Participant Information Form

Acoustic Stimulation to Enhance Slow-Wave Sleep in the Home in People with Parkinson's – A Feasibility Study.

The purpose of this information sheet is to provide you with sufficient information so that you can then give your informed consent. It is very important that you read this document carefully and raise any issues that you do not understand with the researcher.

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Project Title: Acoustic Stimulation to Enhance Slow-Wave Sleep in the Home in People with Parkinson's – A Feasibility Study.

What is the purpose of the project?

Changes to sleep are observable in the general population and an increase of disrupted sleep is often an early indicator of neurodegenerative disorders. Alterations to sleep, timing, duration, quality, and sleep architecture are commonly observed in both healthy and neurodegenerative ageing.

Within neurodegenerative disorders such as Parkinson's disease, changes to sleep are often observed prior to and upon the onset of the disease. Using certain sound frequencies (Acoustic Stimulation) has been shown to enhance restorative deep sleep in laboratory studies.

In this study we are testing the feasibility of using Acoustic Stimulation of deep sleep in the home in conjunction with a wearable brain activity measuring device in People with Parkinson's. To do this, we are recruiting participants for a home-based study, which will involve Acoustic Stimulation in conjunction with the EEG wearable device during sleep on three non-consecutive nights.

If you are interested in participating, it is advised that you read this document carefully, take time to consider your decision and then contact us. You can also get in touch with the researcher to discuss any questions you may have.

Why have you been selected to take part and what are the exclusion criteria?

To take part in this study, you must:

- Be 55+ years of age.
- Have a confirmed diagnosis of Parkinson's without impairment of balance.
- Must be able to complete all detailed study procedures.
- Fluent English speakers.

To take part in this study, you must not:

- Have a diagnosed sleep disorder such as, sleep apnoea, periodic limb movement disorder, REM behaviour disorder, nocturia, insomnia diagnosis.
- Have a diagnosis of atypical Parkinson's disease, or Parkinson's dementia.
- Take medications which could interfere with sleep such as, benzodiazepines, nonbenzodiazepine receptor agonists, orexin antagonists, antiseizure drugs, antidepressants, analgesics, and CNS stimulants.

What will I have to do?

1.0 Ensure you Understand the Study

If you are interested in participating, it is advised that you take time to consider your decision. You should also get in touch with the researcher is discuss any questions you may have. Once you are satisfied with your understanding of the study at this point, email the primary researcher – Emily Jensen (emily.jensen@northumbria.ac.uk) and declare your interest.

2.0 Attend a Screening Session

Initially, you will be invited to have a virtual screening, via video call or via email, at your convenience. During screening you will be fully briefed on the study procedure, and you will have the opportunity to ask any additional questions. If you wish to continue and feel you have enough information, you will be asked to provide consent to participate. Following this you can withdraw at any point without explanation to the research team.

The screening process will then begin. This includes answering some questionnaires to ensure you are eligible to take part in the study. The screening questionnaire consists of demographic questions (age, gender, sex at birth, ethnicity, etc), followed by several sleep health

related questionnaires. Your eligibility to participate in the study will be determined following the screening session.

If you are eligible to participate, you will be invited for an in person visit at Northumbria University. Where you will be provided with the following to take home:

- Study schedule.
- Home wearable non-invasive brain activity measuring equipment. This consists of 4 electrodes placed on the forehead and face. This is to record brain activity during sleep and a tablet that will start and store the recording.
- Wrist activity watch monitor, a watch like device that will record wrist movements, which will enable us to determine your sleep-wake cycle.
- Morning sleep diary.
- Laptop with cognitive tasks.
- Information pack which will include detailed instructions for the use of each equipment and the dates to complete the individual tasks.

Please note, during this visit we will spend as much time as needed for you to get comfortable with using these devices and questionnaires. Also, throughout the home study period we will be available via telephone or video call to answer questions or help you with the devices.

3.0 Home Protocol

The home protocol will take approximately 15 days to complete, during which you should keep a regular sleep schedule this should be ± 1 hour. You will wear the activity monitor watch and complete the morning sleep diaries for the entirety of the protocol. You will then complete 3 nights around 5 days apart using the wearable non-invasive brain activity measuring equipment. Each of these nights will follow the same protocol, this will be detailed below and in your information pack.

One hour before bedtime you should complete the computerised cognitive tasks on the laptop and questionnaires, this should take around 30 minutes. You should then prepare for bed as you normally would with the addition of applying the wearable brain activity measuring equipment, following the instructional video. You will be required to repeat the computerised tasks 45 minutes after waking up from sleep. You should repeat this protocol 3 times over the course of the study, the specified dates will be specified in your information pack.

The first overnight sleep measurement is an acclimation night to allow you to get use the equipment and procedure. Either the second or third night of sleep measurement, will involve acoustic stimulation during sleep. This sound will not wake you up. It is designed to only increase your deep sleep.

4.0 Interview

Following completing the protocol, you will be asked if you wish to attend a 30 – 60-minute interview to discuss your experience with using the device and the acoustic stimulation. This interview can be in person or virtually via video call or phone call at your convenience.

Will my participation involve any physical discomfort or risk?

Electroencephalogram (EEG)

The paste and impedance gel used to attach electrodes to the face and forehead may cause minor discomfort/irritation in a small number of people. A patch test can be completed during the screening to check that no discomfort from this will occur during the home protocol.

Cognitive Tasks and Questionnaires

The cognitive tasks should not cause any distress, but you are encouraged to take a break between each cognitive task to minimise eye strain.

The questionnaires are unlikely to cause any distress, although questions regarding mood and sleep may cause some distress to some people. If you are concerned about any of your responses on any particular questionnaire, you may want to contact your GP for further enquiry.

Procedures to Minimise Potential Risks

The aims and the step-by-step procedure of the study will be explained during the screening session. You will be given the opportunity to ask questions throughout to ensure you fully understand the study. You are also free to withdraw from the study at any point.

All cognitive tasks and questionnaires have been validated and are frequently used in medical setting and research environments. Both cognitive tasks and questionnaires are unlikely to cause any distress, however, if you do find them uncomfortable and wish to stop, let the researcher know, and you can stop completing the tasks.

If you experience any discomfort during the study, or you become unwell, you should report this to the researcher and the study will be stopped.

No findings from this study that could identify you will be published. By using a participant code for each participant rather than your name, your anonymity is assured.

How will confidentiality be assured and who will have access to the information that I provide?

All data will be stored on password-protected computer systems and external hard drives. Information and data gathered during this research study will only be available to the research team named above and SOMNOmedics AG will use the anonymised data for training an AI and/or further development on algorithms. All data will be stored and treated in keeping with the Data Protection

Act (for more information on the Data Protection Act and General Data Protection Regulation, see the following government website: https://www.gov.uk/data-protection).

Will I receive any financial rewards for taking part?

You will be compensated £100 for your participation in this study.

How can I withdraw from the project?

You can withdraw from the study at any time without having to provide a reason by simply letting the primary researcher know that you do not wish to continue. If you do decide to withdraw at any point, any information that you have provided up to this point will be destroyed. You can also withdraw after you have completed the study by emailing the researcher within 1 month of taking part in the study and citing your unique code-word, which you will create during screening. If you do this, any information that you have provided will be destroyed. If you email to be withdrawn from the study after 1 month then it may not be possible to remove you from the study.

If I require further information, who should I contact and how?

This study has received ethical approval from Northumbria University's Ethics Committee (ref:7282).

If you have any concerns or worries concerning this research or if you wish to register a complaint, please direct it to: Prof. Nick Neave (nick.neave@northumbria.ac.uk), Faculty Director of Ethics, Department of Psychology, Northumberland Building, Northumbria University, Newcastle, NE1 8ST

The data collected in this study will be used for a Psychology PhD Research Project. It may also be published in scientific journals or presented at conferences. Information and data gathered during this research study will only be available to the research team named above, and the Faculty Director of Ethics (Prof. Nick Neave). Should the research be presented or published in any form, all data will be anonymous (i.e. your personal information or data will not be identifiable). This anonymous data may be held indefinitely to ensure research integrity.

Any personally identifiable information and data gathered during this research is subject to and will be stored in line with EU General Data Protection Regulation (GDPR) and the UK Data Protection Act (2018). Any personally identifiable information will be destroyed as soon as it is no longer needed (e.g., email addresses used to keep in contact with you will be destroyed as soon as they are no longer required). Consent forms with personal details will be destroyed within six months of the conclusion of the project.

This study and its protocol have received full ethical approval from the Department of Psychology Ethics Committee (Postgraduate Research) in accordance with the School of Health and

Life Sciences Ethics Committee. If you require confirmation of this please contact the Faculty Director of Ethics (Prof. Nick Neave), stating the title of the research project and the name of the researcher.