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

PARTICIPANT INFORMATION STATEMENT

(1) What is this study about?

You and your child have been invited to take part in a research study to find out if a speech therapy program called Rapid Syllable Transition Treatment (ReST) improves children's speech and their ability to take part in daily conversations. This research investigates the following:

- Is ReST effective in improving children's speech intelligibility?
- Does ReST improve children's ability to take part in conversations?
- Are you and your child satisfied with your child's speech and ability to take part in conversations?

You and your child have been invited to participate in this study because your child has cerebral palsy and has some difficulty in speaking.

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

Participation in this research study is voluntary and free. You do not need to use your NDIS funds in any part of this study. Your child will receive therapy from the University of Sydney speech pathology student who is under the supervision of the researcher team members Tricia McCabe, Andy Smidt and Johanna Korkalainen, who are all qualified speech pathologists.

While your child is receiving the 6-week ReST treatment, s/he is not able to receive any other speech pathology service from any service. The reason for this is that speech pathology other than that involved in the study may impact on the results of this study. While your child is waiting to receive ReST, s/he is free to continue with their usual speech pathology program.

We will also ask to show us any reports you may have on your child's cognition, vision, and hearing. If you do not have any reports, we ask you to consent for us to access this information from the Cerebral Palsy Alliance client records. We will also ask you to consent for us to find out the following information from your Cerebral Palsy Alliance medical records: personal information, type and severity of cerebral palsy, level and severity of

communication difficulties and previous speech pathology your child has received. This information helps us to understand both your child's condition and our study better.

All the therapy sessions with your child will be conducted online via The University of Sydney Zoom. You will need to download Zoom videoconferencing software which is free to download. Some assessments may be conducted face to face where required.

All the assessment and therapy sessions will be videoed. This is necessary because information from the sessions will be collected and evaluated after each session. The recordings will be watched and listened to by the members of the research team and the speech pathology students who have agreed to confidentiality. While these people will not be given any information about your child, they may be able identify your child from the videos.

If you decide to take part in the study, you will be randomised to ReST -first group or the usual care -first group. This means that if you are in the ReST -first group, you will start therapy right away. If you are in the usual care -first group, you will wait first and then start therapy. While you are waiting, you will continue with your usual therapy. Once you have been randomised to a group, we are not able to change groups.

(2) Who is running the study?

The study is being carried out by the following researchers:

- Professor Tricia McCabe PhD CPSP, Speech pathologists at the University of Sydney.
- Dr Andy Smidt, Speech pathologists and Lecturer at the University of Sydney.
- Dr Catherine Morgan PhD, Physiotherapist, Cerebral Palsy Research Institute.
- Johanna Korkalainen, Speech Pathologist at Cerebral Palsy Alliance, who is conducting this study as the basis for a PhD at the University of Sydney, under the supervision of Professor Tricia McCabe, Dr Andy Smidt and Dr Catherine Morgan.

(3) What will the study involve?

The study will involve regular on-line speech pathology sessions with you and your child. These involve your child practising saying sounds and made-up words. Your child will also participate in detailed speech pathology assessments to establish skills, difficulties and intervention goals.

Parent attendance during each session is highly recommended, especially as the intervention is online. The child is likely to require your assistance with the online technology. They may also require your support to stay on task.

If the intervention session runs during school hours, it is recommended that a parent or a school staff member, such as a teacher's aide attends the therapy session. Together we will ask the school and arrange with them where the teleconferencing could take place and which school staff member could attend the session if you are not able to.

If the assessment takes place in person, the venue will be negotiated between you and the speech pathology student and based on practicality of travel. The possible venues are your home, the University of Sydney Speech Pathology clinic, or your child's school.

(4) How much time will the study take?

ReST program runs for six weeks, three times a week. Each session takes about 45 minutes. In addition to this, there will be assessments over two or three days before the start of ReST and after the completion of ReST. There will also be three more assessments over two months even though you are not receiving ReST therapy at that time.

While you are not receiving ReST, you are asked to fill in a weekly email with three questions on your child's communication.

(5) Who can take part in the study?

Children who can participate in this study:

- ✓ Children aged 8-14 years with cerebral palsy, with speech difficulties as measured with the Viking Speech Scale
- ✓ Adequate hearing and vision
- ✓ No diagnosis of intellectual disability or other diagnosis

(6) Does my child have to be in the study? Can they withdraw from the study once they have started?

Being in this study is completely voluntary and your child does not have to take part. Your decision whether to let your child participate will not affect your/your child's relationship with the researchers, anyone else at the University of Sydney or at Cerebral Palsy Alliance now or in the future.

If you decide to let your child take part in the study and then change your mind later (or they no longer wish to take part), they are free to withdraw from the study at any time. You can do this by informing Johanna Korkalainen either by person, phone or email.

If you withdraw from the study, we will not collect any more information on your child. Any information that we have already collected, however, will be kept in our study records and may be included in publications if you agree with this.

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

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

Although there is some evidence that ReST works with children with cerebral palsy, there may be a risk that your child's speech does not improve.

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

By taking part in this study, your child will receive high quality, evidence-based speech pathology service for free. The duration and frequency of intervention may not be possible in a standard NDIS intervention offer.

Your child will receive a comprehensive battery of assessments free of charge. You can also use the results of the assessment in any future NDIS application.

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

This study will collect information about your child. This will include:

- ✓ Age, gender, type and severity of cerebral palsy, severity of speech difficulty, hearing and vision levels and IQ.
- ✓ Medical history
- ✓ History of previous speech pathology
- ✓ Videos and voice recordings of all therapy and assessment sessions
- ✓ All communication assessment results

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

Your child's information will be stored securely in the University of Sydney data storage system. Your child's identity and information will only be disclosed with your permission, except as required by law. Study findings may be published, but your child will not be identified in these publications unless you agree to this using the tick box on the consent form. Your child's data will be destroyed after a period of 20 years.

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

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

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

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

When you have read this information, Johanna Korkalainen will be available to discuss it with you further and answer any questions you may have. If you would like to know more at any stage during the study, please feel free to contact Johanna Korkalainen by email on mkor6091@uni.sydney.edu.au, or by phone 0407508290, or any of the research team members.

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

You have a right to receive feedback about the overall results of this study. You can tell us that you wish to receive feedback by ticking the relevant box on the consent form and provide an email address. This feedback will be in the form of a written summary. You will receive this feedback after the study is finished.

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

Research involving humans in Australia is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this study have been approved by the HREC of the University of Sydney. As part of this process, we have agreed to carry out the study according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect people who agree to take part in research studies.

If you (or your child) are concerned about the way this study is being conducted or wish to make a complaint to someone independent from the study, please contact the university using the details outlined below. Please quote the study title and protocol number - The effectiveness of Rapid Syllable Transition Treatment in improving communication in children with cerebral palsy: A randomized controlled study, Protocol number 2020/682

The Manager, Ethics Administration, University of Sydney:

Telephone: +61 2 8627 8176

Email: ro.humanethics@sydney.edu.au

Fax: +61 2 8627 8177 (Facsimile)

If you consent and you and your child agree to be in the study, we can start.

By giving consent you are telling us that you:

- ✓ Understand what you have read.
- ✓ Agree for your child to take part in the research study as outlined above.
- ✓ Agree to the use of your child's personal information as described.
- ✓ Agree that the sessions with your child will be videoed and recorded.
- ✓ Agree that the videos and recordings will be viewed and analysed by additional people who have agreed to confidentiality.
- ✓ Agree to receive intervention from a student speech pathologist.
- ✓ Agree to receive intervention on teleconferencing.

This information sheet is for you to keep