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A Randomised Controlled Trial comparing Dynamic Temporal and Tactile Cueing with Usual Care for Childhood Apraxia of Speech

PARTICIPANT INFORMATION STATEMENT

(1) What is this study about?

Your child is invited to take part in a research study about improving the speech outcomes of children with severe Childhood Apraxia of Speech (CAS). This research project will examine the efficacy of a treatment used to treat Apraxia - Dynamic Temporal and Tactile Cueing (DTTC or Dynamic Therapy). Your child has been invited to participate in this study because they have a diagnosis of Apraxia.

Dynamic Therapy is a treatment developed to treat CAS. The therapy targets a core set of meaningful words which contain sounds that the child can already produce (e.g., "Hi daddy") and sounds which are emerging. Within a session, the Speech Pathologist uses a range of cues to help the child produce a word. These cues include tactile cues and verbal prompts for children to "look at me, listen to me, say what I say".

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 the research. Please read this sheet carefully and ask questions about anything that you do not understand or want to know more about. Participation in this research study is voluntary.

By giving your 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 below.
- ✓ Agree to the use of your child's personal information as described.

You will be given a copy of this Participant Information Statement to keep.

(2) Who is running the study?

The study is being carried out by the following researchers:

- Professor Tricia McCabe (Chief Investigator A, The University of Sydney)
- Associate Professor Alison Purcell (Chief Investigator B, The University of Sydney)
- Associate Professor Jonathan Preston (Chief Investigator C, Syracuse University)
- Associate Professor Edwin Maas (Chief Investigator D, Temple University)
- Associate Professor Brigid McNeill (Chief Investigator E, University of Canterbury)
- Dr Rob Heard (Chief Investigator F, The University of Sydney)
- Dr Paula Cronin (Chief Investigator G, University of Technology Sydney)

- Dr Elizabeth Murray (Chief Investigator H, The University of Sydney)
- Dr Donna Thomas (Chief Investigator I, The University of Sydney)
- Ms Maryane Gomez (Project Manager, The University of Sydney)

This study is being funded by the NHMRC and the University of Sydney DVCR Support Fund for COVID-19 impacted research. The study is being sponsored by The University of Sydney.

(3) What will the study involve?

If your child participates in this study, you and/or your child will be asked to:

- Participate in an initial eligibility screening that will take place via a 20-minute phone call. We will ask for your consent prior to starting this screening.
- If your child meets the specific requirements for this study, we will send you a consent form asking you to consent to audio and video recording of assessment, treatment and follow up sessions.
- Once you have signed and returned the consent form, we will ask you and your child to attend and complete a comprehensive initial face-to-face assessment (120–180-minute assessment across 1-2 days). A speech pathologist will assess your child's speech, language and communication skills, and will determine your child's Apraxia severity level and confirm that your child is suitable for the study.
- After the assessment, if you continue in the study, your child will be randomised to one of two groups:
    - Experimental treatment group: Your child will receive 18 Dynamic Therapy treatment sessions over 5 weeks.
    - Usual Care group: Your child will continue their usual care for 9 weeks.

- Experimental treatment group (Dynamic Therapy): We will not give you speech homework while your child is receiving Dynamic Therapy. We will also collect information about any additional speech therapy your child has during this time so that we can show if Dynamic Therapy is responsible for changes in your child's speech.
- Usual Care group: We will ask for your consent to contact your treating speech pathologist so that we can collect data, using an electronic form, about the therapy the clinician is using with your child, their treatment goals, therapy progress and minutes of therapy per week your child has attended. If the speech pathologist does not consent or cannot give us this information, we will ask you to provide this data.
- We ask that you and your child attend the clinic for three additional testing sessions throughout the project to measure treatment outcomes. These sessions will be conducted by speech pathology assessors who will not know which group your child was allocated to. You will need to attend assessments over a three-month period.

(4) How much time will the study take?

- All participants will complete an initial assessment which will take 120-180 minutes over 1-2 sessions.

- Children who are enrolled in this study will be randomly allocated to either the Experimental treatment group or the Usual care group. Participation in both groups will occur for up to ten weeks in total.
- Your child will be asked to attend an additional three testing sessions throughout the project. These sessions will take no more than one hour each.

(5) Who can take part in the study?

To participate in this study, children need to:

- ✓ Have a diagnosis of Childhood Apraxia of Speech
- ✓ Be 3 to 7 years and 11 months at the time they complete the first baseline probe (after the initial assessment)
- ✓ Have a speech impairment in the moderate-severe range
- ✓ Have normal hearing and vision with or without corrective devices (e.g., glasses, hearing aids)
- ✓ English is spoken at home as their primary language

Children who also have a genetic or neurodevelopmental disorder (e.g., autism) or a primary diagnosis of dysarthria; or have oral/facial structural deficit (e.g., cleft palate) are not eligible to participate in this study.

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

Being in this study is completely voluntary and your child does not have to take part. Your decision whether to let them participate will not affect your/their relationship with the researchers or anyone else at The University of Sydney or any of the other organisations involved in the study, 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), you are free to withdraw from the study at any time. If your child withdraws from the study, we will not collect any more information from them. We will ask you if you consent to data collected until that point being included in the study. If you do not want the data to be included, all information about you and your child will be destroyed.

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

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. If your child becomes distressed during the assessment or treatment sessions, your child will be given a break.

We do not expect that there will be any further risks associated with taking part in this study for your child.

The assessment, reports and treatment are free. If you have to come to us and you have to pay for parking or travel, we will reimburse you up to the cost of $20.00 per visit.

COVID-19 Considerations

Given the outbreak of COVID-19, you and the treating speech pathologist may be required to wear a mask whilst your child receives treatment. This will depend on the recommendations made by the government at the time. Your child will not need to wear a mask as they are under 12 years of age.

If you and the clinician wear a specific level of protective equipment (e.g., a face mask) at the commencement of your child's treatment, you will be required to continue wearing this level of protective equipment for the remainder of your child's treatment sessions. If there are further community outbreaks of COVID-19 whilst your child is receiving treatment, you and the treating speech pathologist may be required to increase your use of protective equipment during treatment sessions.

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

All participants will receive a comprehensive speech pathology assessment conducted by a speech pathologist. If your child is randomised to the experimental treatment group, s/he will receive free Dynamic Therapy – a treatment used for Childhood Apraxia of Speech. At the conclusion of your child's participation in the research project, all children will receive an assessment report, while the children in the Dynamic Therapy treatment group will receive a therapy summary report free of charge.

For children in both groups, your community speech pathologist will receive free professional development and training in Dynamic Therapy at the conclusion of the research.

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

Data that we will collect from your child includes their speech and language assessment results, and treatment data such as their therapy progress (for those allocated to the Dynamic Therapy group). Video and audio recordings from assessment (and all treatment sessions) will also be stored and analysed. This information will be stored on a secure online database system (The University of Sydney's Research Data Store).

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, their identity/information will be kept strictly confidential, and only the investigators approved by the University of Sydney Human Ethics Committee will have access to information about participants, except as required by law. We will keep the data collected about your child until they turn 25. This is how long the law requires us to retain it. After this time, all data will be destroyed.

A report of the study will be submitted for publication, but individual participants will not be identifiable in this report. The published journal articles will be open access and will therefore, be freely available to participants. We will let you know when they become available. Deidentified

information will be presented in journal publications and will also be presented at national and international conferences.

Phonbank

As part of this research, we would like you to consider consenting to having a limited amount of your child's de-identified data uploaded to Phonbank.

Phonbank is an online repository of speech samples saved for the study of communication skills in children both with typical speech and with speech disorders such as childhood apraxia of speech. Researchers from around the world (with permission from parents) store samples of children's speech in Phonbank so that other researchers can access these data over the internet. This allows the other researchers to use the data to check our research and also to analyse it in new ways.
If you participate in this research project, we will ask whether you would like to learn more about Phonbank. We will also provide you with the opportunity to separately consent to your child's data being shared with Phonbank.

If you consent, we will edit the recordings and transcripts of words and sentences your child says during the three probe visits. This will be done to remove any identifying information and then we will upload the audio recordings to Phonbank during the research.

If you are not interested in Phonbank now that is fine and it will not affect your child's participation. We will ask you again at the end of the study to see if you are interested at that time. You can change your mind about Phonbank at any time including after the end of the study.

(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, the Project Manager, Maryane Gomez or the Chief Investigator, Tricia McCabe will be available to discuss it with you further and answer any questions you may have. If you or your child would like to know more at any stage during the study, please feel free to contact us at dttc.trial@sydney.edu.au or call +61 02 9351 0996.

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

You and your child have a right to receive feedback about the overall results of this study. Individual feedback will be provided to parents about their child's assessment results and therapy progress in the form of a comprehensive speech pathology report. Parents will receive the assessment report (and therapy summary report for those in the experimental treatment group) approximately 2 weeks of concluding their involvement in the project.

Until the conclusion of the project, every 6 months, participants will be provided with a lay summary of the results in the form of a newsletter. This will provide participants with updated information on

the progress of the project. The published journal articles will be open access and will therefore, be freely available to participants. We will let you know when they become available.

(13) What if we 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 *[2021/117].* 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 Manager, Ethics Administration, University of Sydney:

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

This information sheet is for you to keep