

Participant information sheet for

people with aphasia

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



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1. Who is doing the research?

Dr Nigel Rogasch

Nigel is a **researcher** at the University of Adelaide

Ellen Williams

Ellen is a **speech pathologist**

Ellen is a **PhD student** at the University of Adelaide

Isabelle Villalta

Isabelle is an Honours student at the University of Adelaide

Associate Professor **Stacie** Attrill

Stacie is a speech pathologist

Stacie is a **researcher** at the University of Adelaide

Dr Brenton Hordacre

Brenton is a **physiotherapist**

Brenton is a **researcher** at the University of South Australia







2. What is the research?

We are doing some **research**.

Research helps us **learn**.

We need to **know** more about **how to help** people **after stroke**.



Repetitive transcranial magnetic stimulation is a type of **brain stimulation**.

It activates brain cells.





repetitive transcranial magnetic stimulation may **help people with aphasia** improve **language skills**.



We want to know what happens inside the brain of a person with

aphasia when naming pictures.





We also want to know what happens in the brain of a person with aphasia after repetitive transcranial magnetic stimulation.





Finally, we want to know if one [1] session of repetitive transcranial

magnetic stimulation **helps** people with aphasia to **name more pictures**.



- 3. Why am I being asked to participate?
 - You are over eighteen [18] years and less than seventy five [75]
 years
 - You were **right-handed** before your stroke
 - You **speak English** as a first language
 - You have aphasia due to stroke
 - You have had aphasia for more than six [6] months
 - You have only had one [1] stroke
 - You can understand basic spoken information
 - You have trouble finding words for things
 - Your **vision** is **OK**
 - You do not have a psychiatric or progressive neurological condition
 - You do not take medications that affect your brain
 - You do not have metallic or electronic implants

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You do **not** have to participate.

Being part of this study is **voluntary**.

If you want to be part of this study, **read the below information** carefully.

You can **ask us** any **questions**.

It is OK if you do not want to participate.

You can have a **support person** with you for **every session** of the study.



4. What will I be asked to do?

Screening session:

First, you will meet a researcher at your home or clinic.

We will do a quick **cognitive test**. This will take about **twenty [20] minutes**.

Next, you will need to give your **consent** to participate in the study.

This means you understand what the study is for and what you need to do.

If you want to participate, you can **sign a consent form**.



Then we will do a **language** test. This will take about **thirty** [30] minutes.

Finally, we will ask you for **information about yourself**, your **stroke**, and **other medical conditions**.



Session 1:

On another day, you will come to the **South Australian Health and Medical Research Institute (SAHMRI)** on North Terrace.

We will do a **full assessment of your language** abilities. This will take about **sixty [60] minutes**.



Then we will take the **elevator** down to **Dr Jones and Partners**.

Here you will have a **magnetic resonance imaging (MRI) scan** of your brain.



During the scan, you will **lie down** on your back **inside** the scanning machine. This will take about **thirty [30] minutes**.

Sessions 2 and 3:

On two [2] separate days, you will come to Level Four [4] of the Adelaide

Health and Medical Sciences Building on North Terrace.

We will record your brain activity while you sit, while you match pictures and words, and while you name some pictures.



You will receive **repetitive transcranial magnetic stimulation** for

ten [10] minutes.



Sound recording will be taken of your **voice** during picture naming tasks.



<u>Timeline</u>:



End

5. How much time will it take?

Screening session: One [1] hour

Session 1: One and a half [1.5] to two [2] hours

Session 2: Two to three [2-3] hours

Session 3: Two to three [2-3] hours

For sessions 1, 2, and 3 you will receive **twenty dollars [\$20] per hour** in the form of a **Woolworths Wish Gift Card**.



6. Is there parking or transport?

You will need to organise transport to and from each session.

There is **free parking** for **two [2] hours** the **Royal Adelaide Hospital** in the Level Two [2] 'pay and display' zone near the Emergency Department for people with a **disability parking permit**.

There is also **free parking** for **two [2] hours** on **Gray Street** for people with a **disability parking permit**.





Paid parking can be found on side streets close to the west end of Hindley Street.

A family member or support person can join you at each session to help with transport.

There are also **bus, train, and tram** services.







7. Are there any risks?

With any study there are:

- (1) Risks we know about
- (2) Risks we don't know about
- (3) Risks we don't expect

Magnetic Resonance Imaging (also called MRI):

Magnetic resonance imaging is a safe and painless technique that

uses magnetic fields and radio waves to take pictures of your brain.



People who have **metallic** or **electronic implants** should **not** have

magnetic resonance imaging.



We will **check** you have no metallic or electronic implants in the screening

session. Dr Jones & Partners will also check **before** your scan.

People who do not like **small spaces** may find magnetic resonance imaging



If you find magnetic resonance imaging uncomfortable, **you can stop** at any time.



With your **consent**, we can give your doctor a copy of these **scans**.

You will be given a **letter** for your **doctor**. This letter will say that we have taken **scans** of your brain.





Electroencephalography (also called EEG):

Electroencephalography is a safe and painless technique that looks at

brain activity.

It records electrical signals from your brain through **sensors on top** of your

head.



During electroencephalography, you will **sit** in a **chair** with the sensors on your head.

We will put **gel between** the **sensors** and your **head**.

People with **sensitive skin** may get small **skin irritation** from the gel. This is **rare**.

<u>Repetitive transcranial magnetic stimulation (also called rTMS)</u>:

Thousands of studies around the world have used repetitive transcranial magnetic stimulation.

It is **safe** and **non-invasive**.

One [1] in five [5] people have **small headaches** after repetitive transcranial magnetic stimulation.



One [1] in fifty [50] people feel light-headed or nauseous after

repetitive transcranial magnetic stimulation.

In **very rare** cases, **seizures** have been reported after repetitive transcranial magnetic stimulation. This has been reported in **one [1] person per sixty thousand [60,000]**.

We will follow international safety guidelines.



We will check your medical history for any reasons not to receive

repetitive transcranial magnetic stimulation, such as history of seizures.

We will follow **emergency protocols** if there is an emergency.

<u>COVID-19</u>

We will follow safety procedures to keep you safe from COVID-19.

We will ask **screening questions** before every session.

The researcher will always wear personal protective equipment.



You will wear a face mask where possible, including entering and exiting

the building.



You and the researcher will **socially distance** where possible.



You and the researcher will **hand wash** often.



All tables and equipment will be cleaned before and after use.



If you **feel sick** or have been told to **isolate**, you should **call** the researcher

before the session. We will **reschedule** the appointment.





8. What are the benefits?

Benefits to other people:

This study will help us to **learn more about aphasia**.



It may help to **improve treatment** for **other people** with aphasia.



Benefits to you:

Being part of this study is **not expected** to **benefit you** directly.

9. What if I change my mind?

You can stop the study at any time.



You will still get your normal therapy treatment.

10.What will happen to my information?

We will keep the **information** about you **safe**.

Only the researchers will see the information about you.



Your **digital** information will be **deidentified** and kept on the **University**

of Adelaide servers.



It will be kept for at least **five [5] years**.

Your **paper** information will be kept in a **locked filing cabinet**.



Paper information will be **scanned** to the computer and **then destroyed**.

If you **consent**, we may **share** data that doesn't identify you with **other researchers**.

If you **consent**, we may **put data** that doesn't identify you on **public** and/or **shared databases**.



We can give you **verbal information** about the **results** of the study **at**

the end of the research.

If you request, we can also give you written information about the results

of the study **before publishing**.

Summary data will be shared in:

- Journal articles
- PhD/Honours theses and posters
- **Presentations** at national and international conferences

We will **only share** your information **according to the consent** form, **except** if required by **law**.

10.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 study will follow the NHMRC National Statement on Ethical Conduct in Human Research 2007 (Updated 2018).

If you have a **complaint** or **concern**, contact the **Prinicipal**

Investigator, Dr Nigel Rogasch:

Phone: (08) 8313 1313 Email: nigel.rogasch@adelaide.edu.au

If you want to speak to an **independent person** about a **complaint** or

concern, 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

If you want to participate or if you have any questions, please contact Ellen:

Ellen Williams

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



Ellen will then **organise** the **screening session**.

Yours sincerely,

Ellen Williams

Isabelle Villalta

A/Prof Stacie Attrill

Dr Nigel Rogasch

Dr Brenton Hordacre