Informed Consent Form

Title: Promoting Transactional Supports to Optimize Social Communication Outcomes for Infants and their Families

NCT Number: NCT03307057

Date of IRB Approval: July 21, 2022

You Are Being Asked to Be in a Research Study

What Is a Research Study?

The main purpose of research studies is to gain knowledge. This knowledge may be used to help others. Research studies are not intended to benefit you directly, though some might.

Do I Have to Do This?

No. Being in this study is entirely your choice. If you decide to join this study, you can change your mind later on and withdraw from the research study.

Taking part in a study is separate from medical care. The decision to join or not join the research study will not affect your status as a patient.

What Is This Document?

This form is an informed consent document. It will describe the study risks, procedures, and any costs to you.

This form is also a HIPAA Authorization document. It will describe how your health information will be used and by whom.

Signing this form indicates you are willing to take part in the study and allow your health information to be used.

What Should I Do Next?

1. Read this form, or have it read to you.
2. Make sure the study doctor or study staff explains the study to you.
3. Ask questions (e.g., time commitment, unfamiliar words, specific procedures, etc.)
4. If there will be medical treatment, know which parts are research and which are standard care.
5. Take time to consider this, and talk about it with your family and friends.

Emory University
Consent to be a Research Subject

Title: Promoting Transactional Supports to Optimize Social Communication Outcomes for Infants and their Families

Principal Investigator: Nathan Call, Ph.D.

Funding Source: National Institutes of Health

Introduction

You are being asked to be in a research study. This form is designed to tell you everything you need to think about before you decide to consent (agree) to be in the study or not to be in the study. **It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study.**

Before making your decision:

- Please carefully read this form or have it read to you
- Please ask questions about anything that is not clear

You can take a copy of this consent form, to keep. Feel free to take your time thinking about whether you would like to participate. By signing this form you will not give up any legal rights.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This Web site will not include information that can identify you. At most the Web site will include a summary of the results. You may search this Web site at any time.

Study Overview

The purpose of this study is to study the effects of preventative parent education and autism treatment starting in infancy. There is not a lot of research about treatment for children this young. We aim to enroll 250 children into this research study. For this study, we are partnering with a research team at Florida State University. We share some of the information we collect about you with them. We do this to help us conduct this research study to the highest of standards.

Procedures

The study will involve teaching caregivers how to support social communication in everyday activities with their child using various intervention methods. This study includes two stages, with Stage 1 beginning at 6 months and Stage 2 beginning at 12 months. We are unable to change the treatment assignment once you are assigned to either Stage 1 or Stage 2 treatment. We will assign your child to a group randomly (e.g., by flipping a coin).

Because your child (or the child for whom you provide care) was assigned during Stage 2 to the Parent Implemented Naturalistic Developmental Behavioral Intervention (PI-NDBI) condition, you are considered to be a participant of the research study. During the 75 minute sessions, you will work with a coach who will ask you and your child to play and interact during everyday activities. The coach will give you feedback on how to support social communication skills with your child and answer questions that you have. During these sessions, we will be collecting data on you and your child. The intervention term is 9 months, with sessions occurring weekly during the first 6 months, bi-weekly during the seventh month, and then once per month during the final two months of intervention.

Parent questionnaires will be given at 9, 12, 16, 21, and 30 months. We will ask you to complete a set of questionnaires focusing on family resources as well as social emotional issues. We will ask you to complete these questionnaires 5 times- at 9, 12, 16, 21 and 30 months. You will also be asked to record the number of hours your child participated in other interventions every month. Completion of these questionnaires and the formal assessment are voluntary and does not impact your ability to participate in the study or limit the services available to you.

Home observations will be conducted at 9, 12, 16, 21 and 30 months. During these 75 minute observations, we will make video recordings of you and your child at home for an hour during everyday activities (e.g., mealtimes, playtime, daily chores) to see how you and your child are interacting.

Risks and Discomforts

Since this study involves personal information, there is always the risk of breach of confidentiality. To minimize this risk, all clinical records and video recordings will be kept by project staff in a locked room. We will use identification codes on all research records; no names or other personal identifying information about you or your child will be included. Because this project is being completed as a partnership between Emory University and Florida State University, we will need to share research information with staff at the other site. All personal details identifying you or your child will be removed before information is shared with the other site. If you do not want you or your child's research information to be used in this way, you should not participate in this study.

As with any research study, there may be additional risks that are unknown or unexpected. The researchers have taken steps to minimize the known or expected risks. However, you may still experience problems or side effects, even when the researchers are careful to avoid them. If you believe that you have been harmed, notify the researchers listed in the "Contact Information" section of this form below. If you sign this form, you do not give up your right to seek additional compensation if you are harmed as a result of being in this study.

New Information

It is possible that the researchers will learn something new during the study about the risks of being in it. If this happens, they will tell you about it. Then you can decide if you want to continue to be in this study or not. You may be asked to sign a new consent form that includes the new information if you decide to stay in the study.

Benefits

You or your child might not receive any personal benefits from being in this study. However, you and your child may benefit from involvement in this project in a few ways. First, you will be provided with a written summary of test results before and after each intervention. This information may be of benefit in planning future school and treatment choices. Second, the parent intervention may improve your ability to support your child's development of social communication. We also hope findings from this research will contribute to better and more effective services for other young children with autism spectrum disorders and their families.

Compensation

Compensation is addressed in the consent for the child participant enrolled in this study.

Other Options Outside this Study

Your access to services at the Marcus Autism Center for yourself and/or your child will not be affected if you do not participate in this study. If you choose not to participate we will provide you with referrals to intervention programs that may be available in your community upon request.

Confidentiality

Certain offices and people other than the researchers may look at study records. Government agencies and Emory employees overseeing proper study conduct may look at your study records. These offices include [the Office for Human Research Protections, the funder(s), the Emory Institutional Review Board, the Emory Office of Research Compliance]. Study funders may also look at your study records. Emory and Children's Healthcare of Atlanta will keep any research records we create private to the extent we are required to do so by law. A study number rather than your name will be used on study records wherever possible. Your name and other facts that might point to you will not appear when we present this study or publish its results.

If you choose to participate, information obtained from you as part of this study will be shared with the National Institutes of Health National Database for Autism Research (NIH NDAR). The information will be available for researchers to use in research about autism and other social-communication disorders to answer questions about the causes of autism, diagnosis, development, and response to treatment. All personal details identifying you or your child will be removed before information becomes a part of this database. No video records will be provided to NDAR. If you agree to be in this study that means that your child's research information will be used in this way. If you change your mind later, we can ask to remove your child's data from NDAR. However, NDAR cannot get back information that was shared before you changed your mind.

Certificate of Confidentiality

There is a Certificate of Confidentiality from the National Institutes of Health for this Study. The Certificate of Confidentiality helps us to keep others from learning that you participated in this study. Emory will rely on the Certificate of Confidentiality to refuse to give out study information that identifies you. For example, if Emory received a subpoena for study records, it would not give out information that identifies you.

The Certificate of Confidentiality does not stop you or someone else, like a member of your family, from giving out information about your participation in this study. For example, if you let your insurance company know that you are in this study, and you agree to give the insurance company research information, then the investigator cannot use the Certificate to withhold this information. This means you and your family also need to protect your own privacy.

The Certificate does not stop Emory from making the following disclosures about you:

- Giving state public health officials information about certain infectious diseases,
- Giving law officials information about abuse of a child, elderly person or disabled person.
- Giving out information to prevent harm to you or others.

Giving the study sponsor or funders information about the study, including information for an audit or evaluation.

Authorization to Use and Disclose Protected Health Information

The privacy of your health information is important to us. We call your health information that identifies you, your "protected health information" or "PHI." To protect your PHI, we will follow federal and state privacy laws, including the Health Insurance Portability and Accountability Act and regulations (HIPAA). We refer to all of these laws as the "Privacy Rules." Here we let you know how we will use and disclose your PHI for this study.

PHI that Will be Used/Disclosed:

We will use your name, your contact information such as address, phone number, and email address, as well as images of you and for the conduct of this research study. We will not use any of your personal information outside of this study.

If you wish to share the findings of this study with other healthcare professionals, you must sign a separate consent to release information.

Purposes for Which Your PHI Will be Used/Disclosed:
We will use and disclose your PHI for the conduct and oversight of the research study. We will use and share your PHI to provide you with study related treatment and for payment for such treatment. We will also use and share your PHI to conduct normal business operations. We may share your PHI with other people and places that help us conduct or carry out the study, such as laboratories, data management centers, data monitors, contract research organizations, Institutional Review Boards (IRBs)and other study sites (Florida State University). If you leave the study, we may use your PHI to determine your health, vital status, or contact information.

Use and Disclosure of Your Information That is Required by Law:
We will use and disclose your PHI when we are required to do so by law. This includes laws that require us to report child abuse or abuse of elderly or disabled adults. We will also comply with legal requests or orders that require us to disclose your PHI. These include subpoenas or court orders.

Authorization to Use PHI is Required to Participate:
By signing this form, you give us permission to use and share your PHI as described in this document. You do not have to sign this form to authorize the use and disclosure of your PHI. If you do not sign this form, then you may not participate in the research study or receive research-related treatment. You may still receive non-research related treatment.

People Who will Use/Disclose Your PHI:
The following people and groups will use and disclose your PHI in connection with the research study:

- The Principal Investigator and the research staff at Marcus Autism Center and Florida State University College of Medicine will use and disclose your PHI to conduct the study and give you study related treatment.
- Emory and Children's Healthcare may use and disclose your PHI to get payment for study related treatment and to run normal business operations.
- The Principal Investigator and research staff will share your PHI with other people and groups to help conduct the study or to provide oversight for the study.
- National Institutes of Health is the Sponsor of the study. The Sponsor may use and disclose your PHI to make sure the research is done correctly and to collect and analyze the results of the research. The Sponsor may disclose your PHI to other people and groups like study monitors to help conduct the study or to provide oversight for the study.
- The following people and groups will use your PHI to make sure the research is done correctly and safely:
    - Emory offices that are part of the Human Research Participant Protection Program and those that involved in study administration and billing. These include the Emory IRB, Western IRB, and other IRBs or privacy boards involved in this study; the Emory Research and Healthcare Compliance Offices; and the Emory Office for Clinical Research.
    - Children's Healthcare offices involved in the study administration and billing.
    - Government agencies that regulate the research including: Office for Human Research Protections; Food and Drug Administration.
    - Public health agencies.
    - Research monitors and reviewer.
    - Accreditation agencies.
    - Emory Department of Finance and Greenphire for study payment purposes.

Expiration of Your Authorization
Because this is a research study, there is no expiration of this authorization.

Revoking Your Authorization
If you sign this form, at any time later you may revoke (take back) your permission to use your information. If you want to do this, you must write to Nathan Call, PhD. Marcus Autism Center 1920 Briarcliff Road, Atlanta, GA 30329

At that point, the researchers would not collect any more of your PHI. But they may use or disclose the information you already gave them so they can follow the law, protect your safety, or make sure that the study was done properly and the data is correct. If you revoke your authorization you will not be able to stay in the study.

Other Items You Should Know about Your Privacy
Not all people and entities are covered by the Privacy Rules. HIPAA only applies to health care providers, health care payers, and health care clearinghouses. If we disclose your information to people who are not covered by the Privacy Rules, including HIPAA, then your information won't be protected by the Privacy Rules. People who do not have to follow the Privacy rules can use or disclose your information with others without your permission if they are allowed to do so by the laws that cover them.

To maintain the integrity of this research study, you generally will not have access to your PHI related to this research until the study is complete. When the study ends, and at your request, you generally will have access to your PHI that we maintain in a designated record set. A designated record set is data that includes medical information or billing records that your health care providers use to make decisions about you. If it is necessary for your health care, your health information will be provided to your doctor.

We may remove identifying information from your PHI. Once we do this, the remaining information will not be subject to the Privacy Rules. Information without identifiers may be used or disclosed with other people or organizations for purposes besides this study.

Voluntary Participation and Withdrawal from the Study
You have the right to leave a study at any time without penalty. You may refuse to do any procedures you do not feel comfortable with, or answer any questions that you do not wish to answer.

The researchers and funder also have the right to stop your participation in this study without your consent if:

- They believe it is in your best interest;
- You were to object to any future changes that may be made in the study plan;
- or for any other reason.

Contact Information
Contact [redacted]

- if you have any questions about this study or your part in it,
- if you feel you have had a research-related injury, or
- if you have questions, concerns or complaints about the research

Contact the Emory Institutional Review Board at 404-712-0720 or 877-503-9797 or irb@emory.edu:

- if you have questions about your rights as a research participant.
- if you have questions, concerns or complaints about the research.
- You may also let the IRB know about your experience as a research participant through our Research Participant Survey at http://www.surveymonkey.com/s/6ZDMW75.

If you are a patient receiving care at Children's Healthcare of Atlanta and have a question about your rights, please contact Sarah Marie Huban, Director of Research Administration at 404-785-7477.

Consent & Authorization

Please, print your name and sign below if you agree to be in this study. By signing this consent form, you will not give up any of your legal rights. We will give you a copy of the signed consent, to keep.

_____
Name of Caregiver/Participant

_____
Name of Child Participant Enrolled

_____
Caregiver's Relationship to Child Participant

_____ _____
Signature of Caregiver/Participant Date

_____ _____
Signature of Person Conducting Informed Consent Discussion Date

PHOTOGRAPHY/VIDEOGRAPHY and AUDIO RECORDING
PERMISSION FORM

Title: Changing Developmental Trajectories through Early Treatment

Principal Investigator: Nathan Call, PhD.
Funding Source: NIH

Name of Child_____ DOB___/___/_____
Name of Parent_____
I understand that audio/video recordings of my child are made at no cost to me for research purposes and that I may watch them. This and the nature of the taping procedure have been explained to me. I understand that the recording is confidential material and will not be used without my specific consent. I understand that I may request the recordings be erased after the study is completed and that my consent for any use of them may be withdrawn by requesting so in writing.

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In addition, I give my consent to the faculty at the Marcus Autism Center Social Neuroscience Laboratory to use these photographic images, video or audio segments for reasons other than research purposes:

- ❑ For educational and training purposes within Emory, Children's Healthcare of Atlanta and Marcus Autism Center ____(initial)
- ❑ For use at national and international conferences ____(initial)

- ❑ I decline to give my consent for any use of my child's image or voice for educational or training purposes.___(initial)
- ❑ I decline to give my consent for any use of my child's image or voice for use at national or international conferences. __(initial)

Your ability to participate in this study is not affected in any way by your willingness to consent to your child's image being used for educational or training purposes as described above.

_____ _____
Signature Date

_____ _____
Signature of Person Obtaining Consent Date

If you have further questions about this project or if you have a research-related problem, you may contact the Principal Investigator, Nathan Call, Ph.D., at 404-785-9400. If you have any questions concerning your rights as a research subject, you may contact the Emory Institutional Review Board at 404-712-0720 or 877-503-9797.