Early Communication Intervention for Toddlers With Hearing Loss

NCT03803943

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Title of Research Study: Communication Intervention for Toddlers with Hearing Loss (Tele-health)

Principal Investigator: Megan Y. Roberts, PhD, CCC-SLP

Supported By: This research is supported by the National Institute for Deafness and Communication Disorders (NIDCD)

Key Information about this research study:

The following is a short summary of this study to help you decide whether you and your child want to participate:

- The purpose of this study is to evaluate the effects of a communication intervention for toddlers with hearing loss and their parents as compared to a control group. The results of this study will help to improve the current standard of care in Early Intervention.
- You and your child will participate for a total of 24 months.
- You and your child will complete play-based assessments virtually over video call every month, in addition to surveys.
- You will complete 3-4 one-hour parent interviews via video call about your child's exposure to different type of communication.
- You and your child will also participate in video-recorded sessions with your child's speech therapist two times, if your child is receiving therapy.
- If you live in Illinois, you will be also be asked to participate in video-recorded sessions with your child's developmental hearing therapist two times, if your child is receiving therapy.
- In addition to assessments, you and your child will be randomly selected to participate in one of two groups. The first group is our control group in which you and your child would receive the following at no cost to you: (a) speech and language assessment reports, and (b) a treatment manual designed to help your child's language skills. The second group is the treatment group, in which you and your child would receive all of the above benefits plus additional virtual parent coaching intervention sessions for 6 months.
- There are no serious risks for you or your child to participate.
- We expect about 96 caregiver/child dyads will be participating in this research study.
- You can ask all the questions you want before you decide.

If you say that "Yes, you want you and your child to be in this research," here is what each of you will be asked to do:

Assessment visits: You and your child will participate in the study for 24 months. At the start of the study, you and your child will complete the following: (1) several play-based assessment via video call with assistance from you and a trained clinician, (2) surveys about your child's language and development, and (3) one 1-hour video interview with you to discuss your child's communication. After initial testing sessions, you will complete a 1-hour assessment visit every month with your child via video call. During these calls, you will be asked to play with some toys to see how your child's communicates. You will also have about 20-90 minutes of surveys to complete within 10 days of each assessment visit. Additionally, we will complete more comprehensive visits during month 7 and month 24. At each of these appointments, we will complete several play-based assessments via video call. Lastly, we will complete a one-hour video interview with you when your child is 24 months old, 36 months old, and again at the end of the study (if they are older than 38 months old). If you or the study team has concerns about autism, we will offer to complete a virtual autism screening with your child.

Early Intervention therapy visits: At the beginning and end of the study, you and your child will be asked to participate in a video-recorded session in your home with your child's speech therapist two times: (1) around Month 4 of the study, and (2) around the time your child is 30-months-old.. These sessions will be the typical therapy sessions you receive with them in your home. After these visits, you will also complete some surveys, which will take about 30 minutes to complete. Therapists will be

contacted separately about their consent to participate in this portion of the study. If your therapist does not consent to these observations, then we will not video record the session. These visits help us to learn more about other services your child is receiving.

If you and your child live in Illinois and are receiving developmental hearing therapy (DTH), we will also ask to video record two sessions with your child's DTH and have you complete surveys, as mentioned above.

Video recording: All appointments will be video recorded via a video call (such as zoom). This allows the research team to assess your child's development over time and to make sure the study team is conducting all sessions according to the research protocol.

What everyone will receive: If you are eligible to participate, you will receive reports that outline your child's skills after each testing major testing session (T0, T7, and T24 months). Exact assessment scores will not be provided in the report. Reports will be emailed to you and password protected with your child's date of birth. You will receive a parent handbook, which outlines how to use different language strategies with your child.

You will be compensated on a virtual reloadable credit card, which can be used for online purchases. For each major time point (that is, at baseline (T0), 7 months into the study (T7), and at the end of the study (T24)), you will receive up to $100 for completing all activities, including assessments and surveys. You will receive $25 per visit for all other monthly visits and survey. You will receive an additional $25 for completing additional surveys after the video-taped sessions with your therapists at the beginning and end of the study. Finally, you will receive $25 for each parent interview throughout the study (up to 4). You could receive up to $950 - $1,150 for completing all study activities. All payments will be reloaded to your card within about 5-10 business days.

All families participating in the study will also receive a tablet and accessories to use throughout their participation in the 24-month study. These items will help facilitate a smooth virtual experience for all parties. You may receive a cellular-enabled tablet if deemed appropriate due to slower internet speeds. This tablet and all accessories are property of Northwestern. All families will be asked to sign an acknowledgement before receiving the tablet and give it back upon completion of the study. However, families have the opportunity to keep the tablet and all accessories if they complete the study in its entirety (that is, they complete all assessments at T24).

Random assignment: You will also be randomly selected (like flipping a coin) to participate in either the control group or the treatment group. Both groups will receive the benefits mentioned above. The only difference between the two groups is that the treatment group will receive additional visits to work on their child's language growth and communication. You will be told which group you will receive after your initial testing appointments. Neither you nor the research team will be able to pick which group your family receives. A computer decides for us and this cannot be reversed.

Control Group: If you are randomly assigned to the control group, you will receive the reports, and the parent handbook with language strategies, and the tablet and accessories described above. You will also continue to receive any services that you are already receiving or would like to receive in the community.

Treatment Group: If you are randomly assigned to the treatment group, you and your child will receive weekly one-hour intervention sessions over video call for 6 months (26 sessions). A trained professional will work on increasing social communication in your child by providing you with strategies to help your child learn language throughout your everyday routines. This means that you will be at every session and your child will never interact direct with the clinician or the video screen. Instead, the therapist will watch you playing with your child and provide live feedback and coaching about how to incorporate language strategies into your play and routines. Other family members can observe, but they will not be able to participate in the session. This therapy uses an evidence-based intervention that we know works well for caregivers and their children with hearing loss. You will also continue to receive all services that you are already receiving or would like to receive in the community.

Audiology records: We will ask you to sign a consent to release your child's audiology records, which allow us access to your child's medical records related to audiology services. This helps learn more about your child's access to sound throughout the study. You will be asked to sign a release about 3 times throughout the study or whenever your child's audiologist changes.

Is there any way being in this study could be bad for me or my child?

There are no obvious serious risks for you to participate. If your child becomes uncomfortable during any of the assessments, we will offer a break and the assessment can be stopped at any time. The only potential risk to participating is the risk of confidentially being broken. To help protect your privacy, we will assign you and your child a unique study identification number and keep your study information on a password protected database, computer server, or hard-drive that only research staff members can access. As a part of downloading and using the video software (such as Zoom), personal data may be collected by the video service. Any videos recorded will be downloaded directly on a research staff member's computer (or saved on a HIPPA compliant cloud), then saved to our password protected and encrypted server, and then deleted from the desktop. We may also use a video-sharing service that will allow you to watch videos of your child or other children for training purposes.

If you say that you do not want you or your child to be in this research:

Participation in this research is voluntary. You can decide if you do not want you or your child to participate in this research, and it will not be held against you or your child in any way. You can continue to receive any additional therapy or services that you wish.

You can end the research study at any time. Just let a research team member know if you want to stop. If this happens, we will ask you if any data collected from you or your child up until that point may be used in the research. If participation in the study becomes too difficult for your family, we can discuss ways to reduce burden on you and your family and discuss options for participation, which could include reduced visits or reduced surveys. This is totally voluntary.

This is what will happen to the information collected for this research:

Efforts will be made to limit the use and disclosure of your and your child's personal information, including research study records, to people who have a need to review this information. No assessment or survey data collected from any child or caregiver will be shared with the child's therapist(s). We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of Northwestern University.

The research team will also use a texting platform, called Mosio, to send you text reminders about upcoming appointments and surveys. Inside Mosio, data is stored in security-controlled, HIPAA-compliant servers. Personal information is never shared outside Mosio without permission.

We will not ask about child abuse, but if you or your child tells us about child abuse or neglect, we are legally obligated to report it to state authorities.

A description of this clinical trial (NCT03803943) will be available at 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.

U.S. residents' taxable payments totaling $600 or more in a calendar year are reportable to the IRS on a Form 1099-MISC.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable

diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects. The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by National Institute for Deafness and Communication Disorders, which is funding this project, or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it. The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of child abuse or neglect.

Here is some other information that is useful for you and your child to know:

If you are eligible for this research study and you agree for you and your child to participate, we will compensate you for your time and participation. All payments will be made by reloadable debit card within 5 business days of completing the study activity.

HIPAA Authorization:

We are committed to respect your privacy and to keep your personal information confidential. When choosing to take part in this study, you are giving us the permission to use your child's personal health information, which includes health information in their medical records and information that can identify them. For example, personal health information may include you or your child's name, address, phone number or social security number. The health information we may collect and use for this research includes:

- Child's audiology records

Any research information shared with outside entities will not contain your name, address, telephone or social security number or any other personal identifier unless disclosure of the identifier is necessary for review by such parties or is required by law or University policy [except that such information may be viewed by the Study sponsor and its partners or contractors at the Principal Investigator's office].

The following entities may receive your health information:

- Authorized members of the Northwestern University workforce, who may need to see your information, such as administrative staff members from the Office for Research, Office for Research Integrity and members of the Institutional Review Board.
- Study monitors and auditors who make sure that the study is being done properly.
- Members of the National Institute on Deafness and Communication Disorders, this study's funding agency.

Those persons who get your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it. Some of those persons may be able to share your information with others without your separate permission.

Although you may revoke consent to participation in this research at any time and in any format, you must revoke authorization for use or disclosure of your health information in writing. To revoke your authorization, write to:

Megan Y. Roberts, PhD, CCC-SLP
Northwestern University
Communication Sciences and Disorders
2240 Campus Drive, Evanston, IL 60208

You do not have to authorize the use or disclosure of your health information; however, you will not be allowed to take part in this research study. If you do not authorize the use or disclosure of your health information, it will not affect your treatment by health care providers, or the payment or enrollment in any health plans, or affect your eligibility for benefits.

Here is who you and your child can talk to:

If you have questions, concerns, or complaints, you can talk to the Northwestern Principal Investigator, Megan Roberts by calling 847-491-3183 or emailing at ei@northwestern.edu.This research has been reviewed and approved by an Institutional Review Board ("IRB"). You may talk to them at (312) 503-9338 or irb@northwestern.edu if:

- You want to get information or provide input about this research.
- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.

Optional Elements:

The following research activity is optional, meaning that you do not have to agree to it in order for you or your child to participate in the research study. Please indicate your permission for yourself and for your child to participate in this optional activity **by placing your initials next to the activity**:

I agree	I disagree	
_____	_____	The researcher may contact me in the future to see whether I am interested in participating in other research studies by the principal investigator of this study.
_____	_____	Video recordings of my participation and my child's participation may be shown to researchers, students, educators, and clinicians at workshops, seminars, trainings, and conferences.
_____	_____	Video recording clips (1-2 minutes) of my participation and/or my child's participation may be shown to future families participating in the Early Intervention Research Group's research studies. The video clips will be used for training purposes to demonstrate and explain strategies that caregivers can use with their children.
_____	_____	Data collected in this study may be used for future research questions and analysis. These data could include video recordings, survey data, or assessment data. These data will not be connected to your name or contact information. Your identifiable data will not be shared with anyone outside of the research team.
_____	_____	ILLINOIS ONLY: If in the Chicagoland area, I am willing to come to the Northwestern University to complete eye-tracking activities (if allowed by the state) with my child at the start of the study and at the end of the study, for an additional $50 per visit ($100 total).
_____	_____	ILLINOIS ONLY: If I am enrolled in the study at Robert H. Lurie Children's Hospital, "Neural Predictors of Language Outcomes in Young Children with Cochlear Implants" (IRB 2018-1959), I give my permission for data from the Language Exposure Assessment Tool (1-hour parent interview that you will complete about your child's communication) to be shared with this study. I understand that only de-identified data (only scores) will be shared and videos will not be shared.

Permission to Take Part in a Human Research Study

Your signature documents your consent to participate and your permission for the named child to take part in this research.

_____

Printed name of **participating child**

_____

Printed name of **participating caregiver**

_____ _____

Signature of **participating caregiver** **Date**

If the participating caregiver is **not** also the individual legally authorized to consent the child, please have the child's legally authorized representative sign below.

_____

Printed name of individual **legally authorized to consent for the child**

_____

Signature of individual **legally authorized to consent for the child**

My signature below documents that the information in the consent document and assent process and any other written and verbal information was accurately explained to, and apparently understood by, the participant, and that consent was freely given by the participant.

_____

Printed name of person **obtaining** caregiver permission and assent

_____ _____

Signature of person **obtaining** caregiver permission and assent Date