

COVER PAGE FOR THE INFORMED CONSENT DOCUMENT

PROTOCOL TITLE: The influence of contextual and constitutional emotional processes on speech motor control and speech motor learning in early childhood stuttering.

NCT number: NCT05003583

PROTOCOL ID: R21DC018103

DOCUMENT DATE: August 6, 2021



SYRACUSE UNIVERSITY

Department of Communication Sciences and Disorders

PARENTAL INFORMED CONSENT DOCUMENT

Protocol Title: The influence of contextual and constitutional emotional processes on speech motor control and speech motor learning in early childhood stuttering.

Principal Investigator: Victoria Tumanova, PhD

Address: 621 Skytop Rd, Suite 1200

Telephone: 315-443-9640

Email: vtumanov@syr.edu

IRB Protocol: 16-177

The following information is provided to inform you about the research project and your and your child's participation in it. Please read this form carefully and feel free to ask any questions you may have about this study and the information given below. You will be given an opportunity to ask questions, and your questions will be answered. Also, you will be given a copy of this consent form.

Printed name of child participant: _____ **Age:** _____

What is the purpose for the research study?

You and your child are invited to participate in the research project "The influence of contextual and constitutional emotional processes on speech motor control and speech motor learning in early childhood stuttering," conducted by the Stuttering Lab at Syracuse University. We are studying how excitement influences speech movement control in preschool-age children. You are being asked to participate in a research study because you and your child can help us better understand the involvement of speech movement control in childhood stuttering. Your participation in this research study is voluntary. You and your child are free to refuse to participate or withdraw from this study at any time without penalty.

What will I be asked to do?

This study will take three visits to the research laboratory in the Department of Communication Sciences and Disorders at Syracuse University. Each visit will last approximately 1½ hours (plus additional time for breaks, at participants' request).

At the first visit, your child will engage in a 10-15 minute conversation with a Researcher, during which we will measure speech disfluencies and language use and complete a series of short tests of attention and memory (this will take 15 mins). Then, your child will watch a neutral video clip showing a fish tank screensaver and will be asked to repeat a simple sentence several times after an audio cue. During this speaking task your child will see pictures (color photographs) that are meant to elicit positive, negative, or neutral response. Each of the pictures will be presented to your child for a brief period (2 seconds). An example of a picture eliciting positive response is that of a puppy or an ice-cream cone, an example of picture eliciting a negative response is that of a threatening animal such as a snake or a dog showing its teeth. An example of neutral valence

picture is that of household objects such as a fork or a rolling pin. This task will take about 20 minutes and will be done at each of three visits.

During presentation of the video clip and the speaking task, we will measure your child's physiological reactions by recording your child's heart rate, skin conductance, and respiration. Heart rate will be measured with two hypoallergenic pediatric sensors that will be placed on your child's chest, and skin conductance will be measured through two more hypoallergenic pediatric sensors placed on his/her fingers. The sensors stick to the skin temporarily like Band-Aids. We will also track the movement of your child's lips and jaw during speech. This will involve placing small (5 mm diameter) adhesive "markers" on the child's upper lip, lower lip, jaw, and forehead. The markers stick to the skin temporarily like Band-Aids. Your child will also wear modified plastic sports goggles with markers attached to them. Before attaching the sensors, we will make sure your child is comfortable with them.

You will be able to watch your child over live-stream video system during all of the activities. The Researcher will monitor your child for signs that he or she is tired and needs a break. If your child wants to take a break or see you, the Researcher will arrange a break so that your child can say hello to you and tell about the games he/she has been playing. Your child is free to decline to complete any of these tasks. However, you will not be able to continue in the study without completing the tasks.

While your child is being tested, you will be asked to complete four to five questionnaires about your child's day-to-day behaviors and family and medical history, which takes approximately 30-40 minutes. At the end of the visit, your child will have his/her blood pressure, height and weight measured and his/her hearing tested.

At the second visit, your child will complete speech-language tests, measuring vocabulary, comprehension, speech sound articulation, and attitudes about talking, and will repeat the speaking task described above. At the third visit, your child will complete the speaking task one last time. This speaking-viewing task is repeated at each visit so we can assess whether children change how they control their speech over time, as the task becomes familiar.

We will audio/videotape/take a still photo of you/your child during the testing. The recordings will be used to analyze the collected data, or for teaching purposes if you give us permission for that. If we show your recordings, they will not contain any personal data or identify you or your child. The still photo will be embedded into a certificate of appreciation that we will send to your child after they complete the study as a token of appreciation and souvenir from his/her visit. If you give us permission, the still photo will be used on our laboratory's website to inform public about our research activities, your or your child's name will not be identified on the website. Assessment information from the speech-language testing will be shared with you during your third visit to the laboratory.

If your child currently receives speech-language therapy or you are interested in receiving speech-language therapy, we may wish to share the assessment information with the speech-language clinician. You may give us permission to contact this person or you may choose not to do so.

What are the possible discomforts and risks from participation in this research study?

Your child may feel bored or tired during participation in the study. These risks will be minimized by providing your child with breaks throughout the experiment. We use hypoallergenic sensors and adhesive markers designed for use with children to avoid any allergic reactions, such as an allergy to tape. Although unlikely, it is possible that some participants may itch in the areas where the sensors or markers are applied. We will instruct the participants to tell us if they begin to itch, and if this happens, we will remove the sensors/markers immediately. Your child may feel some discomfort when we remove the sensors/markers, like removing a small Band-Aid. Some children may become mildly distressed during viewing of negative pictures. These pictures will be presented for brief period (2 seconds) and your child is likely to have seen similar

pictures/objects in their everyday life. If the child shows any signs of distress the child will be comforted and brought to you if he/she so desires. Some children may refuse to name pictures and/or complete the experimental tasks. You and your child may feel uncomfortable when being audio- videotaped. While only the research staff will be able to view the video recordings of you and your child, if you feel uncomfortable about it you and your child can withdraw from study participation without penalty.

What are the possible benefits of participation in this research study?

The potential benefits to science and people that may result from this study are a discovery of factors contributing to the onset and development of childhood stuttering. The potential benefit to you from this study is valuable information free of charge regarding your child's speech and language development.

How will my privacy and confidentiality be protected?

All efforts, within reason, will be made to keep your personal information in your research record confidential, however, please be advised that complete privacy and confidentiality cannot be guaranteed in the laboratory setting. To keep your data confidential, all of the information that we collect from you and your family (audio and video recordings, and paperwork) will only be identified by a random number. Your names and address will be matched with that number in one password-protected data file, accessible only to Dr. Tumanova and her research staff. Electronic documents will be kept on the lab computer, which can only be accessed using a password. Your or your child's name will not be identified in any report of the results of this study. We will keep your child's study data as confidential as possible with the exception of certain information we must report for legal or ethical reasons such as disclosure of situations of abuse or intent to harm self or others.

After the identifiable private information is removed from the data, the data could be used for future research studies or distributed to another investigator for future research studies without additional consent from you.

Will photographs, audio or video recording be used?

During the study procedures your child will be audio and video recorded. Audio/video recording is used for research purposes only. It will allow us to analyze the data, and train other research assistants.

Only authorized researchers will use or review your recorded materials. Recordings will be stored for 10 years, after which they will be destroyed. They may be used for further review until 10 years has elapsed.

You may be asked to allow us to take photographs of you and/or your child during your participation in the study. With your permission, we will display these photographs on a poster board in the laboratory and/or use these photographs on our laboratory's website along with written information about our laboratory's research activities. Your or your child's name will not be posted on the website. Although we will never post your or your child's name in these scenarios, photographs are identifiable so you and/or your child may be recognized. The photograph(s) may be posted on the website indefinitely until you revoke your permission by contacting Dr. Victoria Tumanova in writing. The photos would remain indefinitely on the website, but is not associated with one's research participation.

Will I receive compensation for participation?

You will be paid \$25 for each visit, for a total of \$75 for the three visits. If your child comes in for, but does not complete a visit entirely, you will still be compensated for the entire visit. Your child will also be given a small toy at the end of each visit.

What are my rights as a research participant?

Your participation is voluntary.

You may skip and/or refuse to answer any question for any reason.

You are free to withdraw from this research study at any time without penalty.

Whom may I contact with questions?

If you have any questions, concerns, and/or complaints about the research, contact Dr. Victoria Tumanova at 315-443-9640. If you have any questions about your rights as a research participant, you have questions, concerns, and/or complaints that you wish to address to someone other than the investigator, or if you cannot reach the investigator contact the Syracuse University Institutional Review Board at 315-443-3013.

For Future Contact, please initial your choices below

I consent to the research team contacting me in the future to learn about:

New research opportunities that my child may like to be involved in.
 General information about research findings from this study.
 I do not agree to be contacted in the future.

Your wish does not constitute a guarantee that you will be contacted.

Contacting the participant's speech-language clinician

I agree to allow the researchers to contact my/my child's speech-language therapist as part of this study.
 I DO NOT agree to allow the researchers to contact my/my child's speech-language therapist as part of the study.

By signing this consent form, I agree to participate in this research study and give permission for my child to participate. I have received a copy of this form for my personal records.

I agree to have my child audiotaped Yes No

I agree to have my child videotaped Yes No

I consent to tapes being used for teaching purposes Yes No

I give my consent to have myself and/or my child to be photographed and photographs be placed on the laboratory's public website Yes No

Printed Name of Child Participant

Date: _____

Printed Name of Parent or Guardian

Signature of Parent or Guardian

Printed Name of Researcher

Date: _____

Signature of Researcher