FULL STUDY TITLE

The effectiveness of Rapid Syllable Transition Treatment in improving communication in children with cerebral palsy: A single blind cross over randomised controlled study

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.

.

Contents

Glossary of Terms

Principal Investigator – Professor Patricia McCabe

Associate investigators - Dr Andy Smidt and Dr Cathy Morgan

Study Coordinator - Ms Johanna Korkalainen

Student supervisor – Professor Patricia McCabe, Dr Andy Smidt, Ms Johanna Korkalainen

1. GENERAL INFORMATION

1.1 Protocol title

The effectiveness of Rapid Syllable Transition Treatment in improving communication in children with cerebral palsy: A randomized controlled study

23 November 2020

1.2 Name and address of the sponsor

The University of Sydney, Camperdown NSW 2006
There is no external funding for this study

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 Patricia McCabe
Dr Andy Smidt
Dr Catherine Morgan
Ms Johanna Korkalainen

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 Pathology Clinic
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), U1111-1260-0960

2. SYNOPSIS

TITLE	The effectiveness of Rapid Syllable Transition Treatment in improving communication in children with cerebral palsy: A randomized controlled study
PRIMARY HYPOTHESIS	That ReST will be more effective in improving speech intelligibility and communicative participation with children with CP than usual care.
DESIGN	Single blind cross over randomised controlled trial
BLINDING/MASKING	Single blind As a behavioural intervention trial, the treating clinicians and participants cannot be blinded to allocated group or intervention.
OUTCOMES	<u>The primary outcome</u> Speech intelligibility in single words <u>Secondary outcomes</u> 1. Communicative participation 2. Parent/ Carer and child satisfaction in their child's communicative participation 3. Speech accuracy 4. Sentence complexity and length in speech and AAC use
STUDY DURATION	Estimated study duration from enrolment until completion of data analyses 8 months
INTERVENTION/S	Rapid Syllable Transition Treatment. (ReST)
NUMBER OF PARTICIPANTS	20, 10 per group.
POPULATION	<u>Sample Size</u>: n=20 <u>Gender</u>: Male and female <u>Age</u>: Children aged between 7y0m - 14y11m <u>Demographic group</u>: N/A <u>Diagnosis: Cerebral Palsy</u>
SELECTION AND ENROLMENT	Inclusion criteria: 1) Aged between 8-14 years 2) Diagnosis of CP 3) Viking Speech Scale classification II-III 4) No diagnosis of intellectual disability 5) Normal or adjusted-to-normal hearing and vision

3. RATIONALE / BACKGROUND

3.1 Background

Cerebral palsy (CP) is a group of disorders of movement and posture caused by damage to the developing brain (Rosenbaum et al., 2007). Communication disorders, such as difficult to understand speech, referred to as dysarthria, are common in cerebral palsy (Andersen et al., 2010). Dysarthria is a group of neurological speech disorders that results from abnormalities in the strength, speed, range, steadiness, tone, or accuracy of movements and impacts on the control of the respiratory, phonatory, resonator, articulatory, and prosodic aspects of speech production (Duffy, 2013). There are different severity levels of dysarthria which are described with the Viking Speech Scale (VSS; Pennington et al., 2010). VSS level 1 represents very mild dysarthria, while VSS 4 refers to the most severe form of dysarthria. Reduced speech intelligibility impacts on communicative participation, which is the ability to participate in daily conversations, make social connections and friendships (Mei et al., 2014). Although speech intelligibility promotes successful communicative participation, the exact role intelligibility plays in communicative participation it is not currently well understood (Baylor & Darling-White, 2020).

Current interventions aimed to improve speech for children with CP include; interventions that focus on voice, such as Lee Silverman Voice Treatment, LSVT LOUD (Boliek, et al, 2017); interventions that are based on speech subsystems theory, referred to as Speech Systems Intelligibility Treatments (SSIT; Pennington, et. al., 2010, 2013); and PROMPT therapy which focuses on realigning oral musculature to improve speech (Ward, 2014). These interventions have been demonstrated to improve speech intelligibility with children with CP (Pennington, et. al., 2005), although there is currently no evidence to suggest which of these is more effective, especially with children with significant dysarthria, such as VSS levels II and III.

Neuroplasticity is the ability of the central nervous system (CNS) to change and adapt in response to environmental cues, experience, behavior, injury, or disease (Ludlow et al, 2008). According to the principles of neuroplasticity only what is practised will be leant. Accordingly, intervention should be intensive and consist of frequent opportunities to practise the intervention target. Motor speech interventions that adhere to these neuroplasticity principles should include frequent and exclusive practice of the target behavior, namely speech sounds.

Rapid Syllable Transition Treatment (ReST; McCabe et al., 2017) is a motor speech intervention that deliberately uses the principles of motor learning. Although ReST was designed for children with childhood apraxia of speech, it may provide an alternative speech intervention for children with CP as it uses principles of motor learning. Its suitability for children with CP was trialed in the pilot study preceding this study and was noted to produce positive gains in speech and communication skills in children with significant dysarthria (Korkalainen et al., 2020).

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 melody in the form of relative emphasis, or stress, placed on each syllable within a word (McCabe et al., 2017).

3.2 Rationale for Study

The current motor speech interventions for children with CP, namely LSVT LOUD, SSIT, and PROPMT are based on the Speech Subsystems approach. The Speech Subsystem approach emphasizes the role of the resonatory, phonatory, resonatory, and articulatory subsystems in speech production. The lowest subsystem level is respiration followed by phonation, resonance, and lastly articulation (Hayden & Square, 1994). Speech interventions based on the Speech Subsystems approach start intervention at the lowest speech subsystem level and progress to the higher levels once mastery at each level is obtained (Hayden & Square, 1994). ReST provides an alternative motor speech intervention approach because of its adherence to the principles of motor learning. Rather than focusing on the speech subsystems, it emphasizes the importance of practising the target behavior, specifically speech sounds. Although ReST has not been studied with children with CP, the promising results from the pilot study on using ReST with children with CP (Korkalainen, et. al., 2020) and it's close attention on the principles of motor learning warrant further investigation.

4. AIMS / OBJECTIVES / HYPOTHESES

Aim:

The study aims to investigate if Rapid Syllable Transition Treatment (ReST) is effective in improving speech intelligibility and communicative participation in children with cerebral palsy (CP).

Hypotheses:

1. ReST will be more effective in improving speech intelligibility in children with CP than usual care
2. ReST will be more effective in improving communicative participation in children with CP than usual care.

5. PARTICIPATING SITES

The University of Sydney
Susan Wakil Health Building D18 Western Avenue
Camperdown, NSW 2006

Cerebral Palsy Alliance
187 Allambie Road
Allambie Heights NSW 2100

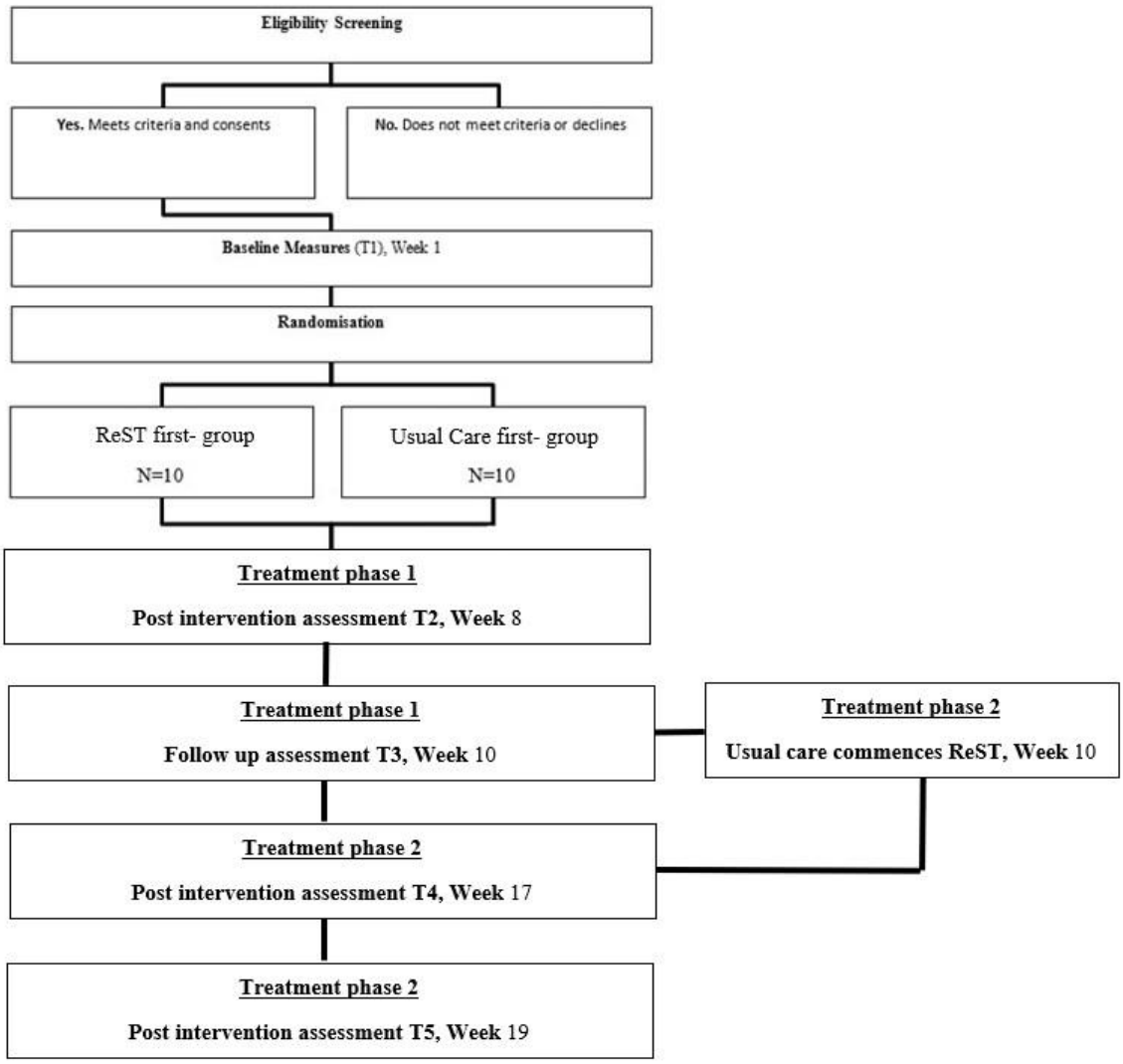
6. STUDY DESIGN

6.1 Type of Study

This is a single blind cross-over randomised controlled trial. The children are randomised to the ReST group first or usual care first.

6.2 Schedule of Events/ Treatment Phases

Table 1: Flowchart of the schedule of events



1. **Rolling Recruitment:** Please see section 6.4.1
2. **Eligibility Screening:** Participants will participate a screening assessment via teleconferencing. This will take 10 - 15 minutes.
3. **Baseline Assessment, T1**: All eligible participants will attend an initial assessment in person at the University speech pathology clinic or at the family's home. If this is not possible, the assessment will be conducted on teleconference.
4. The Consent form will be signed.
5. **Randomisation**: The children who are eligible to participate will be randomised to ReST first- group or usual care- group.
6. **Treatment phase 1**:
    a. **ReST first- group:** Children in the treatment group will receive ReST therapy three times a week for six weeks, totalling 18 sessions**.**
    b. **Usual care- group**: Children in the usual care group will continue their usual care therapy and complete T2 and T3 assessments. See Table 1, The Flowchart of the schedule of events. The content and dosage of usual care will be recorded. If the participant has a speech generating device, the frequency of use and device satisfaction will also be recorded.
7. **Treatment phase 1 Post intervention assessment, T2**: Within one week after the final ReST session.
8. **Treatment phase 1 Follow up assessment, T3:** Three weeks after the final ReST session.
9. **Treatment phase 2:**
    a. **ReST first- group:** The children will complete T4 and T5 assessments.
    b. **Usual care- group:** Children in the usual care group will commence ReST after T3 assessments are completed. See Table 1, The Flowchart of the schedule of events.
10. **Treatment phase 2 Post intervention assessment, T4**: Within one week after the final ReST session.
11. **Treatment phase 2 Follow up assessment, T5**: Three weeks after the final ReST session.

6.3 Population / Sample size including power calculation

Sample size:

The sample size will be 20 children, 10 in each group.

Sample size calculation:

Sample size calculator used: https://www.ai-therapy.com/psychology-statistics/sample-size-calculator)

This pilot RCT is the first to use ReST with children with CP in a randomised controlled trial. There are no previous studies of this intervention with this population using the proposed outcome measures from which sample sizes could be calculated, so studies with similar populations, treatments, and measures were considered for sample size calculations.
ReST is a motor speech intervention for the treatment of childhood apraxia of speech (CAS). While it has been shown to be effective in improving speech in children with CAS, it has not been researched with children with CP. Our exploratory pilot study on the use of ReST with children with CP indicated improvement in mean length of utterance, with a d2 effect size of 0.56. This effect size gives a **sample size of 6**. This was derived from calculating the effect sizes from the group means (baseline and maintenance), and standard deviation for four outcome measures. Speech MLU is a secondary outcome in the current study
ReST effect sizes have primarily been calculated using d2. Using this metric, Thomas (2017) reported an average ReST intervention effect size of 5.55 (SD 2.41, range 2.48–8.52). (Previously published single-case clinician-delivered ReST treatment studies reporting similar dependent measures; McCabe et al., 2014; Thomas et al., 2014; Thomas et al., 2016). Using this effect size with a power of 0.8 and alpha of 0.05 the online sample size calculation produced a sample size of **3 for each group**. The only other RCT using ReST in children with CAS produced an effect size (Cohen's d) of 1.376 giving a sample size of **10 for each group**.
The other motor speech interventions used with children with CP include LSVT LOUD (Boliek & Fox, 2017), Speech Systems Intelligibility Treatment (Pennington et al., 2010; 2013), and PROMPT (Ward, 2012). Sample size calculations were derived for each of these studies.
LSVT LOUD: Boliek & Fox, 2017 reported a Cohen's d effect size of 0.3 for pre and post speech intelligibility measures. The sample size calculation was therefore a sample size of 52.
Speech Systems Intelligibility Treatment: Effect sizes were not reported in these studies, so they were calculated from the published study data. These were (Pennington et al., 2010) Cohen's d effect size of - 0.5 and (Pennington et al., 2013) 0.6 respectively. The sample size calculation was based on these provided sample sizes of 19 and 23 respectively.
PROMPT: Ward (2012) reported a Cohen's d effect size for the percentage of phonemes correct each of the four children. The mean of these was 1.1. The sample size calculation was therefore 7.
The sample size figures calculated from the non-ReST studies on children with CP were notably larger than those based on the ReST treatment studies. Although studies on children with CP may require a large sample size due to their heterogeneity, a sample size that is too large may be presumptuous at this stage as the effectiveness of ReST with children with Cerebral palsy is not known. Besides, the interventions in these studies differed quite significantly from ReST intervention, which may render the sample sizes improbable.
In the absence of previous comparable studies on the effectiveness of ReST in children with CP, studies with other populations using ReST, studies with CP population using different interventions, and an exploratory study on ReST with CP population were considered in sample size calculations. Based on these, and our best estimate, a sample size of six per group was satisfactory. This was increased to ten per group to account for potential attrition and to reflect the calculation from Murray et al. (2015) study on the effectiveness of ReST.

6.4 Participant Enrolment and Randomisation

6.4.1 Recruitment

Participants will be recruited by CP Alliance therapy sites in Sydney, Central Coast, and Central West. Recruitment will also be from the NSW CP register. The study will be advertised at Cerebral Palsy Alliance centres on notice boards, social media (Facebook and Twitter), and through contact with treating therapists. The study flyer will direct interested potential participants to contact the study coordinator, Ms. Johanna Korkalainen.
When families contact the study coordinator, 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, and unless eligibility can be determined from reports, arrangements will be made to meet with the child (teleconferencing or in person) to determine eligibility. The study coordinator will then advise the family if their child satisfies the inclusion criteria.

6.4.2 Inclusion and Exclusion Criteria

Inclusion criteria

1) Aged between 8-14 years
2) Diagnosis of CP
3) Viking Speech Scale classification II-III
4) No diagnosed intellectual disability
5) normal or adjusted-to-normal hearing and vision

Exclusion criteria

1) non-CP diagnoses or multiple diagnoses
2) intellectual disability
3) Viking Speech Scale classification I or IV

6.4.3 Informed consent process

The informed consent process involves the following:
Interested parents will contact the study coordinator or one of the other researchers. They will be provided with the Participant Information Sheet and the Participant Consent Form. Parents will be encouraged to ask questions about the research and the risks and benefits of participation.
The families are 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, the University of Sydney, or Cerebral Palsy Alliance.
The families will be provided the name and contact details of the Principal Investigator and the University of Sydney ethics committee if they have any questions, concerns or complaints about the study. The families will also be provided with the study coordinator's details unless they already have them.

6.4.4. Screening and eligibility

Eligibility on the diagnosis of CP, cognition, and hearing and vision will be determined based on medical reports. The Viking Speech Scale (VSS) level will be determined from reports created within the last 18 months or a screening assessment.

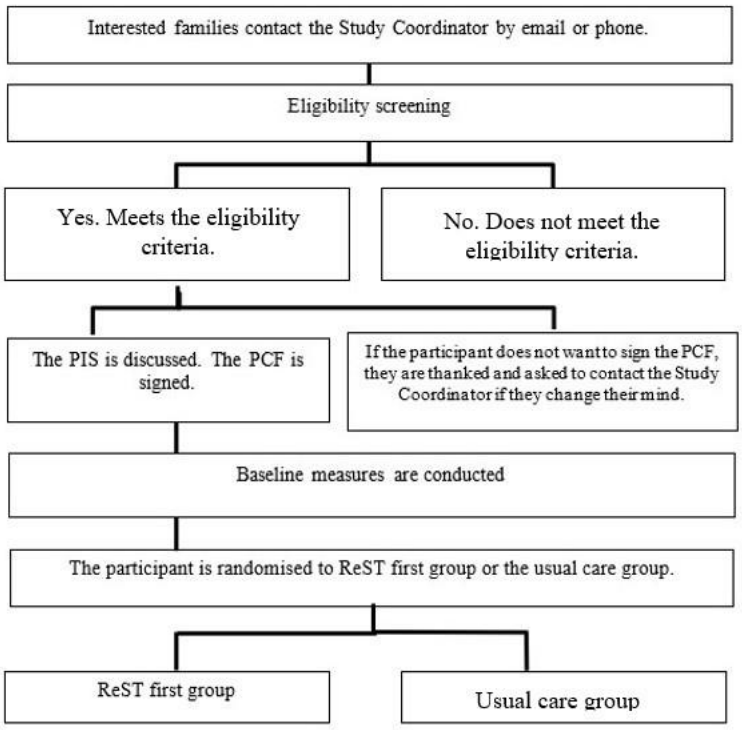
The study coordinator will meet with the child (teleconferencing or in person) to determine the VSS level. Where the VSS level is not clear, a second person from the research team will meet with the child via teleconference. The decision on eligibility will be based on a consensus between the two research team members.

Information on the children's diagnosis, cognitive level, hearing, and vision will be sought from reports at school entry. If the family does not have these reports, information will be searched from Cerebral Palsy Alliance medical records and the Cerebral Palsy CP Register with the family's consent.

6.4.5 Randomisation and Blinding Processes

Randomization

Participant randomization flowchart



After the Informed Consent Form is signed and the baseline assessment has been completed, an officer not connected with the study and at a separate location draws a concealed opaque envelope from a group of 20 identical envelopes. Each envelope contains the group allocation. The officer will inform the study coordinator who informs that family.

Children will be randomly allocated to one of;
1. A ReST first group who will receive ReST 3 days per week for 6 weeks, for a total of 18 sessions.
2. A usual care group who will receive usual care first and ReST after Treatment phase 1 Follow up assessment, T3 assessment.

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 will be blinded to group allocation.

6.5 Primary and Secondary Outcome Measures
The primary outcome measure:
Speech intelligibility. This refers to how easy it is to understand the child's speech. This is measured with:
- The Intelligibility in Context Scale (ICS; McLeod et al., 2012). ICS is an assessment to rate the intelligibility of children's speech in their daily environments.
- Word Intelligibility by Picture Identification (WIPI; Ross & Lerman, 1979). WIPI assesses the intelligibility of the child's speech in single words.

The secondary outcome measures:
1: Communicative participation - This is measured with:
- Focus On Communication Under Six assessment (FOCUS; Thomas-Stonell, et al., 2004). FOCUS is an assessment for parents to rate their perception of their child's communicative participation and confidence in everyday situations. Although FOCUS is designed for children aged 3-6 years, it is used in this study because there are no other assessment tools that measure communicative participation with older children. Previous studies in CP have reported the use of FOCUS with older children (Pennington, et. al., 2013).
- Speech Participation and Activity Assessment of Children (SPAAC; McLeod, 2004). SPAAC is a child-directed rating tool of participation levels for children with speech disorders.

2: Parent/ Carer and child satisfaction with participant's communicative participation. These are measured with:
-The Canadian Occupation Performance Measure (COPM; Law, et al., 2005). COPM is a goal-setting tool and an outcome measure. Participants are directed through a semi-structured interview to set intervention goals and to rate performance and satisfaction. This is done before and after the intervention.

3: Speech accuracy. This is measured with:
- Percentage of phonemes correct in word level. 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.

4: Sentence complexity. - This is measured with:
- Mean length of utterance (MLU) in speech. Changes in the child's mean length of utterance, as measured by calculating the average number of morphemes in a child's utterances (Miller & Chapman, 1981).
- Mean Length of Utterance with an augmentative and alternative communication system (AAC). This is only applicable to children who have a high technology AAC system. MLU is measured from the sentences produced on the high technology AAC system.

6.6 Interventions

6.6.1 Rapid Syllable Transition Treatment (ReST; McCabe et al., 2017)
ReST involves the child 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. The level and type of feedback are controlled. If the child is unable to complete all 100 pseudowords within the session, the remaining unfinished pseudowords are 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 study coordinator 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.

6.6.3 Usual Care Group
Children randomised to the usual care control group will continue to receive their usual care therapy. Families will fill in a weekly online questionnaire that includes questions about i) the family's satisfaction with the child's speech, ii) use of the child's high technology AAC if the child has one, and iii) content and the dose of usual care therapy. Once the Treatment phase 1 Follow up assessment T3 has been completed, this group will begin ReST therapy. The families in the Usual first- group are asked to fill in this questionnaire weekly and emailed to the study coordinator, Ms. Johanna Korkalainen while they are waiting to commence treatment.

The families will email the questionnaire to the study coordinator. If the families neglect to answer the questions, the study coordinator will contact the family and remind the family to email the questionnaire. If the family is unable to email the answers, the questionnaire will be conducted over the phone with the study coordinator or the speech pathology students.

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 the study coordinator or another of the investigators. At this point, parents will be asked if they wish the researchers to retain or destroy already collected 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. Parents 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.

6.7.1 Non-Compliance

A participant's non-compliance with the treatment protocol will be addressed with the family by either the student speech pathologist or the student's supervisor. If the family is unable or unwilling to follow the treatment protocol, they will be advised to discontinue the program. The family will then be asked if they wish the already collected data to be retained or destroyed. If the participant agrees to retention, then their data is recorded. If the participant does not agree, then their data is destroyed. The reasons for non-compliance will be asked and if provided, they will be recorded and reported in the results if consent is provided.

6.7.2 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.

6.7.3 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 calculations.

6.8 Expected Duration of Study

The expected study duration is eight months. Subject to ethics approval We anticipate recruitment of participants to commence in December 2020. In this case, the last participant will finish no later than July 2021.

1. Recruitment to be completed April 2021
2. ReST first group to be completed by May 2021
3. The usual care group to be completed by July 2021
4. All study data analysis to be completed by August 2021

In the event that ethical approval only allows us to start in February, ……

6.9 Ethics Approval

Ethics approval will be sought from the University of Sydney Human Research Ethics committee and Cerebral Palsy Alliance Ethics Committee in that order.

6.10 Modifications to the Protocol

Any modifications to this application will be submitted to each HREC 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 protocol 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 Principal Investigator (PI) or, in case of a student, their student supervisor within 24 hours. The PI 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 PI. 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

The trial will continue provided that no adverse/serious events occur 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 ANOVA and Cohen's d effect sizes to compare the treatments over time.

Repeated measures ANOVA (2 groups x 6-time points) will be run for the primary and secondary outcome measures.

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

For statistically significant comparisons, Cohen's d effect sizes will be calculated (Cohen, 1988).

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 foreseeable risks to the participants or their families. 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 child.

As this is a trial study of ReST with children with CP, there is a risk of no improvement in speech intelligibility or communicative participation at the end of the study. The families are informed of this at recruitment.

Participants 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 (2014) and Murray, et. al. (2015) studies. Students will be supervised by the research team members 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 not be disadvantaged by randomisation as both groups will receive the ReST intervention and all the assessments.

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 child 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. A covid-safe protocol is attached.

7.3 Recruitment

Recruitment will take place from CP Alliance therapy and via the NSW CP register. Potential participants are directed to contact the study coordinator. The research team or the student speech pathologists will not approach or contact the potential participants.

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

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

Participants are also informed that if they decline to participate or withdraw from the study, this will not effect their relationship with the research team, The University of Sydney, or Cerebral Palsy Alliance.

7.4 Informed Consent

The participants are informed about the study and given the PCF and the PIS. The family can choose whether they want to sign the consent form. If the family 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, or Cerebral Palsy Alliance and its staff.
The family is provided the name and contact details of the PI and the study coordinator 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 families are 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, the University of Sydney, or Cerebral Palsy Alliance.

8. SAFETY CONSIDERATIONS

8.1 Assessment and Documentation of Adverse Events

To ensure consistent procedures and safety of the participants, the participants' progress and 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 supervisor provides feedback and support during and after the treatment sessions. Adherence to the treatment protocol and participants' experiences are discussed and adjustments are implemented where required.
Children who become distressed will be provided with a break, with encouragement, and with appropriate support in consultation with them and their parents. If the child and the parent consent to continuing, the session will recommence after a short break. Otherwise, the session will be discontinued.
Direct observation of the students occurs during the first four sessions of the treatment block. After this, the frequency of direct observation is gradually reduced to once a week, in line with usual practice. As all sessions will be recorded, the student and the supervisor can review the sessions where the supervisor was not present.

8.2 Adverse event reporting

All adverse events will be reported to the study coordinator and recorded. The HREC procedures for reporting serious adverse incidents within 72 hours will be followed. Completing and submitting HREC adverse event templates and contacting the HREC office directly with urgent issues will be followed.

The data collection procedures are 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. 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 approved Dropbox 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.
The weekly online questions for the usual care group are collected weekly through REDCap survey and saved electronically.
Consent forms, 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 Dropbox and only retained in the RDS.

9.3 Data retention and archiving process

Data is stored for a minimum of 20 years or until subjects are 25 years following project completion. Since this is research about children, who once they become adults have legal rights for seven years (ie until they are 25), we may be required to be able to re-identify them if they choose to take up these rights. Only the investigators will have access to the code which could re-identify the child.

After this, the project materials will be permanently deleted from the RDS.
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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. It will be included in Ms. Korkalainen's PhD. Cerebral Palsy Alliance may report it in newsletters and the annual report or on their social media.
Authorship will follow the Contributor Roles Taxonomy (Credit). Ms. Korkalainen will be 1st author, other authors will be determined by the nature and extent of their contributions to the papers.

12. REFERENCES

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15. APPENDICES

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