Informed Consent

Expediting Enrollment into Autism Specific Intervention for Black Toddlers: ATelehealth-based Family Navigation Approach

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University of North Carolina at Chapel Hill
Consent to Participate in a Research Study
Adult Participants - WL/NR Group

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IRB Study #23-1823
Title of Study: Expediting enrollment into autism specific intervention for Black toddlers: A telehealth-based family navigation approach
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CONCISE SUMMARY

In this study, we will enroll caregivers of children diagnosed with autism spectrum disorder (ASD) to assess the effectiveness of different strategies to help families enroll in early intervention services for their newly diagnosed children with autism. You will be randomly selected to participate in either the Family Navigation (FN) group or the Educational Materials (EM) group. The aim is to evaluate ways to expedite enrollment for Black toddlers into community-based early interventions.

Caregivers will complete questionnaires about themselves and their child. Participants in the FN group will receive individual support from a trained Navigator to help utilize services available to them in their community/county. Participants in the EM group will receive recommendations for community-based autism interventions. A subset of participants will be invited to complete an interview provide feedback on their experiences accessing services for their child.

You are being asked to take part in a research study because your child is on the waitlist for an evaluation for autism, were referred by their clinical provider, or if you are self-referring for an autism evaluation. You also identify as Black or African American.

Research is designed to benefit society by gaining new knowledge. The benefits to you from being in this study may include:

1) Receiving recommendations for service providers in your community for young children with ASD.

2) Learning about school-based services and intervention supports for young children with ASD.

3) Receiving one-on-one support with a trained navigator to help access support services for your child with ASD.

4) Receiving a developmental evaluation and summary report of your child's scores and clinical outcomes.

The main risk to you is the possibility that a breach of confidentiality could occur. We make every effort possible to ensure that this does not happen.

If you are interested in learning more about this study, please continue to read below.

What are some general things you should know about research studies?
You are being asked to take part in a research study. To join the study is voluntary.

You may choose not to participate, or you may withdraw your consent to be in the study, for any reason, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies. Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study.

You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?
The purpose of this research study is to assess the effectiveness of different strategies to help Black families enroll in early intervention services for their newly diagnosed children with autism. Therefore, we need children with a new diagnosis of ASD to assess the effectiveness of different types of post-diagnostic supports.

You are being asked to take part in a research study because your child is on the waitlist for an evaluation for autism, were referred by their clinical provider, or if you are self-referring for an autism evaluation. You also identify as Black or African American, are older than 18-years old, and speak conversationally fluent English.

Are there any reasons you should not be in this study?
You should not be in this study if you do not identify as Black or African American, if you are not 18 years or older, if you do not speak conversationally fluent English, or if you do not have access to internet access or a cellular device.

How many people will take part in this study?
Approximately 172 participants will take part in this study (86 pairs of children and their caregiver).

How long will your part in this study last?

Participation will occur over the course of 18 months. You will be contacted by our study staff up to 6 times over the course of 6 months for phone call or video visits. These visits will vary in length between 10 minutes and 1 hour at a time. You will also be contacted monthly for the course of the study to complete a brief survey about your child's intervention status, which will take approximately 5 minutes.

An in-person session will occur at study start and a follow-up visit will be conducted 18 months after your first visit. These appointments will take approximately 3 hours.

Approximately 15-20 participants will be invited to complete semi-structured phone interviews that will take about one hour.

What will happen if you take part in the study?

If you agree to talk part in this study, you and your child will first participate in a diagnostic evaluation for autism spectrum disorder. This evaluation will take place at the University of North Carolina, Carolina Institute for Developmental Disabilities. If the evaluation determines that your child meets diagnostic criteria for autism spectrum disorder, you will remain enrolled in the study. If your child does not meet diagnostic criteria for autism spectrum disorder, your participation in the research study will be complete. Either way, you will receive a summary of your child's diagnostic evaluation.

This study will consist of questionnaires, attending in-person and virtual study visits, and participating in interviews. If you choose to take part in this study, you and your child may be asked to complete the following:

1. **Electronic questionnaires:** Participants will complete questionnaires related to you, your child, and your family. These questionnaires are designed to capture behaviors related to stress and general well-being. You will also complete questionnaires regarding your child's behavior and development. You will also be asked to complete an electronic form about your enrollment in community-based intervention at study start and then on a monthly basis until completion of the study. You have the right to choose not to answer any question for any reason. Some of these questionnaires will be completed with the support of research staff on a telephone or video call.

2. **Interview about your experiences navigating services**: You will have the opportunity to share your experiences accessing early intervention services through a 1-hour phone interview.

3. **Random Group Assignment:** You will be randomly selected to participate in either the FN group or EM group. Random selection means that you have equal chance of being placed into each condition, like flipping a coin.

   If you are selected for the FN group:

1. FN-Telehealth sessions: Families will have four one-on-one video or telephone sessions with a family navigator who will provide guidance in accessing community-based autism services. Session duration will vary depending on the level of need for each family but will last approximately 1 hour.

If you are selected for the EM group:

2. Educational Materials: Participants will receive recommendations for autism interventions, including school-based service recommendations, and community-based recommendations. Participants will also receive information about support groups and other resources to support their child.

4. **In-person evaluation:** You and your child will travel to the research site at study start, and 18-months after enrollment to complete follow-up developmental and cognitive testing.

1. Developmental, Cognitive and Autism Assessment: Your child will complete an assessment to measure their learning skills, language development, problem-solving abilities, and behavior. We will also administer an autism assessment to measure symptoms. You will receive a report summarizing the results of your child's learning, language, and behavioral assessments. If you desire, this report can be added to your child's medical record.

2. Subject Interviews: You will be interviewed with questions that address a broad range of your child's behavior including their language, social behaviors, and development both at home and in other settings.

3. Developmental Questionnaires: You will complete standardized rating scales about your child's development, behavior and skills.

What are the possible benefits from being in this study?

Research is designed to benefit society by gaining new knowledge. The benefits to you from being in this study may include:

- Receiving recommendations for service providers in your community for young children with ASD.
- Learning about school-based services and support for young children with ASD.
- Receiving one-on-one support with a trained navigator to help access support services for your child with ASD.
- Receiving a developmental evaluation and summary report of your child's scores, and clinical outcomes.

What are the possible risks or discomforts involved from being in this study?

Learning the outcomes of your child's diagnostic evaluation may cause a range of emotions, which can sometimes be distressing. This information will be discussed with a licensed psychologist who can help you talk through this experience.

Some surveys used in this study assess recent stressful life events may be associated with some psychological distress. Some items in the questionnaires may provoke negative emotion in some individuals. You do not have to answer any question that you do not wish to answer. You have the right to stop participating at any point should the questions become too distressing.

All study staff is trained to create an understanding and welcoming environment for families participating. Supervision for all study staff occurs with the principal investigator, who is a licensed psychologist. Research visits are recorded for data collection and quality purposes.

Although measures are taken to protect the privacy of every participant, there is a remote risk of breach of confidentiality/loss of privacy. To minimize this risk, we assign Study IDs to all participants, so that research data is stored separately from your identifying data. Only the research team will have the link between your Study ID and your identity. All documents are stored electronically on a password protected UNC server, with restricted access to only approved research team members. In addition, there may be uncommon or previously unknown risks that might occur. You should report any problems to the researchers.

What if we learn about new findings or information during the study?

You will be given any new information gained during the study that might affect your willingness to continue your participation.

If the evaluation completed at the start of the study determines that your child does not have autism, your participation in the study will be complete.

How will information about you be protected?

To help protect your confidentiality, any data collected from you as part of this study will be stored under a unique code number that is assigned to you. Only primary research staff will have access to the key that connects the unique code number to their personal health information, which will be kept on a password protected server. Electronic data will be password protected. Research collaborators will only have access to your coded data, they will not be given your identifiable personal information.

Participants will not be identified in any report or publication about this study. We may use de-identified data and/or specimens from this study in future research without additional consent. Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of the University, research sponsors, or government agencies (for example, the FDA) for purposes such as quality control or safety.

Under North Carolina law, confidentiality does not extend to information about abuse or neglect of a child or disabled adult. If the researchers become aware of such information, they are required to report it to state authorities.

What is a Certificate of Confidentiality?

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.

There are some important things that you need to know. 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.

Audio and Video Recording

This study involves audio or video recording your sessions and interviews with research staff. Assessments completed with your child will also be video recorded. Only the research team will be able to listen to the recordings or review the videos, unless you provide explicit consent otherwise. The tapes will be transcribed by the research team and erased once the transcript coding has been completed. Transcripts of your participation may be reproduced in whole or in part for use in presentations or written products that result from this study. Neither your name nor any other identifying information (such as your voice) will be used in presentations or in written products resulting from the study without your explicit consent. You are not required to initial/ sign below and you may refuse to do so without affecting your right to any services you are receiving or may receive from the University of North Carolina at Chapel Hill. However, if you refuse to sign, you cannot participate in this study.

Permission for Audio/Video Recording

Please indicate below that you agree to be audio and video recorded:

_____I agree for my research visits to be audio and video recorded for purpose of this study (e.g., data collection).

_____I DO NOT agree for my research visits to be audio and video recorded for purpose of this study (e.g., data collection).

Please indicate below if you agree that your video tapes to be used for **educational or training purposes (for example, at an academic conference or training).**

_____I agree for the videotapes collected in this research study to be utilized for educational or training purposes.

_____I DO NOT agree for the videotapes collected in this research study to be utilized for educational or training purposes.

Permission for Future Contact

We would like to be able to contact you in the future to see if you would be interested in participating in another research study or to share findings from this research. Please indicate below if you are willing to be contacted in the future.

_____Yes, I agree to be contacted about future research studies or to hear about findings from this research.

_____No, I do not want to be contacted about future research studies or to hear about findings from this research.

Permission for study results to be placed into your child's electronic medical record

As part of your participation in this study, your child will participate in an autism diagnostic evaluation. We will summarize the findings from this evaluation into a summary report. With your permission, we can include this information in your child's UNC medical record. Including this information in your child's medical record may be important for accessing necessary support services for your child.

_____Yes, I agree for this evaluation summary and associated diagnostic outcomes to be included in my child's UNC electronic medical record.

_____No, I do not want this evaluation summary and associated diagnostic outcomes to be included in my child's UNC electronic medical record.

Who is sponsoring this study?

This research is funded by the National Institutes of Health. This means that the research team is being paid by the sponsor for doing the study. The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study.

What if you want to stop before your part in the study is complete?

You can withdraw from this study at any time, without penalty. The investigators also have the right to stop your participation at any time. This could be because you have had an unexpected reaction, or have failed to follow instructions, or because the entire study has been stopped. If you withdraw or are withdrawn from this study all data collected up until the point of

withdrawal will be retained; however, no additional information will be collected unless you provide additional written permission for further data collection at the time of your withdrawal. If you withdraw, you have the right to request the destruction of previously collected data. Make this request directly to the PI in writing to **kelly_caravella@med.unc.edu.**

Will you receive anything for being in this study?

You will be receiving $25 for completion of questionnaires and forms. Participants that complete the interview will receive an additional $50. Families who travel to UNC for in-person assessment will receive an extra $25 per visit. You will also receive a summary of your child's follow up developmental evaluation.

Our study allows more than one caregiver to enroll, although it is not required. If an additional caregiver enrolls, compensation will be provided to the family unit, not to each individual caregiver.

Will it cost you anything to be in this study?

It will not cost you anything to be in this study.

What if you have questions about this study?

You have the right to ask, and have answered, any questions you may have about this research. If you have questions about the study (including payments), complaints, concerns, or if a research-related injury occurs, you should contact the researchers listed on the first page of this form.

What if you have questions about your rights as a research participant?

All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject, or if you would like to obtain information or offer input, you may contact the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

Clinical Trials.Gov

A description of this clinical trial will be available on 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."

Participant's Agreement:

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

_____
Printed Name of Child Participant

_____
Printed Name of Caregiver Participant

_____ _____
Signature of Caregiver Participant Date

_____
Printed Name of Research Team Member Obtaining Consent

_____ _____
Signature of Member Obtaining Consent Date