Maximizing Outcomes for Preschoolers With Developmental Language Disorders

NCT0378293

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Parent Consent and Permission

Title of Research Study: ***Maximizing Language in Preschoolers with Developmental Language Delay (NU)***

Principal Investigators: Megan Y. Roberts, PhD, CCC-SLP at Northwestern University; Ann Kaiser, PhD at Vanderbilt University; Pamela Hadley, PhD at the University of Illinois, Urbana-Champaign

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 language intervention for toddlers with language delays 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.
- All research activities will take place in your home. The visits are conducted virtually using a video call.
- To see if you are eligible to participate in this research study, you and your child will participate in a multi-phase screening process, which consists of surveys and several standardized assessments. The screening visits will take place virtually, over a video call.
- If you are eligible, you and your child will complete language assessments via video call every 3 months for a total of 19 months.
- In addition to assessments, you and your child will be randomly selected to participate in one of two groups. The first group is the control group, in which you and your child would receive the following at no cost to you: (a) speech and language assessment reports, (b) toys and books, and (c) parent handbooks designed to help you aid in the development of 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 intervention sessions for 19 months.
- This research study works with researcher teams from Northwestern University, Vanderbilt University, and University of Illinois at Urbana-Champaign. The data collected from this study will be shared with these universities, but only members of the research team.
- There are no serious risks for you or your child to participate.
- We expect about 108 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:

Screening Visit: To see if your child is an ideal candidate for the study, the screening process will happen in three phases. First, you will complete 30-45 minutes worth of surveys about your child's language and development if you have not done so already. If your child is still eligible after the initial surveys, we will complete an autism screening assessment with your child over a video-call. This will take about 30-45 minutes total. If there are still concerns about ASD after the video-call, the study team will conduct a 90-minute interview with you. After the autism screening, you and your child will complete some play-based language and cognitive assessments over 1-2 video calls. If at any point during the assessment process we find that your child is not eligible, the session will be stopped. A research team member will tell you if you are eligible to participate at the end of your appointments or within two days of your appointment, if the result of any assessment is uncertain and needs to be discussed by the study team. Even if your child is not eligible to participate in the study, all data obtained from the assessment visit will be kept for research purposes, but all information will be stored using a unique study ID to help protect your privacy. Even if your child does not qualify for the

study, you will still receive a parent treatment manual, which outlines the evidenced-based language strategies used in this study.

Assessment Visits: If you are eligible, you and your child will be asked to participate in the study for 19 months, until your child is 49 months old. A research team will conduct assessment visits with your you and your child every 3 months over a recorded video call, such as Zoom, when your child is 30, 33, 36, 39, 42, 45, and 49 months old (4 months after the 45-month timepoint). Assessment materials, such as toys or books, may be shipped or dropped off to your home before each assessment visit. You will help to administer the assessments with your child with instructions from a trained clinician during a video call. You will also be asked to complete surveys throughout your time in the study.

Video recording: All virtual and in-person appointments will be video recorded. 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. 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. There is an option at the end of this consent which would not allow videos of your child to be shared with anyone outside of the research group.

What everyone will receive: If you are eligible to participate, you will receive handbooks designed to help your child's language skills, in addition to a total of $775 worth of toys throughout your 19 months in the study. The toys will be distributed as such (approximate amounts): $165 worth given after you 30-month visit, followed by $85-$110 worth of toys every 3 months. You will also receive reports by email, which will outline your child's skills after your child's 30-, 36-, 42-, and 49-month visits. Exact scores will not be provided. We can also provide you video clips from study sessions on a password protected USB drive, at your request. In addition, eligible families will receive compensation for completing study activities on time. You could receive a total of $550 for completing all assessments and surveys on time throughout your 19 months in the study.

	30 mon.	33 mon.	36 mon.	39 mon.	42 mon.	45 mon.	49 mon.	Total
Assessments	$100	$25	$50	$25	$50	$25	$100	$375
Surveys	$25	$25	$25	$25	$25	$25	$25	$175
Total	$125	$50	$75	$50	$75	$50	$125	**$550**

You will also receive an iPad and accessories (case, tripod) to assist with video recording. This will remain property of Northwestern University throughout the study. However, you can keep the iPad and all accessories if you complete your final research visit at T49.

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 virtual visits. If you are eligible, you will be told which group you will receive at your 30-month appointment. 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.

Regardless of which group you are randomly assigned to, you can continue to receive any additional services that you would like and it will not affect your participation.

Treatment Group: If you are randomly assigned to the treatment group, you and your child will receive 19 months of virtual intervention sessions with a trained professional who will work on increasing language in your child, as well as providing you with strategies to help your child learn language throughout your everyday routines. Since this therapy uses a caregiver coaching model, you must be at every session. During each session, the therapist will teach you language support strategies, provide examples, and coach you on how to use the strategies with your child over the video call. Other family members can observe, but they will not be able to participate in the session. The frequency of sessions will be 2x/week for 3 months, then 1x/week for 9 months, then 1x/month for 6

months, for a total of 66 sessions over 19 months. This therapy uses an evidence-based intervention that we know works well for parents and their children with language delays and blends this with an additional therapy that focuses on vocabulary and grammar. We are testing to see if combining these two interventions improves child language skills.

Control Group: If you are randomly assigned to the control group, you will receive the toys, reports, and language support strategy handbooks described above. Additionally, you could also receive up to an additional $600 for completing all study activities on time. If you complete all your assessment visits and surveys on time, every 6 months you will receive an additional $200 bonus (at your 36-month visit, 42-month visit, and 49-month visit). If you miss a visit or survey during that 6-month time period, you will not receive the bonus, but you will still have the ability to receive the next bonus for completing all assessments and surveys over the next 6 months. You could receive a total of $1,150 for completing all assessments and surveys on time.

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.

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 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 will ask if we can continue to complete any assessment visits with you and your child. 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. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of Northwestern University, Vanderbilt University, or University of Illinois Urbana-Champaign.

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 (NCT03782493) 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.

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. Payments will be made by checked mailed to your house or by virtual reloadable debit card after completing the study activity.

You may be removed from the study if you miss more than three intervention or assessment sessions without contacting a member of the research team or you miss more than 4 intervention sessions in a row and cannot reschedule at least two of them.

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 or you can talk to the Vanderbilt Principal Investigator, Ann Kaiser by calling 615-322-8160 or emailing at kidtalk@vanderbilt.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.

Permission to Take Part in a Human Research Study

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 researchers at Northwestern or Vanderbilt University 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 (1-5 minutes) of my participation and/or my child's participation may be shown to future families participating in the Early Intervention Research Group's or KidTalk research studies. The video clips will be used for training purposes to demonstrate and explain strategies that parents 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.

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 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** parent permission

_____ _____

Signature of person **obtaining** parent permission **Date**