SleepAD (Substudy 1) One-page summary

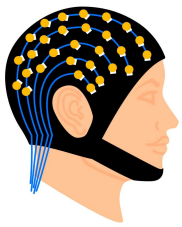
Study Title: SleepAD: Feasibility of measuring sleep-dependent brain activity at home in people with Mild Cognitive Impairment and mild Alzheimer's disease to help delay symptoms.

Purpose of Study: Sleep problems are common in dementia. We need to develop a good way of measuring sleep in people with Alzheimer's or Mild Cognitive Impairment. We are testing whether a new device can measure brainwave activity comfortable and effectively at home.

What does the study involve?

Stage 1: A screening visit over video consultation or at the Brain Centre to check you are eligible to take part and complete baseline assessments. This involves a short memory test, questionnaires on sleep and your health, a blood test to look at proteins related to neurodegeneration, and (if in person) we will check your blood pressure.

Stage 2: For 3 nights, you will be asked to wear an electroencephalography (EEG) cap on your head whilst you sleep to measure your brainwave activity. You will also be asked to wear a pulse oximeter for 2 nights to screen for a sleep disorder called obstructive sleep apnoea. A researcher will visit your home each evening to set up the equipment. To ensure a good connection for the sensors in the EEG cap, the researcher will apply a very small amount of gel where each sensor touches the skin. The whole process usually takes 15-30 minutes.



The cap is designed to be comfortable to sleep in, and allow you to move normally. You will remove the cap yourself when you wake in the morning. A member of the research team will be contactable throughout the study, including overnight, in the unlikely event of experiencing any problems. Other activities include completing a short sleep diary each morning, a further memory test, and a brief questionnaire at the end to give us valuable feedback on the experience.

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.

What are the possible risks of taking part? The risks are few and very low. The main risk is that either the EEG cap or the gel causes irritation or an allergic reaction on the skin. The chance of this happening is very small. If you choose to give a blood sample, this can leave a small bruise, although our staff aim to minimise this.

How will my data be used? In this study we will use information from you and your medical records. We will only use information that we need for the research study. We will let very few people know your name or contact details, and only if they really need it for this study. Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules. At the end of the study we will save some of the data in case we need to check it and for future research. We will make sure no-one can work out who you are from the reports we write.
The full Participant Information Sheet tells you more about this.

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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 1

Summary

We are inviting you to take part in a study that measures your sleep over 3 nights in your home, alongside some tests of memory. 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 of accurately measuring sleep in people with Alzheimer's. Usually the best way to measure sleep is using brain wave recording (electroencephalography = EEG) in a laboratory. However, patients with Alzheimer's tell us they would prefer not to have to stay in a laboratory. Our aim is to test whether state-of-the-art brain wave recording can be applied in the homes of people with memory problems.

Why am I being asked to take part?

You are being invited to this study because you have either recently attended the Cognitive Disorders Clinic at Southmead or have previously expressed an interest in research with your details held on a database.

What does the study involve?

If you are happy to go ahead, you will be asked to attend a screening visit; this will either be conducted remotely (i.e., by video consultation) or in-person at the Brain Centre on the Southmead Hospital site. This initial visit is likely to take a maximum of around 2 hours. We will firstly ask for your consent to take part. If you are happy to go ahead, we will ask you some basic medical questions, and run through a number of questionnaires asking about your sleep and mood, primarily to gauge any problems with sleep. In total there are 10 short questionnaires to complete with the researcher. This typically takes around 45 minutes, however we can always take breaks in between completing them. Routine data may also be collected from your medical notes. We will also ask you to take a short memory test, and those attending in-person will have their blood pressure taken. We will also ask if you are willing to provide a blood sample. We can arrange for this be taken either during a routine clinic appointment at the Brain Centre or during a separate appointment. The blood sample will enable us to measure new markers of Alzheimer's disease in the blood. This will help us work out if the markers are accurate.

Some people may not be eligible to continue in the study depending on the result of the memory test as we want to recruit a range of people. If this is the case and you would still be interested in taking part in research, we can let you know about other opportunities to take part in research

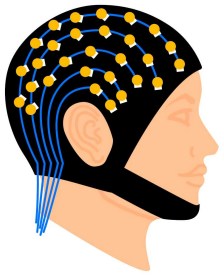
From this point on, all of your involvement in the study will be remote but there will be someone to help and guide you through the process.

In summary, the study lasts 3 nights.

During this main part of the study, a researcher will visit your house to fit an EEG cap for 3 nights in a row. Each morning you will be able to take the device off yourself. You will also be asked to provide a small amount of information about your previous night's sleep by filling in a questionnaire.

Here we provide more detail about each assessment and devices required to complete the study :-

EEG



Brain cells produce electrical activity that can be studied using EEG (or brainwave recording). The brainwaves allow us to assess what is happening in your brain while you sleep. We will also record muscle and eye movements using sensors placed on your scalp, face and chest. Each night you will be asked to wear a comfortable cap which has in built EEG sensors that measure sleep signals and stages throughout the night. The sensor wires connect to a small box which will be attached to a soft strap worn around your upper body.

A researcher will visit your home each evening to set things up and make sure the equipment is working. Before you go to bed, the researcher will help you to put on the EEG cap, which adapts to your head size. To ensure a good connection for the sensors, the researcher will apply a very small amount of gel where each sensor touches the skin. This process usually takes 15-30 minutes. You will then have some time to get used to wearing the sensors before you go to sleep. You can sleep in your favoured position and move almost normally throughout the night, and if you do need to get up in the night, you can do so on your own. A member of the research team will be contactable throughout the study, including overnight, in the unlikely event of experiencing any problems.

When you wake up for the day, you can remove all the devices, and the cap will need to recharged ahead of the next night. The researcher will show you how to do this.

Pulse oximetry

We will also ask you to wear a pulse oximeter for two of the three nights of sleep-testing. This is to monitor your pulse and oxygen saturation during sleep, and screen for obstructive sleep apnoea (OSA), an important cause of disturbed sleep. OSA is a condition where the upper airway narrows while sleeping and restricts the airflow to the lungs. This causes large drops in oxygen levels that wake you up and disrupt your sleep. These are called "micro-arousals" because they are usually very brief and people often do not know they are happening. This can make memory problems worse.

The pulse oximeter is worn as a finger probe and wristband, which measures your pulse and oxygen levels overnight. It can therefore detect drops in oxygen levels and heart rate changes that may suggest micro-arousals during sleep. You will simply put it on before going to sleep and remove it the following morning when you wake up.

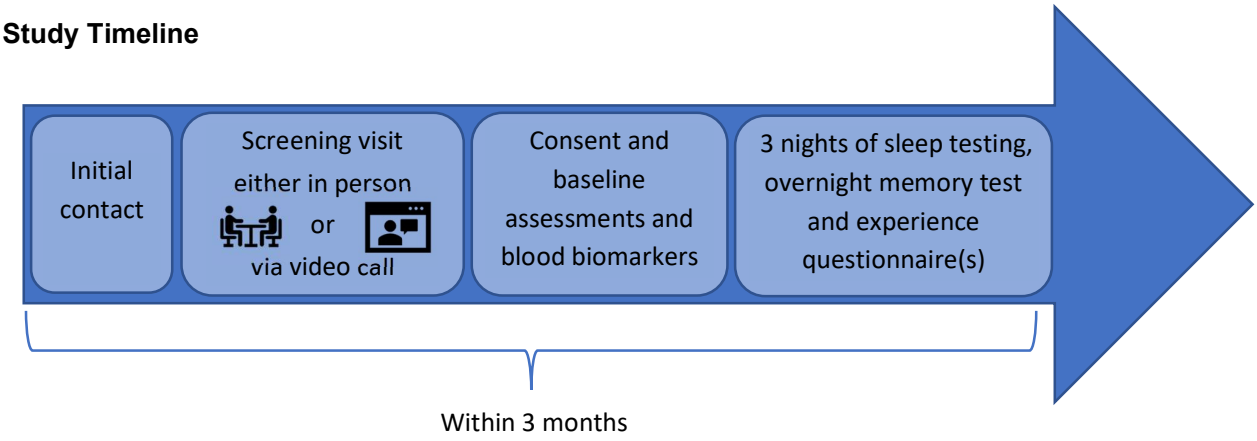
Memory test

On night 2 or 3 of the sleep recordings, we will ask you to complete a short memory test. This will involve learning a list of words in the evening, before you go to bed wearing the EEG cap. This takes approximately 10 minutes. The following morning we will then test your memory for the list of words, which takes approximately 5 minutes.

Experience questionnaire

At the end of the study, we will ask you to complete a short questionnaire asking about your experience of taking part in the study and wearing the EEG cap. This usually takes approximately 10 minutes.

Study Timeline



Will there be anyone to help with the tasks if needed?

A member of the research team will be contactable throughout the study should you have any problems. During the 3 day sleep testing, a member of the research team will be contactable overnight in the unlikely event any problems arise. The researcher visiting your home each night will aim to address all queries as and when they arise. All face-to-face contact with the research team will fully comply with any national COVID-19 guidance or restrictions in place at that time. This will include the use of appropriate personal protective equipment, hand hygiene and social distancing.

What if a device is accidentally damaged?

We completely understand that devices could be lost or damaged and can reassure you that there would be no cost to anyone taking part in the study if this happened.

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. However, if any of our medical or sleep assessments suggest you may have a sleep disorder such as sleep apnoea or restless leg syndrome, we will let you know and ask if you want us to let your GP know (please see the “What if we find something unexpected?” section below for more details). We will reimburse you any travel expenses incurred on all visits to the Brain Centre for the sole purpose of the SleepAD study.

What are the possible risks of taking part?

The risks are few and very low. The main risk is that either the EEG cap or the gel cause irritation or an allergic reaction on the skin. The chance of this happening is very small. If this does happen, you are advised to remove the device and return it to us. You will no longer be expected to take part in the study. You may be advised to see your General Practitioner (GP) to check that the irritation is settling down.

Occasionally blood tests can make people feel faint or leave a bruise. We will stay with you for at last 10 minutes after blood testing to make sure you do not feel faint.

If you have any concerns during the study, you can contact us by e-mail or telephone.

What if we find something unexpected?

Should any findings of clinical significance be discovered through participation in this research we will discuss your options with you.

If a cognitive (thinking skills) test score is lower than we might have expected, or the sleep tests indicate a possible sleep disorder (such as sleep apnoea or restless leg syndrome), the research team will explain this. We will take time to talk to you about this, and with your permission make sure that the appropriate referrals are made so that this can be explored in more depth if needed. With your permission we would also notify your GP.

Cognitive difficulties and daytime sleepiness can both significantly affect your ability to drive. If your test results raised any concerns we would need to explore this with you, although we would not provide clinical advice. We would encourage you to carefully consider whether it is safe to continue driving, as it would be your responsibility to inform the DVLA and your insurance company of any concerns. We would also seek your permission to refer you to a specialist, who may advise not to drive until further investigations have been completed.

Will my GP be informed?

Yes, we will send a letter to your GP to let them know that you are taking part in the study.

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, your 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 feel comfortable to do so this information this 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 key investigator 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.