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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

The study will compare different treatments for people with aphasia. Participants will randomly assigned to one of three treatment groups Constraint-Induced Aphasia Therapy (CIAT), Multi-Modal Aphasia Therapy (M-MAT) or Usual Care. Participants will attend baseline assessments, a two week treatment

period, assessment immediately after treatment and further follow up assessment 12 weeks after completing the treatment.

Participants randomised to the Usual Care group will be offered additional treatment at the end of the 12 week follow up period as part of an optional sub-study. In this sub-study participants will be re-randomised to receive either CIAT or M-MAT. They will attend treatment visits over five weeks with follow up assessments immediately after the treatment period and again at 12 weeks after completing the treatment.

What is involved?

As the partner, carer or close other of the person with aphasia, ideally you would:

- be a close friend or relative of the person with aphasia,
- maintain both a close personal relationship with the other person through frequent personal contact
- take personal interest in the other person's welfare, and
- have known the participant with aphasia for a period of at least one year.

Note: Meeting the above criteria is preferred but not essential. Where possible a carer/significant other will be nominated by the participant however it is not a limiting factor for inclusion into the study.

As the partner, carer or close other of the person with aphasia, you will be asked to participate in some of the assessments during the study.

These assessments will consist of:

- completing a questionnaire about the person with aphasia in terms of their communication and mood
- helping the person with aphasia recall and answer a health costs survey about health service use after stroke

- having a 10-minute conversation with your partner, family member or friend with aphasia. This will be video-recorded.

These assessments will occur at specific time during the study:

- on entering the study
- immediately after the treatment
- 12 weeks after treatment

For participants randomised to Usual Care and who agree to participate in the optional sub-study two additional assessments will occur:

- Immediately after the sub-study treatment
- 12 weeks after sub-study treatment

We ask that you commit to being available to attend the study assessment visits with your partner, family member or friend with aphasia as described above.

During the study we will ask you to help your family member with aphasia to complete a diary about any treatments received or services used. We will text or call you each week to remind you.

Information about you

During assessment 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. We will also video record you and your partner, family member or friend with aphasia 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 and 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.

What will happen to the results of the study?

The results of the study will be presented at conferences and published in journals. Only coded information will be used. Information that could identity you will not be used.

What happens next?

Your decision to participate or not participate in this study will not affect your relationship with La Trobe University or the relationship your partner, family member or friend with aphasia has with La Trobe University. It will also not affect your relationship or the relationship your partner, family member or friend with aphasia may have 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 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 assessment sessions

What are the risks of participating?

There are no risks associated with your participation in this study.

What benefits will I receive?

It is unlikely you will receive any direct benefits from this study. Your involvement will help the Researchers understand the best treatments for people with aphasia and may help future development of treatments for aphasia. You may indirectly benefit from any improved communication skill that your partner, family member of friend obtains during the study.

What are the costs of participating?

There is no cost for participating in this study. Similarly you will not be paid to participate in this study.

Taxi vouchers will be provided to participants to enable attendance at study visits if required.

How do I contact the researchers?

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

Associate Professor Miranda Rose or the COMPARE Clinical Trial Manager

Telephone: 03 9479 2776 or 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.