FULL STUDY TITLE

Rapid Syllable Transition Treatment for Adults

CONFIDENTIAL

STATEMENT OF COMPLIANCE FOR NON DRUG OR DEVICE CLINICAL TRIALS

This document is a protocol for a clinical research study. The study will be conducted in compliance with all stipulations of this protocol, the conditions of ethics committee approval, the NHMRC National Statement on Ethical Conduct in Human Research (as updated) and the Handbook for Good Clinical Research Practice (GCP). The Therapeutic Goods Act has adopted ICH Guideline for Good Clinical Practice.

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Contents

1. GENERAL INFORMATION

1.1 Protocol title

Rapid Syllable Transition Treatment for Adults

1.2 Name and address of the sponsor

The University of Sydney, Camperdown NSW 2006

1.3 Name of the study funder

No external funding

1.4 Name and title of the investigator(s) who is (are) responsible for conducting the research

Professor Tricia McCabe (Chief Investigator)

Dr Petra Avramovic

Dr Elizabeth Bourne

Dr Sophie Brassel

Dr Emma McLaughlin

Dr Donna Thomas

1.5 Name(s) and address(es) of the clinical laboratory(ies) and other medical and/or technical department(s) and/or institutions involved in the research.

The University of Sydney Speech Clinic

Level 5 East, Susan Wakil Health Building D18

Western Avenue, Camperdown, NSW 2006

1.6 Trial registration - Trial identifier and registry name

The Australian New Zealand Clinical Trials Registry (ANZCTR), (reg number to be provided)

2. SYNOPSIS

TITLE	Rapid Syllable Transition Treatment for Adults
PRIMARY HYPOTHESIS	That Rapid Syllable Transition Treatment (ReST) will be effective in improving speech intelligibility of adults with apraxia.
DESIGN	Single case experimental design – multiple baselines within participants
BLINDING/MASKING	Single blind As a behavioural intervention trial, the treating clinicians and participants cannot be blinded to allocated group or intervention.
OUTCOMES	The primary outcome Speech intelligibility in single words Secondary outcomes 1. Participant satisfaction with the intervention 2. Speech accuracy 3. Sentence complexity and length in speech
STUDY DURATION	Estimated study duration from initial enrolment until completion of data analyses is 21 months
INTERVENTION/S	Rapid Syllable Transition Treatment (ReST)
NUMBER OF PARTICIPANTS	6 in 1 group
POPULATION	Sample Size: n=6 Gender: Male and female Age: Adults aged over 18 Demographic group: N/A Diagnosis: Apraxia of speech from any cause
SELECTION AND ENROLMENT	Inclusion criteria: 1) Aged over 18 years 2) Diagnosis of apraxia 3) No diagnosis of intellectual disability, dementia or other significant disorder which effects speech production. 4) Normal or adjusted-to-normal hearing (screened) and vision (self-report).

3. RATIONALE / BACKGROUND

3.1 Background

Apraxia of speech is a brain-based neurological speech disorder that causes people to have difficulty making a plan for how to say words and sentences despite no problems in the function of their muscles or peripheral nerves (ASHA, 2007). This inability to plan can make their speech slow, halting, staccato or slurred. Apraxia has a number of causes including genetics, disease or injury. Apraxia can occur from birth or can be acquired later in life. It is not associated with reduced intellectual capacity or understanding of spoken or written language although these can co-occur.

Rapid Syllable Transition (ReST; McCabe et al., 2017) treatment is an evidence-based speech pathology treatment for apraxia of speech which has been shown to be effective with children and young people (e.g., Murray et al., 2015; McCabe et al., 2023) when provided at least twice per week (Thomas et al., 2014; 2023). ReST involves the use of multisyllabic pseudowords to improve the ability to transition rapidly and fluently from one sound/syllable to the next, and control of the rhythm in the form of relative emphasis, or stress, placed on each syllable within a word (McCabe et al., 2017).

ReST treatment teaches patients to say nonsense words and gets them to copy a model of someone saying the nonsense word correctly. In doing so, the person with apraxia is required to practice planning to speak, thus it is believed that the treatment addresses their difficulty directly. Details about ReST treatment and video examples of the treatment with children are available at www.rest.sydney.edu.au.

3.2 Rationale for Study

Although ReST was designed for those with childhood apraxia of speech and tested on children aged 4-14, it has been used widely in clinical practice with adults (McCabe et al., 2020). This study is an examination of an existing treatment which is being used clinically with this population (adults) and will use within-participant comparisons (single case experimental design) to report the effects of a usual clinical practice. Should ReST be an effective intervention, the results of this study will provide data to power a sample size calculation for a larger study.

4. AIMS / OBJECTIVES / HYPOTHESES

Aim:

The study aims to investigate if Rapid Syllable Transition Treatment (ReST) is effective in improving speech intelligibility in adults with apraxia of speech.

Hypothesis:

1. ReST will be effective in improving speech intelligibility in adults

5. PARTICIPATING SITES

The University of Sydney

Susan Wakil Health Building D18 Western Avenue
Camperdown, NSW 2006

6. STUDY DESIGN

6.1 Type of Study

This is a single blind multiple baselines within participant study

6.2 Schedule of Events/ Treatment Phases

Table 1 study timeline (subject to approval timeframe)

Events and time						
Feb 2024	**March 2024**	**July 2024**	**Feb 2025**	**July 2025**	**Oct 2025**	**Dec 2025**
Ethics, clinical trial registration;	Rolling recruitment, assessment & therapy					Close trial
Train student clinicians		Train student clinicians	Train student clinicians (if required)	Train student clinicians (if required)	Final recruitment	

All patient facing procedures form part of speech pathology usual care except extra data collection listed below in items 3, 7, and 8 where usual procedures are repeated more frequently than would occur in usual care.

Table 2: Flowchart of the participation in the trial for each participant (n=6)

		Visits 1-2	Visits 3-8	Visits 9-22	Visits 8 & 12	Visit 23	Visit 24	Visit 25	Visit 26
Weeks	**0**	**1-2**	**2-4**	**4-10**	**4-10**	**10**	**11**	**12**	**14**
	Consent	Assessment	Pre-treatment probe data collection	Treatment	Within treatment probe data collection	1 day follow up	1 week follow up	2 week follow up	4 week follow up

PROCEDURES

1. Following consent, participants will be assessed by a qualified speech pathologist (one of the investigators) using standard speech pathology tools. This assessment will take no more than one hour. Tasks will include saying words and sentences, reading a passage, having a hearing screening and completing an oral movement assessment (OMA) which includes tasks such as stick out your tongue; lick your lips, alternate between a kiss and a smile and say /a/ for as long as you can (forms attached). The assessment will be audio and video recorded.

2. Following standard ReST protocol, one of the investigators will then create a list of words for each participant consisting of 20 treatment words, 10 control (untreated) words, 10 untreated generalisation sentences and 30 generalisation words. This list of 70 items is called the Probe list and participants will be asked to say it on a number of occasions described below.

3. Prior to treatment, each participant will be asked to say the 70 item probe list on five separate days (max 30 minutes per session) and these will be recorded as the baseline performance.

4. Treatment will be provided by a trained speech pathology student for one hour twice per week for six weeks at a mutually convenient time. Treatment consists of learning to say the nonsense words. No home practice is required. Treatment may be face-to-face in the on-campus speech pathology clinic or it may be on Zoom. This choice will be up to participant preference.

5. Immediately prior to the fifth and ninth sessions, participants will be asked to say the 70 word probe list and this will be recorded. 20 minutes on each occasion.

6. Immediately following the final (twelfth) session, participants will be asked to say the 70 word probe list and this will be recorded. 20 minutes.

7. Participants will return to the clinic one day, one week, two weeks and four weeks after finishing treatment and say the 70 word probe list on each occasion. On the one week and two week post treatment occasions, they will be asked to say the list twice. Each visit will take approximately 30-40 minutes.

8. Four weeks after completion of the treatment, participants will also repeat several of the tasks completed in the initial assessment (step 1) and say the probe list for the final time (60 minutes total)

9. Following the four week appointment a short report on their individual performance in treatment will be sent to each participant for their own records.

NB: Clinic here refers to online or face-to-face clinical services

6.3 Population / Sample size including power calculation

Sample size:

The sample size will be 6 participants

Sample size calculation: This is a phase 1 study to acquire data for a sample size calculation

6.4 Participant Enrolment and Randomisation

6.4.1 Recruitment

Participants will be recruited from The University of Sydney speech pathology clinic and speech-language pathology services in Australia and other English-speaking countries. The study will be advertised on the ReST website, social media (Instagram, Facebook, LinkedIn and Twitter/X), and on Speech Pathology Australia e-newsletters and website. The study flyer will direct potential participants who are interested to contact the chief investigator Prof Tricia McCabe or follow a link to the research website (www.rest.sydney.edu.au).

When participants contact the chief investigator, they will be informed about the purpose of the study and provided with the Participant Information Sheet. An opportunity to ask questions will be provided.

6.4.2 Inclusion and Exclusion Criteria

INCLUSION CRITERIA

Participants will be adults aged over 18 with apraxia of speech. Participants will have English as their primary language and have functional literacy in English. Participants will have adequate hearing and vision to participate in the treatment (glasses and hearing aids are fine). Participants who choose to participate by telehealth will need to have their own laptop or tablet device and access to the internet. Participants will be competent to independently provide consent (i.e. no one with a

guardianship order).

EXCLUSION CRITERIA

Participants will not have another serious genetic or developmental diagnosis which affects speech or cognition such as Down Syndrome or Cerebral Palsy. Participants will not have another serious acquired neurological disorder which affects speech or cognition such as Parkinsons disease or Alzheimers.

6.4.3 Informed consent process

The informed consent process involves the following:

Interested persons will contact the chief investigator or follow links from a social media site or email to the ReST research webpage. They will be provided with the Participant Information Sheet and the Participant Consent Form. Participants will be encouraged to ask questions about the research and the risks and benefits of participation.

Potential participants will be informed that their participation is completely voluntary. They are free to decline to attend the study, and also free to withdraw from the study at any time. This will have no implications on their relationship with the research team or the University of Sydney.

Consent will be recorded in (1) a RedCAP version of the participant consent form or (2) a written consent form which will then be scanned and added to RedCAP.

6.4.4. Eligibility and pretreatment assessment

Following consent, participants will complete the following assessment tasks to (1) measure their performance prior to treatment (2) provide information for therapy planning (3) provide adequate description of each participant's communication skills and (4) to ensure they meet the inclusion and exclusion criteria. All tasks are standard speech pathology practice:

1. Complete a case history questionnaire
2. Hearing screening
3. Oral musculature evaluation – an examination of the structure and function of the muscles of speech
4. Apraxia Battery for Adults 2nd edition (speech and oral apraxia evaluation)
5. Apraxia Severity Rating Scale (speech tasks)
6. Assessment of Intelligibility in Dysarthric Speech (speech tasks)
7. PALPA – nonword repetition, sentence comprehension and reading letter names subtests
8. Picture description – the participant will be asked to verbally describe a picture.

6.4.5 Randomisation and Blinding Processes

Randomization

There is no randomization in this study.

Blinding

Blinding of the treating clinicians or the participants is not possible as this is a behavioural RCT. The treating clinicians are not able to deliver the intervention without knowing about it. The participants will not be blinded to the study treatment as they will know from recruitment that the treatment aims to improve speech. The clinicians scoring the assessments and transcribing the data will be blinded to pre-treatment performance and sequence of recordings.

6.5 Primary and Secondary Outcome Measures

The primary outcome measure:

Speech intelligibility. This refers to how easy it is to understand the person's speech. This is measured with: *Assessment of Intelligibility in Dysarthric Speech* Standard Score

The secondary outcome measures:

2: Satisfaction with the intervention .

a. This is measured with a questionnaire containing Likert scales and open ended responses. The questionnaire will be provided to participants at the 1-week post treatment point and can be completed online at a time of their choosing.

3: Speech accuracy. This is measured with:

a. Percentage of phonemes correct in words. The percentage of phonemes correct (PPC) expresses the percentage of consonant sounds that are articulated correctly. It is considered a robust means of assessing articulation accuracy (Shriberg et al., 1997) and will allow comparison with previous ReST research. It is calculated from the probe data

b. Apraxia of Speech Severity Rating scale (Duffy et al., 2023 etc)**.** This scale will allow us to compare this study with other Apraxia intervention studies.

4: Sentence complexity. - This is measured with:

a. Mean length of utterance (MLU) in speech. Changes in the participant's mean length of utterance, as measured by calculating the average number of morphemes in a person's utterances (Miller & Chapman, 1981). This measure allows us to understand changes in everyday speech as a result of increasing speech success. It is calculated from a picture description or conversation.

6.6 Intervention

6.6.1 Rapid Syllable Transition Treatment (ReST; McCabe et al., 2017)

ReST involves the person saying multisyllabic pseudowords to improve the ability to transition rapidly and fluently from one sound/syllable to the next, and control of the melody in the form of relative emphasis, or stress, placed on each syllable within a word (McCabe et al., 2017).

Based on the baseline assessment, four vowels and four consonants are selected and used to form pseudowords, for example, consonants b, p, k, and m are combined with vowels to create pseudo-words bamaka, makaba, mikabu and bamipa. The practise phase includes 100 attempts at producing the pseudowords. If the person is unable to complete saying all 100 pseudowords within the session, the remaining pseudowords will be practised in additional sessions after the 12th session until a total of 1200 productions is achieved.

6.6.2 Who provides the intervention?

The intervention is provided by The University of Sydney speech pathology students under the supervision of the speech pathologists in the research team. The students will be trained by the chief investigator in the treatment and data collection before the commencement of the intervention block. Supervision is provided throughout the intervention block and in accordance with Speech Pathology Australia and The University of Sydney speech pathology supervision guidelines.

6.7 Participant Withdrawal

Participants will be informed in the Participant Information Statement about their right to withdraw at any time. If the participant wishes to withdraw, they are asked to inform one of the research team. At this point, participants will be asked if they wish for the researchers to retain or destroy already collected research data. If the participant agrees, then their data will be retained and analysed using intention to treat analysis. If the participant does not agree, then their data will be destroyed. Participants who decide to withdraw from the research will be asked for their reasons and these will be recorded and reported if they are provided and if consent is provided.

As the participation is also a student clinical placement, participants who wish to withdraw from the research may continue to receive the treatment if they wish but the research data will not be collected.

6.7.1 Handling of withdrawals and losses to follow-up

Intention to Treat (ITT) will be used to statistically analyse the results if there is loss to follow up, or if there are any deviations from the original assigned groups.

6.7.2 Participant Replacement following withdrawal

Replacements will not be sought for participants who withdraw from the study, as attrition has been accounted for in our sample size.

6.8 Expected Duration of Study

The expected study duration is 21 months. Subject to ethics approval we anticipate recruitment of participants to commence in March 2024. The last participant will finish no later than December 2025.

6.9 Ethics Approval

Ethics approval will be sought from the University of Sydney Human Research Ethics committee.

6.10 Modifications to the Protocol

Any modifications to this application will be submitted to the HREC and CTSO before they are implemented and will be recorded in the clinical trials register (ANZCTR)

6.11 Protocol Violations

To minimise and prevent protocol violation, the following will occur:

The written treatment procedural manual will include instructions on the delivery of ReST, data recording, and data storage.

Provision of adequate training of speech pathology students on the delivery of ReST. Regular and on-going supervision of the students and observation of their treatment sessions.

Procedure for recording treatment dosage and participant responses at each session. Procedure for recording participant behavior and engagement after each session.

Procedure for logging all data recording and storing.

If a protocol violation occurs, the person responsible will inform the Chief Investigator (CI) or, in case of a student, their student supervisor within 24 hours. The CI or the student supervisor records the violation in the protocol violation form. A plan to rectify the violation will be decided between the person responsible for the violation, their supervisor where relevant, and the CI. This is also recorded in the protocol violation form.

6.12 Participant reimbursement

There are no participant reimbursement or incentives.

6.13 Continuation of therapy

Provided that no adverse/serious events occur the trial will continue until either of the following has been met: (i) a sufficient number of participants have been recruited, or (ii) the study period has ended.

6.14 Statistical analyses

Data analysis will utilize repeated measures visual analysis. When a treatment effect is evident visually, statistical analysis within participant, across treatment phase (I.e. baseline, treatment, follow-up) we be calculated using Helmert Planned orthogonal contrasts.

Effect sizes within participant will be calculated using d2, as this measure is appropriate for single case data (Beeson & Robey, 2006).

If there is any attrition, an intention-to-treat analysis will be conducted.

7. ETHICAL CONSIDERATIONS (see data, section 10 for privacy and confidentiality)

7.1 Potential Risks and Proposed Benefits

7.1.1 Potential Risks

This is a relatively low-risk project and does not pose significant foreseeable risks to the participants. The speech pathology involvement is not different from the usual speech pathology practice but may involve mild distress from time to time as tasks may be difficult for the participant.

As this is a trial study of ReST with adults, there is a risk of no improvement in speech intelligibility at the end of the study. The participants are informed of this at recruitment.

Participants will receive treatment from speech pathology students. There is a small risk that the students' inexperience may impact on the intervention quality or the ability to recognise subtle signs of participant fatigue, however previous ReST studies involved speech pathology students successfully in the treatment delivery, including McCabe, et. al (2023), Murray, et. al. (2015) and Thomas et al., (2023) studies. Students will be supervised by the research team members who are experienced clinical supervisors and speech pathologists and will receive guidance and support to maintain a high standard of service delivery and participant care.

Privacy and confidentiality pose a risk. This is covered in Section 9 Data Management.

7.1.2. Participant Benefits

The participants will receive therapy and an individualised report. Attending therapy may in itself have a therapeutic effect due to positive communication interactions with the student clinicians.

7.2 Responsibility for liability of injury

The participants may experience fatigue and frustration during assessments or treatment. The supervising speech pathologists and the speech pathology students will be instructed to note signs of fatigue or frustration and to give the person a short break if these occur.

The students are covered by University of Sydney insurance for clinical placements. The WHS requirements for risk minimization will be adhered to throughout the study intervention. The university will be the sponsor of the study and the FMH Clinical Governance Committee has accepted oversight.

7.3 Recruitment

Recruitment will take place online (social media, email) of people from the community and to those in the University of Sydney Speech Pathology clinic patient list (by an independent clinical team member). Potential participants will be directed to contact the chief investigator or to visit the ReST website. Neither the research team or the student speech pathologists will approach or contact the potential participants prior to consent.

7.3.1. Dual or unequal relationship, potential for coercion or inducement

The participants are protected against potential coercion in that they will not be approached directly by any of the research team members.

Participants will also be informed that if they decline to participate or withdraw from the study, this will not affect their relationship with the research team or the University of Sydney.

7.4 Informed Consent

The participants will be informed about the study and given the PCF and the PIS. The participant can choose whether they want to sign the consent form. If the participant declines to participate in the study, they are assured that this will not impact their relationship with the research team members, The University of Sydney and its staff.

The participant is provided the name and contact details of the chief investigator if they require further information. They are also provided the contact details of the University of Sydney Ethics committee if they have any concerns or complaints about the study.

The participants will be informed that their participation is completely voluntary. They are free to decline to attend the study, and also free to withdraw from the study at any time. This will have no implications on their relationship with the research team or the University of Sydney.

7.5 Clinical governance

The clinical governance for the project is provided by the Faculty of Medicine and Health Clinical Governance committee. The protocol has been added to the Speech Pathology Model of Care (26th October 2023).

8. SAFETY CONSIDERATIONS

8.1 Assessment and Documentation of Adverse Events

To ensure consistent procedures and safety of the participants, the participants' progress and participation will be monitored. Speech pathologists in the research team will supervise the speech pathology students who deliver the treatment. This includes monitoring the maintenance of accurate delivery of ReST treatment and to ensure the participants' experiences during the treatments are positive. The supervising speech pathologist provides feedback and support to the students during and after the treatment sessions. Adherence to the treatment protocol and participants' experiences are discussed and adjustments are implemented where required.

Participants who become distressed will be provided with a break, with encouragement, and with appropriate support. If the participant consents to continuing, the session will recommence after a short break. Otherwise, the session will be discontinued and the discontinue will be noted.

One of the investigators will be present whenever students are providing therapy. Direct observation of the students occurs during the first four sessions of the treatment block. After this, the frequency of direct observation will be reduced to once a week, in line with usual educational

and clinical practice. All sessions will be recorded and the student and the supervisor will review any sessions where the supervisor was indirectly supervising.

8.2 Adverse event reporting

All adverse events will be reported to the chief investigator and recorded. The procedures for reporting serious adverse incidents within 72 hours will be followed.

Standard procedures for completing and submitting HREC adverse event templates and contacting the HREC office directly with urgent issues will be followed.

The data collection procedures will be monitored to ensure the accuracy of the data. Data collection monitoring includes monitoring of the consistency of data analysis, quality of video recordings, and the timeframes for uploading videos to the data storage after each therapy or assessment session. The supervisors check the data collection procedures weekly for the students they supervise. Data collection procedures are discussed at supervision meetings and adjustments are implemented where required.

9. DATA MANAGEMENT

9.1 Data collection and storage

Research data, including video recordings and assessment results are collected in electronic form. Any paper documents will be scanned, uploaded and the paper version deleted within two weeks of collection. Identification codes replace names in all files.

All assessment and treatment sessions are videoed, which will then be uploaded by the treating student therapist to The University of Sydney provided, password protected Sharedrive immediately after the session.

Paper copies of assessment forms are scanned and collected in electronic form. Paper copies of intelligibility ratings are scanned and collected in electronic form. The paper forms are shredded immediately after scanning.

Contact details and identifying codes will be held in a password protected encrypted file in the RDS.

Once the data is no longer being actively used it will be deleted from Sharedrive and only retained in the RDS.

9.3 Data retention and archiving process

Data will be stored for 15 years which is the standard required for clinical trials. At the end of this time the project materials will be permanently deleted from the RDS.

10. FINANCIAL

This study is not externally funded.

11. PUBLICATION POLICY / DISSEMINATION OF RESULTS

This work will be reported in one or more journal articles and conference papers. A public summary will be published on the ReST website.

Authorship will follow the Contributor Roles Taxonomy (Credit). Prof McCabe will be 1st author unless otherwise agreed, other authors will be determined by the nature and extent of their contributions to the papers. An honours student may be added to the project and in this case, authorship will be re-

negotiated.

12. REFERENCES

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