

A randomized control trial comparing ultrasound visual feedback and ReST (Rapid Syllable Transition Training) to improve speech in childhood apraxia of speech (CAS).

ReST v. Ultrasound Biofeedback

CONFIDENTIAL

This document is confidential and the property of Assoc Professor Tricia McCabe and the University of Sydney.

No part of it may be transmitted, reproduced, published, or used without prior written authorisation from the institution.

STATEMENT OF COMPLIANCE

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 (2007) and the Note for Guidance on Good Clinical Practice (CPMP/ICH-135/95).



Contents

STATEMENT OF COMPLIANCE	1
GLOSSARY OF ABBREVIATIONS	4
1. STUDY MANAGEMENT.....	4
2. INTRODUCTION AND BACKGROUND	6
3. STUDY OBJECTIVES	7
4. STUDY DESIGN	8
5. PARTICIPANT ENROLMENT AND RANDOMISATION	12
6. STUDY VISITS AND PROCEDURES SCHEDULE	15
7. ADVERSE EVENT REPORTING	17
8. STATISTICAL METHODS	18
9. DATA MANAGEMENT	19
10. ADMINISTRATIVE ASPECTS	20
11. USE OF DATA AND PUBLICATIONS POLICY	20
12. REFERENCES	21
13. APPENDICES	23



PROTOCOL SYNOPSIS

Title	A randomized control trial comparing ultrasound visual feedback and ReST (Rapid Syllable Transition Training) to improve speech in childhood apraxia of speech (CAS).
Objectives	<p>Primary:</p> <ul style="list-style-type: none"> To evaluate increases in segmental accuracy and prosodic accuracy in children with CAS treated with ReST or ultrasound biofeedback interventions. To determine whether treatment-specific responses will be observed in segmental accuracy and prosodic accuracy. To evaluate whether generalization and retention is facilitated by (a) immediate focus on motor learning principles (i.e., ReST) or (b) a focus on skill stabilization prior to motor learning principles (i.e., ultrasound biofeedback). <p>Secondary:</p> <ul style="list-style-type: none"> To establish an effect size which can be used for subsequent larger trials. To examine treatment responders/non-responders in both interventions.
Study Design	A randomised control trial with 16 child participants with CAS. Participants will be allocated to receive ReST or ultrasound biofeedback treatment over 6 weeks with 2 sessions per week.
Planned Sample Size	16 children
Selection Criteria	<ul style="list-style-type: none"> diagnosis of CAS through consensus over 2 expert judges 7-16 years old no other motor speech disorder (i.e. dysarthria) or structural deficit (e.g. cleft palate) nonverbal intelligence, receptive language and oral-facial exam within normal range normal (corrected to normal) hearing and vision no other developmental or genetic diagnosis Australian English as first and primary language.
Study Procedures	<ul style="list-style-type: none"> Following assessment and enrolment, 16 children will be randomised to receive one of two treatments for Childhood Apraxia of Speech. All children will receive treatment 2 days per week for 6 weeks for a total of 12 sessions. Each session will be 1 hour in duration. Outcomes will be measured at seven points; at the second assessment (1), at the start of the first, fifth and ninth therapy visits (2, 3 & 4), and at 1 week, 4 weeks and 3 months after the final therapy visit (5, 6 & 7).
Statistical Procedures Sample Size Calculation: Analysis Plan:	<p>Sample Size Calculation:</p> <ul style="list-style-type: none"> Using the large effect sizes obtained from Murray, McCabe & Ballard (2012) RCT (Cohen's $d = 1.36$), Thomas, McCabe

	<p>& Ballard (2014) experimental single case design ReST study ($d_2 = 5.6$) and Preston's (2013) experimental single case design CAS ultrasound study ($d_2 = 2.7$), power of 0.9 and probability of 0.05, we calculate a sample size of 7 per group. Adding 15% for possible attrition we will recruit 16 children. Given these large effect sizes, we should have sufficient power to address the first hypothesis (both approaches will facilitate change from pre- to post-treatment).</p> <p>Analysis Plan:</p> <ul style="list-style-type: none"> • ANOVA for significant differences. • ANCOVA for between group changes for percent phonemes correct (PPC) and prosodic accuracy. • Intention-to-treat analysis for withdrawals.
Duration of the study	12 months (July 2015 – June 2016)

GLOSSARY OF ABBREVIATIONS

ABBREVIATION	TERM
ReST	Rapid Syllable Transition Training
CAS	Childhood Apraxia of Speech
PPC	percent phonemes correct
PCC	percent consonants correct
nonword	nonsense word
CASANA	Childhood Apraxia of Speech Association of North America

1. STUDY MANAGEMENT

1.1 Principal Investigator

Tricia McCabe PhD CPSP

Associate Professor and Course Director of the Bachelor of Applied Science (Speech Pathology)
Speech Pathology
Building C43S, Room S153
Cumberland Campus
The University of Sydney
NSW 2006, AUSTRALIA
Telephone: +61 2 9351 9747



1.2 Associate Investigators

Jonathan Preston PhD CCC-SLP

Assistant Professor
Communications Sciences and Disorders
Syracuse University
Syracuse, NY 13244, USA
Telephone: +1 315-443-3143
Email: jopresto@syr.edu

Pippa Evans BA, MSLP

Practising Speech Pathologist & Research Assistant
Speech Pathology
Building C43S, Room S142
Cumberland Campus
The University of Sydney
NSW 2006, AUSTRALIA
Telephone: +61 2 9351 9713
Email: pippa.evans@sydney.edu.au

1.3 Statistician

Robert Heard PhD

Senior Lecturer, Postgraduate Coordinator, and Faculty Research Advice Group Unit Coordinator
Building C43T, Room T405
Cumberland Campus
The University of Sydney
NSW 2006, AUSTRALIA
Telephone: +61 2 9351 9498
rob.heard@sydney.edu.au

1.4 Internal Trial Committee

Tricia McCabe, Jonathan Preston & Pippa Evans (details above)

1.5 Independent Safety and Data Monitoring Committee

Associate Professor Angela Morgan, Murdoch Children's Research Institute, Melbourne VIC.
Professor Kathy Jakielski, Augustana College, Illinois USA.
Dr Alison Purcell, Senior Lecturer, Faculty of Health Sciences, University of Sydney.

1.6 Funding and resources

The study is a joint project between Dr Tricia McCabe of the University of Sydney and Dr Jonathan Preston of Syracuse University & Haskins Laboratories in the USA. Funding received from The Childhood Apraxia of Speech Association of North America (CASANA) is being allocated directly to the project by employing a part-time Research Assistant (Pippa Evans). University of Sydney Speech Pathology Students will treat some of the study participants for one paediatric placement under the supervision of a University of Sydney experienced certified practising speech pathologist. This



arrangement is beneficial for both groups as CASANA are always looking to update the evidence base surrounding CAS and the University of Sydney is keen to develop strong, evidence-based intervention programs that can be delivered by speech pathologists.

2. INTRODUCTION AND BACKGROUND

2.1 Background Information

CAS is a motor speech disorder involving impairments in speech sound accuracy along with disrupted transitions between sounds and syllables, prosodic disturbances (e.g., lexical stress), and token-to-token inconsistency (ASHA, 2007). As such, treatments should be designed to address these speech-specific characteristics through motor-based approaches. However, to date, there are few treatments with strong empirical support. In fact, in 2009, Morgan and Vogel stated there is a “critical lack of well controlled treatment studies addressing treatment efficacy for CAS, making it impossible for conclusions to be drawn about which interventions are most effective for treating CAS in children or adolescents.” (p. 1). This represents a significant challenge for clinical practice, as research has yet to provide sufficient guidance on effective treatment options for this population. Thus, there is need for rigorous study of treatments in order to build an evidence base. The overarching goal of this proposal is to address this theme. The present investigation will compare two treatments for children with CAS which have been developed using the principles of motor learning: Repeated Syllables Transition Training (ReST) and ultrasound biofeedback. This research presents a pilot examination of the comparison between the treatments and if successful will be scaled up to a multisite, international study.

2.2 Research Questions

This study will compare two treatments for children with CAS which have been developed using the principles of motor learning: Repeated Syllables Transition Training (ReST) and ultrasound biofeedback. This research presents a pilot examination of the comparison between the treatments and if successful can be scaled up to a multisite, international study.

2.3 Rationale for Current Study

Treatments for Childhood Apraxia of Speech (CAS) need to help children create the new motor routines required for intelligible speech production. Motor learning is therefore an essential goal in CAS treatment and demonstrating motor learning will determine efficacy. “Motor learning is a set of processes associated with practice or experience leading to relatively permanent changes in the capacity for skilled movement” (Schmidt & Lee, 2011, p. 327).

A recent review by Murray, McCabe and Ballard (2014) sought to evaluate which treatment approaches for CAS have sufficient evidence to warrant larger-scale trials (i.e., a RCT, Phase III research). We identified phonological awareness training, Dynamic Temporal and Tactile Cueing, and Rapid Syllable Transition Training (ReST) as candidate interventions with sufficient evidence. Since this review was conducted, research has also been published on ultrasound biofeedback treatment (Preston et al., 2013). Thus, both ReST and ultrasound biofeedback have sufficient empirical support to justify further investigation. This study will be the second ever randomised control trial of speech pathology treatment in this population and will add information that extends the scope of available treatments for this persistent disorder.



3 STUDY OBJECTIVES

3.1 Primary Objectives

To evaluate increases in segmental accuracy and prosodic accuracy in children with CAS treated with ReST or ultrasound biofeedback interventions. As children are randomized to one treatment condition, they will be exposed to interventions that place emphasis on addressing particular speech patterns: ultrasound biofeedback focuses on precision of consonants and vowels within a target syllable, but does not specifically address across-syllable aspects of speech such as lexical stress or syllable segregation; on the other hand, ReST is designed to address all elements of connected speech including segments, syllable transition, and lexical stress. It is hypothesized that both treatment conditions will result in an increase in the respective sound patterns targeted for treatment from pre- to post-treatment assessments.

To determine whether treatment-specific responses will be observed in segmental accuracy and prosodic accuracy. Both segmental accuracy and prosodic accuracy in connected speech are desirable outcomes for children with CAS. However, when the feedback provided in treatment emphasizes specific domains (i.e., segments only vs. segments/syllable transitions/lexical stress), outcomes are likely to reflect this emphasis. Thus, it is hypothesized that sentence-level generalization to segments is likely to be greater for children treated in the ultrasound biofeedback condition, whereas sentence-level generalization to prosody is likely to be greater for children treated in ReST.

To evaluate whether generalization and retention is facilitated by (a) immediate focus on motor learning principles (i.e., ReST) or (b) a focus on skill stabilization prior to motor learning principles (i.e., ultrasound biofeedback). The treatment programs that will be compared here differ on the point at which principles of motor learning (PML) are implemented. ReST is designed to plan for motor learning immediately, and therefore each session is designed to explicitly implement these principles. By contrast, ultrasound biofeedback is initially focused on skill acquisition (high performance) as a precursor to motor learning; while this progression may help children gradually transition to different types of feedback and practice, it is unclear whether this will accelerate or hinder learning.

3.2 Secondary Objectives

To establish an effect size which can be used for subsequent larger trials. Pending the results, effect sizes observed here can be used to drive power calculations for future larger-scale studies that may involve variations on the implementation of the procedures for these approaches.

To determine which, if any, participant variables predict performance in this study. Additional qualitative analysis will be conducted to examine treatment responders/non-responders in both interventions. Although our sample sizes will be limited, we will use the current data to explore whether there are pre-treatment profiles that indicate which children respond well within each intervention. Future studies could then be devised to plan around pairing children to the approach that is most appropriate for their profile.



4. STUDY DESIGN

4.1 Type of Study

Randomised control trial.

4.2 Study Design

This is a two arm small RCT. The trial will conform to the CONSORT non-pharmacological RCT checklist. Using the large effect sizes obtained from Murray, McCabe & Ballard (2012) RCT (Cohen’s $d = 1.36$), Thomas, McCabe & Ballard (2014) experimental single case design ReST study ($d = 5.6$) and Preston’s (2013) experimental single case design CAS ultrasound study ($d = 2.7$), power of 0.9 and probability of 0.05, we calculate a sample size of 7 per group. Adding 15% for possible attrition we will recruit 16 children. Given these large effect sizes, we should have sufficient power to address the first hypothesis (both approaches will facilitate change from pre- to post-treatment).

RECRUITMENT

We will use rolling recruitment. Parents responding to recruitment advertisements will participate in eligibility screening over the phone or by email. They will be asked questions to ascertain whether they meet the eligibility criteria. They will be emailed the Participant Information Statement. If they are able to attend all assessment, therapy and probes, an initial assessment will be booked. Initial testing will establish each child’s speech, language skills and developmental history and measure severity of speech impairment.

Parents of children in both treatment groups are required to (a) do no speech homework and (b) refrain from other speech therapy during the treatment period and for 4 weeks following treatment completion. In our prior ReST studies, this has not been an issue for parents or clinicians.

TIMELINE

- August-September 2015: Following ethics approval, the University of Sydney will recruit the first wave of participants. A minimum of 8 participants is needed in this first wave with each clinician treating 2 participants.
- October –December 2015: Follow up data collection for participants in the first wave will be completed. Second wave participants will begin treatment.
- January – March 2016: Final treatment wave and follow-up probes and data collection.
- April – June 2016: Finalise data analysis and manuscript. Trial finishes.

Year \ Mth	1	2	3	4	5	6	7	8	9	10	11	12
2015	Setup, initial recruitment and training of staff						Rolling recruitment and treatment					
2016	Final treatment wave	Complete follow-up and data collection	Finalise analysis and manuscript submissions									



DIAGNOSIS

Following completion of the assessment, the single word and connected speech measures will be transcribed and the frequency of features of CAS recorded. Diagnosis of CAS will require each child to meet all ASHA minimum consensus based criteria as operationalised by Murray et al., (2014). Transcription will be performed by assessors independent of the examiner and blind to treatment condition. Intra and inter-rater reliability of transcription will be done on 20% of samples and acceptable if 85%. Diagnostic reliability will be reported.

TREATMENT PROCEDURES

ReST Treatment Protocol

Stimuli: ReST uses multi-syllable nonword stimuli that include varied consonants and vowels (C, V). Three C sounds are selected from each child's impaired sounds, plus 3 Vs. All possible CV units for the 6 sounds are randomly combined to form 40 strings, half with strong-weak (SW) stress and half weak-strong (WS) stress (e.g. KAdiku, biTUga), presented orthographically. A random selection of 50% of the stimuli will be treated and 50% will be tested for treatment generalization. Children unable to read the stimuli are given spoken models for imitation until independent production emerges (Ballard et al, 2010). No statistical difference in treatment outcome has been noted between imitation and reading (McCabe et al, 2014). To test ecological validity, 20 real words (same length and sounds as treated items, e.g. toboggan) are tested with naming in a 100-utterance speech sample.

Individual treatment sessions conducted by one of a pool of SPs will include 10 minute pre-practice and 50 minute practice in accordance with PML in ReST (Ballard et al, 2010). Pre-practice: Using 10 randomly selected stimuli, the clinician defines parameters of a correct response and guides the child through attempts at reading stimuli aloud or imitating a clinician model, with cues on articulatory accuracy and stress, with 100% feedback on performance. When the child achieves 5 correct productions with the guided cueing, or 10 minutes has elapsed, the session moves on to practice. Practice: 100 trials of reading aloud or imitating production of randomly selected treatment stimuli. Feedback on correctness is provided for 50% of randomly selected trials. Children randomised to ReST will receive 1 hour treatment per day for 2 days per week for 6 weeks, a total dose of 1200 practice trials at half the intensity of the completed RCT.

Ultrasound Treatment Protocol

Based on our previous work in the ultrasound biofeedback program, both in CAS and in Residual Speech Sound Errors, each child will have 4 target sequences available for treatment (CV, VC, or CC), although each session will be structured to address only two of those sequences; thus the target sequences will be cycled through in pairs (target sequence 1 and 2 treated for two sessions, followed by target sequence 3 and 4 treated for two sessions). Individual treatment sessions will be conducted by SPs for 60 minutes. Within the session, 10 minutes of pre-practice with the ultrasound will be provided to allow the clinician to instruct the client in the visual patterns associated with the two desired sequences. This will be followed by 50 minutes of structured practice, broken down into four 12-minute time blocks. These time blocks will alternate, allowing practice with the ultrasound in Time Block A, followed by practice without the ultrasound (i.e., generalization) in Time Block B, ultrasound in Time Block C, and finishing with no ultrasound training in Time Block D. A timer will be used to ensure adherence to this structure.

Practice items will begin with the target sequence in isolation (CV, VC, or in the case of a CC target this will be paired with a vowel e.g. CCV), but complexity will increase based on performance (from syllables to monosyllabic words, multisyllabic words, phrases, and sentences). Six trials will be attempted in a block, and advancement to more complex items with the same target sequence will



be contingent upon achieving at least 5 of 6 trials correct in the block (i.e., “step up”). Achieving 1 or 0 correct items will mean that the next practice attempt on that target sequence will “step down” to a simpler level of linguistic complexity. If the participant does not successfully “step up” to advance to more complex stimuli, then the next practice block will commence on the other treatment target sequence. Hence, practice will involve alternating between the two treatment targets throughout the session as a way to incorporate practice variability.

Within each block, the amount of feedback (knowledge of performance and knowledge of results) will be dependent upon the level of complexity that the child is attempting. Higher frequency feedback with more knowledge of performance (KP) will be provided in blocks targeting simpler linguistic items, and lower frequency feedback with less KP will be used in blocks addressing more complex items.

CLINICIANS

Practicing speech pathologists and the CI will assess all potential participants as well as treating some participants. Four student speech pathologists will treat participants as part of a supervised clinical placement. Students will be closely supervised during all treatment sessions via the clinic audio visual system. To avoid clinician bias each clinician (experienced or student) will treat at least 1 child from the ReST group and 1 child from the ultrasound biofeedback group.

DATA COLLECTION SCHEDULE

All children in both arms will complete an initial assessment and a baseline probe. Following completion of the treatment trial, children in both groups will participate in three post baseline probe data collection sessions conducted by SP assessors blinded to condition.

TREATMENT FIDELITY AND RELIABILITY

Treatment fidelity between SPs and CI 90% in mock sessions will be established prior to running participants as in previous studies. The SPs will measure inter-clinician treatment fidelity and reliability against each other (reliability in previous studies 92% and 90%, respectively; Murray et al, 2014).

DEPENDENT VARIABLES

The primary dependent variable in the experimental probes is the number of treated words correct, judged by a blinded assessor on a three point scale 2 = correct, 1 = one or two errors, 0 = more than two errors, as per DTTC (Strand et al, various). To be correct a child would need to articulate all sounds correctly, have no syllable segregations and use accurate prosody and resonance. Because target selection is different for both groups, this first analysis will involve only a within-group pre- to post-treatment comparison. However, the secondary dependent variables will be derived from a sentence imitation task. These will include (a) percent phonemes correct, and (b) the number of untreated real words produced with accurate prosody and without syllable segregation, as scored by two blinded assessors again judged using the three point scale. This perceptual measure is the gold standard and ecologically valid. Intra- and inter-rater reliability against a second, blinded assessor will be reported.

4.3 Number of participants

16 children (7-16 years) with CAS will be recruited through our existing research database, clinical SPs, our CAS research webpage, and community groups. Based on our previous work, to achieve 16 enrolled children we anticipate assessment of 28 potential participants (Murray, McCabe, Heard & Ballard, 2014). Child assent and carer consent will be obtained as per The University of Sydney



Human Ethics Committee (IRB).

4.4 Study sites

All assessment and treatment will be conducted at the Cumberland Campus (Lidcombe) of the University of Sydney in the Discipline of Speech Pathology.

4.5 Expected Duration of Study

Expected start date is August 2015 and expected end date is December 2015. Advertising and recruitment will begin in August 2015 and continue until 16 participants have been confirmed. The recruitment phase will take approximately 3 weeks from participants identifying themselves, screening and then 2 assessments. Treatment phases will last 6 consecutive weeks. 3 follow-up appointments will be booked after treatment for 1 week, 4 weeks and 3 months after treatment finishes. Data collection and treatment for final participants is expected to be December 2015.

4.6 Primary and Secondary Outcome Measures

Primary Outcome Measures

- Change over time in target consonants and vowels correct for ultrasound biofeedback condition
- Change over time in treated nonwords correct for both phonemes and lexical stress in the ReST condition
- Pre-treatment and post-treatment comparison of sentence level accuracy for:
 - percent phonemes correct (PPC), and;
 - prosodic accuracy (words with accurate stress and connected syllables).
- Percent consonants correct (PCC) and prosodic accuracy comparison between immediate post-treatment probe and at three month follow-up assessment

DATA ANALYSIS

Planned orthogonal contrasts will test for differences according to the aims and hypotheses and data probe collection.

Hypothesis 1: Paired t-tests will examine acquisition for treated targets to address the first aim. We hypothesize a significant difference between baseline performance and immediate post-treatment for both groups on the treated items (target consonants and vowels in the ultrasound biofeedback condition, and treated nonwords correct for both phonemes and lexical stress in the ReST condition). This will allow us to demonstrate that both treatments are efficacious when participants are randomly allocated to the respective conditions.

Hypothesis 2: The groups will be compared on pre-treatment to post-treatment change in sentence-level accuracy for (a) percent phonemes correct (PPC) and (b) prosodic accuracy (words with accurate stress and connected syllables). It is hypothesized that the ultrasound biofeedback group will show superior gains over the ReST group on PPC; conversely, it is hypothesized that the ReST group will show superior gains in prosodic accuracy over the ultrasound biofeedback group.

Hypothesis 3: To address the critical construct of learning, generalization and retention are required. Thus, we will compare PCC and prosodic accuracy at the immediate post-treatment session with a three month follow-up assessment. We hypothesize that ReST, which emphasizes principles of motor learning during all sessions will result in greater learning than ultrasound biofeedback, which begins with focus on skill acquisition prior to motor learning. However, if a gradual transition from

skills acquisition to motor learning is more effective, we anticipate that ultrasound biofeedback will result in greater growth from immediate post-treatment to follow-up.

Secondary Outcome Measures

To establish an effect size which can be used for subsequent larger trials. The current study is designed to be a preliminary investigation that could lead to future funding. Pending the results, effect sizes observed here can be used to drive power calculations for future larger-scale studies that may involve variations on the implementation of the procedures for these approaches.

To examine treatment responders/non-responders in both interventions. Qualitative analysis will be conducted to examine treatment responders/non-responders in both interventions. Although our sample sizes will be limited, we will use the current data to explore whether there are pre-treatment profiles that indicate which children respond well within each intervention. Future studies could then be devised to plan around pairing children to the approach that is most appropriate for their profile.

5. PARTICIPANT ENROLLMENT AND RANDOMISATION

5.1 Recruitment

Initial contact will be made by via flyers in a clinic waiting room or an email from administrative staff at the University's Communication Disorders Treatment and Research Clinic (CDTRC).

Please see copies of the flyer (Appendix E), email text to Speech Pathologists (Appendix F), and email to previous research participants (Appendix G).

- The flyer will be placed in the waiting room of the Communication Disorders Treatment and Research Clinic once ethics approval is granted.
- The email, with the flyer attached, will be sent to Speech Pathology contacts of the Speech Pathology Discipline and the Communication Disorders Treatment and Research at The University of Sydney on one occasion only after approval from the ethics committee.
- The email to previous research participants will be sent once.

Only previous participants who have given written consent for information about future research will be emailed the flyer. People on the Speech Pathology/ CDTRC mailing list have given their email address for information about activities of the clinic including upcoming research. Participants will be advised to notify the discipline/ clinic if they no longer wish to be on the mailing list.

Initial emails about the research will be sent to participants who are in possible unequal relationships with the Chief Investigator by the Project Manager Pippa Evans who has no relationship with them and will answer their queries.

Potential participants will be screened for eligibility over the phone or by email. Parents/carers will be asked questions to ascertain whether children meet the eligibility criteria. They will be emailed the Participant Information Statement. If they are able to attend all assessment, therapy and probes, an initial assessment appointment will be booked.

5.2 Eligibility Criteria

5.2.1 Inclusion Criteria

Children who meet the following criteria will be included:

- diagnosis of CAS through consensus over 2 expert judges
- 7-16 years old
- no other motor speech disorder (i.e. dysarthria) or structural deficit (e.g. cleft palate)
- nonverbal intelligence, receptive language and oral-facial exam within normal range
- normal (corrected to normal) hearing and vision
- no other developmental or genetic diagnosis
- Australian English as first and primary language

5.2.2 Exclusion Criteria

Previous participation in ReST treatment research in since 1st January 2013.

5.3 Informed Consent Process

All parent/carers of participants will provide written consent as outlined in the NHMRC National Statement on Ethical Conduct in Human Research (2007), section 2.2.5. For all participants, their parent/carer will provide written consent and the child will provide written assent. Participants under the age of 12 will be provided with a Child Assent Form (Appendix D) explaining the study in child friendly language with contact details for members of the research team if they require any further clarification. Participants 12 years and older will be provided the same Participant Information Statement (PIS) as their parent and both will be asked to sign the Parent & Child Consent Form (Appendices B & C). The PIS and consent forms will be emailed to participants before the first assessment appointment. They will be asked to bring these to the assessment in order to avoid the risk of coercion.

5.4 Enrolment and Randomisation Procedures

Once parent consent and child consent/assent has been given and all inclusion criteria have been met allocation will take place. Children will be allocated to one of two groups using online randomisation tool <https://www.sealedenvelope.com/simple-randomiser/v1/lists>. Block randomisation will be used for each treatment wave.

5.5 Blinding Arrangements

Members of the research team will not be blind to the treatment groups. Participant and therapist blinding is not possible due to the behavioural intervention in ReST and ultrasound biofeedback. Children randomised to either treatment group will complete the same probe list session one week prior to commencement of their treatment. Probes during and after treatment phases will be completed by blinded clinicians (either speech pathologist or different student clinician). After all treatment waves, randomised recordings from all participants will be assessed by an independent researcher to ensure blinding of outcome assessment.

Treatment will not stop for participants with no progress because in previous studies (Murray, McCabe & Ballard, 2012); Thomas et al. 2014) some participants did not improve until the 10th treatment session. Treatment will be stopped for non-compliant parents (e.g. continue to give child

speech homework/attend external speech therapy). The PIS advises participants can resume external speech therapy/homework after attending the 4 week post-treatment follow-up.

5.6 Participant Withdrawal

5.6.1 Reasons for withdrawal

Participating in the research project may have a financial cost for participants' families. They need to travel to the university campus for their initial assessment and treatment. For most families the small cost associated with transporting their child to the clinic and having internet access is outweighed by the benefit of a free comprehensive speech pathology assessment and 12 free speech pathology sessions. Participants will be advised via the Participant Information Statement about the commitment required, they are under no obligation to participate and they are free to withdraw at any time.

The child participants could find completing the assessment tasks and treatment frustrating due to the difficulties associated with CAS, which should be no more than they experience when communicating in daily life. All care will be taken to ensure that treatment tasks completed are appropriate for the participant's skills and pre-practice will be provided to make the treatment tasks clear. Assessments will be completed as appropriate for their skills level, with discontinuous rules observed. Verbal reinforcement and games will be used to ensure the experience is fun and participants are praised for their attempts and compliance. If participants become frustrated rest breaks will be provided.

If participants are sick/unable to attend sessions once they have been recruited, make-up sessions will be arranged for the near future.

5.6.2 Handling of withdrawals and losses to follow-up

Participants are welcome to withdraw from the project at any time, without jeopardising their relationship with the Speech Pathologist, the clinic or the University. At the point of withdrawing from the study they will be asked if they would prefer their information destroyed or for it to be included in the study. The sample size of 16 participants was based on 15% possible attrition. All participants who withdraw will be included in the reporting of the outcomes as withdrawn and results imputed on an intention to treat basis.

5.6.3 Replacements

No replacements will be used for participants who withdraw mid-treatment. Rolling recruitment should allow researchers to recruit additional participants if withdrawals occur.

5.7 Trial Closure

Follow-up sessions will occur over 3 months (at 1 week, 4 weeks and 3 months). No adverse effects are expected after the follow-up period. Parents/carers will be provided with reports indicating their child's individual speech skills following each measure (including pre and immediately post measures). At the conclusion of the study, every participant will be provided with a one page lay summary if they have indicated they would like one on their consent forms. There will be no further follow up outside of the 3 month measures.



6. STUDY VISITS AND PROCEDURES SCHEDULE CLINICAL ASSESSMENTS

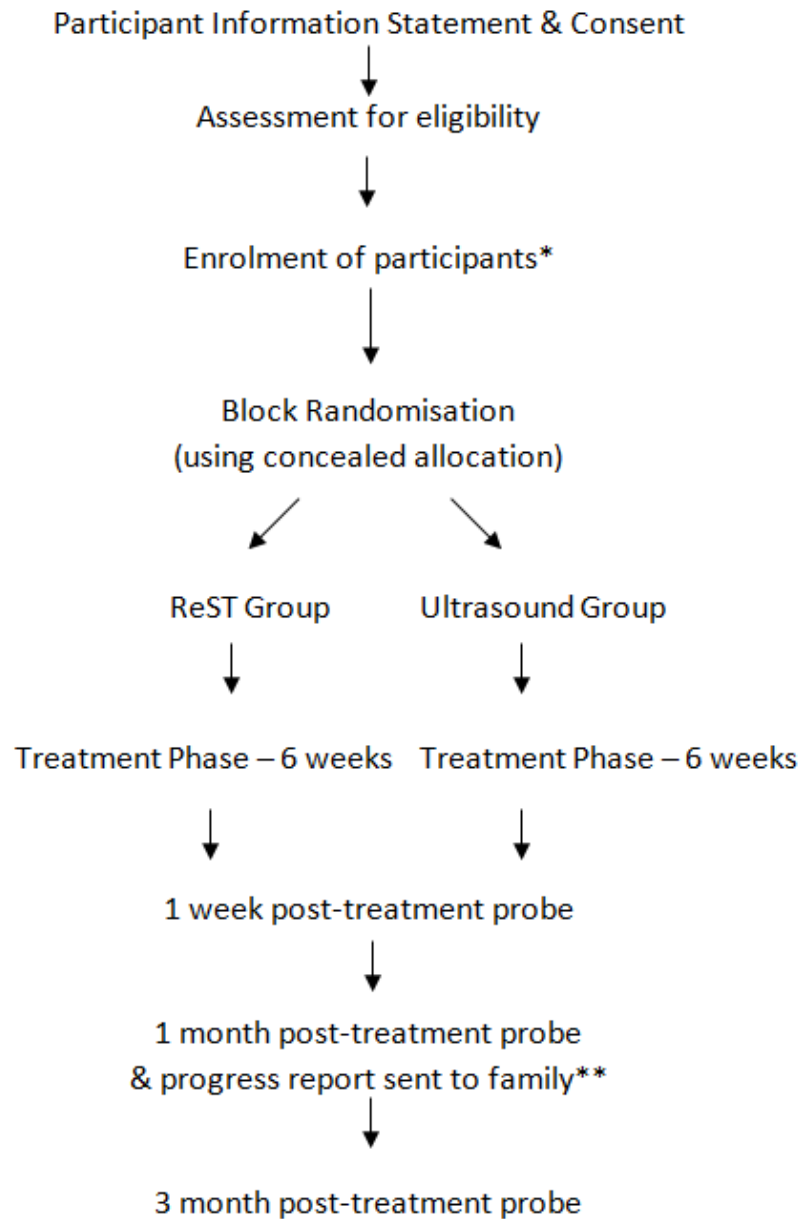
The initial eligibility and description assessment will comprise:

- single word measures (GFTOA-2; Single Word Test of Polysyllables-SWTP)
- connected speech measures (conversation)
- oral musculature assessment (OMA)
- assessment of digit span (verbal memory subtest of the CTOPP)
- nonword repetition (SRT)
- expressive and receptive language (CELF-4 Australian Ed)
- receptive vocabulary (PPVT-4)
- nonverbal intelligence (TONI-3)
- hearing screening.

Depending upon age and performance the assessment will take 90-120 minutes. Parents will be provided with a written summary report from the assessment. The screening component will run first (Hearing, OMA, TONI-3, CELF-4 receptive language, SWTP) with the detailed diagnostic and descriptive components following if the child passes the screening. All assessments will be video and audio recorded for later analysis.



Study Flow Chart



*Any external speech therapy and home therapy pauses

** external therapy/home therapy can resume



Participant visits

List Interventions	Visit number	Informed Consent	Inclusion / Exclusion criteria	Treatment session	Probe List
Assessment Visit 1	1	✓	✓		
Assessment Visit 2	2		✓		✓
Therapy 1	3			✓	✓
Therapy 2	4			✓	
Therapy 3	5			✓	
Therapy 4	6			✓	
Therapy 5	7			✓	✓
Therapy 6	8			✓	
Therapy 7	9			✓	
Therapy 8	10			✓	
Therapy 9	11			✓	✓
Therapy 10	12			✓	
Therapy 11	13			✓	
Therapy 12	14			✓	
1 week post therapy	15				✓
4 weeks post therapy	16				✓
Final Study Visit	17				✓

7. ADVERSE EVENT REPORTING

7.1 Definitions

Adverse event

An adverse event is any untoward occurrence which does not necessarily have a causal relationship with the investigational intervention. An adverse event could be expected or unexpected. An intervention is use of a drug, device, procedure or tool that is made with the intention to gauge health benefits or potential health benefits to people. For instance this can involve testing a drug, surgical procedure, or other therapeutic procedures and devices, a preventative procedure, or a



diagnostic device or procedure. Such interventions are not restricted to medical research and would also include interventions in speech pathology, exercise studies, cognitive therapy and other psychological interventions.

(Modified from http://sydney.edu.au/research_support/ethics/human/adverse-event-types.shtml)

Assessment and Documentation of Adverse Events

The following adverse events are considered possible:

- Child participants could find completing the assessment tasks and treatment frustrating due to the difficulties associated with CAS, which should be no more than they experience when communicating in daily life. All care will be taken to ensure that treatment tasks completed are appropriate for the participant's skills and pre- practice will be provided to make the treatment tasks clear. Assessments will be completed as appropriate for their skills level, with discontinue rules observed. Verbal reinforcement and games will be used to ensure the experience is fun and participants are praised for their attempts and compliance. If participants become frustrated rest breaks will be provided. All researchers are also experienced speech pathologists who will ensure any independent assessors are appropriately supervised.
- Following assessment of a child, a language delay/disorder or hearing difficulty is diagnosed which is then reported to the parent/carer causing the parent/carer to become upset. All reports will be written professionally in line with Speech Pathology Australia's guidelines (<http://www.speechpathologyaustralia.org.au/library/PrivatePracticeResources/Guide%20to%20report%20writing%20Feb%202015.pdf>). Parents will be provided with a number of therapy options both within the community and private sectors. The contact details of the research team, all experienced Certified Practising Speech Pathologists, will also be provided on the written report so that parents/carers can contact them if they would like to further discuss their child's results'. There is a small risk this could occur however due to the age of participants being sought, children with CAS have generally been seeing speech pathologists since infancy and have had hearing and, speech and language assessments before.

Specific Safety Considerations

Participants receiving ultrasound treatment may ask about the imaging technology and safety. Participants will be advised ultrasounds convert high frequency sound waves into a real time picture. There is no known radiation, toxicity or side effects from using an ultrasound machine. Ultrasound gel is hypoallergenic, bacteriostatic, non-sensitizing, non-irritating and should not stain clothes.

8. STATISTICAL METHODS

8.1 Sample Size Estimation

Using the large effect sizes obtained from Murray et al.'s RCT (cohen's $d = 1.36$), Thomas et al's (2014) experimental single case design rest study ($d_2 = 5.6$) and Preston's (2013) experimental single case design CAS ultrasound study ($d_2 = 2.7$), power of 0.9 and probability of 0.05, we calculate a sample size of 7 per group. Adding 15% for possible attrition we will recruit 16 children. Given these large effect sizes, we should have sufficient power to address the first hypothesis (both approaches will facilitate change from pre- to post-treatment).

8.2 Population to be analysed

Children aged 7-16 years with CAS.

8.3 Statistical Analysis Plan

ANOVA will be used to check for significant differences between participants. For statistically significant comparisons, Cohen's d effect sizes will be calculated.

Treatment effects between the two groups will be analysed using ANCOVAs for treated and untreated stimuli with age likely being the covariate. Comparisons for each primary and secondary outcome measure will address study aims and hypotheses: (1) pre-treatment versus within 1-week post-treatment to assess acquisition of treatment and generalization effects, (2) 1-week versus 1-month post-treatment to assess short-term maintenance of these effects, and (3) 1-week versus 3-months post-treatment to test longer maintenance. For each comparison, the within-subjects variables were based on time (e.g., treated items at pre- and 1-week post-treatment) and between-subjects variable was treatment (ReST or Ultrasound), giving results for each type of variable and the interaction between them (Time x Group).

An intention-to-treat analysis will be used with participants who withdraw.

9. DATA MANAGEMENT

9.1 Data Collection

Data will be collected;

- directly from children during assessment session at the clinic in which a practising speech pathologist will provide a detailed speech and language. Treatment data will be collected by practicing speech pathologist/student clinician in the clinic room with the child as well as by supervising speech pathologist observing via the audio-visual system.
- indirectly from forms filled out by parents

9.2 Data Storage

All hard copies of study materials will be stored in locked filing cabinet's Tricia McCabe's office. Pippa Evans will respond to interested participants and assess them. During the actual assessment (2 x 1.5 hours) sessions, treatment (12 sessions) and follow up appointments (3 sessions), paper files will be held for that period in the clinical room where the participant is being assessed or treated and then returned to secure storage. Electronic copies of the audio and video data will be stored the University's password protected research server. Once potential participants are assessed their assessment results will be kept in S153. Potential participants' contact details may be stored in emails to Pippa Evans as part of the screening process as per electronic records procedure.

9.3 Data Confidentiality

Participants will be referred to by a code or pseudonym in all publications. No information which could be used to identify participants specifically such as date of birth or suburb of residence will be referenced in any publication or presentation. Pseudonyms or codes e.g. M03 will be used for participants when reporting results. No video or audio recordings of participants will be shown as part of research dissemination. No identifying information will be used in any presentation or publication.

It is important to be able to re-identify data if parents or participants have legal or medical reasons to do so. As this is treatment, parents may ask us at a future date to describe how their child performed or to talk with another health professional. To not be able to re-identify the files would



limit this real- world clinical relationship/ function. The code will be securely stored separately to all other information including the consent forms. Only the CI will have access to the code once data collection is complete.

9.4 Study Record Retention

Records will be retained for 20 years or until subjects are 25 due to legal reasons (participants are children and therefore these treatment records will be retained for the period). At the end of the record retention period, paper data will be securely shredded and audio and video files deleted from the University server.

10. ADMINISTRATIVE ASPECTS

10.1 Independent HREC approval

This study has been approved by the University of Sydney HREC, **2015/516**

10.2 Amendments to the protocol

Any amendments will be submitted to the HREC for review prior to implementation as per HREC guidelines.

10.3 Protocol deviations

Any protocol deviations will be submitted to the HREC for review.

10.4 Participant reimbursement

Individual participants will receive a speech pathology report outlining their own progress as a result of participation in the treatment study. All participants will receive an electronic newsletter outlining the overall research outcomes. Participants will receive a comprehensive speech and language report and 12 free treatment sessions. They will not be paid for being part of the study.

10.5 Financial disclosure and conflicts of interest

This RCT is being funded by CASANA grant of US\$35,000 (<http://www.apraxia-kids.org/casana-accepting-requests-for-apraxia-research-funding/>).

Tricia McCabe is an Associate Professor in the Discipline of Speech Pathology, University of Sydney, Honorary Research Fellow at the Murdoch Children's Research Institute and Speech Pathologist at Cate Madill Voice & Speech. Jonathan Preston is Assistant Professor, Syracuse University and Research Scientist, Haskins Laboratories. Pippa Evans is a speech pathologist at the University of Sydney and Sylvanvale Foundation.

11. USE OF DATA AND PUBLICATIONS POLICY

Use of data:

The primary goal of this research is to contribute to the current evidence base for improving treatment for CAS. The results are expected to be published in peer reviewed journal articles, presented at conferences in the USA and Australia.

All participants will be offered the opportunity via a tick-a-box option on their Participant Consent Forms to receive a lay summary of the research once the study is complete.



Publication Policy:

The authors of any papers written as a result of this study will be drawn from the research team; Tricia McCabe, Jonathan Preston and Pippa Evans. Additionally, honours students not yet recruited may be brought in to assist on the project and their names (currently unknown) would also be added to the relevant paper.

12. REFERENCES

- Adler-Bock, M., Bernhardt, B., Gick, B., & Bacsfalvi, P. (2007). The use of ultrasound in remediation of north american english /r/ in 2 adolescents. *American Journal of Speech-Language Pathology*, 16, 128-139. doi: 10.1044/1058-0360(2007/017)
- ASHA. (2007). Childhood apraxia of speech [Technical report]. Available from www.asha.org/policy.
- Bacsfalvi, P. (2010). Attaining the lingual components of /r/ with ultrasound for three adolescents with cochlear implants *Journal of Speech-Language Pathology and Audiology*, 34, 206-217.
- Bacsfalvi, P., & Bernhardt, B.M. (2011). Long-term outcomes of speech therapy for seven adolescents with visual feedback technologies: Ultrasound and electropalatography. *Clin Linguist Phon*, 25, 1034-1043. doi: 10.3109/02699206.2011.618236
- Bacsfalvi, P., Bernhardt, B.M., & Gick, B. (2007). Electropalatography and ultrasound in vowel remediation for adolescents with hearing impairment. *International Journal of Speech-Language Pathology*, 9, 36-45. doi:10.1080/14417040601101037
- Ballard, Robin, McCabe & McDonald (2010). A treatment for dysprosody in childhood apraxia of speech. *Journal of Speech Language and Hearing Resesearch*, 53, 1227-1245.
- Bernhardt, B., Bacsfalvi, P., Adler-Bock, M., Shimizu, R., Cheney, A., Giesbrecht, N., . . . Radanov, B. (2008). Ultrasound as visual feedback in speech habilitation: Exploring consultative use in rural british columbia, canada. *Clinical Linguistics & Phonetics*, 22, 149 - 162.
- Bernhardt, B., Bacsfalvi, P., Gick, B., Radanov, B., & Williams, R. (2005). Exploring the use of electropalatography and ultrasound in speech habilitation. *Journal of Speech-Language Pathology and Audiology*, 29(4), 169-182.
- Bernhardt, B., Gick, B., Bacsfalvi, P., & Adler-Bock, M. (2005). Ultrasound in speech therapy with adolescents and adults. *Clinical Linguistics & Phonetics*, 19, 605-617.
- Gierut, Morrisette & Ziemer (2010). Nonwords and Generalization in Children With Phonological Disorders. *American Journal of Speech-Language Pathology*, 19, 167-177.
- Forrest (200)3. Diagnostic criteria of developmental apraxia of speech used by clinical speech-language pathologists. *American Journal of Speech-Language Pathology*, , 12, 376-380.
- Maas, E., Robin, D.A., Austermann Hula, S.N., Freedman, S.E., Wulf, G., Ballard, K.J., & Schmidt, R.A. (2008). Principles of motor learning in treatment of motor speech disorders. *American Journal of Speech-Language Pathology*, 17(3), 277-298. doi: 10.1044/1058-0360(2008/025)
- McAllister Byun, T., Hitchcock, E.R., & Swartz, M.T. (in press). Retroflex versus bunched in treatment for rhotic misarticulation: Evidence from ultrasound biofeedback intervention. *Journal of Speech, Language, and Hearing Research*. doi: 10.1044/2014_JSLHR-S-14-0034
- McCabe & Ballard. (2008). *An Innovative Syllable Transition Treatment Trial for Childhood Apraxia of Speech*. Motor Speech Conference, March 2008, Monterey, CA, USA.
- McCabe, Macdonald-D’Silva, van Rees, Ballard & Arciuli (2014). Orthographically sensitive treatment for dysprosody in children with Childhood Apraxia of Speech using ReST intervention. *Developmental Neurorehabilitation*.
- Modha, G., Bernhardt, B., Church, R., & Bacsfalvi, P. (2008). Ultrasound in treatment of /r/: A case study. *Intl. Jnl. of Lang. & Communication Disorders*, 43(3), 323-32



- Morgan, A., & Vogel, A. (2009). A Cochrane review of treatment for childhood apraxia of speech. *European Journal of Physical and Rehabilitation Medicine*, 45(1), 103-110.
- Murray, McCabe & Ballard (2012). A comparison of two treatments for childhood apraxia of speech: Methods and treatment protocol for a parallel group randomised control trial. *BMC Pediatrics*, 12, 112.
- Murray, McCabe & Ballard (2014). A Systematic Review of Treatment Outcomes for Children With Childhood Apraxia of Speech. *American Journal of Speech Language Pathology*, 23(3), 486-504.
- Murray, McCabe, Heard & Ballard (2014). A Randomized Control Trial of Treatments for Childhood Apraxia of Speech. *J Speech Lang Hear Res*.
- Preston, J.L., & Leaman, M. (2014). Ultrasound visual feedback for acquired apraxia of speech: A case report. *Aphasiology*, 28(3), 278-295. doi: 10.1080/02687038.2013.852901
- Preston, J.L., Brick, N., & Landi, N. (2013). Ultrasound biofeedback treatment for persisting childhood apraxia of speech. *Am J Speech Lang Pathol*, 22(4), 627-643. doi: 10.1044/1058-0360(2013/12-0139)
- Preston, J.L., McCabe, P., Rivera-Campos, A., Whittle, J.L., Landry, E., & Maas, E. (in press). Ultrasound visual feedback treatment and practice variability for residual speech sound errors. *Journal of Speech, Language, and Hearing Research*. doi: 10.1044/2014_JSLHR-S-14-0031
- Pring, Flood, Dodd & Joffe 2012. The working practices and clinical experiences of paediatric speech and language therapists: A national UK survey. *Int J Lang & Comm Dis*, 47, 696-708.
- Robey, R.R. (2004). A five-phase model for clinical-outcome research. *Journal of Communication Disorders*, 37(5), 401-411.
- Schmidt & Lee (2011). *Motor control and learning: A behavioral emphasis*, Champaign, IL, Human Kinetics.
- Thomas, D., McCabe, P. & Ballard, K.J. (2014). Rapid Syllable Transitions (ReST) Treatment for Childhood Apraxia of Speech: The Effect of Lower Dose Frequency. *Journal of Communication Disorders*, 51, 29-42.
- van Rees, Ballard, McCabe, Macdonald-D'Silva & Arciuli (2012). Training Production of Lexical Stress in Typically Developing Children with Orthographically Biased Stimuli and Principles of Motor Learning. *American Journal of Speech-Language Pathology*, 1058-0360_2012_11-0008.
- Williams & Stephens (2010). The Nuffield Centre Dyspraxia Programme. In: Williams, McLeod & McCauley (eds.) *Interventions for Speech Sound Disorders in Children*. Baltimore, MD: Paul H. Brookes Publishing Co.



13. APPENDICES

Appendix A: Parent/Carer Participant Information Statement (PIS)	24
Appendix B: Parent/Carer Consent Form (PCF)	26
Appendix C: Parent Consent & Child (12-16yrs) Assent Form	28
Appendix D: Child (7-11yrs) Assent Form	30
Appendix E: Flyer	33
Appendix F: Email text to Speech Pathologists re. recruitment flyer	34
Appendix G: Email text to previous research participants	35
Appendix H: Web ad	36



ABN 15 211 513 464

PATRICIA McCABE PhD
Associate Professor, Course Director BAppSc (Speech Pathology)

Room S153
Building C43
The University of Sydney
NSW 2006 AUSTRALIA
Telephone: +61 2 9351 9747
Facsimile: +61 2 9351 9173
Email: tricia.mccabe@sydney.edu.au
Web: <http://www.sydney.edu.au/>

Participant information sheet

A randomized control trial comparing ultrasound visual feedback and ReST (Rapid Syllable Transition Training) to improve speech in Childhood Apraxia of Speech (CAS).

PARTICIPANT INFORMATION STATEMENT

You and your child are invited to take part in a research study looking into the effectiveness of two treatments for children with childhood apraxia of speech (also known as dyspraxia). This study will compare the Rapid Syllable Transitions (ReST) treatment and Ultrasound Biofeedback treatment. Both of these treatments have been effective in previous studies. Children in this study will be randomly allocated to receive either ReST or Ultrasound Biofeedback treatment.

The study is being conducted by Dr Tricia McCabe at the University of Sydney in consultation with Dr Jonathan Preston from Syracuse University in New York.

If you agree to your child participating in this study, we will ask you and your child to do the following:

1. Attend two (2) assessment sessions (1 – 1.5 hrs each) to obtain information about your child's current speech and language skills. The assessment will involve tests typically used in speech pathology services. You will receive a brief report of your child's assessment results. Your involvement may end at this time.
2. If you continue in the study, your child will be asked to:
 - a. Attend one 30 minute session to assess his/her ability to say a set of words one week before the first therapy session.
 - b. Attend twelve 1 hour treatment sessions across 6 weeks. Treatment will be either Ultrasound Biofeedback or ReST for all 12 sessions.
 - c. Attend one 30 minute session to assess his/ her ability to say the set of words one week after the final therapy session.

A randomized control trial comparing ultrasound visual feedback and ReST (Rapid Syllable Transition Training) to improve speech in Childhood Apraxia of Speech (CAS).

Version 2 (22 July 2015)

Page 1 of 2



APPENDIX A: PIS For Parents/Carers

- d. Attend one 30 minute session to assess his/her ability to say the set of words 4 weeks after the treatment to measure any changes in speech skill after the treatment has finished.
- e. Attend one 30 minute 3 months after the end of the treatment to measure any changes in speech skills.

We require that your child receives no other treatment and no home practice while they are participating in the study, up until the assessment 4 weeks after the end of treatment. He or she is able to return to regular speech pathology sessions between the 4 week and 2 month follow up sessions.

The assessments, all of the treatment sessions and all follow-up sessions will be conducted at the Communication Disorders Treatment and Research Clinic at the University of Sydney at Lidcombe.

There is some possibility that your child may become frustrated during an assessment or treatment session. This should not be greater than any frustration s/he experiences when communicating in daily life. The clinic-based sessions will be conducted or supervised by qualified speech pathologists experienced in working with children who have speech difficulties.

All aspects of the study, including results, will be strictly confidential and only the investigators named above will have access to information on participants. A report of the study will be submitted for publication, but individual participants will not be identifiable in the report.

Participation in this study is entirely voluntary: your child is not obliged to participate and – if s/he does participate – you can withdraw your child from the study at any time. Whatever your decision, it will not affect your treatment or your relationship with speech pathology staff or the University.

When you have read this information, Pippa Evans or Tricia McCabe will discuss it with you further and answer any questions you may have. If you would like to know more at any stage, please feel free to contact Pippa on 9351 9713 (Mon, Wed, Fri) or Tricia on 9351 9747.

Any person with concerns or complaints about the conduct of a research study can contact the Deputy Manager, Human Ethics Administration, University of Sydney on +61 2 8627 8176 (Telephone); +61 2 8627 8177 (Fax); ro.humanethics@sydney.edu.au (Email).

This information sheet is for you to keep.

A randomized control trial comparing ultrasound visual feedback and ReST (Rapid Syllable Transition Training) to improve speech in Childhood Apraxia of Speech (CAS).



APPENDIX B: Parent/Carer Consent Form



ABN 15 211 513 464

PATRICIA McCABE PhD

Assoc Professor, Course Director BAppSc(Speech Pathology)

Room S153
Building C43, Cumberland Campus
The University of Sydney
Lidcombe NSW 2141 AUSTRALIA
Telephone: +61 2 9351 9747
Email: tricia.mccabe@sydney.edu.au
Web: <http://www.sydnev.edu.au/>

PARENTAL (OR GUARDIAN) CONSENT FORM

I, agree to permit

who is aged years, to participate in the research project:

A randomized control trial comparing ultrasound visual feedback and ReST (Rapid Syllable Transition Training) to improve speech in Childhood Apraxia of Speech (CAS).

In giving my consent I acknowledge that:

1. I have read the Information Statement, which explains the aims and the nature of the study and the possible risks.
2. The procedures required for the project and the time involved for my participation and my child's participation in the project have been explained to me, and any questions I have about the project have been answered to my satisfaction.
3. I agree that research data gathered from the results of the study may be published provided that my child is not identified.
4. I understand that there is a small risk of my child becoming tired or frustrated during the study. I understand that the researcher Dr Tricia McCabe is an experienced speech pathologist and is used to managing such situations. Dr McCabe will be supervising other treating speech pathologists and student speech pathologists during the study. I am aware that if my child becomes tired or frustrated, he/she will be offered a rest break.
5. I understand that being in this study is completely voluntary – I am not under any obligation to consent to my child's participation.
6. I understand that I can withdraw my child from the study at any time without affecting my/my child's present or future relationship with the researchers or the University of Sydney.

A randomized control trial comparing ultrasound visual feedback and ReST (Rapid Syllable Transition Training) to improve speech in Childhood Apraxia of Speech (CAS).



APPENDIX B: Parent/Carer Consent Form

- 7. I understand with my withdrawal from the study, I will be asked if I would prefer to all audio and video recordings to be erased and the information provided excluded from the study or whether I am happy for the data already collected to be used in the study.
- 8. If I have any questions relating to my child's participation in this study, I can contact Pippa Evans (9351 9713, pippa.evans@sydney.edu.au) or Tricia McCabe (9351 9747, tricia.mccabe@sydney.edu.au).
- 9. I have a received a copy of this Consent Form and the Parental Information Sheet.
- 10. I consent to:

i) Audio and video recording YES NO

I understand that these recordings will be used for data collection and analysis purposes, and that they will be viewed by the researchers.

If you do not consent to recording we thank you for your time but will not be able to include you in the research further.

ii) Being contacted for other projects YES NO

iii) Receiving feedback at the end of the study YES NO

If you answered YES to the "Receiving Feedback"- Question (iii), please provide your details i.e. mailing address, email address.

Contact details:

Parent (Guardian's) Consent

.....
Signature of Parent/ Guardian

.....
Please PRINT name

.....
Date

Any person with concerns or complaints about the conduct of a research study can contact The Manager, Human Ethics Administration, University of Sydney on +61 2 8627 8176 (Telephone); +61 2 8627 8177 (Facsimile) or ro.humanethics@sydney.edu.au (Email).

A randomized control trial comparing ultrasound visual feedback and ReST (Rapid Syllable Transition Training) to improve speech in Childhood Apraxia of Speech (CAS).

APPENDIX C: Parent Consent & Child (12-16yrs) Assent Form



Discipline of Speech Pathology
Faculty of Health Sciences

ABN 15 211 513 464

PATRICIA McCABE PhD
*Associate Professor, Course Director BAppSc(Speech
Pathology)*

Room S153
Building C43
The University of Sydney
NSW 2006 AUSTRALIA
Telephone: +61 2 9351 9747
Facsimile: +61 2 9351 9173
Email: tricia.mccabe@sydney.edu.au
Web: <http://www.sydney.edu.au/>

PARENTAL (OR GUARDIAN) & PARTICIPANT CONSENT FORM

I, agree to permit,
who is aged years, to participate in the research project

A randomized control trial comparing ultrasound visual feedback and ReST (Rapid Syllable Transition Training) to improve speech in Childhood Apraxia of Speech (CAS).

In giving my consent I acknowledge that:

1. I have read the Information Statement, which explains the aims and the nature of the study and the possible risks.
2. The procedures required for the project and the time involved for my participation and my child's participation in the project have been explained to me, and any questions I have about the project have been answered to my satisfaction.
3. I agree that research data gathered from the results of the study may be published provided that my child is not identified.
4. I understand that there is a small risk of my child becoming tired or frustrated during the study. I understand that the researcher Dr Tricia McCabe is an experienced speech pathologist and is used to managing such situations. I am aware that if my child becomes tired or frustrated, he/she will be offered a rest break.
5. I understand that being in this study is completely voluntary – I am not under any obligation to consent to my child's participation.

A randomized control trial comparing ultrasound visual feedback and ReST (Rapid Syllable Transition Training) to improve speech in Childhood Apraxia of Speech (CAS).

Version 1

Page 1 of 2



APPENDIX C: Parent Consent & Child (12-16yrs) Assent Form

- 6. I understand that I can withdraw my child from the study at any time without affecting my/my child's present or future relationship with the researchers, the University of Sydney or the CDTRC.
- 7. I understand with my withdrawal from the study, I will be asked if I would prefer to all audio and video recordings to be erased and the information provided excluded from the study or whether I am happy for the data already collected to be used in the study.
- 8. I understand that if I have any questions relating to my child's participation in this study, I can contact Pippa Evans (9351 9713, pippa.evans@sydney.edu.au) or Tricia McCabe (9351 9747, tricia.mccabe@usyd.edu.au).
- 9. I have a received a copy of this Consent Form and the Parental Information Sheet.

10. I consent to:

i) Audio and video recording YES NO

I understand that these recordings will be used for data collection and analysis purposes, and that they will be viewed by the researchers (Dr. McCabe and Dr Preston) and research assistant of the study (Pippa Evans).

ii) Being contacted for other projects YES NO

iii) Receiving feedback at the end of the study YES NO

If you answered YES to the "Receiving Feedback"- Question (iii), please provide your details i.e. mailing address, email address.

Contact details:

.....
Signature of Parent/ Guardian

.....
Signature of Participant (Child)

.....
Please PRINT name

.....
Please PRINT name

.....
Date

.....
Date

Any person with concerns or complaints about the conduct of a research study can contact The Manager, Human Ethics Administration, University of Sydney on +61 2 8627 8176 (Telephone); +61 2 8627 8177 (Facsimile) or ro.humanethics@sydney.edu.au (Email).

A randomized control trial comparing ultrasound visual feedback and ReST (Rapid Syllable Transition Training) to improve speech in Childhood Apraxia of Speech (CAS).

APPENDIX D: Child (7-11yrs) Assent Form

Study Information Sheet: A study comparing 2 treatments for Apraxia in children.



Hello. Our names are

- Pippa Evans
- Tricia McCabe

We want to find out more about therapy for kids with speech problems.

We are asking you to be in our study because we would like to see how well our speech therapy works.

You can decide if you want to take part in the study or not. You don't have to - it's up to you.

This sheet tells you what we will ask you to do if you decide to take part in the study. Please read it carefully so that you can make up your mind about whether you want to take part.

If you decide you want to be in the study and then you change your mind later, that's OK. All you need to do is tell us that you don't want to be in the study anymore.

If you have any questions, you can ask us or your family or someone else who looks after you. If you want to, you can call Pippa any time on 9351 9713 or Tricia on 9351 9747.

What will happen if I say that I want to be in the study?

If you decide that you want to be in our study, we will ask you to do these things:

- The first 2 or 3 sessions you will come and we will check your speech sounds. You may not need to come again after these sessions.

If you do keep coming, we will ask you to do these things:

- Come to the speech therapy clinic at the University of Sydney 2 times a week for 6 weeks. You may have visited the clinic before.
- Practise saying sounds and words with the speech therapist.
- You will always come with an adult you know. They will wait for you in the waiting room while you have speech therapy.
- After therapy is finished, we would like to see you 3 more times to check your speech.

APPENDIX D: Child (7-11yrs) Assent Form

When we ask you questions, you can choose which ones you want to answer. If you don't want to talk about something, that's OK. You can stop talking to us at any time if you don't want to talk to us anymore.

If you want to do the research we will record what you say with a computer or voice recorder and a video recorder.

Will anyone else know what I say in the study?



We won't tell anyone else what you say to us, except if you talk about someone hurting you or about you hurting yourself or someone else. Then we might need to tell someone to keep you and other people safe.

All of the information that we have about you from the study will be stored in a safe place and we will look after it very carefully. We will write a report about the study and show it to other people but we won't say your name in the report and no one will know that you were in the study.

How long will the study take?



- We will see you 2 or 3 times to check your speech.
- Then we will start speech therapy and see you 2 times a week. We would see for 6 weeks of therapy.
- Sessions will be for 1 hour but we won't be practising sounds for the whole hour. You will get little breaks during the session where we will play games or do activities.

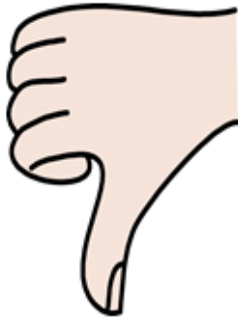
Are there any good things about being in the study?



Your talking should get a bit better if you are in the study. It won't be perfect but we think it will get a little easier for you to say some words. You won't get any money for being in the study, but you will be helping us do our research.

APPENDIX D: Child (7-11yrs) Assent Form

Are there any bad things about being in the study?

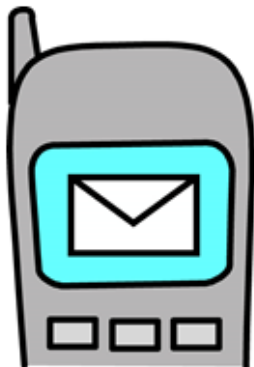


This study will take up some of your time, but we don't think it will be bad for you or cost you anything.

Will you tell me what you learnt in the study at the end?

Yes, we will if you want us to. There is a question on the next page that asks you if you want us to tell you what we learnt in the study. If you circle Yes, when we finish the study we will tell you what we learnt.

What if I am not happy with the study or the people doing the study?



If you are not happy with how we are doing the study or how we treat you, then you or the person who looks after you can:

- Call the university on 02 8627 8176 or
- Write an email to ro.humanethics@sydney.edu.au.

If you have read these sheets and want to be in the study, please write your name and the date below.

.....
Please PRINT name

.....
Date

These sheets are for you to keep.

The pictures we used in this sheet are from Microsoft Clip Art and from the people at Inspired Services Publishing (www.inspiredservices.org.uk). They said it's ok for us to use them.



A randomized control trial comparing ultrasound visual feedback and ReST (Rapid Syllable Transition Training) to improve speech in Childhood Apraxia of Speech (CAS).

Flyer Version 2. 6th July 2015

Does your child have Apraxia?

Children with Childhood Apraxia of Speech (dyspraxia) have severe speech difficulties which often affect their literacy, social and academic skills.

Recent studies have shown that there are different ways a Speech Pathologist can treat Childhood Apraxia of Speech. We want to compare two treatments in order to better understand why they work.

What is involved?

- An assessment of your child's speech and language skills
- Twelve 1 hour treatment sessions at the clinic over 6 weeks. No home practice is required.
- Other assessments after treatment
- No cost involved

Who can take part?

We are looking for children who.....

- Have Childhood Apraxia of Speech (Verbal dyspraxia)
- Are 7 – 16 years old
- Have normal or adjusted to normal vision and hearing
- Have no other developmental diagnoses
- Australian English as first and primary language.

What will I gain from the study?

- Report on your child's assessment
- 12 sessions of free speech therapy
- An improvement in your child's speech



Contact

If you want to know more or are interested in taking part, please contact:

Pippa Evans
Speech Pathologist
pippa.evans@sydney.edu.au
9351 9713 (M, W, F)

Dr Tricia McCabe
Speech Pathologist
tricia.mccabe@sydney.edu.au
9351 9747

This study has been granted ethics approval by the University of Sydney Human Research Ethics Committee

**APPENDIX F: Email text to Speech Pathologists re recruitment flyer.
Version 1. 11th May 2015***Text of email to Speech Pathologists in the CDTRC/ Discipline of Speech
Pathology mailing list***Subject: Research into Treatment of Childhood Apraxia of Speech (Dyspraxia).**

Dear Speech Pathologist or Health Professional,

We are doing a pilot Randomized Control Trial providing treatment for children with Childhood Apraxia of Speech using the ReST treatment or Ultrasound Biofeedback. ReST is a newly developed program, based on motor learning principles. It was shown to be effective in treating CAS in a Randomized Controlled Trial and Single Case Design study.

Ultrasound Biofeedback treatment trains articulatory patterns using real-time visual displays of the tongue. It has recently been shown to improve productions of consonants and vowels involving the tongue in several Single Case Design studies. This study aims to compare ReST and Ultrasound Biofeedback results when treating CAS in school-age children. Treatment sessions will be delivered by Speech Pathologist or trained Student Speech Pathologist with no home practice required.

We are looking for potential participants with a current diagnosis of dyspraxia or Childhood Apraxia of Speech who will be between the ages of 7;0 and 16;0 years between May 2015 and January 2016. Participants will also have normal or adjusted to normal hearing and vision; no receptive language disorder; speak Australian English and have no other developmental or genetic diagnoses.

I would be very grateful if you could display the attached flyer in your waiting room or hand it to any parents you think may be interested and am happy to answer any questions you might have. I do not need you to ask the parents if they want to be involved.

The research is being conducted by myself and Dr Jonathan Preston. All clinic-based sessions will take place at the Communication Disorders Treatment and Research Clinic on East Street at Lidcombe. This study has been granted ethics approval by the University of Sydney Human Research Ethics Committee.

Sincerely,
Dr Tricia McCabe
Discipline of Speech Pathology
Faculty of Health Sciences
University of Sydney
Phone: 9351 9747

Pippa Evans
Speech Pathologist
Faculty of Health Sciences
University of Sydney
Phone: 9351 9713 (M,W,F)
Email: pippa.evans@sydney.edu.au



McCabe & Preston

A randomized control trial comparing ultrasound visual feedback and ReST (Rapid Syllable Transition Training) to improve speech in childhood apraxia of speech (CAS).

APPENDIX G: Email text to previous research participants Version 1

Text of email to previous research participants who consented to information about future research.

Subject: Research into treatment of Childhood Apraxia of Speech

Dear Parent/ Guardian,

I am writing to you because you indicated you were interested in information about future research in Childhood Apraxia of Speech, when your child participated in previous CAS research at the University of Sydney.

Please find attached a flyer about a treatment study for children with Childhood Apraxia of Speech being conducted by Speech Pathologists at The University of Sydney. This study will compare the Rapid Syllable Transitions (ReST) treatment and Ultrasound Biofeedback treatment. The study involves 12 therapy sessions at the clinic over 6 weeks with no home practice required.

There is no obligation for you to be involved in this research.

If you are interested in participating or would like more information please contact Pippa Evans, Speech Pathologist (9351 9713 (M, W, F) or pippa.evans@sydney.edu.au) or Dr Tricia McCabe, Speech Pathologist (9351 9747 or tricia.mccabe@sydney.edu.au).

Regards
Simone Drizos
Administration Assistant
Communication Disorders Treatment and Research Clinic

Version 1. 12.5.15

APPENDIX H: Web ad

Randomised Control Trial for childhood apraxia of speech.

Do you have a child with Childhood Apraxia of Speech (CAS) / verbal dyspraxia?

Children with CAS have speech difficulties which can impact on their literacy, social and academic skills.

Recent research studies have shown that there are different ways a Speech Pathologist can treat Childhood Apraxia of Speech. We want to compare two treatments in order to better understand why they work. This study will compare the Rapid Syllable Transitions (ReST) treatment and Ultrasound Biofeedback treatment.

We are looking for children who:

- Have dyspraxia or Childhood Apraxia of Speech
- Are 7-16 years of age
- Have normal or adjusted to normal hearing and vision
- Australian English as first and primary language.
- Have no other developmental diagnoses

What does the study involve?

- Assessment of your child's speech and language skills
- Audio and video recording of your child's speech and language
- 12 x 1 hour free treatment sessions over 6 weeks
- 3-4 follow up assessments after treatment

If your child meets these criteria and you would like to be involved, then we would like to hear from you.

Contact

Pippa Evans
Speech Pathologist
pippa.evans@sydney.edu.au
9351 9713 (Mon, Wed, Fri)

Dr Tricia McCabe
Speech Pathologist
tricia.mccabe@sydney.edu.au
9351 9747