



The role of sleep in Down syndrome Alzheimer's disease

Participant information sheet

12th July 2022 (Version 2.1)

Study title: The role of sleep in Down syndrome Alzheimer's disease

REC Reference Number: 22/YH/0123

IRAS Project ID: 313674

Introduction

We would like to invite you to take part in our research study.

We have some questions about how peoples' brains change as they get older.

We also want to know why some people with Down syndrome have memory problems when they get older.



Our study will be carried out at the Addenbrooke's and Royal Papworth hospitals in Cambridge.

Who are we?



We are doctors and researchers from the University of Cambridge (Cambridge Intellectual and Developmental Disabilities Research Group) and from the Wolfson Brain Imaging Centre at Addenbrooke's Hospital.



This work is supported and funded by Alzheimer's Research UK.

What is this research about?



Some people with Down syndrome have trouble remembering things as they get older. Sometimes this is because they have Alzheimer's disease.

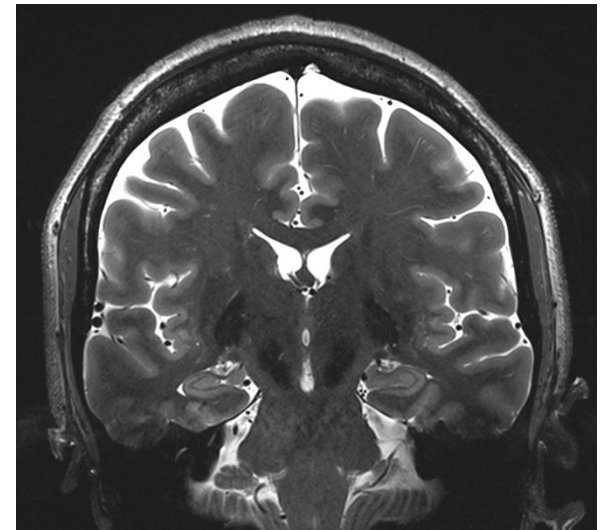
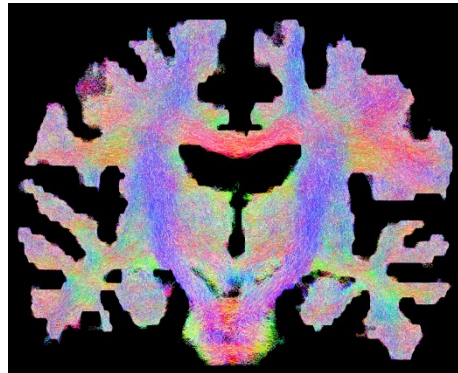
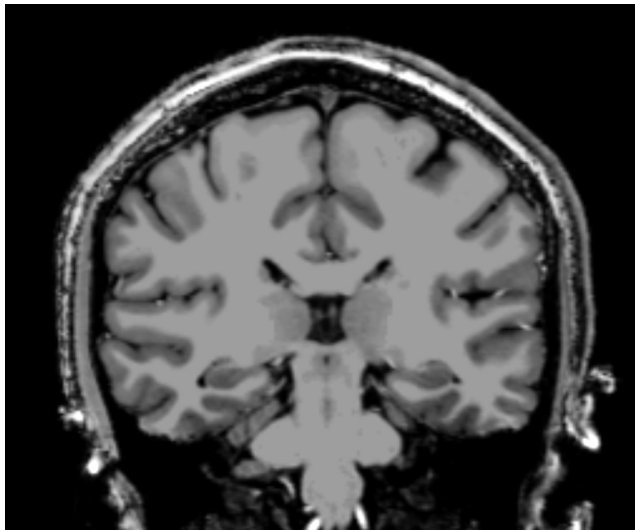
Scientists think that a risk for Alzheimer's disease is sleeping badly or having problems with sleep. It is thought that sleep can affect brain health.

We are interested in looking at how changes in the brain and sleep problems might cause memory problems for people with Down syndrome.

Scientists have discovered a new way of taking very detailed pictures of the brain.

This machine is called a 7 Tesla MRI scanner.

Here are some of the pictures the 7 Tesla MRI scanner can take.



We want to know how the brain changes as people with Down syndrome get older.

We hope these detailed pictures of the brain will help us to understand why people with Down syndrome might have memory problems.

We also hope it will help us to understand what medicines could help to prevent people with Down syndrome from getting memory problems and Alzheimer's disease.

Why have I been chosen?

We have asked you if you would like to take part in this research because you have Down syndrome, and you might find it difficult to remember things.

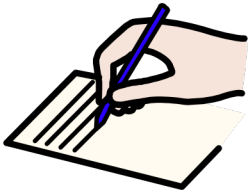


Who can take part in the study?

You can take part in the study if:

- You have Down syndrome.
- You are aged between 25 – 50 years old.
- You have a mild to moderate learning disability.
- You do not have a diagnosis of dementia
- You do not have any metal inside your body.
- You can lie still for a long time to have the scans.

What will happen if I take part?



We will ask you to sign a consent form saying that you understand what will happen and that you want to take part.

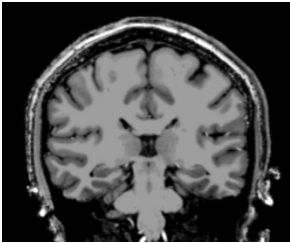


You do not have to take part if you do not want to. You can say no. This will not affect the care that your doctors give you.



Even if you do sign the form, you can still stop at any time. You do not have to tell us why you want to stop.

What will happen if I take part?



You will take part in an MRI scan, which take detailed pictures of your brain



You will have a sample of your blood taken from your arm



We will pay for all of your transport to Cambridge, and for your accommodation if you need to stay overnight.



We will ask you to do some puzzles and quizzes to test your memory.



You will wear a Fitbit around your wrist, which will track your sleep for 1 week



We will ask you to return the Fitbit to us after you have used it for 1 week, via post. We won't be able to replace the Fitbit if it is broken or lost.



You will also wear a monitor on your finger, while you are sleeping for 2 days. This will show us information about your breathing while you're asleep



If you want to, you can also attend the sleep clinic for one night at the Royal Papworth Hospital



You will sleep in a bed in the clinic, with an ensuite bathroom

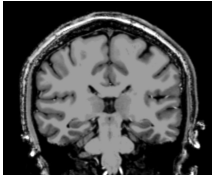
A member of your family can stay with you too



While you're there, a doctor will monitor your sleep using a machine with wires while you're sleeping

What will happen on the study visit?

You will come to Cambridge for 1 or 2 days.



- You will have a brain scan, which will take about 1 hour
- You will do some puzzles and answer some questions, which will take about half an hour
- You will have a blood test where we will take about 2 teaspoons of blood. This will take about 5 minutes
- We will give you a Fitbit to wear around your wrist and a monitor to wear on your finger. You will take these home and use the finger monitor for 1 night and wear the Fitbit for 1 week
- You can also choose to spend a night in the sleep clinic. This is optional

What is like to have the brain scans?

This section of the information booklet will show you what it is like to have the 7 Tesla brain scan.



First we will go the MRI scanner at Addenbrooke's hospital.



You can see the entrance in this picture.

The reception



When you come in, you will see the reception. A friendly person works at the reception desk.



There are some chairs for you to sit down. We will ask you some questions to check if you have any metal in your body.

The MRI scanner



This is what an MRI scanner looks like.

We will ask you to lie down on the bed that is part of the scanner.

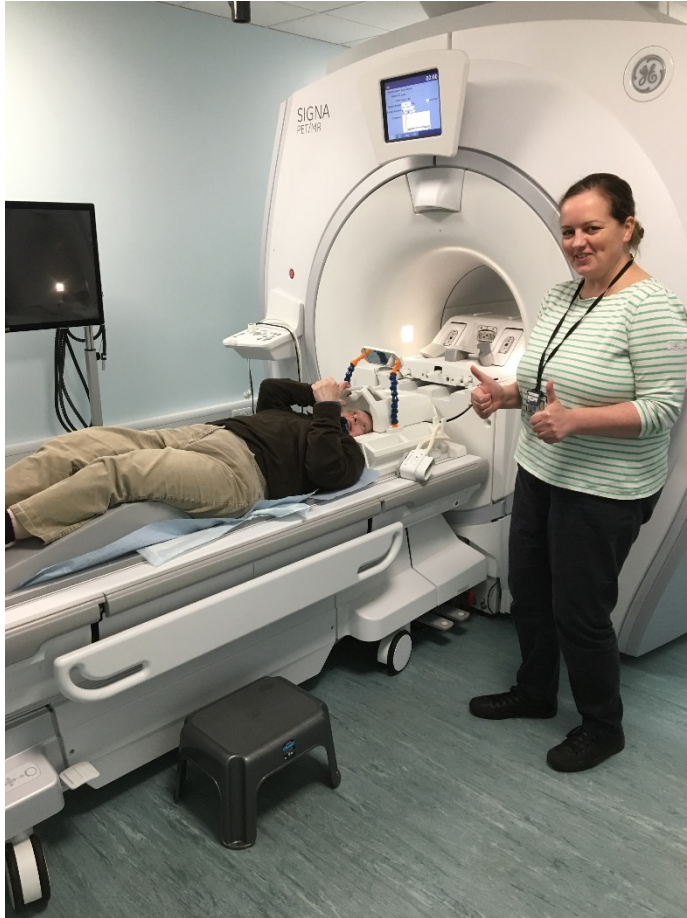
When you are ready and comfortable, the researcher will press a button to make the bed move up slowly.

The MRI scanner



The MRI scanner is very noisy. You will hear loud buzzing and knocking sounds, but you won't feel anything. It does not hurt to have the scans. We will put some soft earplugs in your ears to protect them from the noise.

The MRI scanner



We will give you some cushions and blankets to help you feel comfortable.

When you are ready, the bed will move back into the tube.

You will be inside the tunnel with your feet sticking out.

You will need to lie very still, or the pictures will be blurry. You will need to lie very still for about 1 hour.

The MRI scanner



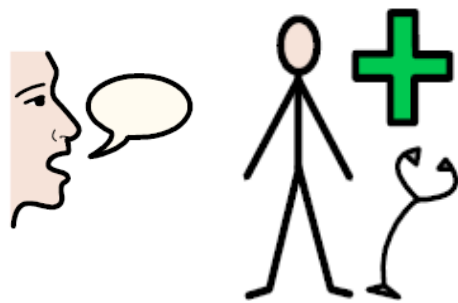
When you are in the scanner, we will go into the next room, where we can see you through a window.

We will be able to talk to you through a microphone while you are in the scanner, and you will be able to speak to us.

What will happen after the study

We will not be able to tell you if there are changes in your brain.

This is because we will not know what it means until all the results have been checked by other scientists.



If the scans shows something is wrong with your brain, we will tell your doctor.

But this is unlikely.

General questions

Are there any risks of taking part?



- The brain scans are not known to be dangerous as long as you do not have any metal in your body.
- We will ask you some questions to make sure and do an X-ray if we are not sure.
- The scan may be a little noisy, and you will be given earplugs to reduce the sound.
- The 7 Tesla MRI scanner may make you feel a little dizzy – this is normal and nothing to worry about.

General questions

Are there any risks of taking part?



- Putting the needle in your arm can be uncomfortable, but this will be done by someone who has done this lots of times before.
- Your arm may be a bit sore afterwards. We have never had anyone seriously hurt before.

General questions

Are there any benefits of taking part?



- We will learn more about how this chemical affects the brain and causes memory problems. We hope that this information will help scientists develop new medicines.

Do I have to take part?



- This study is optional, which means that it is up to you whether you take part. If you would like to take part you will be asked to sign consent form. It is alright for you to stop at anytime. If you do not want to take part in the study, or decide partway through that you want to stop, this will not affect the care that you currently get from your doctor.

Will I be paid to take part?



- We are not able to pay you for taking part, but we will pay for your transport for the research, for your accommodation if you need to stay overnight and for your **paid carer**. We will also pay for your food and drink while you taking part.

General questions

What happens if the brain scans show something wrong?

- The pictures that we take of your brain are looked at by scientists to see if there is anything in the pictures that suggests that you might be poorly.
- If they find something that suggests that you might be poorly, they will tell us. We will then tell you this and ask if it is okay with you for us to tell your GP about it, so that they can help you to get better.
- It is very rare that we will find something wrong with you that we were not expecting.

General questions

What if something goes wrong?

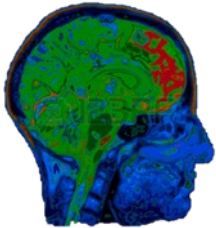
- Cambridgeshire and Peterborough NHS Foundation Trust, as a member of the NHS Clinical Negligence Scheme for Trusts, will accept full financial liability for harm caused to participants in the study caused through the negligence of its employees and honorary contract holders. There are no specific arrangements for compensation should a participant be harmed through participation in the study, but no-one has acted negligently.
- The University of Cambridge will arrange insurance for negligent harm caused as a result of protocol design and for non-negligent harm arising through participation in the study.
- If you wish to complain about the way you have been treated in this study, you can call Dr. Stephanie Brown. Her details are on the last page. You can also complain to the National Health Service via their Patient Advice and Liaison Service (PALS).

General questions

What will happen to the results of the research study?



- All information about you will be kept confidential.



- The pictures of your brain will have your name and date of birth on, but will be kept safely at the Wolfson Brain Imaging Centre (WBIC).



- Information collected by the Fitbit will also be shared with the Fitbit company. You can see the Fitbit privacy policy here:
<https://www.fitbit.com/global/us/legal/privacy-policy>

General questions

What will happen to my blood sample?



- Your blood sample will be kept for the current and future studies, which will not have your name on.
- You can still take part in the study even if you do not want your blood to be stored for future research.

General questions



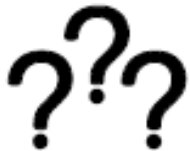
- The results will be published in scientific journals. We will send you a letter to let you know the results of the research.

Who has reviewed the study?



- This study was reviewed by the research team, and by other scientists and experts in the field. We have asked a Research Ethics Committee for guidance and approval before conducting this research.

Can I ask questions?



Please contact us if you have any questions:

- Dr Stephanie Brown: sb2403@medschl.cam.ac.uk
- The Research team: 07510 923864 or 07510 923866
- Or email: CIDDRG@medschl.cam.ac.uk

General questions

How will we use information about you?

- We will need to use information from you for this research project.
- This information will include your initials, name and contact details. 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.
- Some of your information will be sent to Canada and the United States of America. They must follow our rules about keeping your information safe.
- 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.

General questions

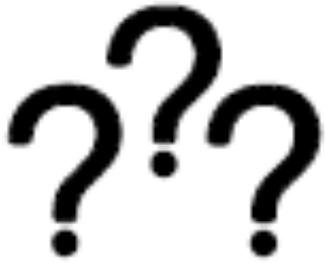
What are your choices about how your information is used?

- 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.
- 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.

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/
- by asking one of the research team
- by sending an email to Dr. Stephanie Brown: sb2403@medschl.cam.ac.uk
- www.hra.nhs.uk/patientdataandresearch

Can I Ask More Questions?



Please contact us if you have any questions:



- Dr Stephanie Brown:
sb2403@medschl.cam.ac.uk
- The Research Team: 07510 923864 or
07510 923866
- Email: ciddrg@medschl.cam.ac.uk



Joint sponsor statement

Cambridgeshire and Peterborough NHS FT (CPFT) and the University of Cambridge are joint sponsors for this study based in the United Kingdom. CPFT and the University of Cambridge will be using information from you and your medical records in order to undertake this study and will act as joint data controllers.

This means that both organisations are responsible for looking after your information and using it properly. The University of Cambridge will keep identifiable information about you for 5 years after the study has finished.

CPFT 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.

For Cambridgeshire and Peterborough NSH Foundation Trust, please visit: <https://www.cpft.nhs.uk/about-us/privacy-policy.htm>, or email the Data Protection Officer at: informationgovernance@cpft.nhs.uk

For University of Cambridge, please visit: <https://www.medschl.cam.ac.uk/research/information-governance/>, or email the Information Governance team at: researchgovernance@medschl.cam.ac.uk

<https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/templates/transparency-wording-for-all-sponsors/>