Long-Term Outcomes of Early Communication Intervention for Deaf/Hard of Hearing Toddlers

NCT#: Pending

Approved by NU IRB for use on or after 6/30/2025

Upload to clinicaltrials.gov on 8/05/2025

Consent to Participate in Research

Title of Research Study: Long Term Effects for Toddlers with Hearing Loss

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 to be a part of this study. Information that is more detailed is explained later on in this form.

- The purpose of this study is understand the long term effects of the communication intervention taught in the previous study.
- You will be asked to complete assessments and surveys when your child is in kindergarten and second grade.
- We expect that you will be in this research study until your child completes assessments in second grade.
- The primary potential risk of participation is a breach of confidentiality.
- The main benefit of being in this study is learning more about your child's development.

Why am I being asked to take part in this research study?

We are asking you to take part in this research study because you and your child participated in a previous research study at Northwestern University, called "Communication Intervention for Toddlers with Hearing Loss."

How many people will be in this study?

We expect about 88 people will be in this research study.

What should I know about participating in a research study?

- Someone will explain the research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.
- You do not have to answer any question you do not want to answer.

What happens if I say, "Yes, I want to be in this research"?

Your child will complete assessments with the research team over zoom when they are in kindergarten and again in second grade.

In kindergarten, we will also ask you and your child to play to together for 20-minutes using a standard set of toys. We will also ask your child to complete standardized language and literacy assessments with a trained clinician from the research team using zoom. Additionally, we will ask you to complete 1-2 hours worth of surveys. Finally, we will ask you to do a 20-minute parent interview about the language used with your child and their access to sound. In total, we expect to complete three virtual visits, last 1-2 hours each.

In second grade, we will ask your child to play with a peer for 20-minutes using a standard set of toys (pending permission from the peer's parents). We will also ask your child to complete standardized language and literacy assessments with a trained clinician from the research team using zoom. Additionally, we will ask you to complete 30 minutes of surveys. Finally, we will ask you to do a 20-minute parent interview about the language used with your child and their access to sound. In total, we expect to complete three virtual visits, last 1-2 hours each.

All assessments and interviews will be video recorded using zoom.

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include learning more about your child through obtaining formal assessment reports regarding your child's language and literacy development.

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

A possible risk for any research is that confidentiality could be compromised – that is, that people outside the study might get hold of confidential study information. We will do everything we can to minimize this risk, as described in more detail later in this form.

What happens if I do not want to be in this research, or I change my mind later?

Participation in research is voluntary. You can decide to participate or not to participate. If you do not want to be in this study or withdraw from the study at any point, your decision will not affect your relationship with Northwestern.

You can leave the research at any time and it will not be held against you.

If you decide to withdraw from this study, the researchers will ask you if information already collected from you can be used.

How will the researchers protect my information?

All assessments, videos, and surveys will be kept on a secure, password-protected, and encrypted database (REDCap), cloud service (SharePoint), or hard drive. We will also give you and your child a unique family ID number and we will label everything we collect with that ID number, that way it is not connected to your name or other personal information.

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.

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.

Who will have access to the information collected during this research study?

Efforts will be made to limit the use and disclosure of your personal information, including research study records, to people who have a need to review this information. We cannot promise complete secrecy.

There are reasons why information about you may be used or seen by other people beyond the research team during or after this study. Examples include:

- University officials, government officials, study funders, auditors, and the Institutional Review Board may need access to the study information to make sure the study is done in a safe and appropriate manner.

We will not ask you about child abuse, but if you tell us about child abuse or neglect, we may be required or permitted by law or policy to report to authorities.

How might the information collected in this study be shared in the future?

We will keep the information we collect about you during this research study for study recordkeeping Your name and other information that can directly identify you will be stored securely and separately from the rest of the research information we collect from you.

De-identified data from this study may be shared with the research community, with journals in which study results are published, and with databases and data repositories used for research. We will remove or code any personal information that could directly identify you before the study data are shared.

Despite these measures, we cannot guarantee anonymity of your personal data.

Will I be paid or given anything for taking part in this study?

You will receive electronic cash payment for your participation in this study.

Kingergarten: Up to $550 for completing surveys ($100) and up to three assessment visits ($150/visit)

Second Grade: Up to $450 for completing up to three assessment visits ($150/visit)

HIPAA Authorization -- Permission to Use Personal Health Information For Research

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 clinical providers may give the researchers information about you: all current and previous health care providers, including but not limited to the Shirley Ryan AbilityLab (SRALAB) and Northwestern Memorial HealthCare/Northwestern Medicine entities and its current and future affiliates.

Once we have the health information listed above, we may share some of this information with the following offices or entities outside of Northwestern University and its clinical partners (or affiliates): the Northwestern University Institutional Review Board Office and Office for Research Integrity; the US Office of Research Integrity; the US Office for Human Research Protections; the US Food and Drug Administration.

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.

Unless you revoke your consent, it will June 1, 2032.

Who can I talk to?

If you have questions, concerns, or complaints, you can contact the Principal Investigator Megan Roberts at ei@northwestern.edu and Laura Sudec at laura.sudec@northwestern.edu.

This research has been reviewed and approved by an Institutional Review Board ("IRB") – an IRB is a committee that protects the rights of people who participate in research studies. You may contact the IRB by phone at (312) 503-1376 or by email at irbcompliance@northwestern.edu if:

- The research team is not answering you questions, concerns, or complaints.
- 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.
- You want to get information or provide input about this research.

Optional Elements:

The following research activities are optional, meaning that you do not have to agree to them in order to participate in the research study. Please indicate your willingness to participate in these optional activities by placing your initials next to each activity.

I agree	I disagree	
_____	_____	The researcher may use **video recordings** of me and my child in scholarly presentations or publications when showing my face or hearing my voice might serve to help others understand the research. I may be identifiable as part of this activity.
_____	_____	The researcher may keep my contact information in order to contact me in the future to see whether I am interested in participating in other research studies by the Principal Investigator.

Your signature documents your permission to take part in this research and for disclosure and use of personal health information from your medical record for purposes of this study.

_____ _____
Signature of participating parent Date

_____
Printed name of participating parent

_____
Printed name of participating child

_____ _____
Signature of person obtaining consent Date

_____
Printed name of person obtaining consent