Optimizing Outcomes Through Sequencing Parent-Mediated Interventions for Young Children With Autism

NCT05926687

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Parent Consent and Permission with Child Assent

Title of Research Study: ***Optimizing Outcomes for Young Children with Autism***

Principal Investigator: ***Megan Roberts, PhD, CCC-SLP***

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

Collaborating Institutions: University of Texas at Austin

Key Information about this research study:

The following is a short summary of this study to help you decide whether you want to participate as well as whether you want to permit your child 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 to determine the best intervention sequence (order) for autistic children and to test two commercially available child development interventions to work on social communication and behavior regulation in autistic children.
- We expect that you and your child will be in this research study for 6 months (24 weeks).
- You and your child will be asked to participate in a social communication and/or behavior regulation intervention 1-2x/week virtually in your home for 6 months.
- We will also ask you to complete some parent-child observations and surveys before therapy starts, halfway through therapy, and after therapy is finished.
- All activities will be virtual.
- The primary potential risk of participation is break of confidentiality, but the research team takes precautions to help protect your privacy and confidentiality.
- The main benefit of being in this study is expected to include improved strategies for working on your child's social communication skills or their behavior regulation.

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

We are asking you and your child to take part in this research study because you are a parent of an autistic child who is willing to learn intervention strategies to work on social communication and behavior regulation.

How many people will be in this study?

We expect about 184 parent/child dyads will be in this research study.

What should I know about participating in a research study?

- Someone will explain the research study to you and your child.
- Whether or not you and your child 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 either you or your child.
- You can ask all the questions you want before you decide.
- You do not have to answer any questions you do not want to answer.

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

You and your child will be asked to participate in the research study for 6 months. During that time, you will be asked to complete therapy sessions, in addition to observations and surveys.

Everything will take place virtually over a Zoom call in your home with you and your child. At the very end of the study, we may also ask you to participate in an interview to explain your thoughts on the intervention strategies, so that we understand what works and what doesn't work for different families. A schedule of activities is in the table below:

Activity	Who	Setting (home)	Length
Beginning of the study (before therapy)			
Autism Screening	You, Your Child, Clinician	Virtual	60 minutes
Introduction Session	You, Your Child, Clinician	Virtual	75 minutes
Caregiver-Child Interaction *(twice)*	You, Your Child	Virtual	45 minutes
Surveys	You	Virtual	90 minutes
During the first 3-months of therapy			
Strategy Log *(weekly)*	You	Virtual	5 minutes
Caregiver-Child Interaction *(biweekly)*	You, Your Child	Virtual	10 minutes
Middle of the study (after 3-months of therapy)			
Caregiver-Child Interaction	You, Your Child	Virtual	45 minutes
Surveys	You	Virtual	10 minutes
During the second 3-months of therapy			
Strategy Log *(weekly)*	You	Virtual	5 minutes
Caregiver-Child Interaction *(biweekly)*	You, Your Child	Virtual	10 minutes
End of the study (after 6-months of therapy)			
Caregiver-Child Interaction *(twice)*	You, Your Child	Virtual	20 minutes
Surveys	You	Virtual	60 minutes
Interview	You, Clinician	Virtual	75 minutes

You and your child will be randomly assigned to receive a social communication intervention, a behavior regulation intervention, or both interventions. Frequency of intervention will vary from twice a week to every other week, depending on the intervention and stage of intervention. The group you're randomized to is random. Neither you or the researchers control which interventions families receive. This is to help make sure we are not influencing results, as we need to understand which interventions work and for whom. Your time in the intervention could look like any of the following:

1st Stage Intervention: Randomly assigned to one (Month 1-3)	**2nd Stage Intervention:** Next, you'll be randomly assigned to one of the options below, based on your stage 1 intervention (Months 3-6)		
Starting Intervention	**Reduce Frequency (-)**	**Add Tools (+)**	**Switch Intervention (→)**
Intervention: Social Communication Who: Parent & Child & Therapist Frequency: 1-hour twice/week	Intervention: Social Communication Who: Parent & Child & Therapist Reduce Frequency: 1-hour **once/week**	Intervention: Social Communication Who: Parent & Child & Therapist Frequency: 1-hour twice/week Add: **Video feedback**	Switch Intervention → **Behavior Regulation** Who: Parent & Therapist only Frequency: 1-hour once/week

Intervention: Behavior Regulation Who: Parent & Therapist only Frequency: 1-hour once/week	Intervention: Behavior Regulation Who: Parent & Therapist only Reduce Frequency: 1-hour **every other week**	Intervention: Behavior Regulation Who: Parent & Therapist Frequency: 1-hour once/week Add: **Video feedback**	Switch Intervention → **Social Communication** Who: Parent & Child & Therapist Frequency: 1-hour twice/week

Will being in this study help me or my child in any way?

We cannot promise any benefits to you or your child from taking part in this research study. However, possible benefits include improved strategies for working on your child's language and communication skills or their behavior regulation. Benefits also include increased knowledge of your child's development.

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

There are no obvious serious risks for you to participate. If you or 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 confidentiality being broken, and we describe how we protect your information below.

How will the researchers protect our information?

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 video software (such as Zoom), personal data may be collected by the video service. Any videos recorded will be downloaded directly onto a research staff member's computer (or saved on a HIPPA compliant cloud), 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.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

Identifiable information that could still be disclosed beyond the research team: The Certificate does not stop reporting that federal, state, or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate cannot be used to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate does not stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also does not prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers, or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

What happens if my child or I do not want to be in this research, or we change our minds later?

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.

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

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.

There are reasons why information about you and your child 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 your child about abuse, but if they tell us about child abuse or neglect, we may be required or permitted by law or policy to report to authorities.

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

We will keep the information we collect about you and your child during this research study for study recordkeeping and for potential use in future research projects. If the study data contain information that directly identifies participants (e.g., your name, your child's name, other information that can directly identify you or your child), it will be stored securely and separately from the rest of the research information we collect.

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 or your child before the study data are shared. Despite these measures, we cannot guarantee anonymity of your personal data or your child's personal data.

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

You will be compensated up to $200 for your time in the study. Compensation will include $75 at the beginning of the study ($50 total for two observation visits and $25 for surveys), $50 in the middle of the study ($25 for an observation visit and $25 for surveys), and $75 at the end of the study ($50 total for two observations visits and $25 for surveys). All payments will be made using the Northwestern Virtual Hyperwallet, which acts as a reloadable debit card that participants will keep throughout their time in the study, or a cash equivalent. Participants will receive payment within two weeks of completing the study activity.

All families participating in the study will also receive a tablet and accessories to use throughout their participation in the 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 can keep the tablet and all accessories if they complete the study in its entirety (that is, they complete all assessments at the end of the study).

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

A description of this clinical trial 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.

Who can I talk to?

If you have questions, concerns, or complaints, you can talk to the Northwestern Principal Investigator, Megan Roberts, by emailing 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:

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) 503-9338 or by email at irb@northwestern.edu if:

- 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.
- You want to get information or provide input about this research.

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	
		If my child participated in the "Reduce The Wait" (RTW) study, I give the researchers permissions to use the autism evaluation measures we completed to confirm my child's autism diagnosis.
_____	_____	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.
_____	_____	Data from this study may be submitted to the National Database for Autism Research (NDAR). NDAR is a computer system run by the National Institutes of Health that allows researchers studying autism to collect and share information with each other. With an easier way to share, researchers hope to learn new and important things about autism more quickly than before. During and after the study, the researchers will send information about you or your child's health and behavior to NDAR. However, before they send it to NDAR, they will remove information such as name, address, and phone number, and replace that information with a code number.

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**

_____

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

_____ _____

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