PARTICIPANT INFORMATION SHEET

PROJECT TITLE: The physiological and behavioural effects of one session of low-frequency repetitive transcranial magnetic stimulation in post-stroke aphasia.
HUMAN RESEARCH ETHICS COMMITTEE APPROVAL NUMBER: H-2022-035
PRINCIPAL INVESTIGATOR: Dr Nigel Rogasch
STUDENT RESEARCHER: Ellen Williams/Isabelle Villalta
STUDENT'S DEGREE: PhD/Bachelor of Health and Medical Science (Honours)

Dear participant,

You are invited to participate in the research project described below.

1. Who is doing the research?
This project is being conducted by Dr Nigel Rogasch, in conjunction with Ellen Williams and Isabelle Villalta. This research will partly form the basis for Ellen Williams' PhD at the University of Adelaide under the supervision of Dr Nigel Rogach, A/Prof Stacie Attrill, and Dr Brenton Hordacre. Additionally, this research will form the basis for Isabelle Villalta's Bachelor of Health and Medical Science (Honours) degree at the University of Adelaide under the supervision of Dr Nigel Rogasch. Funding for this project is provided by the Australian Research Council Future Fellowships Grant and Adelaide Medical School.

2. What is the research?
Repetitive transcranial magnetic stimulation (rTMS) is a method to increase activity of the brain after stroke. This technique is safe and non-invasive and has shown early promising results as a treatment for aphasia. However, to better understand how this treatment works, we need to conduct further experiments.

Our study aims to answer the following key questions:

A. How does the brain activity of individuals with aphasia differ from healthy brain activity during language tasks?
B. How does one session of rTMS alter brain activity during language tasks in people with aphasia?
C. How does one session of rTMS alter brain activity at rest in people with aphasia?
D. How does one session of rTMS alter naming accuracy and response times in people with aphasia?

3. Why am I being asked to participate?
You are being invited to participate in this project as you:

- Are aged 18-75 years old
- Were right-handed prior to stroke
- Speak English as a first language
- Have non-fluent aphasia due to stroke
- Have been living with aphasia for 6 or more months
- Have only had one known stroke event
- Can understand basic spoken information

- Have trouble finding words for things
- Do not have significant vision impairment
- Do not have a diagnosis of psychiatric or progressive neurological disease
- Do not take medication affecting the central nervous system
- Do not have metallic or electronic implants

Participation in this study is voluntary. If you would like to be part of this study, please read the below information carefully. You are welcome to have a support person with you at each session during the study.

4. What will I be asked to do?

Screening session:

First, an in-person screening session will be held at a location convenient for you. The screening session will involve a brief cognitive assessment, reading and signing a consent form, a brief language assessment, a brief medical history questionnaire, an rTMS and magnetic resonance imaging (MRI) safety screen, and a handedness survey.

Session 1:

If you are eligible for inclusion, you will be invited to attend the South Australian Health & Medical Research Institute (SAHMRI) on a day that suits you for a full language assessment. Immediately after, you will then take the elevator downstairs to Dr Jones & Partners on the ground floor of SAHMRI for a 30-minute MRI scan.

Sessions 2 & 3:

On two later dates, you will then attend two stimulation sessions separated by at least seven days on Level 4 of the Adelaide Health and Medical Sciences Building (AHMS). During these sessions, we will record your brain activity during two picture naming tasks and two picture-word matching tasks using electroencephalography (EEG). We will also perform rTMS. Audio recording will be taken of your voice during the picture naming tasks.

5. How much time will it take?

Screening session: 1 hour
Session 1: 1.5-2 hours
Session 2: 2-3 hours
Session 3: 2-3 hours
For sessions 1, 2, & 3, you will be reimbursed at a rate of $20 per hour in the form of a Woolworths Wish Gift Card.

6. Is there transport/parking available?

You will need to arrange your own transport to and from each session. Free parking is available for 2 hours for disability parking permit holders at the Royal Adelaide Hospital (next to SAHMRI) in the level 2 'pay and display' zone near the Emergency Department. Free parking is also available for 2 hours on Gray Street (South side of North Terrace across from SAHMRI) for disability parking permit holders. Paid parking can be found on side streets close to the west end of Hindley Street. If you do not drive, you are welcome to bring a family member/support person along to the sessions who can assist with transport. Bus, train, and tram services are also available.

7. Are there any risks?

While the techniques in this study are used in thousands of clinical and research settings around the world, all studies involve a small but finite risk.

MRI

MRI is a safe and painless technique that uses magnetic fields and radio waves to obtain detailed images of the brain. There are no known health risks associated with MRI, provided that you do not have any metallic or electronic implants. You will be screened for any reasons not to receive MRI in the initial screening session and again by Dr Jones & Partners – SAHMRI prior to receiving MRI. People who do not like small spaces may find MRI uncomfortable. You can stop the scan at any time if you begin to feel uncomfortable. With your consent, we can share a copy of these scans with your medical professional. You will be provided a letter for your medical professional stating that scans have been taken.

EEG

EEG is a safe and painless technique for recording brain activity. There is no known risk or discomfort associated with EEG, with the exception of the rare possibility of minor localised skin irritation in sensitive individuals due to the use of conductive gel.

rTMS

Thousands of studies around the world have used rTMS. rTMS is safe and non-invasive. You will be screened for any reasons not to receive rTMS, such as electronic or metallic implants in the face/head. Some people (approximately 1 in 5) have reported minor tension headaches in other studies that have used rTMS due to the contraction of scalp and face muscles during stimulation. Headache may persist for 30 minutes following stimulation, however this is rare. In a small number of people (approximately 1 in 50), the sensation of the rTMS pulse can cause temporary feelings of light-headedness and nausea. In very rare cases (1 in 60,000), seizures have been reported in studies using rTMS. To minimise risk of seizures, we will follow international safety guidelines for the use of rTMS and your medical history will be screened for any history of seizures. If you have a medical emergency, we will follow established emergency protocols.

COVID-19

As the COVID-19 situation is rapidly evolving in South Australia, safety procedures will be followed throughout the study in line with current SA Health recommendations and regulations. This includes asking screening questions on arrival, social distancing where possible (1.5m distance, $2m^2$ space per person), and hand washing throughout each session. The researcher will wear personal protective equipment (PPE) at all times. Participants will be required to wear a face mask where possible, including entering and exiting the building. A thorough cleaning protocol of all surfaces and equipment will be conducted at the beginning and end of each session. Any participants demonstrating cold or flu symptoms, or who have been told to isolate, should contact the researcher prior to the session to reschedule the appointment.

8. What are the benefits?

Findings from this study may have important scientific and clinical implications in the research and treatment of post-stroke aphasia. We may learn more about the brain activity that leads to symptoms of aphasia. We may also understand more about the effects of rTMS in people with aphasia so that we can improve our current aphasia treatment approaches. However, participants are not expected to benefit as a direct result of involvement in this study.

9. What if I change my mind?

If you agree to participate, you can withdraw from the study at any time. This will not affect your normal therapy treatment.

10. What will happen to my information?

Special care will be taken to preserve confidentiality during data collection and analysis. Data will be stored digitally by assigning a unique numeric code with all identifying information removed. Digital data will be stored on the University of Adelaide server for a minimum of five years from date of publication, in a protected drive only accessible to researchers. Non-digital data will be stored in a locked and secured filing cabinet. Ultimately these documents will be scanned and uploaded digitally to the University of Adelaide server, and then destroyed. With your consent, your de-identified data may be shared with other researchers. With your consent, your de-identified data (MRI, functional MRI (fMRI), EEG, rTMS) may also be available on public and/or shared databases, such as the ENIGMA-Stroke Recovery database. If you would like, you will be provided with verbal feedback from the study at the completion of research. Upon request, you may also receive a written summary of the main findings of the study via email prior to publication. Summary data from testing sessions (MRI, fMRI, EEG, rTMS, naming task performance) will be shared in the form of journal articles, PhD/Honours theses and posters, and presentations at national and international conferences. Your information will only be used as described in this Participant Information Sheet and it will only be disclosed according to the consent provided, except as required by law.

11. What if I have a complaint or concern?

The study has been approved by the Human Research Ethics Committee at the University of Adelaide (approval number H-2022-035). This research project will be conducted according to the NHMRC National Statement on Ethical Conduct in Human Research 2007 (Updated 2018). If you have questions or problems associated with the practical aspects of your participation in the project, or wish to raise a concern or complaint about the project, then you should consult the Principal Investigator, Dr Nigel Rogasch:
Phone: (08) 8313 1313
Email: nigel.rogasch@adelaide.edu.au

If you wish to speak with an independent person regarding concerns or a complaint, the University's policy on research involving human participants, or your rights as a participant, please contact the Human Research Ethics Committee's Secretariat on:
Phone: +61 8 8313 6028
Email: hrec@adelaide.edu.au
Post: Level 4, Rundle Mall Plaza, 50 Rundle Mall, ADELAIDE SA 5000
Any complaint or concern will be treated in confidence and fully investigated. You will be informed of the outcome.

12. If I want to participate, what do I do?

If you are interested in participating in this study, or if you have any questions about this study, please contact the researcher listed below. The researcher will then arrange a time to conduct the initial screening session**.**

Ellen Williams
Email: ellen.williams@student.adelaide.edu.au

Yours sincerely,

Ellen Williams
Isabelle Villalta
A/Prof Stacie Attrill
Dr Nigel Rogasch
Dr Brenton Hordacre