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Rapid Syllable Transition Treatment for Adults

PARTICIPANT INFORMATION STATEMENT

(1) What is this study about?

You are invited to take part in a research study about whether Rapid Syllable Transition Treatment (ReST) is effective with adults who have apraxia.

You have been invited to participate in this study because you have apraxia. This Participant Information Statement tells you about the research study. Knowing what is involved will help you decide if you want to take part in the research. Please read this sheet carefully and ask questions about anything that you don't understand or want to know more about.

Participation in this research study is voluntary.

By giving your consent to take part in this study you are telling us that you:

- ✓ Understand what you have read.
- ✓ Agree to take part in the research study as outlined below.
- ✓ Agree to the use of your personal information as described.

You can keep a copy of this Participant Information Statement.

(2) Who is running the study?

The study is being carried out by the following researchers:

- Professor Tricia McCabe PHD CPSP FSPAA who is a speech pathologist and researcher.
- Dr Petra Avramovic PHD CPSP who is a speech pathologist and researcher.
- Dr Elizabeth Bourne PHD CPSP who is a speech pathologist and researcher.
- Dr Sophie Brassel PhD CPSP who is a speech pathologist and researcher.
- Dr Emma McLoughlin PHD CPSP who is a speech pathologist and researcher.
- Dr Donna Thomas PHD CPSP who is a speech pathologist and researcher.

(3) What will the study involve for me?

You can have assessment and treatment in the University of Sydney speech pathology clinic at Camperdown in Sydney or online using the Zoom app or a mixture of both.

If you choose the Zoom version you will need a computer or a tablet, internet access and somewhere quiet to do therapy. If you don't have headphones we will send you some to use and keep. We cannot do assessment or therapy using just a phone as the screen is too small.

If you choose to have therapy on Zoom we will provide you with a short zoom set-up session to make sure you are can fully join in on your treatment.

You can have a support person present at any time to help you understand this information, decide if you want to participate, or assist you in completing the assessment and therapy activities.

There are four stages in this research project. All stages will be audio and video recorded.

1. Assessment

If you decide to be a part of this study, we will ask you to do some speech assessment tasks such as saying made-up words, repeating sentences, describing a picture and naming pictures or objects, we will also test your hearing and how the muscles of your mouth work and ask you to answer some surveys about your communication. There will be up to two visits to the clinic for this assessment and at the end of the first session we will tell you whether you are eligible for the study or not.

2. Pre-treatment measurement

We need to see if your speech is changing from week to week before you start so we want you to say some words and sentences five different times over three weeks. These will be short appointments.

3. Treatment

The treatment sessions will be one hour twice per week for six weeks. Treatment will be provided by a speech pathology student who is being supervised by one of the researchers. In each treatment session we will teach you how to say some made up words and ask you to repeat those made up words five times each. There will be no homework. On two of your clinic days we will ask you to stay for 90 minutes so that we can record you saying the same words and sentences that you said in stage 2.

4. Follow up after treatment

After we have finished the treatment we want you to come to the clinic another three times over the next four weeks so that we can see if your speech has changed and also see if any changes stay after 4 weeks without the treatment. During these sessions we will get you to say the word and sentences from stage 2 and also to repeat some of the pre-treatment assessment tasks such as picture naming, describing a picture and repeating sentences.

(4) How much of my time will the study take?

Overall, from beginning to end you will be in the research project for approximately three months.

There are four stages in this research project.

1. Assessment – This will be two clinic visits of up to 90 minutes each.
2. Pre-treatment measurement – This will be five clinic visits of 30 minutes each.
3. Treatment – This will be 12 treatment sessions either face-to-face or online – each of approximately 60 minutes. Before session 5 and 10 we will ask you to do an extra 20 minutes.
4. Follow up after treatment – This will be two visits of about 30 minutes and one visit of approximately 60 minutes.

(5) Who can take part in the study?

You can take part in this study if:

1. You have apraxia of speech (also known as dyspraxia).
2. Your hearing and vision are normal for your age (using glasses or hearing aids is fine).
3. You do not have any other serious health conditions which might effect your speech such as Parkinson's disease or cerebral palsy. Please let us know if you are unsure and we will talk it through with you.
4. If you have aphasia, it does not stop you participating unless you cannot understand the easy to read version of this information statement or the easy to read consent form.
5. You can read in English
6. You are aged 18 or older

(6) Do I have to be in the study? Can I withdraw from the study once I've started?

Being in this study is completely voluntary and you do not have to take part. Your decision whether to participate will not affect your current or future relationship with the researchers or anyone else at the University of Sydney.

If you decide to take part in the study and then change your mind later, you are free to withdraw at any time. You can do this by *telling us in person, by email or over the phone*. Withdrawal from the study is not the same as withdrawal from treatment so if you withdraw from the study you can continue with treatment if you want or you can withdraw from both the study and treatment.

If you decide to withdraw from the study, we will not collect any more information from you related to the research. Please let us know at the time when you withdraw what you would like us to do with the research information we have collected about you up to that point. If you want, your research information will be removed from our study records and will not be included in the study results, unless we have already analysed and published the results.

Regardless of your decision to withdraw from the research we will need to keep your treatment records as these are required to be retained as part of providing you with speech pathology services.

(7) Are there any risks or costs associated with being in the study?

Aside from giving up your time, we do not expect that there will be any risks or costs associated with taking part in this study.

(8) Are there any benefits associated with being in the study?

We cannot guarantee that you will receive any direct benefits from being in the study.

(9) What will happen to information about me that is collected during the study?

By providing your consent, you are agreeing to us collecting personal information about you for the purposes of this research study. Your information will only be used for the purposes outlined in this Participant Information Statement, unless you consent otherwise.

Every time you participate in the study we will collect audio and video recordings and make notes about how you produce words and sentences. This information will be used to work out what to do in treatment and then we will use it to understand if the treatment works for you.

We will store the notes, audio and video recordings separately to the clinical record of your name, address, date of birth etc. The research notes and recordings will be called by your participant number in all of our research records. The notes and recordings will be stored on university owned, password protected computers for fifteen years and then deleted.

Only people named as researchers and approved by the University of Sydney Human Research Ethics Committee will be able to see or hear your recordings or notes unless you tell us otherwise. We may ask an honours student to analyse some of the data. We don't know her/his name yet but we will make sure she/he is properly trained and registered with the ethics committee.

If you give us permission to use the recordings and notes when we teach people about the treatment we will never use your name or any other information that could directly identify you however there is a small risk that somebody might recognise you from a video if we show it to other speech pathologists.

If you choose to have therapy online we will use the Zoom service to record your sessions. We will record these sessions to a University of Sydney approved and password protected computer.

We will move the notes and recordings to a University of Sydney password protected research data storage and delete it from our other computers as soon as we can. Your information will be stored securely and your identity/information will be kept strictly confidential, except as required by law. Study findings may be published, but you will not be individually identifiable in these publications.

We will keep the information we collect for this study for 15 years, and we may use it in future projects. By providing your consent you are allowing us to use your information in future projects. We don't know at this stage what these other projects will involve. We will seek ethical approval before using the information in these future projects.

(10) Can I tell other people about the study?

Yes, you are welcome to tell other people about the study.

(11) What if I would like further information about the study?

When you have read this information, one of the researchers will be available to discuss it with you further and answer any questions you may have. If you would like to know more at any stage during the study, please feel free to contact Professor Tricia McCabe (tricia.mccabe@sydney.edu.au, 9351 9539) or visit the ReST website www.rest.sydney.edu.au

(12) Will I be told the results of the study?

You have a right to receive feedback about the overall results of this study. You can tell us that you wish to receive feedback by ticking a box on the consent form. This feedback will be in the form of a one-page summary. You will receive this feedback after the study is finished. We will also post it on our website.

We will also send you a summary of your own speech pathology assessment and therapy results soon after your final visit with us. You can share this with your next speech pathologist as it may help them decide how to help you.

(13) What if I have a complaint or any concerns about the study?

Research involving humans in Australia is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this study have been approved by the HREC of the University of Sydney [2024/162]. As part of this process, we have agreed to carry out the study according to the *National Statement on Ethical Conduct in Human Research (2023)*. This statement has been developed to protect people who agree to take part in research studies.

If you are concerned about the way this study is being conducted or you wish to make a complaint to someone independent from the study, please contact the university using the details outlined below. Please quote the study title and protocol number.

The Manager, Ethics Administration, University of Sydney:

- **Telephone:** +61 2 8627 8176
- **Email:** human.ethics@sydney.edu.au
- **Fax:** +61 2 8627 8177 (Facsimile)

This information sheet is for you to keep