Predictors of Speech Ability in Down Syndrome
Informed Consent Document
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VUMC Institutional Review Board
Informed Consent Document for Research

Principal Investigator: Stephen Camarata, PhD Revision Date: 12/31/2021 Study Title: Predictors of Speech Ability in Down Syndrome
Institution/Hospital: VUMC/Bill Wilkerson Center

Name of participant: _____ Age: _____

The following information is provided to inform you about the research project 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.

Key Information:

This is a consent document for parents. The first section of this document contains some key poin ts that the research team thought you would find important. The study is described in more detail after this section. If you do not understand something, please ask someone.

Key information about this study:

The goal of this study is to have a better understanding of how people with Down syndrome produce speech, and when their speech changes, what factors, such as intonation and consonant and vowel production are altered. The study will include assessment of your child's speaking ability, listening skills, language, and problem solving using pictures. In addition, the study also provides speech enrichment sessions, which will be conducted twice per week for three months. Each session is one hour long. The sessi on are interactive and include asking your child to name pictures and to engage in play activities. The speech enrichment sessions do not include drill on individual speech sounds. A follow up testing session will be completed after three months and will once again include assessment of your child's speaking ability, listening skills, and language abilities. We will provide you with a summary of the results of the assessments. Note that all results are otherwise confidential and that all research records will be deidentified. Total participation time will be approximately four months. Approximately 20 participants will be involved in the study.

None of the assessment or speech enrichment activities have been shown to cause harm and these activities are similar to testing and learning experiences at school and in speech pathology sessions. Your child may benefit from the speech enrichment sessions in terms of speaking more clearly, but we are not promising improvements. Note that participation does involve attending the assessment and speech enrichment sessions, which will be scheduled at your convenience, but nonetheless do require travel to the Bill Wilkerson center. The benefits to society for this information include potentially gaining new insights into how people with Down syndrome learn to speak and study may yield improvements in speech intervention.

Finally, there is no prohibition on participating in any other studies including outside treatment for speech. We do ask that you will inform us of outside treatment including the number of sessions and duration that are occurring while your child is participating in the study.

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Detailed Information:

The rest of this document includes detailed information about this study (in addition to the information listed above).

You are being asked to take part in this research study because your child has Down syndrome and meets the eligibility criteria for participation.

You do not have to be in this research study. You may choose not to be in this study and get other treatments without changing your healthcare, services, or other rights. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study.

Procedures to be followed and approximate duration of the study:
You will be asked to bring your child to the Bill Wilkerson Center at Vanderbilt for an initial testing session. Testing sessions will take place over 1-2 visits for ~2-6 hours. After the initial testing, speech enrichment sessions will occur two times weekly and last approximately one hour each. Sessions may take place at VBWC, remotely or in the participant's home. The speech sessions will continue for three months. After three months, within one month after the enrichment sessions have ended, you will be asked to bring your child back to the VBWC for another day of testing. You are welcome to use the waiting room on the 10th floor of the Bill Wilkerson Center while your child is being tested and while attending the speech enrichment sessions. You are not required to watch the testing or the enrichment sessions, but you are welcome to do so if you wish. Please let your child's clinician know when you wish to observe.

The testing sessions last for approximately two to six hours and include naming pictures, pointing in response to verbal instructions and matching. Testing will also include recording your child's speech during play activities with the clinician. This testing will be video recorded and will be analyzed by different people working on the study, who may view the video. These video records (using SD format) will be stored in a secure, password protected server in a locked room on the 10th floor of the Wilkerson Center.

The speech enrichment sessions will include play-based activities designed to increase your child's speaking ability. These include playing with toys and naming pictures. The clinicians completing the enrichment sessions will be licensed speech-language pathologists or students studying to be speech-language pathologists. In the enrichment sessions, when your child attempts to speak, the speech teacher will repeat, using correct pronunciation, the words your child attempted to say (but using incorrect pronunciation). There will be no speech pronunciation drill or aversive procedures whatsoever during enrichment sessions. While enrolled in the study, you are free to continue other speech services. You will be asked to complete a short description of the speech treatment your child is receiving in addition to the speech enrichment session within the study if your child is receiving other speech services.

For sessions conducted at VBWC, you will need to bring your child to the sessions and pick them up promptly when the session is finished, You or someone you appoint may drop off and pick up your child. If you appoint someone, this must be arranged in advance by contacting the clinician working with your child. If you are unable to attend a scheduled session, please contact your child's clinician in advance so the session can be rescheduled. You are welcome to observe all sessions, but are not required to observe or attend the testing and/or treatment sessions.

The total time period for the study will be approximately four months.

Expected costs:

There is no cost other than the time required to attend the sessions and the transportation expense traveling to

VBWC. You are expected to transport your child to the Bill Wilkerson Center at Vanderbilt University for two testing sessions and two times weekly for three months for speech enrichment sessions. There is no compensation for participating in the study.

Description of the discomforts, inconveniences, and/or risks that can be reasonably expected as a result of participation in this study:

The sessions will be scheduled at your convenience, but this will require time and effort to attend the sessions. At this time, there are no known risks associated with the speech assessments or speech enrichment sessions. However, your child may not wish to participate in a testing or an enrichment session. They can indicate this dissent by telling the clinician they wish to stop the activity or to leave. They can also indicate dissent by pushing away the materials, attempting to leave the room or by crying or other sign of displeasure such as yelling. If your child indicates dissent, they will be brought to you by the cl inician and you will immediately told what your child did to indicate their dissent.

Good effects that might result from this study:

a) The benefits to science and humankind that <u>might</u> result from this study. The potential benefits to science and humankind that may result from this study are an increased knowledge of how to treat speech disorders in Down Syndrome

b) The benefits you might get from being in this study. The potential benefits to you from this study are a possible improvement in speech comprehensibility for your child. Improvement is not always seen, so your child may not directly benefit.

Study Results:
A summary of the results of your child's testing will be provided. Also, if you wish, we can provide a copy of the articles that are published that describe the results of the study

Alternative treatments available:
There is no prohibition on continuing current speech services and/or enrolling in additional services while your child is enrolled in the study

Circumstances under which the Principal Investigator may withdraw you from study participation: Enrolling in the study indicates an interest in participating. You are free to change your mind and discontinue participation at any time and for any reason. The Principal Investigator may ask you to withdraw from the study if there are five (or more) unexcused absences from testing and/or speech enrichment sessions.

What happens if you choose to withdraw from study participation?
You are free to withdraw from the study at any time. This will in no way harm your relationship with Dr. Camarata, Bill Wilkerson Center or Vanderbilt University Medical Center. You can withdraw by contacting Dr. Camarata (936-5111) to inform him that you are withdrawing from the study. Alternatively, you are free to e-mail your intent to withdraw (Stephen.camarata@vumc.org) or via letter (Stephen Camarata, PhD, 1215 21st Avenue South, Room 8310, Nashville, TN 37232).

Contact Information. If you should have any questions about this research study or possibly injury, please feel free to contact (Stephen Camarata, PhD CCC-SLP) at (615-936-5111). You are also welcome to contact Dr. Camarata via email (Stephen.camarata@vumc.org)

For additional information about giving consent or your rights as a participant in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to contact the Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

Confidentiality:

All efforts, within reason, will be made to keep your personal information in your research record confidential but total confidentiality cannot be guaranteed. Your child will be assigned a code number for identification on all records. All testing and speech enrichment sessions will be video recorded and will be analyzed by different people working on the study, who may view the video. These video records (using SD format) will be stored in a secure, password protected server in a locked room on the 10th floor of the Wilkerson Center. The ID for each participant will be kept on a paper record that will be kept in a locked drawer in Dr. Camarata's office.

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Privacy:

We will maintain your child's privacy and release information only to external sources (e.g., schools, other clinical services such as speech intervention) only if this is specifically authorized by you in writing.

Authorization to Use/Disclose Protected Health Information What information is being collected, used, or shared?

To do this research, we will need to collect, use, and share your private health information. By signing this document, you agree that your health care providers (including both Vanderbilt University Medical Center and others) may release your private health information to us, and that we may use any and all of your information that the study team believes it needs to conduct the study. Your private information may include things learned from the procedures described in this consent form, as well as information from your medical record (which may include information such as HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

Who will see, use or share the information?

The people who may request, receive or use your private health information include the researchers and their staff. Additionally, we may share your information with other people at Vanderbilt, for example if needed for your clinical care or study oversight. By signing this form, you give permission to the research team to share your information with others outside of Vanderbilt University Medical Center. This may include the sponsor of the study and its agents or contractors, outside providers, study safety monitors, government agencies, other sites in the study, data managers and other agents and contractors used by the study team. We try to make sure that everyone who sees your information keeps it confidential, but we cannot guarantee that your information will not be shared with others. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may no longer protect it.

Do you have to sign this Authorization?

You do not have to sign this Authorization, but if you do not, you may not join the study.

How long will your information be used or shared?

Your Authorization for the collection, use, and sharing of your information does not expire. Additionally, you agree that your information may be used for similar or related future research studies.

What if you change your mind?

You may change your mind and cancel this Authorization at any time. If you cancel, you must contact the Principal Investigator in writing to let them know by using the contact information provided in this consent

form. Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your authorization.

If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

STATEMENT BY PERSON AGREEING TO PARTICIPATE IN THIS STUDY

I have read this informed consent document and the material contained in it has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to participate.

Date Signature of Parent/Guardian

Consent obtained by:

Date Signature

Printed Name and Title

Photography/Videography and Audio Recording Consent

During some social communication and developmental assessments, we may audio and video record you and your child for research purposes. All recordings are confidential material and will not be used without your

specific consent. You may request that the recordings be erased after the study is completed and that your consent for any use of them may be withdrawn by requesting so in writing.

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In addition, I give my consent to the faculty and fellows at the Vanderbilt University Music Cognition Lab to use photographic images, video or audio segments for reasons other than research purposes:

❑ For educational and training purposes within Vanderbilt University ____(initial) ❑ For use at national and international conferences ____(initial)
❑ For use in publications ____(initial)
❑ For use in press releases, social media, or media materials _____(initials)

Your ability to participate in this study is not affected in any way by your willingness to consent to your child's image being used for educational or training purposes as described above.

_____ _____
Signature Date

_____ _____
Signature of Person Obtaining Consent Date

Institutional Review Board

VANDERBILT

Date of IRB Approval: 01/06/2022