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Investigating auditory stimulation during sleep to boost consolidation

of motor learning (SleepStim)

PARTICIPANT INFORMATION SHEET – study 1C

Central University Research Ethics Committee Approval Reference: R79095/RE001

Version 3.0, 02/02/2023

1. Introductory paragraph

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

2. Why is this research being conducted?

Our research aims to find out whether we can improve learning of movement tasks by using auditory (sound) stimulation delivered during sleep. We think that this technique has the potential to boost rehabilitation in people who have had a stroke.

There are many underlying factors that may influence how well people sleep and it is not well understood how stroke impacts on sleep characteristics. We would therefore like to better understand people's sleep at home before we can fully test the auditory stimulation.

3. Why have I been invited to take part?

You have been invited to take part because you responded to an advertisement, or because you have taken part in other studies and agreed to be contacted again. We are recruiting people who have had a stroke, and people who have not had a stroke. You should be aged 18 years or over and living in the United Kingdom. You should also have access to a device (e.g. smartphone, tablet) to be able to download an "app". We will be recruiting up to 40 stroke survivors and 40 people who haven't had a stroke for this study.

You will be unable to take part in this study if you have a neurological or psychiatric condition (other than stroke if applicable) which precludes participation (please ask the researchers if you are unsure).

4. Do I have to take part?

No. It is up to you to decide whether or not to take part. You can withdraw yourself from the study, without giving a reason, and without negative consequences, by advising us of this decision. Any data that have been collected from you may still be used in the study, unless you request otherwise. If you want to withdraw your data, please advise the researcher within 1 month from when you took part.

5. What will happen to me if I take part in the research?

If you would like to take part after reading this information, please let the researcher know by email or phone (contact details at the end of this document). We will then discuss the study with you and answer any questions you may still have. Once you are happy that all your questions have been answered we will email you a web link to provide informed consent online or we will send you a paper consent form with a postage-paid envelope so that you can send it back to us (depending on your preference). We will then arrange a date that is convenient for you to perform the study procedures in your home (details below).

- We will ask you to complete questionnaires about yourself (including your age, sex assigned at birth, ethnicity, height and weight), details about your stroke (if you are a stroke survivor) and some questions about your medical history. You will be sent a weblink to answer these questionnaires or we can send paper versions instead if you prefer.
- We will provide you with an Electroencephalography (EEG) headband which will record your brain activity at home. Depending on your preference we can post this to you, deliver it to your home, or you can collect it from the Wellcome Centre for Integrative Neuroimaging (WIN – formerly FMRIB), John Radcliffe Hospital, Oxford.
- You will need to download an app (e.g. on to a smartphone or tablet) which will be used to record the signal from the EEG headband. The researchers will send you a link to the app and instructions for using it. Please do not hesitate to ask if you have any questions about this process.
- You will be asked to wear the EEG headband for 3 nights. The researcher will provide you with instructions for how to wear the headband and can talk you through the process if you have any questions.
- You can ask to pause or stop the research activities at any time by contacting the researcher
- At the end of the study, we will ask you to return the equipment, by posting it back (we will provide postage materials), delivering it to the WIN, or a researcher will collect it from you (depending on your preference). The headband is cleaned according to the manufacturer's instructions once we receive it back, and before it is sent to another participant.

Picture showing EEG headband

6. What are the possible disadvantages and risks in taking part?

Some people find it unusual to wear the EEG headband while they sleep, however for most people this does not disrupt sleep too much, they get used to it fairly quickly and are able to sleep normally. If you have any questions or concerns, please do let us know.

One of the questionnaires (called the STOP-BANG) is used to identify people who are at risk of breathing problems during sleep. Although we are using this questionnaire purely for research purposes, if your score on the questionnaire indicates that you might be at risk of having breathing problems during sleep then we will send you a letter with information which you can take to your GP.

7. Are there any benefits in taking part?

While there are no immediate benefits for those people participating in the project, it is hoped that this research will lead to development of this technique, which may in the future be tested as a way of improving recovery after stroke.

8. Expenses and payments

You will receive £25 for participation. This will be transferred from the University to your bank account, or if you prefer we can send you a shopping (e.g. Amazon) voucher.

9. What information will be collected and why is the collection of this information relevant for achieving the research objectives?

Identifiable data (name, bank and contact details) will be stored on the University server, accessed through encrypted and password protected University laptops. Electronic consent forms will be downloaded from Jisc and saved on the University server. Paper consent forms will be kept in a locked cabinet at the Wellcome Centre for Integrative Neuroimaging. All consent forms will be kept for at least 5 years.

With your consent, we will keep your contact details on a secure database indefinitely in order to contact you for future studies. We will keep a copy of your consent form with this database, as your consent is our legal basis for re-contacting you under UK data protection law. If you are contacted about a future study, it is up to you whether you want to participate or not. You can have your details removed from the database at any time by contacting the researchers. Where you have not agreed to be contacted for future studies, your contact details will be securely destroyed as soon as no longer required.

Other research data will be stored (using a code rather than your name) for at least 5 years after publication or public release of the work of the research.

Your personal details (name, address, bank account number, nationality or National Insurance number) need to be shared with the finance department of the University of Oxford in order for you to receive payment for your participation. If you do not want to provide this information for this purpose, then we can provide you a shopping (e.g. Amazon) voucher instead.

The research team will have access to the research data. Responsible members of the University of Oxford may be given access to data for monitoring and/or audit of the research.

Research data may be transferred to, and stored at, a destination outside the UK and the European Economic Area. Identifiable data will be removed whenever possible and any data transfer will be done securely and with a similar level of data protection as required under UK law.

We may use this data in future studies, and share data with other researchers (e.g. in online databases). Data will be de-identified using a unique code rather than using your name.

Brain activity data from the EEG headbands are recorded and stored by Dreem (www.dreem.com). You will need to download an 'app' onto your phone in order for the data to be recorded. The researchers will provide you a link to the application and instructions to set it up. You will be given a username and password to use rather than registering with your personal details. As such, brain activity data will be stored in a de-identified manner. The researchers will download the data from the Dreem server and store it on the University server.

10. Will the research be published? Could I be identified from any publications or other research outputs?

The findings from the research may be written up in a thesis, dissertation, academic publications and presentations. It will not be possible to identify you in these outputs.

A copy of the thesis/ dissertation will be deposited both in print and online in the Oxford University Research Archive where it will be publicly available to facilitate its use in future research.

11. Data Protection

The University of Oxford is the data controller with respect to your personal data, and as such will determine how your personal data is used in the study. The University will process your personal data for the purpose of the research outlined above. Research is a task that is performed in the public interest. Further information about your rights with respect to your personal data is available at https://compliance.admin.ox.ac.uk/individual-rights.

12. Who is funding the research?

This study is funded by the Wellcome Trust.

13. Who has reviewed this study?

This study has received ethics approval from a subcommittee of the University of Oxford Central University Research Ethics Committee. (Ethics reference: **R79095/RE001)**.

14. Who do I contact if I have a concern about the research or I wish to complain?

If you have a concern about any aspect of this study, please contact Dr Melanie Fleming: melanie.fleming@ndcn.ox.ac.uk or 01865 611 461, and we will do our best to answer your query. I will acknowledge your concern within 10 working days and give you an indication of how it will be dealt with. If you remain unhappy or wish to make a formal complaint, please contact the Chair of the Medical Sciences Interdivisional Research Ethics Committee at the University of Oxford who will seek to resolve the matter as soon as possible:

Email: ethics@medsci.ox.ac.uk; Address: Research Services, University of Oxford, Boundary Brook House, Churchill Drive, Headington, Oxford OX3 7GB

15. Further Information and Contact Details

If you would like to discuss the research with someone beforehand (or if you have questions afterwards), please contact:

Dr Melanie Fleming or Miss Triin Ojakäär

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