

Participant Information Sheet

You are being invited to take part in a research study. Before you decide if you would like to take part 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 please ask if anything is unclear.

1. What is the research study about?

This is a research study in which we are testing whether a process called galvanic vestibular stimulation (GVS), a non-invasive type of brain stimulation, has an effect on brain activity and behaviour. We want to investigate why GVS (which involves applying gentle electrical currents to the part of the scalp behind the ear) might help relieve some features of Parkinson's.

2. 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.

3. What will happen to me if I take part?

Before you begin the study, we must check that you are eligible to take part. To participate in this study you must:

- Have no skin abrasions or lesions behind the ears, no metallic objects (such as shrapnel, surgical clips or fragments from welding or metalwork) in your head or electronic implants in your body.
- Be 18 years or over.
- Have good ear health.
- Be able to provide documentary evidence of your Parkinson's diagnosis from your neurologist.
- Be on stable anti-parkinsonian medication.
- Have no previous history of other neurological disease (e.g., stroke, epilepsy, brain tumour, etc.).
- Have no implanted devices (e.g., deep brain stimulation).
- Not be receiving apomorphine or dopamine infusion therapy.

If you are eligible to take part, you will be asked to come to the University of Kent campus for **three separate sessions**.

In **Session 1**, you will be asked to complete some assessments that will involve:

- Questions that measure your thinking skills.
- Simple physical exercises to measure your movement and mobility.
- Questions about your Parkinson's symptoms.

You will then come in for the first experimental session, **Session 2**:

- The researcher will first fit your head with an EEG cap with electrodes that measure brain activity.
- The research will apply electrodes (small patches that stick to the skin) to the chest to measure heart rate.

- The researcher will also place some electrodes on your arm and leg to measure your muscle activity.
- Next, the researcher will apply electrodes behind your ears that will gently deliver the vestibular stimulation.
- You will then be asked to complete a finger or foot tapping task.
- You will also be asked to complete a brief computerised cognitive task looking at how quickly you can respond to a stimulus on the screen.
- At some points during these tasks you will receive GVS.

Finally, you will return for **Session 3**, which will take place 24 hours after **Session 2**:

- All of the tasks and procedures in this session will run identically to Session 2 as outlined above.

All sessions should take approximately two hours to complete. Throughout the sessions, you will be given the opportunity to take several short breaks.

At the end of the experiment the aims of the study will be fully explained to you and any questions which you might have will be answered.

4. What are the side-effects?

GVS is not usually painful but you may feel a slight tingling or itching behind the ears during the stimulation. There is also a slight risk of dizziness and nausea. However, these effects are uncommon and should subside after the first few minutes of stimulation.

There is also a small risk of burn at the electrode sites if they become detached for a prolonged period. To prevent this, we will check that they are properly attached at several points throughout the experiment.

In addition to the risks listed above, there may be a previously unknown risk or side effect. If you have any unusual sensations or side-effects then you should inform one of the experimenters straight away. If any side-effects appear later after you have left then, again, please get in touch.

The electrodes applied to your chest, arms, legs and scalp are not considered to be painful or dangerous. You will not feel any different to your normal state during these tests. Applying the EEG electrodes to your head involves the use of a gel. This means you may need to wash your hair once the experiment is finished. Hair washing facilities are available, although you may bring your own shampoo and conditioner if you wish.

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 of any unexpected symptoms or medical consultations sought during or soon after the study session.

5. What are the possible benefits of taking part?

Your contribution to this project will increase our knowledge about how GVS works. We may contact you at a later date about other studies that may be beneficial to you. Please let us know if you prefer us not to contact you in the future.

6. 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 or loss of rights if you 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 be withdrawn by the study director.

7. What if there is a problem?

If you have a concern about any aspect of the study then you should email the researcher, Jade Fawkes, at jlc57@kent.ac.uk. Alternatively, you can speak with research Professor 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 via email at psychethics@kent.ac.uk

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.

8. 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. Your study records will be kept in password protected computer programs and in locked file cabinets to which only the study investigators 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.

9. What will happen to the results of the research study?

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.

10. Who has reviewed this study?

This study was given ethical approval by the ethics committee of the School of Psychology at the University of Kent.

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.

*Jade Fawkes, Msc-R Researcher
Professor David Wilkinson*

Danae Malyan, Research

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