University of South Australia

Participant Information Sheet

Title	*Evaluating the Effect of Non-Invasive Vagus Nerve Stimulation Combined with Physiotherapy to Enhance Balance and Mobility in People with Stroke*
Short Title	*Evaluating non-invasive vagus nerve stimulation for enhancing balance and mobility after stroke.*
Project Number	205153
Chief Investigator	Ashraf Gerges

Introduction – What does my participation involve?

You are invited to take part in this research project. You have been invited because you have previously had a stroke. The research project is testing a new treatment for improving recovery of balance and mobility.

This Participant Information Sheet tells you about the research project. It explains the tests and treatments involved. Knowing what is involved will help you decide if you want to take part in the research. Please read this information carefully. Ask questions about anything that you do not understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative and/or friend.

Participation in this research is voluntary. If you don't wish to take part, you don't have to. Your regular healthcare will not change whether you do or do not participate in this study. If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

- Understand what you have read
- Consent to take part in the research project
- Consent to have the tests and treatments that are described
- Consent to have the use of your personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

What is the purpose of this research?

The aim of this study is to assess whether combining non-invasive vagus nerve stimulation with physical rehabilitation can enhance the recovery of balance and mobility after stroke. In addition, we are interested in exploring whether people find this treatment method acceptable, easy to use, and safe.

We are particularly interested in new ways of helping people with stroke to enhance their ability to walk and their balance as this is frequently identified as one of their primary rehabilitation goals.

What does participation in this research involve?

Verbal and written consent (consent form) will be required prior to any assessments. A consent form will need to be signed by all participants.

You will be participating in a randomised study which helps researchers accurately understand whether a treatment is in fact a better option to help people. This means, if you choose to participate, you may be randomly allocated to a control group or to the intervention. Your specific allocation will be concealed until study is completed. Those in the control group will receive physiotherapy alone.

To be able to participate in this study, you will need to be:

- Over 18 years of age
- Have experienced stroke for first time at least six months ago
- Have reduced balance and/or mobility but can walk with or without mobility aid (e.g. walker or walking stick) for 10 meters, with or without physical assistance.

You will not be eligible if you:

- Have other neurological conditions
- Have had had previous vagus nerve surgery
- Have moderate to severe cognitive or language impairment that might impact your ability to understand instructions or provide consent

- Have severe pain in any of affected limb joints
- Have advanced cardiac, pulmonary, kidney or liver conditions
- Are pregnant
- Are on neuroactive medications
- You have pre-existing mobility impairments not related to stroke

Prior to attending the appointment at the University of South Australia research facility, all participants are randomly allocated to one of two groups. This random allocation will be done using a computer. You will be assigned to either the intervention or control group. All participants will receive therapy to improve balance and mobility.

During the intervention phase of the project, you will be asked to attend the UniSA City West Health and Medical Clinic two to three times per week for a 60-minute session each time (15 sessions in total). Treatment will continue for 6 weeks. If you are allocated to the intervention group, you will receive physiotherapy combined with non-invasive auricular vagus nerve stimulation. If you are allocated to the control group, you will receive physiotherapy alone.

You will be asked to fill out an information sheet that will provide us of details of your age, sex, and clinical characteristics (e.g. type of stroke). Knowing all this information is important as it helps us know who we can apply the results to at the conclusion of this study.

Figure 1: Non Invasive Auricular Vagus Nerve Stimulation

Treatments and assistance levels will be individualised to your abilities. Each session will have a duration of ~60 minutes. These treatments will be delivered for a period of 6 weeks. At the

beginning and end of this 6 week treatment period, we will obtain some measures to understand the possible benefit of this training. Briefly, these outcome measures will include the following:

- A measure of mobility (~2 minute duration)
- A measure of walking speed (~5 minutes duration)
- A measure of walking quality (~ 2 minutes duration)
- A measure of balance (~ 5 min duration)
- A measure of global disability (~5 minutes duration)
- A measurement of self-efficacy (~ 5 min)

Furthermore, we will obtain these same outcomes at the end of the treatment phase and at one month after the treatment.

Following the treatment, we will obtain some additional information to gain insight to your experiences. This will include;

- A questionnaire to understand your experience using the non-invasive vagus nerve stimulation device (~5 minutes)
- Document any falls (completed throughout the treatment period)
- A brief interview to gain insight to your experiences with this device and the whole treatment (~30 minutes)

What are the possible benefits of taking part?

All participants in this study will receive 6 weeks of mobility and balance rehabilitation therapy. However, it should be noted that we cannot guarantee improvements in balance and/or walking ability.

What are the possible risks and disadvantages of taking part?

People in this study might experience increased fatigue or discomfort due to completing a large dose of balance and mobility training. Sessions will be tailored to each individual to minimise discomfort.

It is expected that some people might experience mild adverse effects from the use of non-invasive vagus nerve stimulation. The most common adverse effects are skin irritation/pain at electrode site, headache, and dizziness

There may be side effects that the researchers do not expect or do not know. Tell your study investigator immediately about any new or unusual symptoms that you get. If side effects occur during the intervention, the intervention may need to be ceased and contact made with your GP. If side effects are severe, the principle investigator will get medical help.

Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with the University. Please note, however, that should you choose to withdraw from the study, you have until one month after the completion of your involvement to request that this data be removed from the study

What will happen to information about me?

Your results from the study will be non-identifiable (identifying information removed and coded with a participant ID number) and will be securely stored on the UniSA server, password protected computers and in locked filing cabinets at the UniSA City East Campus. This information will be stored for at least 15 years after the completion of the project. All records containing personal information will remain confidential and no information which could lead to the identification of any individual will be released, unless where this is required by law.

What if something goes wrong?

Standard first-aid procedures will be applied. All staff are trained to apply immediate first-aid.

What happens when the research project ends?

A summary of the project results will be available at the completion of this study (intended to be December 2024). This will be a group level result and individual results have little meaning.

With your consent, your demographic and contact details will be stored in a secure database so that you may be contacted regarding involvement in potential future studies (for which further ethical clearances will be obtained). Please note that this consent can be removed at any point in the future by discussion with the research team

Who is organising and funding the research?

This research project is being conducted by Ashraf Gerges from the University of South Australia. There project was funded by the University of South Australia.

Who has reviewed the research project?

The ethical aspects of this research project have been approved by the Human Research Ethics Committee (HREC) of the University of South Australia as required by the Australian government research requirements, specified in the National Statement on Ethical Conduct in Human Research (2007 - updated 2018). This statement has been developed to protect the interests of people who agree to participate in human research studies.

COVID-19 Safety

Please note, COVID safety measures will be implemented during the data collection process. This will include hand washing procedures, implementing physical distancing where possible, disinfecting all equipment between each experiment, the use of personal protective equipment and screening all participants.

Further information and who to contact

The person you may need to contact will depend on the nature of your query. If you want any further information concerning this project or if you have any problems which may be related to your involvement in the project, you can contact the researcher on [Phone number] or any of the following people:

Research contact person

Name	Ashraf Gerges or contact UniSA Clinical Trial Facility
Position	PhD Candidate
Telephone	08 8302 1365
Email	Ashraf.Gerges@mymail.unisa.edu.au or unisa.researchvolunteers@unisa.edu.au

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, please contact:

Reviewing HREC approving this research and HREC Executive Officer details

Reviewing HREC name	University of South Australia Human Research Ethics Committee
Telephone	+618 8302 6330
Email	humanethics@unisa.edu.au