

**Participant Information Sheet**

|  |  |
| --- | --- |
| **Title** | *The effect of a single bout of moderate intensity aerobic exercise on synaptic plasticity in patients presenting with chronic ischaemic stroke: a pilot randomised-controlled trial.* |
| **Short Title** | *The effect of exercise on brain function in people with stroke* |
| **Project Number** | *203568* |
| **Chief Investigator** | *Brenton Hordacre* |
| **Associate Investigator(s)** | *Jeric Uy, Ines Serrada, Finn Johnson, Gabrielle Hill* |

# 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 treatment that may increase brain function after stroke. The treatment that will be used in this study is aerobic exercise on a stationary (recumbent) bike.

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 don’t 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. You will also need to discuss participation with your doctor to ensure it is safe for you to participate in a brief period of moderate intensity exercise.

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 within the 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 find out if a single session of exercise on a stationary bike can increase brain function in people who have had a stroke. Increasing brain function is important as it may improve movement and recovery after stroke. This study is therefore important as aerobic exercise could be added to future rehabilitation programs to improve how well people recover.

Currently, we lack ways to increase a person’s recovery post stroke, especially when they are longer than 6 months post-stroke. This project aims to fill this gap and determine whether aerobic exercise can help facilitate stroke recovery.

The results of this study can be used as a basis for further larger studies, whose results could be used to create change to current stroke rehabilitation programs.

Previous evidence has shown that aerobic exercise is beneficial to brain tissue, however further information is required about what type of exercise and for how long. Majority of previous research has focused on changes happening in the brain on the same side as the stroke. This study also will clarify whether changes happen in the side of the brain that is opposite to the stroke.

# 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 controlled research project which helps researchers accurately understand whether a treatment is in fact a better option to help people. We put people into groups and give each group a different treatment. The results are compared to see if one is better. To try to make sure the groups are the same, each participant is put into a group by chance (random). You have a 50% chance of being in the intervention (aerobic exercise) group.

To be able to participate in this study, you will need to be over 18 years of age, have a history of stroke and be medically stable. You will not be able to participate in this study if:

* You have a history of another neurological disease e.g. Parkinson’s Disease
* If you have had recent skull surgery or any other neurological intervention
* If you are unable to provide consent
* Are on medications that increase your likelihood of seizures
* If you have contraindications to brain stimulation such as metallic implants in your skull, history of seizures or a pacemaker.

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 was done using a computer. You will be assigned to either the intervention (exercise bike) or control (sedentary) group.

During the two-hour time period, all participants will undergo a pre- and post-measure of the pathways in the brain. The way we do this is using brain stimulation. Brain stimulation is a non-invasive procedure. Brain stimulation uses magnetic fields to stimulate brain cells. Brain stimulation involves holding a coil (a circular ‘wand looking’ device) over the scalp for a short period of time (less than a few minutes). To measure the effect of this stimulation, electrodes will be place on the muscles in one of your hands. Both groups will have this assessment at the beginning and also after the intervention (0 minutes). Further assessment will also occur at 5 minutes, 10 minutes and 15 minutes post intervention. If you are in the intervention group, you will be asked to cycle on the stationary bike for 20 minutes at a moderate intensity. The exact speed will depend on your age and will be calculated for each participant. If you are in the sedentary (or ‘control’) group, you will be asked to sit and watch an animal documentary for the 20 minutes.

You will be asked to fill out an information sheet that will provide us of details of your age,

gender, stroke side, date of stroke, dominant hand side and current level of physical

activity. Knowing all this information is important as it helps us know who we can apply the results to at the conclusion of this study. When your brain pathways are being assessed at the 0-minute, 5-minute, 10-minute and 15-minute time slot, you will be seated comfortably and not have to actively do anything. The electrodes that are on your hand will give a value for the

amount of electrical signal that is coming from the brain. The project investigator will record

these values and use this to determine if the intervention has had an effect.

# This study involves a once off appointment, there is no follow up involved. The appointment will be approximately two hours long. There is no cost for participating in this research.

# What are the possible benefits of taking part?

We cannot guarantee that you will receive any benefits from this research. Changes to your strength and limb function are unlikely after the one session. However, the results will be used to determine if aerobic exercise should be added to stroke rehabilitation programs to improve performance in other activities, for example, arm or finger tasks.

# What are the possible risks and disadvantages of taking part?

Aerobic exercise can often cause side effects. You may have none, some or all of the effects listed below, and they may be mild, moderate or severe. If you have any of these side effects, or are worried about them, talk with your study investigators. The study investigators will also be looking out for side effects.

There may be side effects that the researchers do not expect or do not know about and that may be serious. Tell your study investigator immediately about any new or unusual symptoms that you get.

Many side effects will go away shortly after intervention ends. However, sometimes side effects can be serious, long lasting or permanent. If a severe side effect or reaction occurs, the study investigators need to stop your treatment. Your study investigators will discuss the best way of managing any side effects with you.

Potential side effects during the intervention may be:

* Sweating
* Muscle fatigue/soreness
* Upset stomach

The above side effects should only occur during exercise or the days following and only be mild or moderate. If they continue longer than this, you are advised to talk to your GP.

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.

Adverse psychological outcomes are not commonly associated with this intervention. If you become distressed or upset during participation, participation can be stopped, and contact will be made with your GP.

# 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 following the completion of the testing session, the researchers will be unable to remove your results as data will be rendered non-identifiable and it will not be possible to distinguish and remove your individual responses

# What will happen to information about me?

Your results from the study will be non-identifiable 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 seven 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.

Please note that non-identifiable data collected in this project may be used as comparative data in future projects, for which ethics approval will be sought

# 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 2021). 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 Dr Brenton Hordacre from the University of South Australia. There is no funding directly supporting this work.

# 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.

# 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 | Brenton Hordacre |
| Position | Senior Researcher |
| Telephone | 83021286 |
| Email | Brenton.hordacre@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 name | University of South Australia Human Research Ethics Committee |
| HREC Executive Officer | Ms Vicki Allen |
| Telephone | +618 8302 6330 |
| Email | humanethics@unisa.edu.au |

**Reviewing HREC approving this research** **and HREC Executive Officer details**

# 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.