RESEARCH PARENTAL/GUARDIAN CONSENT FORM:
IRB-FY 2026-11371

Study Title: A randomized control trial of motor-based intervention for childhood apraxia of speech: DTTC CONNECT

Clinicaltrials.gov NCT07526246

June 23, 2026

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RESEARCH PARENTAL/GUARDIAN PERMISSION FORM
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STUDY TITLE: A randomized control trial of motor-based intervention for childhood apraxia of speech: DTTC CONNECT
INVESTIGATOR: Dr. Maria Grigos

INVITATION TO BE A PART OF A RESEARCH STUDY

Your child is invited to participate in a research study to learn more about the effectiveness of treatment in children with childhood apraxia of speech (CAS). This will involve your child receiving a comprehensive speech and language assessment and, if your child meets eligibility, they can enroll and receive 8-weeks of motor-based intervention at no cost to you. The information gained from this work will contribute to our knowledge about CAS treatment.

This form has information to help you decide whether or not you wish to provide permission for your child to participate. Please review it carefully. Your child's participation is voluntary. Please ask any questions you have about the study or about this form before deciding to provide permission for your child to participate.

First, participation will involve your child receiving testing of speech, language, cognition, motor speech and hearing skills. Testing will be spread over four days (up to 2-hours per session). During this time, your child will also produce words and phrases while we record their speech and measure lip and jaw movement using a facial movement capture system. Second, if your child meets eligibility criteria, participation will involve your child receiving experimental treatment twice a week for eight-weeks. The total time for participation in this study, considering pre-testing, treatment sessions and post-testing is approximately 20 hours.

Children will not be permitted to receive any other speech treatment elsewhere (including DTTC) for the duration of the study. However, non-speech services, such as language therapy or Augmentative and Alternative Communication (AAC) support, are permitted throughout all phases of the study

PURPOSE OF THE STUDY

The purpose of this study is to learn about the effectiveness of a motor-based intervention for children with CAS that involves phrase-level practice.

ELIGIBILITY TO PARTICIPATE

Your child is eligible to participate in this study if they meet the following criteria:

- Have a diagnosis of CAS, as determined by our research team.
- Be between the ages of 3 years, 6 months and 12 years, 11 months
- Have normal structure of the oral-peripheral mechanism
- Have no history of major cognitive difficulties or hearing loss
- Primary language is English

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- Not receiving speech treatment elsewhere over the course of this study, although language, augmentative and alternative communication (AAC) treatment, or similar non-speech treatment, would be permitted

Your child should not participate if they:

- Do not have a diagnosis of CAS, as determined by our research team, even if they have a different speech sound disorder
- Are not between the ages of 3 years, 6 months and 12 years, 11 months
- Have abnormal structure of the oral-peripheral mechanism
- Have a history of major cognitive difficulties or hearing loss
- Primary language is not English

To determine whether your child has CAS, we need to confirm that your child's speech difficulties match the unique profile of CAS. Two experienced speech-language pathologists will independently review your child's performance across multiple speaking tasks (e.g. single words and connected speech). To be eligible for the study, your child must display at least four characteristics unique to CAS (e.g. vowel distortions, articulatory groping, or speech timing errors) on at least three different speaking tasks. We also carefully check to ensure the difficulties are not caused by underlying muscle weakness. If your child is determined to have CAS, their performance during the assessment tasks will guide the research team in developing treatment targets tailored to their strengths and weaknesses.

DESCRIPTION OF STUDY PROCEDURES

If you give permission for your child to participate in this study, your child will be asked to:

- **Complete a comprehensive evaluation** of speech, language, nonverbal cognition and oral motor skills, as well as a hearing screening over four days of assessment (Note: the order of testing can vary depending on the child's needs). Your child will be reinforced throughout all activities to maintain compliance and interest.
- **Be randomly assigned to a start date:** To help us measure the impact of the intervention, children are assigned to either a "treat-first" group (starting immediately after the initial assessment) or a "wait-first" group (starting treatment eight weeks after the initial assessment).
- **Complete probe data collection:** This involves producing words and phrases while speaking into a microphone before, during and after the treatment phrase.
- **Complete facial movement data collection:** This involves producing words and phrases while wearing reflective markers (placed on the jaw, lips, forehead, and nose) and speaking into a microphone to record facial movement and speech production, before, during and after the treatment phrase.
- **Participate in eight-weeks of treatment:** Children will receive Dynamic Temporal and Tactile Cueing-Connect (DTTC-Connect), 2 times per week/45-minute sessions, with a clinician who specializes in CAS. DTTC-Connect is a motor-based intervention for CAS where children practice refining speech movements during the production of phrases.

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- **Return for follow-up sessions**: Children will return one-week and eight-weeks post-treatment to collect follow-up data on speech production and facial movement. Some children will be asked to return at 16-weeks post-treatment.

The time commitment for this study includes the following:

- Pre-Treatment Phase (Assessment)
  - Day 1 (120 minutes) involves formal and informal speech, language and oral motor testing, as well as a hearing screening.
  - Day 2 (80 minutes) involves cognitive testing, probe data collection, and facial movement data collection. Additional testing remaining from Day 1 will also be completed, if needed.
  - Day 3 (40 minutes) involves probe data collection. Additional testing remaining from Days 1 & 2 will also be completed, if needed.
  - Day 4 (90 minutes) involves probe data collection and gathering information about communicative participation from the children and caregivers. The latter involves answering questions about the child's ability to communicate effectively in everyday social and functional situations.
- Treatment Phase: 2 times per week/45-minute sessions for 8-weeks (12 hours)
- Post-Treatment Phase: one-week post-treatment, 8-weeks post-treatment, and for some children 16-weeks post-treatment (60 minutes per visit). This involves probe data collection and facial movement data collection.

If you give permission for your child to participate in this study, you will be asked to:

- Complete an intake form about your child's developmental, medical, family and educational histories. The form will also include questions about caregiver/household demographics.
- Complete two brief surveys about your child's communication skills.

Treatment will be provided by a NYS licensed and ASHA certified speech language pathologist with expertise in childhood apraxia of speech. During parts of this study, your child will be audio and video recorded. Data from each part of the study will be integrated at the individual level so that we can accurately track your child's specific communication changes over time. This treatment is experimental though existing research has demonstrated successful intervention with this approach in children with speech sound disorders (e.g., Grigos et al., 2023; 2024).

ALTERNATIVE TO PARTICIPATION

As an alternative to participation, the original version of DTTC remains an option for all children with CAS, as it is a motor-based intervention supported by research evidence. There are also other motor-based interventions for children with CAS including Rapid Syllable Transition Treatment (ReST, McCabe et al., 2024), Speech Motor Chaining (SMC, Preston et al., 2024) and the Nuffield Dyspraxia Programme (NDP, Murray et al., 2015).

RISKS OR DISCOMFORTS

This study involves the following risks or discomforts:

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- Facial movement data collection involves your child wearing reflective markers on his/her face while speaking. There is a very slight risk that your child could swallow one of the reflective markers (3mm in diameter) placed on his/her face and mouth. Your child will be continuously monitored during testing to ensure that markers remain on the face and mouth.
- There is a slight risk that your child may be allergic to or develop a skin irritation from the adhesive we use for the markers. If your child has a history of allergy to or irritation from bandage adhesive, he/she should not participate in this study.
- There is a slight risk that your child may demonstrate initial apprehension to placement of the markers on their face. We will alleviate any apprehension by first placing markers on the investigator or placing stickers on your child's face (or a doll's face) prior to the markers. Anxiety will also be reduced by rapidly placing markers on your child's face.
- There is a slight risk of breach of confidentiality. This will be mitigated through several data-security protocols in place within the lab.
- The study may include unforeseeable risks. If the researchers became aware of new risks, then we will communicate this information to you.

BENEFITS
There is no guaranteed benefit if you choose to have your child participate in this study.
It is hoped that this study will contribute to knowledge about motor-based intervention for CAS.
Your child may also display improved speech production as a result of the study.

Your child will receive a free speech and language assessment and free treatment over an eight-week period as part of his/her participation in this study.

COMPENSATION
You will receive $15 in the form of a Visa Gift Card to cover the cost of public transportation for each treatment session (16 treatment sessions in total). In the event of withdrawal, gift card distribution will conclude at the participant's final attended session.

VOLUNTARY PARTICIPATION
Participating in this study is completely voluntary. Your child may choose not to take part in the study or to stop participating at any time, for any reason, without penalty or negative consequences. You may choose to revoke your permission for your child's participation in the study or stop their participation at any time, for any reason, without penalty or negative consequences. We will inform you if we know of any new findings during the course of the study that might influence their decision to participate.

We may end your child's participation in the study if your child cannot comply with the study protocol. If the decision is made to discontinue participation in the study, your child would no longer receive treatment. If your child withdraws or is withdrawn from the study early, we will keep information about your child that is already collected, as such information can still be helpful in understanding the diagnosis of CAS and the effectiveness of the treatment. There are no consequences of your choice to withdraw from the study at any time.

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PRIVACY & DATA CONFIDENTIALITY

In this study, you or your child may be asked to provide information that could be used to identify them personally. Unless you indicate otherwise (see below) and your child also agrees, this information will be kept confidential. Only researchers and others that will keep the information confidential (e.g., regulatory agencies or oversight groups) may access information that could personally identify your child. Confidentiality of your child's research records will be strictly maintained by keeping all information that could be used to identify your child separate from the data we report. All paper materials will be stored in a locked, secure place. Audio and video recordings will be stored on a password-protected computer.

You also have the choice to allow the researchers to include your child's name or other identifying information about them in research publications or presentations. Would you like for the identifiable information about your child to be kept confidential? (Select one):
___ Yes, I would like any information that could identify my child to be kept confidential.
___ No, I do not wish for my child's participation in this study to be kept confidential. I understand that information that could identify my child may be used in publications or presentations and it may potentially be associated with other data collected about them.

If you wish to change your decision, you may notify the researchers at any time during or soon after your child's participation in the research study. Your child will also be asked if they would like for their identity to be kept confidential. If you indicate Yes above for your child, then you will also be asked to confirm your agreement after the information is collected.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. Researchers with this Certificate will not disclose or use information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, even if there is a court subpoena. Exceptions include:

- A federal, state, or local law requires disclosure, information about suspicion of child abuse or neglect.
- Your explicit approval for the researchers to release your name or any other personally identifiable information.

We may wish to use information about your child collected for this study for future research, share it with other researchers, or place it in a data repository. These studies may be similar to this study or completely different. We will not ask for your additional permission before sharing this information. Please indicate below your permissions regarding this use of your child's information:
___ I do *not* give permission to use my child's data for future research or to share it with other researchers. Use it only for this research study.
___ I give permission to use my child's ***de-identified*** data for future research, share it with other researchers, or place it in a data repository. Remove all information that could identify my child before sharing or using the data for future research.

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___ I give permission to use my child's ***identifiable*** data for future research, share it with other researchers, or place it in a data repository. I understand that this information may be used to identify my child personally.

You may change your decision by notifying the researchers at any time during your child's participation in the research study.

ACCESS TO YOUR CHILD'S STUDY INFORMATION
We will give you access to the information that is collected about your child in this study. All diagnostic test results - including speech, language, cognitive, oral motor, and hearing - will be reviewed and discussed with you, along with the specific characteristics of CAS that your child displays. These results will be discussed with you either in-person or via zoom/phone following the completion of all diagnostic testing. Any additional medical or clinical data that may be relevant to your child will be communicated to you either in-person or via zoom/phone following the completion of all diagnostic testing. Appropriate medical and/or clinical follow-up may be recommended, if warranted.

All testing, treatment sessions and follow-up sessions will take place in the Department of Communicative Sciences and Disorders at NYU (665 Broadway, 6th floor).

CONTACT INFORMATION
You and your child are encouraged to ask questions at any time during this study. For information about the study, contact Dr. Maria Grigos at 212-998-5228, maria.grigos@nyu.edu, 665 Broadway, 6th floor, New York, NY 10012.

If you have questions about your child's rights as a research participant or if you believe your child has been harmed from the research, please contact the NYU Human Research Protection Program at (212)998-4808 or ask.humansubjects@nyu.edu.

AGREEMENT TO PARTICIPATE
By signing this document, you are giving permission for your child to participate in this study. Make sure you understand what the study involves for your child before you sign. If you have any questions about the study after you permit your child to participate, you can contact the research team using the information provided above. You may keep a copy of this form.

Name of Parent/Guardian (print) _____

_____ _____
Signature of Parent/Guardian Date

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Person Obtaining Consent: Your signature below means that you have explained the research to the participant/participant representative and have answered any questions they may have about the research.

Name of Person Obtaining Consent (print) _____

_____ _____

Signature of Person Obtaining Consent Date

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