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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?

You are invited to take part in a research study about improving the speech outcomes of children with moderate - severe Childhood Apraxia of Speech. This research project will examine the efficacy of a treatment used to treat Apraxia - Dynamic Temporal and Tactile Cueing (DTTC or Dynamic Therapy).

You have been invited to participate in this study because you are currently treating a child with Childhood Apraxia of Speech. This Participant Information Statement tells you about the research study. Knowing what is involved will help you decide if you want to take part in the 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.

By giving your consent to take part in this study you are telling us that you:

- ✓ Understand what you have read.
- ✓ Agree to take part in the research study as outlined below.
- ✓ Agree to the use of your personal information as described.

You will be given a copy of this Participant Information Statement for your own records.

(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 for me?

An overview of the study:

- In this Randomised Controlled Trial, we are comparing the effectiveness of Dynamic Temporal and Tactile Cueing (DTTC) to 'Usual Care'. Usual Care is defined as any other treatment a child with Childhood Apraxia of Speech is currently receiving, for example, one hour per week of a different treatment (to DTTC) with a speech pathologist.
- Child participants who participate in this study will complete an initial eligibility screening that will take place via a phone call.
- Children who meet the specific requirements for this study will be required to attend an initial face-to-face assessment. This assessment will determine the child's Apraxia severity level and provide additional information on other communication areas, such as their language skills.
- Child participants will then be randomised to either the Dynamic Therapy experimental treatment arm (where s/he will receive Dynamic Therapy for five weeks) or the Usual Care arm (where s/he will continue their usual care for 9 weeks as part of their participation in this study.
- Children will be involved in the study for up to 13 weeks which involves the initial evaluation, therapy/usual care and follow up assessments.

Your Role:

- If we have contacted you about this study, this means that we have received consent from your client's parent/guardian to contact you.
- Your client can continue seeing you whilst they are participating in this study, even if they're receiving Dynamic Therapy from our research clinicians.
- We would like to understand what treatment they are receiving from you during their participation in this study. We will ask you to report on the treatment approach you are using with the client, the treatment goals, therapy progress your client has made and minutes of therapy per week your client has attended.
- Data will be collected in the form of an electronic form. You will be asked to complete 9 brief online surveys (one survey each week your child is involved in this research project). In the first survey we will also collect extra information about you, such as your highest SLP-related qualification, and your experience treating Apraxia.

(4) How much of my time will the study take?

You can continue providing therapy to your client throughout their involvement in this research project as you usually would.

The electronic form we ask you to complete should take no longer than 15 minutes to complete the first time and no more than 10 minutes in subsequent weeks. We will ask you to complete this for 9 consecutive weeks.

(5) Who can take part in the study?

Qualified Speech Pathologists who have completed either an undergraduate or postgraduate degree in speech pathology are eligible to participate in this study.

(6) Do I have to be in the study? Can I withdraw from the study once I've started?

Being in this study is completely voluntary and you do not have to take part. Your decision whether to participate will not affect your current or future relationship with the researchers or anyone else at The University of Sydney. If you do not consent to participating in the study, we will ask the parent of your client to provide us with their child's usual care data.

You are free to withdraw from this study at any time. You can do this by contacting the leading researcher or any researcher you are liaising with in the contact details provided below. If you withdraw from the study, we will not collect any more information from you. We will keep all data that you have collected about the child participant up until the point at which you withdraw from the study unless the child's parent asks us to delete it. We will ask you if you consent to us keeping personal data about you and ask if you if we can include this data in the study. If you do not want the data to be included, all information about you will be destroyed.

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

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

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

Speech Pathologists who participate in the study will be provided with free online professional development in Dynamic Temporal and Tactile Cueing (DTTC) at the conclusion of the research project.

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

The data we will be collecting from you during this study includes data about the therapy and treatment you provide to the child participant, treatment goals, therapy progress and minutes of therapy per week your client has attended. Other information we may collect from you includes some of your demographic information, and your experience with treating Childhood Apraxia of Speech.

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

Your information will be stored securely and your identity/information will be kept strictly confidential, except as required by law. We will keep data about your personal information for fifteen years after the completion of this research project. We will keep the data collected about your client until they turn 25. This is how long the law requires us to retain it. After this time, all data will be destroyed. Deidentified information will be presented in journal publications and may be presented at national and international conferences.

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

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

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

After you have read this information, Ms Maryane Gomez, the Project Manager or Professor 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 Maryane Gomez or Tricia McCabe by email - ddtc.trial@sydney.edu.au or by phone 02 9351 0996.

(12) Will I 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. This feedback will be in the form of a newsletter which will contain a lay summary of results, and will be available every 6 months until the conclusion of the research project. You will also have access to the published journal article which will be open access and freely available.

(13) What if I 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 are concerned about the way this study is being conducted or you 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