

Online assessment and enhancement of auditory perception for speech sound errors

Protocol NCT04858022

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PARENT/GUARDIAN CONSENT FORM

Please read below with care. You can ask questions at any time, now or later. You can talk to other people before you fill in this form.

Title: Online assessment and enhancement of auditory perception for speech sound errors

Study Number: IRB-FY20-21-2137, Sub-studies 2 & 3

Why is this study being done?

The purpose of this study is to test the effectiveness of different types of speech interventions using video calls for children who have trouble producing the “r” sound.

What will happen while your child or dependent is in the study?

Before and after the study we will ask you to complete questions about your child’s health and language history and how he/she are affected by his/her difficulty with the “r” sound. These questions take about 15 minutes to complete.

Next, we will arrange a video call to check if your home technology setup meets study requirements. We will then test your child or dependent’s hearing, language, speech, and thinking skills. We will ask him/her to say different words and sentences. We will also test his/her speech perception skills by having him/her listen to “r” sounds in words and rate him/her as correct or incorrect. This first part of the study is expected to take up to 2-3 hours over 2 sessions using video calls. These tests will be used to decide if your child or dependent is a good fit for this study. It is possible that based on the results of these tests he/she might not be able to continue to the remainder of the study.

If your child or dependent is a good fit for the study, he/she will be assigned to either Sub-study 2 or Sub-study 3 based on the results of his/her testing. You must agree to be willing to have your child or dependent participate in any training to which he/she are assigned. Since study assignment is based on testing results, the type of training your child receives cannot be changed. Both study assignments are outlined below:

Sub-study 2

If your child or dependent is assigned to Sub-study 2, he/she will have one more session where he/she will be asked to say “r” in different words and sentences, and answer questions about how he/she feel about his/her speech. This session will last about 30 minutes. Then he/she will either start the treatment phase of the study or wait 10 weeks to begin the treatment phase.

In Sub-study 2, all children receive the *same treatment* regardless of when treatment starts. In the treatment phase of the study, we will ask your child to participate in 2 treatment sessions per week for about 10 weeks (20 treatment sessions total). Each session will last about 60 minutes. In each session, your child will work with a speech therapist who will model and verbally help him/her produce a better “r” sound using *visual-acoustic biofeedback* treatment. During this treatment, we use a computer to create a visual representation of a child’s “r” sound, which can then be compared against a model “r” sound.

There will be an additional session at the transition point between the treatment phase and the wait phase. There will also be an additional session at the end of the 20-week study duration. During these sessions, your child or dependent will be asked to say “r” in different words. Each of these sessions is expected to last about 30 minutes.

Sub-study 3

If your child or dependent is assigned to Sub-study 3, we will ask him/her to complete 1-4 additional sessions in which we will test how he/she say “r” sounds. We will also test his/her speech perception skills by having him/her listen to sounds in words and rate them as correct or incorrect. Each session is expected to last between 30 minutes and 1 hour.

In Sub-study 3, there are 2 phases of training; perceptual (listening) and production phases. In the perceptual training phase of the study, we will ask your child or dependent to participate in 3 sessions per week for about 4 weeks (12 sessions total). These sessions will take about 30 minutes. During these training sessions, your child/dependent will complete 3 different listening tasks, where he/she will be asked to evaluate correct and incorrect productions of the “r” sound.

After the 12 perceptual training sessions, your child or dependent will receive 2 production training sessions per week for 2 weeks (4 sessions total). These sessions will take about 1 hour. In these sessions, your child or dependent will work with a speech therapist verbally helps your child move his/her mouth and tongue to make a correct “r” sound.

After completion of the study, we will ask your child or dependent to complete 3 post-training sessions in which we will test your child’s perception and production of “r” sounds. Each of these sessions is expected to last between 30 minutes to 1 hour.

Recordings

In both sub-studies, we will collect audio recordings of your child or dependent’s speech in some sessions. We will ask him/her to record his/her speech to a computer and upload the recordings to a secure website for our study team to review. We may also make video recordings of the computer screen during video calls. We may use these recordings to check whether study staff are following the study’s rules correctly and for research and teaching purposes. We will not release video of your child or dependent without your permission.

Time

Sub-study 2

Your child or dependent’s participation in Sub-study 2 is expected to last about 23 weeks (approximately 1-2 weeks of testing prior to training, 10 weeks in the training phase, 10 weeks in the wait phase, 1 week of testing after treatment). A sample timeline for Sub-study 2 is listed below:

Sub-study 2		
	Group A	Group B
Week 1	Assessment 1-2hr/x2	Assessment 1-2hr/x2
Week 2	Assessment 30min/x1	Assessment 30min/x1
Week 3	Production training 60min/x2	wait
Week 4	Production training 60min/x2	wait
Week 5	Production training 60min/x2	wait
Week 6	Production training 60min/x2	wait
Week 7	Production training 60min/x2	wait
Week 8	Production training 60min/x2	wait
Week 9	Production training 60min/x2	wait
Week 10	Production training 60min/x2	wait
Week 11	Production training 60min/x2	wait
Week 12	Production training 60min/x2	Assessment 30min/x1
Week 13	Assessment 30min/x1	Production training 60min/x2
Week 14	wait	Production training 60min/x2
Week 15	wait	Production training 60min/x2
Week 16	wait	Production training 60min/x2
Week 17	wait	Production training 60min/x2
Week 18	wait	Production training 60min/x2
Week 19	wait	Production training 60min/x2
Week 20	wait	Production training 60min/x2
Week 21	wait	Production training 60min/x2
Week 22	wait	Production training 60min/x2
Week 23	Assessment 30min/x1	Assessment 30min/x1

Sub-study 3

Your child or dependent's participation in Sub-study 3 is expected to last about 10 weeks (approximately 2-3 weeks of assessment prior to training, approximately 6 weeks of training, 1-2 weeks of assessments after treatment). A sample timeline for Sub-study 3 is listed below:

Sub-study 3	
Week 1	Assessment 1-2hr/x2
Week 2	Assessment 30min/x2
Week 3	Assessment 30min/x2
Week 4	Perceptual training 30min/x3
Week 5	Perceptual training 30min/x3
Week 6	Perceptual training 30min/x3
Week 7	Perceptual training 30min/x3
Week 8	Production training 60min/x2
Week 9	Production training 60min/x2
Week 10	Post Assessment 30-60min/x3

Responsibilities

If you choose to enroll your child or dependent in this study, we will ask that you withdraw your child from any other therapy targeting the "r" sound for the duration of this study. Speech therapy targeting goals other than "r" is allowed. We will be happy to speak with your child or dependent's speech therapist to make sure he/she will continue to receive services after the end of our study.

Since we will be doing all treatment over video calls, we need to make sure that your home internet connection is stable. For this reason, we ask that you plug your child's computer directly into your home router for all evaluation and treatment sessions. We can provide an Ethernet cable for this purpose, if necessary. We also ask

that your child be in a quiet environment with minimal background noise from siblings, pets, etc. during our sessions. Finally, we may ask you to help your child get set up with video calls and/or troubleshoot technology issues during the sessions.

Risks

The risks associated with this study are the same as in ordinary life. If needed, your will be given breaks and can stop sessions at any time. Your participation in this study will not result in any additional costs. If your child or dependent is assigned to biofeedback treatment, the risks associated with this therapy are no greater than in ordinary life. Use of visual-acoustic software (Pentax Sona-Speech II) shared from the clinician's computer using a video call does not pose any additional risk beyond traditional therapies.

Benefits

Participating in this training may help your child or dependent produce a better "r" sound and/or improve his/her ability to perceive productions of "r" sounds as correct or incorrect. There is no guarantee that your child's speech and perception will improve as a result of his/her participation in this study. However, the information learned from this study may help other people with speech disorders in the future.

If any new information is learned about this study that might affect your child's willingness to stay in this study, you will be told about it promptly.

Compensation

To compensate you for the time your child or dependent spent in this study, all assessment and training sessions will be provided with no cost to you.

Who will know that your child or dependent is in this study?

This study is covered by a Certificate of Confidentiality from the National Institutes of Health. Researchers with this Certificate will not share 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 as information about suspicion of child abuse or neglect.
- Your explicit approval for the researchers to release personally identifiable information.

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. These recordings will never contain identifying information such as your child's name. Data will be collected online using secure websites without identifying information. The results of this research project may be presented at meetings or in publications; however, your child will not be identified in these presentations and/or publications.

To track participant progress, we need to obtain outside listeners' ratings of participants' productions of words containing "r." We get these ratings by playing recordings of participants' utterances in a randomized, de-identified fashion for untrained individuals recruited to complete speech rating tasks in our lab or on the internet; these recordings will never contain identifying information such as your child's name.

Below, we will ask for your permission to share recordings of your child's "r" productions as part of future research studies. Finally, we will ask permission to share recordings of your child in an academic context, such as a conference or classroom. These would be audio or screen-capture video recordings that do not contain your child's name. You are free to tell us not to share audio/video of your child in these ways. We will not release recordings of your child without your consent.

Study records that identify your child and the consent and assent forms signed by you and your child may be looked at by the Institutional Review Board and individuals responsible for overseeing the conduct of this research. While these parties are aware of the need to keep your information confidential, total confidentiality cannot be guaranteed. The results of this research project may be presented at meetings or in publications; however, your child will not be identified in these presentations and/or publications.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This website will not include information that can identify your child. At most, the website will include a summary of the results. You can search this website at any time.

Does your child or dependent have to be in the study?

Your child or dependent does not have to be in this study. He/She is a volunteer! It is okay if he/she want to stop at any time and not be in the study. Your child or dependent does not have to answer any questions that he/she do not want to answer. Nothing will happen to him/her and he/she will still get the things that are promised for the duration of the time he/she is enrolled in the study. If he/she decide to leave the study, please tell the study staff.

Do you have any questions about this study?

Phone or email Elaine R. Hitchcock, PhD, CCC-SLP at 973-655-7355 or hitchcocke@montclair.edu

Do you have any questions about your rights as a research participant?

Phone or email the IRB Chair, Dr. Dana Levitt, at 973-655-2097 or reviewboard@montclair.edu.

One copy of this consent form is for you to keep.



Statement of Consent

I have read this form and decided that I agree to my child's participation in the project described above. Its general purposes, the particulars of involvement, and possible risks and inconveniences have been explained to my satisfaction. I understand that my child can withdraw at any time. My signature also indicates that I have received a copy of this consent form.

If you choose to have your child or dependent in this study, please fill in the lines below.

Child's Name: _____

Name of Parent/Guardian

Signature

Date

Name of Witness

Signature

Date

Name of Principal Investigator

Signature

Date

It is okay to use his/her data in future studies:

Please initial:

_____ Yes

_____ No

It is okay to use his/her audio recordings in an academic setting. These recordings would not contain his/her name.

Please initial:

_____ Yes

_____ No

It is okay to use his/her video recordings in an academic setting. These recordings would not contain his/her name.

Please initial:

_____ Yes

_____ No