Participant Information for People With Aphasia

Constraint Induced or Multi-Modal aphasia rehabilitation: A Randomised Controlled Trial (RCT) for stroke related chronic aphasia

RESEARCHER: **Associate Professor Miranda Rose**
Discipline of Speech Pathology
College of Science health and Engineering
Telephone: +61 (03) 9479 2776
Email: compareaphasia@latrobe.edu.au

Introduction

Following a stroke, some people find they have difficulty saying words and sentences. This language problem is called **aphasia**. Speech pathology treatment can help individuals improve their language and make it easier to communicate. There are **different types of treatments** and at present, we don't know which treatment is best for each individual with aphasia. Therefore, treatment has to take a 'try-it-and-see' approach.

This study aims to **compare** different treatments for people with problems talking after a stroke. We want to see if one treatment is better than the other, and to compare these treatments to usual speech pathology treatment.

Who is doing the research?

The research is led by **Associate Professor Miranda Rose**. Miranda is a **speech pathologist** working in **research** at La Trobe University.

The study has been granted **permission** to proceed by the **La Trobe University Ethics Committee** (Application No. 15-043).

About the study

Group A

Constraint-Induced Aphasia Therapy (CIAT)

Constraint-Induced Aphasia Therapy (**CIAT**) focuses on **talking**. It is an **intensive** treatment with individuals receiving **30 hours** therapy spread across **2 weeks**. Treatment is delivered in a **group** of **2-3 people** with aphasia. You **can** continue to have your usual aphasia therapy during this time.

Group B

Multi-Modality Aphasia Treatment (M-MAT)

Multi-Modality Aphasia Treatment (**M-MAT**) focuses on various forms of communication including **talking**, **drawing**, **writing**, and using **gestures**. It is an **intensive** treatment with individuals receiving **30 hours** therapy spread across **2 weeks**. Treatment is delivered in a **group** of **2-3 people** with aphasia. You **can** continue to have your usual aphasia therapy during this time.

Group C

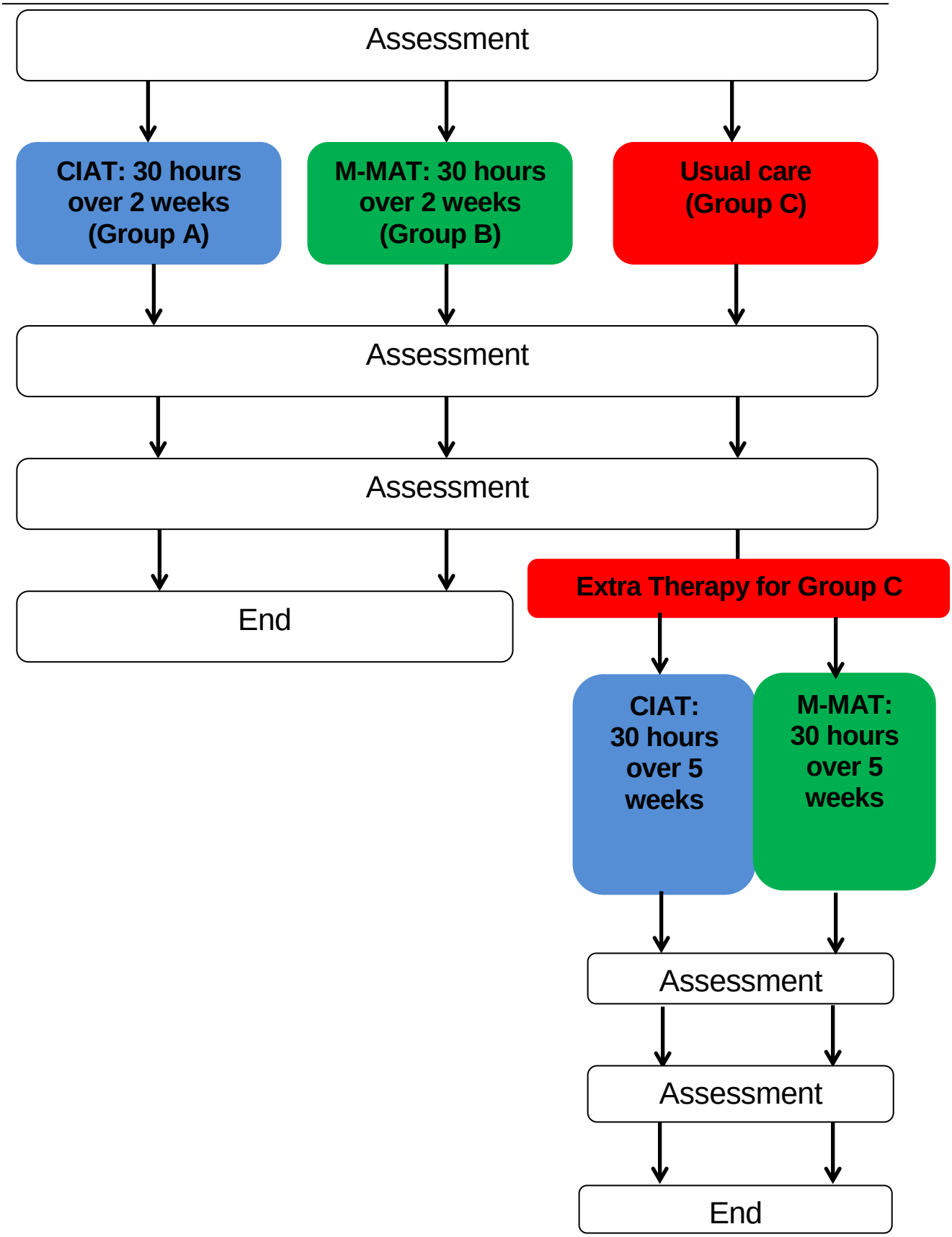
Usual Care

Usual Care is the treatment that the individual **normally** receives. This might be no therapy at all or social/support group sessions, for example, once a week.

Extra Therapy for Group C

Later in the study, we will **check** that you are **still able to participate** in treatment so that we can offer you **CIAT** or **M-MAT**: **30 hours** therapy spread across **5 weeks**.

About the study



What is involved

This study has 7 main phases:

1. **Assessment**

- You will complete assessments of **language**, **communication**, **memory**, and **thinking**.
- We will ask questions about how you feel about your communication.
- The assessment will take place in **private** at a **clinic** or at your **home**.
- You will be **asked to provide** copies of your **brain scans** from **after your stroke** if possible or **allow** one of the **researchers** to follow up a **copy** of these **scans for you**.
- There will be **2 - 3** assessment sessions, with each lasting for 1 – 2½ hours.

2. **Treatment**

- A treatment will be offered to you. The choice of group is done **randomly** by a **computer**. The research team has **no control** which treatment individuals receive.
    - **CIAT**: some people will work on their **talking** for 30 hours over two weeks
    - **M-MAT**: some people will work on their **talking**, **writing**, **drawing** and **gestures** for 30 hours over two weeks
    - **Usual care**: some people will continue their normal routine and **not** receive **extra treatment** at that time.

3. Assessment:

- You will be **re-assessed** on some of the tests you completed before therapy.
- This will happen in the **week after treatment**.
- The assessment will take place in **private** at a **clinic** or at your **home**.
- There will be **2 - 3** assessment sessions, lasting for 1 – 2½ hours.
- Between this and the final assessment (12 weeks later) we will ask you to complete a **diary**. We will **text or call you regularly to remind you**.

4. Follow-up Assessment:

- **Twelve weeks** after treatment, you will be **re-assessed** on some of the tests you completed before therapy.
- The assessment will take place in **private** at a **clinic** or at your **home**.
- There will be **2 - 3** assessment session, lasting for 1 – 2½ hours.

5. Extra Therapy for Group C

After the 12 week follow up assessment if you are in **Group C** we will **check** that you are **still able to participate** in therapy. If **yes**, you may receive **CIAT** or **M-MAT**.

- **CIAT**: some people will work on their **talking** for 30 hours over five weeks
- **M-MAT**: some people will work on their **talking**, **writing**, **drawing** and **gestures** for 30 hours over five weeks

6. Extra Therapy Assessment for Group C:

- You will be **re-assessed** on some of the tests you completed before therapy.
- This will happen in the **week after treatment**.
- The assessment will take place in **private** at a **clinic** or at your **home**.
- There will be **2 - 3** assessment session, lasting for 1 – 2½ hours.
- Between this and the final assessment (12 weeks) we will ask you to complete a **diary**. We will **text or call you regularly to remind you**.

7. Extra Therapy Follow-up Assessment for Group C:

- **Twelve weeks** after treatment, you will be **re-assessed** on some of the tests you completed before therapy.
- The assessment will take place in **private** at a **clinic** or at your **home**.
- There will be **2 - 3** assessment session, lasting for 1 – 2½ hours.

Information about you

During assessment and treatment sessions, we will use a **voice recorder** and **camcorder** to record what is happening. This is so that the researchers can look over the recordings to help them **collect information** about the treatments.

Information about you will also be collected in the **tests** you complete and the **questions** that you answer in assessment sessions. We will also **video record** you and your partner, family member or friend having a **conversation**. Your information will be stored with a **code** – your name will **not** be used.

This information will be kept in a **secure environment**: **paper** information will be kept in a **locked filing cabinet** in the office of Associate Professor Rose. **Electronic** information will be kept in a **password-protected server** maintained by La Trobe University. After **15 years**, the information may be **destroyed**.

We will only share information about you if we are obliged to under **law** or if you or someone else is at **risk of harm**.

Am I the right person to take part?

To take part, you have to:

- be **over 18** years of age
- have had your **stroke/brain injury** more than **6 months**
- have **Aphasia**
- have used **English well before** your stroke/brain injury
- be able to **manage going to the toilet**
- be able to **attend** all study **visits**
- have a **carer / close** other who can **attend study visits**

You must **not**:

- have a diagnosed **cognitive deficits** (problem with **thinking** or **memory**)
- have severe **apraxia** of speech
- **Cannot attend** all study **visits**

Other problems will need to be **managed**, such as:

- **current depression**, **anxiety** or **mental illness**
- **taking illegal drugs**
- **vision** or **hearing problems** they need to be **managed** for you to **participate**.

  For example: by wearing **glasses** or taking **medication**.

- **WHAT WILL HAPPEN TO THE RESULTS OF THE STUDY?**

The results of the study will be presented at **conferences** and published in **journals**.

Information that could identity you will not be used.

HOW MIGHT THE RESEARCH BENEFIT ME?

We **cannot guarantee** that you will benefit from taking part in the research. However, you might benefit from:

- **Meeting new people** and having **conversations**
- Practicing your **communication skills**
- Trying **new things**
- Building **confidence** in yourself
- **Taking part** in something that will **help other people with aphasia**

WHAT ARE THE COSTS OF TAKING PART?

- You will need to **travel** to the treatment sessions. This will take **time**. We will pay your **travel expenses**.
- You may feel **tired** after the assessment and treatment sessions.

WHAT ARE THE RISKS OF TAKING PART?

- You may feel **tired** after the assessment and treament sessions.
- You may feel **sad** or **depressed** after the assessment and treatment sessions

What happens next?

Your decision to participate or not participate in this study **will not affect your relationship with La Trobe University**. It will also **not affect your relationship with any of the researchers**, or your opportunity to receive other services from them.

If you agree to participate in this study, you will be asked to **sign a consent form**.

This means you:

- **understand** the information you have read or that has been explained to you
- have had the chance to **ask** us any **questions**
- **agree** to all of this **information**.

What if I want to change my mind?

You have the **right** to change your mind at any time. You can:

- **stop** the **questions** and **testing**
- **stop** going to the **treatment sessions**, and
- receive **free counselling** if you want it.
- If you **decide** to **withdraw** it **may not** be possible to **withdraw your data** from the study, however **all data** will be **coded** and **will not** identify you by name.
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How do I contact the researchers?

If you have any questions about this project, please contact:

Associate Professor Miranda Rose

Telephone: (03) 9479 2776

Email: compareaphasia@latrobe.edu.au

Who do I contact about a complaint?

If you have any complaints or concerns about your participation in the study that the researcher has not been able to answer to your satisfaction, you may contact the Senior Human Ethics Officer, Ethics and Integrity, Research Office, La Trobe University, Victoria, 3086 (P: 03 9479 1443, E: humanethics@latrobe.edu.au) . Please quote the application reference number 15-043.