



MAY 28 2015

MAY 27 2016

SYRACUSE UNIVERSITY
COLLEGE OF ARTS AND SCIENCES
DEPARTMENT OF COMMUNICATION SCIENCES & DISORDERS
GEBBIE SPEECH-LANGUAGE-HEARING CLINIC

**Informed Assent Form for
Ultrasound biofeedback for therapy-resistant speech sound disorders**

My name is Jonathan Preston, and I am from the department of Communication Disorders at Syracuse University (SU). We are asking you to participate in a research study because you may have had some difficulty learning to say certain speech sounds.

PURPOSE: A research study is a way to learn more about people. In this study, we are trying to learn more about how people learn to talk. The study will help us learn new things about how children use information on a computer screen to move their tongue differently when they speak. We want to see if you'll be a good candidate for the study.

PARTICIPATION: If you decide you want to be part of this study, you will be asked to do several things. The first day, we'll do some tasks that involve having you talk and listen. We'll record you talking. It will take about an hour and a half. This will help us decide if you would be a good candidate for the rest of the study.

If you qualify for the rest of the study, we will invite you to come see us for several visits. We will do some more tasks where you talk, listen, repeat words, and name pictures. We will then do some speech lessons for 14 separate hour long visits. These may be similar to other speech lessons you've had. In this case, though, an ultrasound wand will be held under your chin as you talk to give you a video of your tongue. We will use this to show you what your tongue is doing as you speak. We will try to use this video to help you figure out how to move your tongue differently when you try to pronounce sounds and words. After the speech lessons, we'll ask you to come in for 3 more short visits to see if you still remember how to do the things we worked on.

RECORDING: By signing this form you agree to be audio recorded. We will also ask your permission to be video recorded. The other researchers and I will use these to listen to how your speech changes over time. We might also use it at workshops to show other speech teachers how your speech changes. The recordings will be deleted after 5 years unless you and your parent(s) say it is okay for us to keep them longer.

RISKS & BENEFITS: There are some things about this study you should know. The study should not hurt, but you may feel tired, bored, or unsure as you do some of the tasks. The ultrasound has to be held tightly under the chin, so you may find it a little uncomfortable. Anytime you want to take a break, you can just ask. Or if you want to stop, you can tell us and we'll stop.

Not everyone who takes part in this study will benefit. The study might help you to speak words more clearly. We aren't certain if it will help but we will try.

During the days when we are doing testing you will receive \$20 per hour. If you choose to end the study early, we will receive money for the time you have already put in. We do not give you money for every visit, only the days when we are testing and not the days when we do speech lessons.

I have to let you know that if you were to tell me about anyone or anything that has hurt you or made you feel very upset, whether it's related to this study or not, I would have to tell someone who is not in the study.

ALTERNATIVES: If you do not want to be in this research study, we will tell you what other kinds of treatments there are for you.

REPORTS: When we are finished with this study we will write a report about what was learned. This report will not include your name or that you were in the study.

VOLUNTARY: Voluntary means that you do not have to be in this study if you do not want to be. We have already asked your parents if it is ok for us to ask you to take part in this study. Even though your parents said we could ask you, you still get to decide if you want to be in this research study. You can also talk with your parents, grandparents, and teachers to deciding whether or not to take part. No one will be mad at you or upset if you decide not to do this study. If you decide to stop after we begin, that's okay too. You can also skip any of the questions you do not want to answer.

QUESTIONS: You can ask questions now or whenever you wish. If you want to, you may call me at 585-797-7056. If you are not happy about this study and would like to speak to someone other than me, you or your parents may call the Syracuse University Institutional Review Board (IRB) at 315-443-3013.

Please sign your name below, if you agree to be part of my study. You will get a copy of this form to keep for yourself.

Signature of Participant _____ Date _____

Name of Participant _____

I agree to be videotaped I do not agree to be video taped

Signature of Investigator _____ Date _____

Print name of Investigator _____

Syracuse University IRB Approved

MAY 28 2015

MAY 27 2016



MAY 28 2015

MAY 27 2016

SYRACUSE UNIVERSITY

COLLEGE OF ARTS AND SCIENCES
DEPARTMENT OF COMMUNICATION SCIENCES & DISORDERS
GEBBIE SPEECH-LANGUAGE-HEARING CLINIC

INFORMED CONSENT FOR PARENT OR ADULT PARTICIPANT

Project Title: Ultrasound biofeedback for therapy-resistant speech sound disorders

My name is Dr. Jonathan Preston, and I am a professor at Syracuse University. I am inviting you or your child to participate in a research study. Involvement in the study is voluntary, so you may choose to participate or not. This sheet will explain the study to you. Please feel free to ask questions about the research if you have any. I will be happy to explain anything in detail if you wish.

I am interested in learning more about speech sound disorders (individuals who have trouble pronouncing words clearly). This includes learning about how to treat speech problems, as well as understanding how certain speech and language behaviors relate to outcomes in speech therapy.

Description of Procedures and Time Commitment

If you agree to participate/have your child participate in this study, we will ask you to provide some information about your/your child's developmental and educational history.

During the first visit, the Participant (you or your child) will be asked to participate in several standardized tests of speech and language that involve naming pictures, repeating words and sentences, following directions, reading words, and listening for sounds in words. These tasks will be completed in about an hour and a half. These tests will be used to determine eligibility for the remainder of the study; it is possible that, based on the results of the tests, you/your child might not be eligible to participate in the remainder of the study.

Based on the results of the standardized speech tests, the Participant may qualify for the next part of the study. If so, this would include:

1. Two more "pre-treatment" visits that involve further speech and language assessments. This includes naming pictures, repeating real and nonsense words, listening to recordings on a computer, and manipulating blocks. Each of these sessions will last approximately 90 minutes.
2. Up to 14 one-hour sessions in which we will provide speech lessons to improve the clarity of your/your child's articulation. We will aim to schedule two sessions per week. Some of the sessions will be similar to traditional speech therapy lessons where we discuss how certain speech sounds are made in the mouth; we practice syllables and words over and over in different activities while giving cues and feedback on how the sound is made. Some of the lessons will also involve ultrasound visual feedback (no more than 26 minutes per session). This involves placing an ultrasound transducer under the chin to give us a video on a computer screen of the tongue shape as the Participant is making certain speech sounds. Because this video is shown in real time, we

can use it to cue the Participant to make a different shape with the tongue. We will try to explain how to recognize the tongue shape that results in a clearer production of the speech sounds we are working on. We will practice the sounds over and over. We will audio and video record these sessions. This will take an hour each for 14 visits.

3. After the lessons, we will ask the Participant to return for 3 short sessions to see if his/her speech clarity has improved by re-assessing speech accuracy while reading words and repeating sentences. We will also ask the Participant about their experiences with the study.

You will be told of any significant new findings that are developed during the course of your/your child's participation in this study that may affect your willingness to continue to participate.

If the Participant currently receives speech-language therapy, we may wish to coordinate with the speech-language clinician. You may give us permission to contact this person or you may choose not to do so.

I will assign a number to the Participant's responses, and only I and my research team will have the key to indicate which number belongs to which participant. In any articles I write or any presentations that I make, I will not reveal details about you/your child.

Your study data will be kept as confidential as possible, with the exception of certain information we must report for legal or ethical reasons (e.g., child abuse which must be reported to state authorities).

Audio and Video Recording

To help us ensure reliable study procedures, we wish to audio and video record the sessions. This provides us with the ability to review the recordings to ensure that the information we collect is accurate and that any testing or treatment that we provide is conducted in a valid way. Additionally, our data analysis involves tracking improvements in speech clarity, and this requires collecting recordings. By signing the consent, you agree to allow us to collect audio recordings. Video recordings are optional.

The recordings will be stored by ID number on a password protected computer. Recordings will be destroyed after 5 years of publication of the data unless you provide us with permission to retain the files for instructional purposes/presentations. You may request to have the recordings destroyed by contacting Dr. Preston and requesting data destruction.

Economic Considerations

The only costs you will incur will be traveling to/from the laboratory. We will reimburse you \$5 per session for transportation costs. We will reimburse you \$20/hour (paid at \$5 for each quarter hour) for behavioral testing. During sessions in which we provide the speech lessons, no reimbursement will be provided except for \$5 transportation costs. For Participants who do not complete all aspects of the study or who withdraw, we will reimburse you for the time provided.

The following benefits may be expected:

- After completing the speech and language testing, we will share standard scores with you, so you may learn more about your/your child's communication strengths and weaknesses.
- As a result of the ultrasound visual feedback sessions, the Participant may improve the clarity of his/her speech production.

Syracuse University IRB Approved

- The advancement of scientific knowledge may improve our understanding of speech difficulties and how to treat them

Risks and Inconveniences

- *Behavioral Testing*. Because some of the language tests may be challenging, you/your child may experience some frustration when completing the tasks. However, there are no known risks. Breaks will be offered, and you/your child may choose not to complete any of the tasks.
- *Ultrasound* is often used to see internal body structures such as the heart or bladder, although in this instance we use it to obtain images of the tongue. There are no known side effects associated with this type of ultrasound examination because we use a safe, low-intensity device that is not capable of producing the adverse effects of very strong ultrasound devices. Participants occasionally report mild discomfort where the ultrasound probe is placed tightly under the tongue, but this is temporary. Ultrasound involves sound waves, which does *not* have the risks associated with ionizing radiation from other procedures such as x-rays. Thus, the primary risks include transmission of communicable diseases such as the common cold, which we address by sanitizing the ultrasound equipment before and after every session.

If you/your child do not want to take part, you/your child have the right to refuse to take part, without penalty. If you decide to take part and later no longer wish to continue, you/your child have the right to withdraw from the study at any time, without penalty.

Contact Information:

If you/your child have any questions, concerns, complaints about the research, contact Dr. Jonathan Preston at jopresto@syr.edu or at 315-443- 9637. If you have any questions about your rights as a research participant, you have questions, concerns, 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.

All of my questions have been answered, I am 18 years of age or older, and I wish to participate/have my child participate in this research study. I have received a copy of this consent form.

Please check: 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.

Please check: Audio and Video Recording Permission

I agree to be/have my child be video and audio recorded

I agree to be/have my child be audio recorded ONLY

Syracuse University IRB Approved

MAY 28 2015 MAY 27 2016

Please check: Permission to use recordings for Instruction/Presentations

We like to have examples of our research procedures available to train students or speech-language clinicians. It is often helpful to have recordings to support these presentations. If you allow this, no names will be used when these recordings are shown. If you choose not to allow this, you may still participate in this study.

I agree to allow VIDEO and AUDIO recordings to be used for instructional purposes

I agree to allow ONLY AUDIO recordings to be used for instructional purposes

I do NOT agree to allow recordings to be used for instructional purposes.

Signature of participant or Parent/ Guardian

Date

Printed name of adult participant or Parent/Guardian

If participant is child, print name of child

Signature of researcher

Date

Printed name of researcher

Syracuse University IRB Approved

MAY 28 2015 MAY 27 2016