University of South Australia

INFORMATION FOR PARTICIPANTS

Using Brain Stimulation to Treat Post-Stroke Depression

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Thank you for considering participating in this research study. This information sheet is intended to provide you with enough information to make an informed decision about your participation. If there is any aspect that is not clear to you, please discuss this with one of the investigators listed on the bottom of the sheet.

Background of the study

Depression is a common and serious complication after stroke that can have significant negative consequences for quality of life. A new treatment which has shown promising signs for treating depression within the wider population is brain stimulation, but its efficacy in post-stroke depression is not yet proven. Brain stimulation involves weak and painless electrical currents passing through the scalp. It's thought that these electrical currents can be targeted to brain networks which have reduced activity. This may be an appropriate treatment for people who are experiencing post stroke depression.

The purpose of this study is to investigate how different brain characteristics after stroke might enable a greater response to this depression treatment. Determining who might respond best to this treatment is likely to improve our ability to use this form of treatment clinically to reliably help people suffering depression following stroke.

What will the study involve?

If you meet the inclusion criteria and agree to participate, we will conduct an eligibility screen using a common questionnaire for depression. Participants who score higher than the cut-off for inclusion will be invited to partake in the study.

If you do score higher than the cut-off score for depression, it may be that this is the first time that you have been made aware of the possibility of having depression or depressive symptoms. While this assessment does not provide a clinical diagnosis, we would like to pass on your screening results to your General Practitioner (GP) for further explanation and follow-up (see consent form). There are additional services to support you through Lifeline (13 11 14; https://www.lifeline.org.au).

For participants who do score above the cut-off on the depression screening, we will invite you to attend eleven sessions at the University of South Australia or Dr Jones and Partners (South Australian Health and Medical Research Institute, SAHMRI). The first session will involve a magnetic resonance imaging (MRI) scan of your brain at Dr Jones and Partners. This scan will have a duration of 30-40 minutes and does not incur any cost to you. The remaining ten sessions will involve brain stimulation as a treatment as well as some measure to test the effectiveness of this treatment. These ten sessions will need to occur on consecutive days (Monday to Friday) at a similar time of day each day.

The treatment technique will involve brain stimulation which is painless and safe. All participants in this study will receive brain stimulation treatment and there is no sham or control condition. Assessments to measure the effects of brain stimulation will involve questionnaires to assess your activities and symptoms of depression.

We estimate that each session will take approximately 1 hour (total of 10 hours for the whole experiment).

Explanation of measurement tools and data collected:

Personal Information

If you agree to participate in this study we will ask you some brief demographic questions (age, gender and time since stroke). Any information that is obtained from this study will remain confidential (unless required by law).

Questionnaires and behavioural assessments

There will be a series of questionnaires or assessments at before and after the treatment to assess depressive symptoms. These assessments will be important to measure the change facilitated by the brain stimulation and will involve answering simple questions or performing simple tasks.

Transcranial Magnetic Brain Stimulation

Transcranial magnetic stimulation (TMS) is a technique that employs a magnetic field to activate the brain. A coil is held over the scalp by the experimenter and a brief current pulse flows through the coil. This in turn generates a magnetic field that activates the brain beneath the coil. When positioned over the part of the brain which controls the hand muscles, the opposite hand will twitch. These responses are recorded with electrodes taped to the skin overlying the muscles. The technique of TMS is painless and non-invasive. It has been in use for more than 15 years and is used routinely to investigate the motor system. An example of TMS is shown in the Figure.

Brain Stimulation

A brain stimulation treatment known as repetitive transcranial magnetic stimulation (rTMS) will be used in this study. This technique uses low-intensity currents to stimulate the brain and facilitate a change in brain activity which can result in behavioural or functional changes depending on which area of the brain is targeted. International guidelines have been established for the safe use rTMS and the parameters used in this study are well below all recommended limits.

Medical Imaging

An MRI scanner is a machine that uses strong magnets and radio waves to create pictures of the body. You will be asked to complete a screening form to make sure that it is safe for you to undergo MRI. If you meet the screening requirements, the imaging procedure involves lying with your head inside the MRI scanner. It is very important that you keep very still during the procedure. The scanner makes loud noises so you will wear earphones and/or headphones to protect your ears.

During the scan you will be able to communicate with staff through a microphone system in the scanner, and you will also have a "squeeze ball" to alert staff. There should be no significant discomfort during this procedure, although some people may experience symptoms of claustrophobia from lying in a confined space. If you notice any discomfort you should notify the staff.

There are no proven long-term risks related with MRI scans. MRI is considered a safe procedure when performed at a centre with appropriate guidelines. However, the magnetic attraction for some metal objects can pose a safety risk, so it is important that metal objects are not taken into the scanner room. Staff at The Clinical and Research Imaging Centre will thoroughly examine you to make sure there is no reason for you not to have the scan. You must tell us if you have metal implanted in your body, such as a pacemaker, or metal pins after being involved in an accident.

The scans we are taking are for research purposes. They are not intended to be used like scans taken for a full clinical examination, and will not be used to help diagnose, treat, or manage a particular condition. A radiologist will review the images and we will provide a letter stating clinically significant outcomes if appropriate, for yourself or your doctor if preferred.

Data storage and privacy issues:
All records containing personal information will remain confidential and no information which could lead to identification of any individual will be released, unless required by law. Data will be stored in a form that is re-identifiable, but we will keep the coding for re-identification password secured and separately from the data file. All hard copy data files will be stored in a locked filing cabinet in the Centenary Building (C7-37) UniSA City-East campus. All electronic data will be stored in a password protected folder and backed up on the University drive. Only the listed investigators will have access to the data, and all data will be kept for 5 years.

Although we plan to publish the results of this study, results will only be published at a group level and non-identifiable.

If you are willing, we would like to keep your contact details on file so we may send you study updates and/or invitations to participate in follow up studies. This consent can be given on the participant consent form and can be withdrawn at any stage. Your decision to agree to this or not does not have any bearing on your ability to participate in this study.

You should be aware that data obtained from this study may be used in future investigations for research with is closely related to the current project or an extension of the current work. In this instance, data will only be used for future projects which have obtained ethical approval.

You are free to withdraw from this study at any stage if you wish to and do not have to explain your reasons for doing so. Any data collected prior to withdrawing from the study will be retained by the investigators.

If you would like to receive a summary of the research finding, please contact the Chief Investigator (Dr Brenton Hordacre; contact details at end of this document).

What are the risks/benefits to you?
While all research personnel will maintain strict confidentiality, the nature of this project is that all participants are experiencing some level of depression or depressive symptoms following stroke. You may

consider this to be sensitive personal information and should be aware that participating in this project could lead to people becoming indirectly aware of this personal information.

It is not expected that there will be any side-effects as a result of receiving brain stimulation in this study. Some people have, however, reported mild headaches in other studies that have used this technique. In the many of thousands of studies using brain stimulation there have been two reported seizures. These were in non-screened participants who would normally have been excluded from study. Participants are asked to advise researchers if they experience headaches or any other side effects.
A full list of possible side effects and their likelihood is given below:
1. Seizure induction - (very rare)
2. Fainting (possible secondary effect – not related to direct brain effect)
3. Temporary headache or neck pain (possible, ~3%)

This study follows international guidelines for safe use of brain stimulation. If you are not safe to participate the research team will not include you in the study.

If you become emotionally distressed we recommend you immediately withdraw and debrief with peers or seek professional counselling. You don't need to face your problems alone. Lifeline is one of the services available to you, https://www.lifeline.org.au, and phone: 13 11 14. Guide Dogs SA is another service which is more than happy to help, https://www.guidedogs.org.au/, and phone: 1800 757 738.

Ethical approval
This project has been approved by the University of South Australia's Human Research Ethics Committee. If you have any ethical concerns about the project or questions about your rights as a participant please contact the Executive Officer or this Committee, tel: +61 8 8302 3118; email: vicki.allen@unisa.edu.au.
If you have any concerns either before or following the experiment, or would like any further information, please feel free to contact one of the following researchers:

Complaint process
Participants or third parties who wish to lodge a complaint about either the study or the way it is being conducted should contact the Executive Officer of UniSA HREC in the first instance, email: humanethics@unisa.edu.au or tel: 8302 3118.

Contact Details

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