Caloric Vestibular Stimulation in Parkinson’s Disease

Participant Information Sheet

You are being invited to take part in a research study. 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. Talk to others if you wish.

- Part 1 tells you about the purpose of this study and what will happen if you take part.
- Part 2 gives you more detailed information about the conduct of the study.

Please ask if anything is unclear, and do not feel rushed into making a decision.

PART 1

1. What is the research study about?
This is a research study in which we are testing whether stimulating the external ear canal via a process called vestibular stimulation can help reduce symptoms of Parkinson’s Disease. We plan to recruit 32 individuals with Parkinson’s Disease to our study here in Kent.

3. Do I have to take part?
No. It is up to you to decide whether or not to take part. If you do, you will be given this information sheet to keep and asked to sign a consent form. You are still free to withdraw at any time without giving reason. A decision to withdraw at any time, or a decision not to take part, will not affect any other medical care or treatment that you receive.

4. What will happen to me if I take part?
The study will take place over 12 weeks and involves daily sessions of stimulation that you, with the help of your partner or carer, will self-administer at home, once in the morning and once in the afternoon or evening. Prior to any stimulation, you will take part two baseline assessments to give us an idea of your natural abilities and some of the difficulties that you report. The baseline assessments will last 2-4 hours and will involve:

- Questions that measure your thinking skills
- Simple physical exercises to measure your movement and mobility
- A recording of your electrical brain activity using the EEG test (see Point 12 below)
- A short video recording of your mobility and thinking skills

You will be randomly allocated to one of two groups in the study which will determine whether you receive active stimulation or placebo stimulation. Those assigned to the active
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stimulation group will receive the actual treatment while those in the placebo will not receive anything. You will not know which group you belong to until after the study has finished.

Every 4 weeks we will see you to repeat the same assessments that you did at baseline. We can either come to your home or you can come to the University. If you come to the University then we may be able to pay for your travel expenses.

Follow up assessment will be performed 4 weeks after the stimulation period has finished. The EEG test will only be carried out at baseline and at the end of the study.

The stimulation is delivered by a small probe, mounted on a headset, that sits just inside the ear canal. Stimulation lasts approximately 20 minutes. The stimulation device that we will use has not been approved by the Medicines and Healthcare Products Regulatory Agency (MHRA) and its use in this study is considered purely investigational.

5. What are the side-effects?
The ear probe is not painful or distracting but in a few participants there have been reports of feeling a little dizzy during stimulation but this usually subsides a few minutes after stimulation has stopped.

In addition to the risks listed above, there may be a previously unknown risk or side effect.

If you require medical treatment during the study, regardless of whether you believe it to be associated with your study participation, then you should contact your normal medical provider (e.g. GP, out-of-hours NHS service, A&E department). The University of Kent is unable to provide medical care. You must inform your study researcher if any unexpected symptoms or medical consultations sought during the study period.

6. What are the possible benefits of taking part?
There is no guarantee that you will benefit from taking part. The treatment is at an early stage so it is difficult to know how well it will work, if at all. The information we get however, might help the treatment of others who experience similar problems in the future.

7. What happens when the research study stops?
- If you were in the active stimulation group then you will not have continued access to stimulation, even if you feel that you have benefited. We may, however, contact you at a later date if we decide to conduct another study and believe that you may be eligible.

- If you were in the placebo group then you will be offered access to the treatment if the study showed it to be beneficial.

8. What if there is a problem?
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Any complaint that you have will be addressed. Please see Part 2.

9. Will my taking part be confidential?
Yes. All information that we collect from you will be confidential. Please see Part 2.

10. Contact details
You should contact your research doctor if at any time you require further information relating to the study: Dr. David Wilkinson, School of Psychology, University of Kent, Canterbury, Kent, CT2 7NP. Tel: 01227 824772.

This completes Part 1 of the Information Sheet. If you are still interested in participating then please read the extra information in Part 2 before making any decision.

PART 2

11. What if relevant new information becomes available?
Sometimes we get new information about the treatment being studied. If this happens, your research doctor will tell you and discuss whether you should continue in the study.

12. Are EEG painful or unsafe?
The procedure is widely used in the NHS and is considered as a standard procedure. EEG measures activity in your brain by placing little electrodes on your scalp which detect the electric currents produced by the brain. This test will take about 40 minutes and will require you to sit as still as you can. You may need to wash your hair afterwards. You will not feel any different to your normal state during this test.

The EEG is not considered painful or dangerous to your health.

13. What will happen if I don’t want to carry on with the study?
You may withdraw yourself or your data from the study at any time. There is no penalty, loss of rights or loss of other medical benefits that you have a right to receive if you refuse to take part or decide to withdraw. If you do choose to withdraw, or are no longer able to participate, then unless directed otherwise, study investigators will keep the data collected up to that point. Your participation in the study can also been withdrawn by the study director.

14. What if there is a problem?
If you have a concern about any aspect of the study then you should speak with research doctor David Wilkinson, who is director of the study. He can be reached on 01227 824772. If you remain unhappy and wish to complain formally, you can do this through the Chair of the University of Kent School of Psychology ethics committee on 01227 824775.
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In the unlikely event that something goes wrong and you are harmed during the research study, there are no special compensation arrangements. If you are harmed and this is due to someone’s negligence, then you may have grounds for a legal action for compensation against the University of Kent but you may have to pay your legal costs.

15. Will my taking part in this study be kept confidential?
Information collected for the purpose of this research study will be kept confidential as required by law. In providing consent, you will however authorise us to inform your GP about your study participation. Your study records will be kept in password protected computer programs and in locked file cabinets to which only the study investigators, and if necessary the study sponsors, will have access. Only your consent form will bear your actual name. All other data forms will bear a study number in place of your name. All personal data will be destroyed after 1 year.

16. What will happen to the results of the research study?
The results of this study will be used to determine whether vestibular stimulation has the potential to reduce symptoms of Parkinson’s Disease. The results of the present study may be published for scientific purposes, but your records or identity will not be revealed unless required by law.

17. Will my GP be made aware of my participation in the study?
Yes. We will send a letter to your GP informing them of your participation in the study.

18. Who is organising and funding the research?
The study is organised by Dr. David Wilkinson, who is employed by the University of Kent as a Reader in Psychology and holds an honorary research contract with East Kent Hospitals University NHS Foundation Trust. The research is not currently funded by an outside body.

19. Who has reviewed this study?
This study was given a favourable ethical opinion by an NHS independent ethics committee.

We thank you for taking time to read this sheet. If you decide to participate in the study then you will receive a copy of this Information Sheet and the consent form that you must later sign.

David Wilkinson, PhD.