Technology Assisted Language Intervention (TALI)

NCT04857255

TALI Parental Permission Consent_v4_11.6.21_CCHMC

STUDY TITLE: IMPROVING OUTCOMES USING AUGMENTATIVE AND ALTERNATIVE COMMUNICATION FOR CHILDREN WHO ARE DEAF OR HARD OF HEARING

FUNDING ORGANIZATION: National Institute on Deafness and Other Communication Disorders (NIDCD)

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Name of Principal Investigator

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INTRODUCTION

We are asking for your permission for your child to be in a research study so that we can learn new information that may help others. If you decide not to give your permission for your child to be in this study, we will still take good care of him/her. If you decide to allow your child to be in this study, you may change your mind at any time during the study and your child can stop being in the study. Take all the time you need to make your choice. Ask us any questions you have. It is also okay to ask more questions after you decide to allow your child to be in the study. You can ask questions at any time.

WHY ARE WE DOING THIS RESEARCH?

In this research study we want to learn more about different types of language therapies or interventions that might help a child's language development.

We are asking your child and other children with permanent hearing loss to be in the research, because children who are deaf or hard of hearing are at risk for problems with their language development.

WHO IS IN CHARGE OF THE RESEARCH?

Dr. Jareen Meinzen-Derr is the researcher at Cincinnati Children's Hospital Medical Center that is in charge of this study.

Cincinnati Children's Hospital Medical Center is being paid by NIDCD to do this study.

WHO SHOULD NOT BE IN THE STUDY

Your child cannot be in this study if he/she has any of the following:

- Does not speak English as the primary language;
- Has severe vision impairment (i.e. deaf-blind);
- Has a disability or syndrome that affects language (e.g., autism, severe motor disabilities);

If your child is not diagnosed with a hearing loss, but you or your physician is concerned about your child's ability to hear, then you may not be eligible to participate until a hearing test has been conducted.

WHAT WILL HAPPEN IN THE STUDY?

The research staff will explain each visit to you and may give you a handout that explains each visit in more detail. You will be able to ask questions to make sure that you understand what will happen to your child.

These are the things that will happen to your child while in the study:

Your child will have up to 3 evaluation visits.

At the initial evaluation visit, your child will receive a language test by a speech and language pathologist (SLP), and a cognitive assessment by a psychologist. The SLP will assess current language skills and determine if your child is eligible to continue on in the study. You will be asked to fill out some forms about your child's functional skills. You will be asked a few questions which will include your child's communication, school, and therapies. We will also ask a few questions about yourself, including your educational level.

Your initial evaluation visit might take 2-3 hours (~1.5 hour for the language assessment and language sample. and ~1 hour for the cognitive assessment).

After the initial evaluation visit is completed, if your child is eligible, he/she will be randomized into one of two study groups. Being randomized means your child will be put into a study group by chance, like flipping a coin. Your child will have a one in two chance of being in any one study group.

The two study groups are the augmentative and alternative communication (AAC) intervention group and the usual or standard care group.

If you are randomized to the **group that uses the AAC device**, you will be asked to attend weekly language therapy sessions for 6 weeks. During these sessions, your child will receive a tablet, such as an iPad, which contains a special program that will be used for helping your child learn and improve his/her language. The SLP will teach you and your child how to use the program at home. Your child will also be given an hour of language therapy during this time, which will use the tablet and the software program so that you and your child will be comfortable with it. You will get to take the iPad home during this period so you can start using the language program at home. After the first 6 weeks, you will then be asked to continue the therapy using the iPad at

home. Your SLP will give you instructions on how you will be using it and you will have the chance to practice. You will continue using the iPad at home for 6 weeks. You will then come in for 6 more weeks of weekly therapy with the SLP. The SLP will monitor your child's progress and set additional language goals that are important for your child at this time. You will have the opportunity to tell the SLP and the research coordinator what you liked or did not like about the use of the iPad at home. Your final 6 weeks will occur at home using the tablet.

Each study therapy for the AAC intervention group visit after that should take approximately 1 hour (similar to the standard care therapy). Information that is part of your child's medical record may also be included.

If you are randomized to the AAC group, your therapy sessions will look as follows:

- 6 weeks of weekly therapy with SLP.
- 6 weeks at home with iPad and AAC
- 6 weeks of weekly therapy with SLP
- 6 weeks at home with iPad and AAC

You will return for a 2nd evaluation visit at around 24 weeks. At this time your child will receive a language assessment and you will be asked to fill out some forms about your child's functional skills. At this time the AAC intervention sessions will be complete.

We will ask you to return for a follow up and final evaluation visit 6 months later (at 12 months from your enrollment) to help determine whether the effects of the AAC intervention lasted over time. Your child will receive a language assessment and you will be asked to fill out some forms about your child's functional skills.

If you are randomized to the **standard or usual care group**, you will continue to attend your usual speech-language therapy sessions with no change.

You will return for a 2nd evaluation visit at around 24 weeks. At this time your child will receive a language assessment and you will be asked to fill out some forms about your child's functional skills.

If your child is deemed ineligible at the time of initial evaluation that is okay. It will in no way affect the care your child receives and information about your child from this study will still be available to you at any time.

For all children, a 10-20 minute language sample will be gathered by the speech pathologist via auditory recording to at various time points throughout the study. If your child's expressive language skills are difficult to understand, we may also record the language sample using a video recorder. All recordings will be coded with a unique identifier and stored on a password protected hard drive.

You have two options regarding the collection of these language samples:

- Option 1—Have auditory and video (video only as needed) recorded language samples collected and participate in all therapy sessions
- Option 2—Have only auditory recordings (no video recordings)

For those who participate in the group that uses the AAC device, we will collect

time stamp data of usage of the TouchChat app during the course of the study. You will also have the option to allow us to collect what words your child accessed in the app. This information can be used to help us better understand how families use the device.

WHAT ARE THE GOOD THINGS THAT CAN HAPPEN FROM THIS RESEARCH?

We still have a lot to learn about this study treatment. We hope that it will help improve your child's language development, but we don't know if it will. When we finish the research, we expect that we will know more about this type of language therapy. As part of this research your child will receive language and cognitive assessments at no charge. Because you will be able to have access to the results of your child's evaluation, you may find these results helpful in understanding your child's abilities. You will be able to share these results with anyone you choose.

WHAT ARE THE BAD THINGS THAT CAN HAPPEN FROM THIS RESEARCH?
Some children become bored or frustrated if they are asked questions during testing they do not know how to answer. We will tell them that all children are going to be asked questions that they cannot answer. They will be told at the beginning of the testing and reminded during the testing that they do not need to answer any questions that they do not wish to answer and that they can stop the testing at any time. There is a potential risk for loss of confidentiality of your medical information. Measures are taken to protect this information. There may be other risks that we do not know yet.

There is also a risk that the treatment being tested in this study will not work as well as your child's current or other standard treatment.

WHAT OTHER CHOICES ARE THERE?

Instead of being in this study, you can choose not to have your child be in it. This decision will in no way affect the care your child receives.

HOW WILL INFORMATION ABOUT YOUR CHILD BE KEPT PRIVATE?

Making sure that information about your child remains private is important to us. To protect your child's privacy in this research study we will make sure that interviews occur in a private setting. Forms will remain in the possession of the interviewer and transported in a closed file folder. All study files will be kept in a locked file in the Division of Biostatistics and Epidemiology. Information will be kept in a password protected database and language samples will be coded and stored on a password protected server for the duration of the study period. Only study staff who have received permission from Dr. Meinzen-Derr will have access to this database. Every patient will be assigned a unique number, in addition to his/her medical record number.

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 study results. You can search this website at any time.

WHAT IF WE LEARN NEW INFORMATION DURING THE RESEARCH?

The investigator will tell you if they find out about new information from this or other studies that may affect your child's health, safety, or your willingness for your child to stay in this study.

The information from this study may be published. We will keep your child's data from this study to help us with future studies on language. However, your child will not be identified in any publications. The publication will not contain information about your child that would allow someone else to identify your child as a research participant.

WILL IT COST YOU ANYTHING EXTRA FOR YOUR CHILD TO BE IN THE RESEARCH STUDY?

There are no costs to you for your child to participate in this study. If your child is assigned to the intervention group, there will be no costs for the intervention. If your child is assigned to the standard or usual care group, your child will continue with his/her standard care.

You will not be billed for any of the assessments that are administered as part of this study.

WILL YOU/YOUR CHILD BE PAID TO BE IN THIS RESEARCH STUDY?

At the end of the 24 weeks, we will provide you with a tablet or iPad. If your child was randomized to use the iPad during therapy, your child will keep that iPad after study completion. If your child was in the standard or usual care group, he/she will receive an iPad after study completion.

If your child was in the standard care group and you want your child to participate in the AAC intervention after 24 weeks (at the end of your study), you will use the iPad your child receives for the AAC intervention. You will then follow the protocol for the AAC intervention.

At each evaluation visit (up to 3 evaluation visits) you will receive the following:

- You will also receive $25 at the end of the visit.
- You will receive the following reimbursement for mileage:
    - If you travel up to 50 miles round trip= $25
    - If you travel 51-100 miles round trip= $50
    - If you travel 101-150 miles round trip= $75
    - If you travel >150 miles round trip= $100

Recruited study participants will receive payment through the GreenPhire/Clincard system. We will give you your payment in the form of a reloadable debit card (Clincard) and you will receive a handout that will explain how to use the card. We will provide you with a card and we will load money onto your card after each visit that you

complete based on the schedule listed above.

Because this research study involves payment for participation, we are required by Internal Revenue Service (IRS) rules to collect and use your social security number (SSN) or taxpayer identification number (TIN) in order to track the amount of money that we pay you. Unless you have given specific permission for another use of your SSN or TIN related to this research study, we will only use your SSN or TIN to keep track of how much money we pay you and your SSN or TIN will not be used as part of this research

WHO DO YOU CALL IF YOU HAVE QUESTIONS OR PROBLEMS?

For questions, concerns, or complaints about this research study you can contact the study person listed on page 1 of this document.
If you would like to talk to someone that is not part of the research staff or if you have general questions about your research study rights or questions, concerns, or complaints about the research, you can call the CCHMC Institutional Review Board at 513-636-8039.

AUTHORIZATION FOR USE/DISCLOSURE OF HEALTH INFORMATION FOR RESEARCH

To be in this research study you must also give your permission (or authorization) to use and disclose (or share) your child's "protected health information" (called PHI for short).

What protected health information will be used and shared during this study?
CCHMC will need to use and share your child's PHI as part of this study. This PHI will come from:

- Your child's CCHMC medical records
- Your child's research records

The types of information that will be used and shared from these records include:

- Laboratory test results, diagnosis, and medications
- Reports and notes from clinical and research observations
- Imaging (like CT scans, MRI scans, x-rays, etc.) studies and reports
- If applicable, information concerning HIV testing or the treatment of AIDS or AIDS-related conditions, drug or alcohol abuse, drug-related conditions, alcoholism, and/or psychiatric/psychological conditions (but not psychotherapy notes).

Who will share, receive and/or use your child's protected health information in this study?

- Staff at all the research study sites (including CCHMC)
- Personnel who provide services to your child as part of this study
- Other individuals and organizations that need to use your child's PHI in connection with the research, including people at the sponsor and organizations that the sponsor may use to oversee or conduct the study.
- The members of the CCHMC Institutional Review Board and staff of the Office of Research Compliance and Regulatory Affairs.

How will you know that your child's PHI is not misused?
People that receive your child's PHI as part of the research are generally limited in how they can use your child's PHI. In addition, most people who receive your child's PHI are also required by federal privacy laws to protect your child's PHI. However, some people that may receive your child's PHI may not be required to protect it and may share the information with others without your permission, if permitted by the laws that apply to them.

Can you change your mind?
You may choose to withdraw your permission at any time. A withdrawal of your permission to use and share your child's PHI would also include a withdrawal from participation in the research study. If you wish to withdraw your permission to use and share your child's PHI you need to notify the study doctor, listed on the first page of this document, in writing. Your request will be effective immediately and no new PHI about your child will be used or shared. The only exceptions are (1) any use or sharing of PHI that has already occurred or was in process prior to you withdrawing your permission and (2) any use or sharing that is needed to maintain the integrity of the research.

Will this permission expire?
Your permission will expire at the end of the study. If the study involves the creation or maintenance of a research database repository, this authorization will not expire.

Will your child's other medical care be impacted?
By signing this document you agree for child to participate in this research study and give permission to CCHMC to use and share your child's PHI for the purpose of this research study. If you refuse to sign this document your child will not be able to participate in the study. However, your child's rights concerning treatment <u>not</u> related to this study, payment for services, enrollment in a health plan or eligibility of benefits will not be affected.

SIGNATURES

The research team has discussed this study with you and answered all of your questions. Like any research, the researchers cannot predict exactly what will happen. Once you have had enough time to consider whether your child should participate in this research you will document your permission by signature below.

You will receive a copy of this signed document for your records.

Language Samples:

☐ Option 1—Have auditory and video (video only as needed) recorded language samples collected and participate in all therapy sessions

☐ Option 2—Have only auditory recordings (no video recordings)

Word Usage:

☐ Yes—I agree to let the research team collect what words my child accessed in the TouchChat app

_____
Printed Name of Research Participant

_____ _____
Signature of Parent or Legally Authorized Representative* Date

_____
* If signed by a legally authorized representative, a description of such representative's authority must be provided

_____ _____
Signature of Individual Obtaining Consent Date