Informed Consent Form

Title: A Randomized Control Trial of Motor-based Intervention for CAS

NCT number: NCT04642053

Official Date: 12/1/2021

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Department of Communicative Sciences and Disorders
665 Broadway, 9th Floor
New York, NY 10012
P: 212-998-5230

PARENTAL PERMISSION FORM for IRB-FY2021-4936

Your child is invited to take part in a research study to learn more about the effectiveness of treatment in children with childhood apraxia of speech (CAS). This study will be conducted by Dr. Maria Grigos of the Department of Communicative Sciences and Disorders at New York University's Steinhardt School of Culture, Education, and Human Development.

Participation will first involve the testing of speech, language, cognition, motor speech and hearing skills, as well as the collection of baseline data. Testing will be spread over 4 days (up to 2-hours per session) with tracking of facial movement also performed on the second day. During this time, your child will produce a set of words while we record their speech and measure lip and jaw movement using a facial movement capture system.

Following initial testing, your child will be randomly assigned to either an Immediate or Delayed treatment group. If your child is assigned to the Immediate treatment group they will receive 8-weeks of experimental treatment following the evaluation. If your child is assigned to the Delayed treatment group they will receive experimental treatment 8-weeks after completing the evaluation. Random assignment means that your child has an equal chance of being chosen to be in the Immediate or Delayed treatment group. Children in both groups will complete steps outlined below. The total time for participation in this study is approximately 32 hours.

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

1. Complete an evaluation of speech, language, nonverbal cognition and oral motor skills.
2. Complete a hearing screening.
3. Produce words while wearing a microphone and reflective markers (placed on the jaw, lips, forehead, and nose) to record speech and facial movement.
4. Participate in 8-weeks of treatment, 4 times per week/45 minute sessions, with a clinician who specializes in childhood apraxia of speech
5. Return 1-week and 8-weeks post-treatment to collect follow-up data on speech production and facial movement. If your child is assigned to the Immediate treatment group, they will also return for one additional session at 16-weeks post-treatment. Each of these sessions will be 60 minutes in length.

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. This treatment is experimental though existing research has demonstrated successful intervention with this approach in children with speech sound disorders (e.g., Maas et al., 2014).

Participation in this study involves minimal risk to your child. Your child will wear reflective markers on his/her face to track facial movement during speech. 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

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remain on the face and mouth. There is also 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.

Your child will receive a free speech and language assessment and free treatment over an 8-week period as part of his/her participation in this study. In addition, you will receive $20 to cover the cost of transportation to and from NYU for each treatment session for your child and an adult.

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.

Your child's treatment will be audio and video recorded. You may review these recordings and request that all or any portion of the recording be destroyed. Below, we will ask for your permission to share audio and/or video recordings of your child. We would only do this in an academic context, such as a conference or classroom. You are free to tell us not to share audio or video recordings of your child. We will not release recordings of your child without your consent. Additionally, if you choose to participate, data that does not containing any identifying information may be used in future research, shared with other researchers, or placed in a data repository without your additional permission or your child's additional consent.

Participation in this study is voluntary. Your child may refuse to participate or withdraw at any time. In addition, participation could also be terminated by the investigator if your child is not participating in the treatment protocol or due to noncompliance. If the decision is made to discontinue participation in the study, your child would no longer receive treatment. Finally, there is no guaranteed benefit if you choose to have your child participate in this study.

The initial contact with your child, which can include aspects of speech, language and motor speech testing, may be conducted using Zoom. Other testing and all treatment sessions and follow-up sessions will take place in the Department of Communicative Sciences and Disorders at NYU (665 Broadway, 9th floor and 726 Broadway, 5th floor).

If there is anything about the study or your child's participation that is unclear or that you do not understand, if you have questions or wish to report a research-related problem, you may contact Dr. Maria Grigos at 212-998-5228, maria.grigos@nyu.edu, 665 Broadway, 9th floor, New York, NY 10012.

For questions about your child's rights as a research participant, you may contact the University Committee on Activities Involving Human Subjects, New York University, 212-998-4808 or ask.humansubjects@nyu.edu.

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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 or your child 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, such disclosures of suspected child abuse or neglect.
- Your explicit approval for the researchers to release your or your child's name and/or personally identifiable information.

A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by U.S. Law. This website may include a summary of the results, but will never include information that can identify you. You can search this website at any time.

You have received a copy of this parental permission form to keep.

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Permission to Participate for IRB-FY2021-4936

Name of minor subject: _____
Name of Child

If you give permission for your child to participate in this study, please sign here.

_____ _____
Parent's Signature Date

Please answer the following questions:

1. Will you allow us to use audio recordings of your child in academic contexts (i.e., in person presentations, remote presentation, in person classes, remote classes, publications)?
   Please initial: _____Yes _____No

2. Will you allow us to use video recordings of your child in academic contexts (i.e., in person presentations, remote presentation, in person classes, remote classes, publications)?
   Please initial: _____Yes _____No

3. Will you allow us to use your child's data in other studies?
   Please initial: _____Yes _____No