Personalising the dose of cued picture naming treatment for the rehabilitation of post-stroke aphasia

The research is being carried out by the following researchers:

Role	Name	Organisation
Investigators	Professor Miranda Rose	La Trobe University
	Associate Professor Michael Walsh Dickey	University of Pittsburgh, USA
	Dr Marcella Carragher	La Trobe University
	Sam Harvey	La Trobe University

1. **What is the study about?**
   You are invited to participate in the study of aphasia treatment.
   The treatment is designed to improve a person's ability to say the name of different pictures.
   We want to learn about how the amount of treatment a person receives affects recovery of picture naming skills.

2. **Do I have to participate?**
   Being part of this study is voluntary. If you want to be part of the study, please read the information below carefully. You can ask us any questions.

   You can read the information below and decide at the end if you do not want to participate. If you decide not to participate this will not affect:
   - your relationship with La Trobe University,
   - your relationship with any other listed organisation, or
   - your relationship with any professionals listed.

3. **Who is being asked to participate?**
   You have been asked to participate because:
   - You are **over eighteen** [18] years of age
   - You **have aphasia** due to **stroke**
   - You have been living with aphasia **for more than six [6] months**
   - You are able to **consent** to participating
   - You **have trouble finding words** for things
   - You **can understand basic spoken information**
   - You have **normal or corrected vision** and **hearing**
   - You **do not have** a **progressive neurological disease**
   - You are **not** currently **attending speech therapy** – if you are attending a community aphasia group or if you complete therapy independently (e.g., using a therapy app), you will be asked to keep a diary of these activities

4. **What will I be asked to do?**

   Provide **consent** to participate:

   If you want to participate, we will ask you to **sign a consent form**.
   This would be **before** you do any **study assessments**.

The form is **in English**. There will be **no translator** available.

After you **consent** to participate, the **study begins**.

The study will involve **assessments** and **treatment**.

In total, the study will take **about twenty-eight [28] hours** of your time **over about four [4] months**

Information about the assessments:

You will do assessments at four [4] different stages of the research project:
- Immediately **before treatment starts**
- Immediately **after treatment finishes**
- **One [1] month after** treatment finishes
- **Three [3] months after** treatment finishes

All **assessments** will take place **on a computer in your home**.

The assessment sessions will be **video recorded**.

The assessments will give us information about your:
- Aphasia
- Thinking skills like problem solving and attention

Information about the treatment:

The treatment will be done on **computer in your home**.
A **speech pathologist** will help run the treatment program over the **internet**.
The speech pathologist **will not be in your home**.

You will see **lots of pictures**. You will be asked to **say the name of the pictures** you see.

The **number of pictures** you see will be **different each week**.

Each session we will **count how many pictures you can say**. Each session **we will ask** you **how tired** and **how motivated** you feel. We will also ask **how difficult** the session was for you.

Study timetable:

First, we will ask you for **information about yourself**, your **stroke**, and **other medical conditions**. If you are eligible, we will invite you to **begin the study**.

You will **need to give consent** to participate. This means **you understand what the study is** for and **what you need to do** and you **agree to participate**.

If you are eligible and you consent, the study will begin.

Week	Task	What will happen	Why do I need to do this?
Week 1	Assessment 1	You will do some **assessments.** The assessment will be done over three [3] days and will take about three [3] hours in total. The assessments will be done on **computer in your home**. A **speech pathologist** will do the assessments with you over the **internet**.	We need to know what your communication and thinking skills are like before treatment so we can tell how effective the treatment is.
Week 2	Pre-treatment	In week 2, you will attend a fifteen [15] minute session each day, for five [5] days. You will: • Name some pictures • Answer questions about how tired and motivated you are, and how difficult you found the session	We need to know how your naming ability changes each day We also need to know how tired and motivated you are and how difficult you find the session. This information might help us understand how the treatment works.
Week 3 – 5	Treatment	Then, you will **start treatment**. Treatment involves naming lots of pictures. Each week, the number of pictures you name will change. Treatment will happen: • Five [5] days a week • For about one [1] hour each day • For three [3] weeks.	This treatment is designed to help you get better at naming pictures. We want to know if changing the number of pictures used in treatment makes the treatment more effective.
Week 6	Assessment 2	You will do **assessments again** immediately after you finish treatment. This will be about four [4] weeks after the first assessment. It will be similar to Assessment 1. This assessment will take about two [2] hours.	
Week 7 – 9	No assessment or treatment Researchers will contact you to remind you to complete your therapy diary		

Week	Task	What will happen	Why do I need to do this?
Week 10	Assessment 3	You will do **assessments again** one [1] month after you finish treatment. It will be the same as Assessment 2. This assessment will take about two [2] hours.	We will use this information to see how long the effects of treatment last.
Week 11 – 17	No assessment or treatment Researchers will contact you to remind you to complete your therapy diary		
Week 18	Assessment 4	You will do **assessments again** three [3] months after you finish treatment. It will be the same as Assessment 2 and Assessment 3. This assessment will take about two [2] hours.	We will use this information to see how long the effects of treatment last.

Other information about the study

The study will be run **online**. You will **need a computer** and **internet** connection. If you **do not have a computer or internet** connection, **we can arrange** these for you.
It will take about **twenty-eight [28] hours** of your time to be part of this research **over four [4] months**.
The sessions will be **video recorded**.
You **will not be paid** to participate in this study.

5. What are the benefits?

Likely **benefits to participants**:

We **cannot guarantee** or promise that you will receive **any benefits** from this research.
However, **possible benefits** may include:

- You may find it **easier** to **say** the name of different **pictures used in treatment**
- You may find it **easier** to **say** these **words in a conversation**

Likely **benefits to other people** in the future:

The **goal** of this research is to **improve the efficiency** of this treatment.
We want to know **how much** of this treatment a **person needs** to get the **best recovery** of picture **naming skills**.
We will use a **new method** to **adjust** the **amount of treatment** for each individual.
Speech pathologists might be able to **use this method** to determine the **right amount** of this treatment **for other people with aphasia**.

Researchers might be able to **use this method** to **personalize other aphasia treatments.**

6. **What are the risks?**

With any study there are:
(1) risks we know about,
(2) risks we don't know about and
(3) risks we don't expect.

This will help you decide if you want to be part of the study.

- Participating in assessments and treatment may be upsetting at times.
- You may feel tired after the assessment or treatment sessions. If you are very tired, you might find it hard to do everyday activities.

The researchers have plans in place in case you become upset or distressed during the assessments or the treatment.
We will **talk** to you **about how you are feeling** and **how to manage fatigue**.
If you experience something that you aren't sure about, please contact us immediately so we can discuss the best way to manage your concerns.

Name/Organisation	Position	Telephone	Email
Professor Miranda Rose, La Trobe University	Chief Investigator	(03) 9479 2088	m.rose@latrobe.edu.au

7. **What will happen to information about me?**

We will **collect information** about you in ways **that will reveal who you are**:
- personal information
- video recordings of assessment and treatment sessions

We will keep the information we collect for this study, and **we may use it in future research studies**. By providing your consent you are allowing us to use your information in future research. We don't know at this stage what these other studies will involve. We will seek ethical approval before using the information in these future studies.

We will **store** information about you in ways that **will not** reveal who you are however staff who watch the videos may recognise you.

We will **publish** information about you in ways that **will not** be identified in any type of publication from this study.

We will **keep** your information for 15 years after the project is completed. After 15 years we will destroy all of your data.

The storage, transfer and destruction of your data will follow La Trobe University Research Data Management Policy https://policies.latrobe.edu.au/document/view.php?id=106/.

The personal information you provide will be handled in accordance with applicable privacy laws. Your health information will be handled in accordance with the Health Records Act 2001 (Vic). Subject to any exceptions in relevant laws, you have the right to access and correct your personal information.
You can contact the research team to do this.

8. Will I hear about the results of the study?

We will let you know about the overall results of the study by providing you with a written summary and a video summary of the outcomes.

9. What if I change my mind?

At any time, you can choose to no longer be part of the study. You can let us know by:
- completing the 'Withdrawal of Consent Form' (provided at the end of this document);
- calling us; or
- emailing us

Your decision to withdraw at any point will **not** affect your relationship with La Trobe University or any other organisation listed.

If you withdraw, we would:
- stop asking you for information
- withdraw any identifiable information about you from the research study.

If results **have not** been analysed you can choose if we use those results or not.

However, once the results have been analysed we can only withdraw information, such as your name and contact details.

10. Who can I contact for questions or want more information?

If you would like to speak to us, please use the contact details below:

Name/Organisation	Position	Telephone	Email
Professor Miranda Rose	Chief Investigator	(03) 9479 2088	m.rose@latrobe.edu.au

11. What if I have a complaint?

If you have a complaint about any part of this study, please contact:

Ethics Reference Number	Position	Telephone	Email
HEC20414	Senior Research Ethics Officer	+61 3 9479 1443	humanethics@latrobe.edu.au

Consent Form – Declaration by Participant

I ……..(the participant) have read (or, where appropriate, have had read to me) this participant information statement. I understand the content. I have asked any questions I wanted to. I am satisfied with the answers. I agree to participate in the study. I know I can withdraw at any time. I agree my research information may be included in:

- presentations and/or
- published in journals,

on the condition that I cannot be identified.

☐ I agree to have my assessment sessions video recorded

☐ I agree to have my treatment sessions video recorded

I would like my information collected for this research study to be:

☐ Only used for this specific study;

OR

☐ Available for use in future research.

Participant Signature

☐ I have received a signed copy of the Participant Information Statement and Consent Form to keep

Participant's printed name	
Participant's signature	
Date	

Declaration by Researcher

☐ I have given a verbal explanation of the study, what it involves, and the risks and I believe the participant has understood;

☐ I am a person qualified to explain the study, the risks and answer questions

Researcher's printed name	
Researcher's signature	
Date	

* All parties must sign and date their own signature

Withdrawal of Consent

I wish to withdraw my consent to participate in this study. I understand withdrawal **will not** affect:

- my relationship with La Trobe University
- my relationship with any other listed organisation
- professionals listed in the Participant Information Statement.

I understand my information will be withdrawn as outlined below:

- ✓ Any identifiable information about me will be withdrawn from the study
- ✓ The researchers will withdraw my contact details. This will mean they cannot contact me about future research. They can only contact me if I have given separate consent for my details to be kept in a participant registry.

***if you have consented for your contact details to be included in a participant registry you will need to contact the registry staff directly to withdraw your details.*

I would like my already collected and unanalysed data:

☐ Destroyed and not used for any analysis

☐ Used for analysis

Participant Signature

Participant's printed name	
Participant's signature	
Date	

Please forward this form to:

CI Name	Professor Miranda Rose
Email	m.rose@latrobe.edu.au
Phone	(03) 9479 2088
Postal Address	Centre of Research Excellence in Aphasia Recovery & Rehabilitation Health Sciences 1, Room 212 La Trobe University Bundoora VIC, 3083