made for insurance/indemnity purposes.

If you would like more information about this study, you can contact the lead study clinicians Dr David Woodstoke at the Bristol Brain Centre, Elgar House, Southmead Hospital, Monks Park Way, Bristol, BS10 5NB. Telephone : +44 (0)117 414 8232.

Thank you for taking the time to read this information sheet.
Please do not hesitate to contact us if you have any questions or require further information.