



CONTROL PARTICIPANT INFORMATION SHEET

12th July 2022 version 2

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

Invitation to take part in a study

We would like to invite you to take part in a research study. We are interested in why some people with Down's syndrome develop Alzheimer's disease as they get older. We are investigating how Alzheimer's disease is linked to sleep problems and brain changes in people with Down's syndrome. This information sheet explains what the research is about and what would happen if you take part. It is important that you read this information sheet before you make a decision as to whether you would like to take part in this research.

What is the research about?

We are interested in looking at how Alzheimer's disease develops and affects the brain in people with Down syndrome. A 7 Tesla MRI scan uses a stronger magnet than other MRI scanners, which means the pictures of the brain are much more detailed and clear. This allows us to examine changes to the brain which are not visible on other scans. This will help us understand why people with Down's syndrome have such a high risk for developing Alzheimer's disease, as well as what medicines could help. We are looking at how sleep quality might relate to brain changes and memory changes.

We would like to ask you, as a person without a diagnosis of Down's syndrome or dementia, to form part of our age-matched healthy control group. It is important that we can compare any suspected Alzheimer's disease changes seen in people with Down's syndrome with what is seen in a normal, healthy population.



What will I be asked to do?

We will ask you to sign a form saying that you understand what will happen and that you want to take part in the research study. You will be asked to come to Cambridge to have a 7 Tesla brain scan, answer some questions about your sleep and have a sample of blood taken. We will also ask you to take home a Fitbit device and wear it for 1 week, and an oximetry device, which you will wear on your finger and measures your breathing while you sleep, for two nights.

The Fitbit device will be returned to the study team via post after the 1 week of usage. You will be provided with mailing materials. In event of the Fitbit being broken or lost, please contact the research team. Unfortunately, we will be unable to replace broken or lost devices.

We will take care of all your transport to and from Cambridge. If you have to stay overnight in Cambridge for the visits, we will arrange this accommodation for you.

The 7 Tesla MRI scan will take place at the Wolfson Brain Imaging Centre. If there is a chance that you may be pregnant, we will ask you to take a pregnancy test before completing the scan. You will be asked to lie very still in the MRI scanner for 1 hour. If you feel worried, then you can ask that the scanning stops at any time.

Are there any risks of taking part?

The brain scans are not dangerous as long as there is no metal in your body. We will ask you some questions to make sure, and we can do an X-ray if there is any doubt.

MRI is a noisy imaging technique, so you will be given earplugs to reduce the noise level. Our experience suggests that this is an effective method for reducing the level of noise to comfortable levels. At 7T some participants can transiently experience nausea as they move through the magnetic field, and this will be explained prior to such imaging sessions. Considerable care will be taken to ensure that you remain comfortable throughout the session. You will also be encouraged to interrupt the experimental session if you feel pain or discomfort. You will also be told that you can withdraw consent at any point, with no justification required.

Also, you may experience some discomfort during the blood test, and your arm may be a little sore afterwards. Blood tests are very safe and do not pose any additional risks.

Are there any benefits of taking part?

We will learn more about how the brain of people with Down syndrome changes as they grow older. We hope to find new tests for seeing very early on when some people with Down syndrome get Alzheimer's disease and we hope that this information will help scientists

develop new medicines to help them.

Do I have to take part?

You do not have to take part in this study, you may also choose to stop at any time and you do not need to give a reason why. Taking part in this study is completely optional. If you decide that you do not want to take part, or would like to stop at any point during the study, it will in no way affect the standard of care you receive from your doctors. If you do want to take part in this study we will ask you to sign a consent form. Part of this consent form will ask if you are happy to be contacted about future studies with this research group, if you agree to this you may be contacted in the future but are under no obligation to take part in any further research.

Who is funding this study?

This study is being funded by Alzheimer's Research UK (ARUK-RF2021B-001). There are additional but much smaller funds from various other sources.

Will I be paid to take part?

We are not able to pay you for taking part, but we can pay for all transport to and from the hospital for the research. We will also pay for your food and drink whilst you are at the hospital.

What if something goes wrong?

It is unlikely that something will go wrong, but if you are harmed by taking part in this research project, and it was not because of someone's fault, there are no special compensation arrangements. However, if you are harmed due to someone's fault, you may have grounds for legal action, but you may have to pay for it. This study has been approved by a Research Ethics Committee and this research has insurance to cover negligent and non-negligent harm under the University's Clinical Trials policy.

If you wish to complain about the way you have been treated in this study, you are able to complain directly to Dr. Stephanie Brown (sb2403@medschl.cam.ac.uk). If you remain unhappy and wish to complain formally, you can do this by contacting the Patient Advice and Liaison Service (PALS) at the National Health Service (01223 216756).

What if the brain scans show something is wrong?

It is unlikely that the brain scan will show anything wrong with your brain. If there is, we will ask for your permission to contact your doctor and let them know. With your permission, we will also let your doctor know that they are taking part in this study, unless you would prefer us not to.



What will happen to the results of the research study?

All information will be kept private, and your name will never be used in any publication. Pseudo-anonymised data and images will be shared with third party researchers who are undertaking similar studies. All information and data collected in this study will be stored securely at the University of Cambridge by the research team for up to 5 years after the study has ended. The results of the study will be published in scientific journals.

The Wolfson Brain Imaging Centre does keep a record of brain scans and this data alone will be linked to your name and date of birth and may be stored indefinitely. The scanning data however is confidential and will be stored on a secure network only accessible by responsible Wolfson Brain Imaging Centre staff.

Your data collected by the Fitbit device will also be shared with Fitbit. The Fitbit privacy policy can be found here: <https://www.fitbit.com/global/us/legal/privacy-policy>

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.

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

Who has reviewed the study?

This study was reviewed by the research team the University of Cambridge and Alzheimer's Research UK. The National Research Ethics Committee has issued a favourable opinion of this research.

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->

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Who can I contact about the study?

You can contact Dr. Stephanie Brown, who will be happy to answer any questions you have;

Name: Dr. Stephanie Brown

Email: sb2403@medschl.cam.ac.uk