

Parent Telehealth Intervention for Children With Autism

NCT02632773

Approved by NU IRB for use on or after 11/3/2020

Upload to clinicaltrials.gov on 1/3/2022

Consent for Parent Permission

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Title of Research Study: ***Parent Language Intervention for Children with Autism Spectrum Disorders (Telecoaching – Stay at home)***

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Supported By: This research is supported by the National Institute of Health (NIH) and Northwestern University.

Key Information about this research study:

The following is a short summary of this study to help you decide whether to permit your child to be a part of this study.

- The purpose of this study is to learn how mothers learn to use specific language support strategies and how mothers' use of these strategies affect child social communication.
- Your child will be asked to participate in assessments before therapy, after therapy, and then again 3 months later.
- We expect that you and your child will be in this research study for about 5 months.
- The primary risk of participation is that absolute confidentiality cannot be guaranteed.
- The main benefit of participation is that your child may say more words.
- We expect about 50 parent/child dyads will be in this research study.
- You can ask all the questions you want before you decide.

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

Before therapy: You will complete four different assessments. You will complete a 30-minute play-based assessment with your child to confirm your child's autism diagnosis. You will complete a 30-minute video call with a staff member and answer questions about your personality style. We will conduct a 1-hour parent interview to learn more about your routines with your child. Finally, you will complete a 12-45-minute play session with your child, one using a standard set of toys that a staff member will drop off to you and a set of toys you have at home. If you are not in the Chicagoland area, you will just play with toys you have at home and will not be asked to play with the standard toy set. You will also complete several surveys that will take about 1.5 hours to complete.

During therapy: You and your child will receive weekly, 1-hour sessions for 8 weeks using a video call, for a total of 8 sessions over two months. The first session will be a 1-hour parent workshop to review the strategies you will learn. After that, there will be 7 intervention sessions with you and your child. At the beginning of every session, your therapist will observe you and your child playing for 6 minutes. Then, you and your therapist will discuss the strategies and how you're using them, followed by 15-minute of you playing with your child and receiving live coaching from your therapist. At the end, you will review and make a plan for the upcoming week.

After therapy: You and your child will complete a 12-45-minute play session with a standard set of toys and a set of toys you have at home and 90 minutes of surveys.

3 months after therapy: You and your child will complete a 12-45-minute play session with a standard set of toys and a set of toys you have at home and 90 minutes of surveys.

All assessments and therapy sessions will be video-recorded for research and coaching purposes.

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

All reasonable efforts will be made to keep the personal information in your and your child's research records (including video and audio recordings) private and confidential, but absolute confidentiality cannot be guaranteed. To minimize this risk, we will assign you and your child a unique study

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identification number and keep your study information on a password protected database, computer server, or hard-drive. You or your child may have a negative reaction to some of the testing measures or intervention sessions. If this should occur, that particular test or intervention will be stopped. 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 your child to be in this research:

Participation in research is voluntary. You can decide you do not want your child to participate in this research and it will not be held against you or your child in any way.

You can say "Yes," but change your mind later:

You and your child can leave the research at any time and it will not be held against you. If you withdraw from the study, the information you have already provided will be used unless you provide a written request for your data to be destroyed.

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

Efforts will be made to limit the use and disclosure of you 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 this institution. An exception to our promise of confidentiality is when we in good faith are permitted by law or policy to report evidence of child abuse or neglect.

A description of this clinical trial (NCT02632773) will be available at <http://www.ClinicalTrials.gov>, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

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

If you agree to take part in this research study, we will pay you \$225 for your time and effort. This includes \$125 before therapy, which includes \$25 for the play-based assessment, \$25 for each parent interview (\$50 total), \$25 for the 12-minute play session and \$25 for surveys. You will receive \$50 after therapy (\$25 for each 12-minute play session and \$25 for surveys) and another \$50 for the final time period 3 months after therapy (\$25 for the 12-minute play session and \$25 for surveys). All payments will be made using a reloadable virtual debit card within 5 business days of completing the study activity. The virtual debit card can only be used to purchase things online.

The Early Intervention Research Group (EIRG) appreciates all of your time and effort to help us gather this important data. You're free to skip any survey questions that you do not wish to answer.

Here is who you and your child can talk to:

If you have questions, concerns, or complaints, or think the research has hurt you or your child, talk to the research team 847-491-3183 or 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:

- 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.

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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	
_____	_____	If you and your child are eligible for future research opportunities, I agree to be contacted by researchers.
_____	_____	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 research studies. The video clips will be used for training purposes to demonstrate and explain strategies that parents can use with their children.
_____	_____	Video recordings of my participation and my child's participation may be shown to researchers, students, educators and clinicians at workshops, seminars, trainings or conferences.
_____	_____	Data collected in this study may be used for other research studies and analysis. This data could include video recordings, survey data, or assessment data. This data will not be connected to your name or contact information. Your data will not leave the Early Intervention Research Group.
_____	_____	If I participated in a study screening for STU207758, "Maximizing outcomes for preschoolers with developmental language disorders," I agree to allow researchers to use the autism screening assessment for this study, so that I do not have to complete the assessment a second time.
_____	_____	If your child has a younger sibling or twin that is 6 months old or older, you may also participate in some additional language assessments with this child to monitor mother/child communication. This would include a 10-minute mother/child play session and three additional surveys about your child's language, household, and routines. We would complete these activities before therapy begins and after therapy is completed and you would be compensated an additional \$50 at these time points for completion of these activities (\$25 for each visit to EIRG and \$25 for completing the surveys). If you have any concerns about the sibling's development, we can do an autism screening 2-4 months later or as soon as the child is old enough (18-24 months), for which you will receive another \$50. You could receive an additional \$150 total.

Signature Block for Parent Permission and Child Assent

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

Printed name of child

Printed name of parent [] or individual legally authorized []
to consent for the child to participate

Date

Signature of parent [] or individual legally authorized []
to consent for the child to participate

Date

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Printed name of the person obtaining the consent/witness

Date