CLINICAL STUDY PROTOCOL

Expediting enrollment into autism specific intervention for Black toddlers: A telehealth-based family navigation approach

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Expediting enrollment into autism specific intervention for Black toddlers: A telehealth-based family navigation approach

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Confidentiality Statement:

Study Personnel

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SYNOPSIS

Primary Objective The primary objective of this study is to determine whether telehealth-based Family Navigation (FN) expedites enrollment (e.g., reduces time in days) in community-based autism intervention for Black toddlers under the age of 4 after their initial diagnosis of autism.
Secondary Objectives (if applicable) The secondary objectives of this study include: 1) determining whether family navigation meaningfully improves developmental outcomes at 18 months post-diagnosis of autism, 2) determining whether FN improves caregiver well-being, and 3) assessing implementation outcomes of FN, including acceptability, appropriateness, and feasibility.
General Design Description This study uses a two-condition, randomized control trial design. Participants are caregivers of Black toddlers (<4yo) whose child has just received a first diagnosis of autism spectrum disorder (ASD). Participants will be recruited through parent research studies and UNC Pediatrics. Participants will be randomized at a 1:1 rate into two conditions, 1) Educational Materials (Standard of Care; SOC), or 2) Family Navigation. Due to the nature of the interventions, group allocation is non-blinded.
Primary Outcome Variables The primary outcome variable is time to initiation of autism-specific early intervention with a community provider. This will be the number of days between diagnosis and their first appointment with the interventionist.
Secondary and Exploratory Outcome Variables (if applicable) The secondary/exploratory objectives of this study include: 1) determining whether family navigation improves developmental outcomes at 18 months post-diagnosis of autism, 2) determining whether FN improves caregiver well-being, and 3) assessing implementation outcomes of FN, including acceptability, appropriateness, and feasibility.
Number of Participants n = 86, randomly divided evenly between the two conditions.
Visit Schedule Table (Optional)
Study Flow Chart (Optional)

ABBREVIATIONS

Abbreviation	Explanation
ABC	Adaptive Behavior Composite
AIM	Acceptability of Intervention Measure
ASD	Autism spectrum disorder
EM	Educational Materials
FIM	Feasibility of Intervention Measure
FN	Family Navigation
GWBS	General Well Being Schedule
HIPPA	Health Insurance Portability and Accountability Act
IAM	Intervention Appropriateness Measure
ID	Identification Number
IRB	Institutional Review Board
MSEL	Mullen Scales of Early Learning
MSEL ELC	Mullen Scales of Early Learning Early Learning Composite
NIH	National Institutes of Health
SOC	Standard of Care
UNC	University of North Carolina
ABAS-3	Adaptive Behavior Assessment System, Third Edition

ADOS-2	Autism Diagnostic Observation Schedule, Second Edition

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1. Statement of Compliance

This document is a protocol for a human research study. The purpose of this protocol is to ensure that this study is to be conducted according to the Common Rule at 45CFR46 (human subjects) and other applicable government regulations and Institutional research policies and procedures.

2. Background

Effectiveness of early behavioral intervention on developmental outcomes in autism relies on intervention timing and dose. Early intensive behavioral interventions (EIBIs) are the most effective treatment to improve cognition, language development and social skills in young children with autism spectrum disorder (ASD)[7]. However, their magnitude of effectiveness relies on being delivered during critical developmental windows. Recent research reported that even a 9-month delay in the initiation of autism-specific intervention results in poorer developmental outcomes for young children with ASD[8].

Black children experience systemic delays and inequities, which lead to poorer outcomes. Black children with ASD experience delays to diagnosis and intervention of up to 3 years after symptoms emerge[9,10], often entirely missing the critical developmental window for the most effective intervention. Compounding these delays to diagnosis, Black children are less likely to receive early intervention services once diagnosed[11]. These systemic delays and inequities, in turn, contribute to striking health disparities in outcomes, where Black autistics are disproportionately impacted by intellectual disability and profound autism, the most impairing form of ASD, at a rate of almost 2x that of White autistics[12].

Early identification and diagnosis must be paired with timely initiation of an autism-specific intervention to achieve improved outcomes. A significant public health effort has been made to reduce the time to diagnosis for children with ASD, with the most recent surveillance data showing decreases in the average age of first diagnosis[13]. However, reductions in time to diagnosis alone do not result in improved developmental outcomes, as children experience delays to interventions of up to 3+ years once diagnosed[10]. Preliminary data from my mentorship team (Figure 1) shows that when Black children receive both an early ASD diagnosis and expedited enrollment in intervention, they evidence an average 7-point gain in cognition, while a small control group, who also received an early diagnosis of ASD but no expedited intervention, made no such gain, and deteriorated in their adaptive function[14]. Therefore, it is vital to identify solutions that close the gap between diagnosis and intervention and assess their effectiveness in improving developmental outcomes.

Family navigation has shown efficacy in ASD, is desired by families and can be an important element of anti-racist healthcare. Family navigation (FN) addresses structural barriers for families seeking healthcare by providing a knowledgeable support person to help overcome these barriers while providing emotional support during an often-overwhelming time of a new diagnosis[15]. This is especially important for racial and ethnic minoritized families, who disproportionately experience structural barriers in access to healthcare[16]. For children with ASD, FN has been shown to reduce time to first diagnosis by one year compared to families in services as usual[13]. Additionally, published qualitative work has highlighted parents' frustrations with lack of guidance following an initial diagnosis, with parents reporting feeling underprepared to navigate the complex early intervention system[17,18]. When asked for their desired solution, parents overwhelmingly reported a desire for 1:1 support to navigate the early intervention

system. Families who have received FN report that guidance from a knowledgeable support person significantly helps overcome systemic challenges in accessing services[19].

Telehealth interventions can reduce access barriers, improve treatment adherence, and are well-liked by patients. Clinical services for ASD via telehealth have increased significantly because of the COVID-19 pandemic. Overwhelmingly, families report being satisfied with ASD services (e.g., diagnostic evaluations, parent-mediated intervention) delivered through telehealth[20—22]. Additionally, the North Carolina Council on Developmental Disabilities has highlighted virtual delivery as being a key component of the scalability and sustainability of family navigation[23].

3. Rationale/Significance

3.1 Problem Statement

Black autistics experience intellectual disability at a rate of almost 2x that of White autistics. These differences in functional outcome are hypothesized to be a result of the significant delays to initiation of intervention that exist for Black children with autism compared to their white counterparts. We hypothesize that if disparities in time to intervention can be eliminated, equity in outcomes for Black autistic children can be reached.

Family navigation was selected as the intervention because it is desired by families of autistic children and has been shown to decrease time to diagnosis when used in young children who show concerns for autism. It has not yet been tested to see if it can decrease the time to intervention for Black toddlers.

The comparison condition ("Educational Materials") consists of providing the participant's caregivers with individualized recommendations for intervention for their child at the time of the diagnosis of autism spectrum disorder. The control condition was selected to mimic what is the current standard of practice in the community where families receive recommendations for intervention at the time of diagnosis and receive no further individualized support in accessing these interventions.

3.2 Purpose of Study/Potential Impact

First, we will establish the effectiveness of FN-Telehealth in 1) expediting the initiation of autism specific intervention, and 2) improving developmental functioning 18 months post diagnosis for Black toddlers. We will also report the impact of FN-Telehealth on caregiver well-being. Next, we will describe actionable aspects of the FN-Telehealth implementation that can be incorporated in future trials for maximum impact, reach and acceptability for Black families.

3.3 Potential Risks and Benefits

3.3.1 Potential Risks

Risks to the participants are predicted to be minimal, however may include possible feelings of discomfort in answering questions about themselves or their family, discussing their child's autism diagnosis, and/or discussing structural racism and/or systemic inequities. Additionally, even though we have precautions in place to protect the privacy of participants, because we will be collecting identifiable data, there is a remote risk of breach of confidentiality. To maximally protect participants' identities and information, we have taken multiple precautions. Wherever possible, we will use unique anonymous codes (i.e., participant IDs) that will be used to identify and link study documentation. We will maintain one master document with linkage codes to the identifiers in a password-protected file that is only accessible by study staff. All data will be stored on a secure, Health Insurance Portability and Accountability Act (HIPAA)-compliant network accessible only by Institutional Review Board (IRB)-approved research staff.

3.3.2 Potential Benefits

Study participation is likely to provide the following benefits:

Participants in Condition A (Educational materials) will receive standard recommendations for early intervention services for young children with autism in their state. Receiving these recommendations may help families access and enroll in early intervention services.

Participants in Condition B (Family Navigation) will receive personalized support through phone/video calls, up to 4 times over the course of 3 months. Receiving this support may help families feel more supported in their journey to accessing early intervention for their children. Additionally, receiving these recommendations may help families access and enroll in early intervention services.

4. Study Objectives

4.1 Hypothesis

Aim 1a: Assess the effectiveness of Family Navigation (FN) in decreasing the time between diagnosis and treatment of ASD. Hypothesis: Children of caregivers who receive FN will initiate autism-specific intervention services more quickly than those in the Educational Materials (EM) condition.

Aim 1b. Assess the effectiveness of FN in improving developmental outcomes for young children with autism. Hypothesis: Children whose caregivers receive family navigation will show improvements or maintenance of developmental skills at 18 months post-diagnosis.

Aim 2: Assess whether FN improves caregiver well-being. Hypothesis: Caregivers in the FN condition will have higher well-being scores at 6 months post-diagnosis than caregivers in the EM condition.

Aim 3: Assess implementation outcomes of FN, including acceptability, appropriateness, and feasibility. Hypothesis: Caregivers in the FN group will report acceptability, appropriateness, and feasibility as being high.

4.2 Primary Objective

The primary objective of this study is to determine whether telehealth-based Family Navigation (FN) expedites enrollment (e.g., reduces time in days) in community-based autism intervention for Black toddlers under the age of 4 after their initial diagnosis of autism.

4.3 Secondary Objectives (if applicable)

The secondary objectives of this study include: 1) determining whether family navigation meaningfully improves developmental outcomes at 18 months post-diagnosis of autism, 2) determining whether FN improves caregiver well-being, and 3) assessing implementation outcomes of FN, including acceptability, appropriateness, and feasibility.

5. Study Design

5.1 General Design Description

This study uses a two-condition, randomized control trial design. Participants are caregivers of Black toddlers (<4yo) whose child has just received a first diagnosis of autism spectrum disorder (ASD). Participants will be randomized at a 1:1 rate into two conditions, 1) Educational Materials (Standard of Care; SOC), or 2) Family Navigation. Due to the nature of the interventions, group allocation is non-blinded.

5.2 Outcome Variables

5.2.1 Primary Outcome Variables

The primary outcome variable is the time between diagnosis of autism spectrum disorder and initiation of autism-specific intervention. The date of diagnosis will be documented as the date when families receive the outcome of their diagnostic evaluation through the parent study and recommendations for intervention. The date of initiation (date 1) of autism-specific intervention will be the date that families report the first session with a therapist following the diagnosis (date 2). Time will be calculated as the number of days elapsed between these two dates (date 2 - date 1).

5.2.2 Secondary and Exploratory Outcome Variables (if applicable)

- Change from baseline in caregiver well-being on the General Well-being Schedule
- Change from baseline in adaptive behavior on the Adaptive Behavior Assessment System, Third Edition
- Scores on the AIM, FIM, and IAM

6. Study Population

6.1 Study Population

Caregiver and child pairs (family units) of children under the age of 4 diagnosed with autism spectrum disorder within the last month. Caregivers are pre-defined as the adult who provided consent for their child's participation in the parent research study. See below for more details.

6.1.1 Number of Participants

n = 86, randomly divided evenly between the two conditions.

6.1.2 Eligibility Criteria/Vulnerable Populations

To be eligible for inclusion in the study, a family unit must meet all of the following criteria:

- Caregiver and their child with a clinical diagnosis of autism spectrum disorder
- Over the age of 18
- Their child with autism must be Black/African-American
- Speak conversationally fluent English.

Exclusion criteria include:

- No access to a telephone or internet connection for phone calls or video conferencing.

7. Methods

7.1 Intervention

7.1.1 Description of Intervention

Family navigation is a patient-centric healthcare service aimed at reducing barriers to accessing and maximally utilizing care. In Family Navigation (FN), patients receive individualized support to overcome barriers to increase timely access to recommended healthcare (e.g., therapy, intervention, medication). In this study, participants randomized to the FN condition will receive up to 4 research-based individual sessions with a trained navigator to support them in identifying and enrolling in recommended autism early intervention services. All navigation sessions will be delivered virtually via phone or Zoom. This intervention is benign, as it is harmless, painless, and physically non-invasive.

7.1.2 Method of Assignment/Randomization

Once participants are enrolled, they will be randomly assigned to either receive 1) Family Navigation or 2) Educational Materials (Standard of Care). A random assignment generator will be used to result in approximately 50% of the sample in each condition. Assignment to condition will not be blinded to either study staff or participants.

7.1.3 Selection of Instruments/Outcome Measures

Instruments were selected apriori based on a review of the literature.

7.1.4 Intervention Administration

The intervention will be administered virtually via telephone and Zoom, based on participant preference.

7.1.5 Reaction Management

If during the FN sessions with the navigator, information regarding the mental health of the caregiver or their family requires follow-up, the navigator will communicate this to the PI (Caravella) to provide the necessary support or recommendations. The PI also will review recorded sessions, so she can intervene if necessary. If necessary, participants can directly contact the PI via email (contact information provided in the consent form).

7.2 Assessments

7.2.1 Efficacy

For Aim 1a, efficacy will be assessed by comparing the time to initiation of intervention between the two conditions.

For Aim 1b, efficacy will be assessed by comparing changes in developmental skills (between baseline and 18 months post-diagnosis) between the two conditions. Developmental skills will be measured using the Mullen Early Learning Composite and the Adaptative Behavior Assessment System, Third Edition (*ABAS-3*).

For Aim 2, efficacy will be assessed by comparing scores on the General Well-Being Schedule at 6 months post-diagnosis between the two groups.

Aim 3 is an implementation aim, and therefore is not related to trial efficacy.

7.2.2 Safety/Pregnancy-related Procedure

There is no risk to participants who may be pregnant or become pregnant during the study.

7.2.3 Adverse Events Definition and Reporting

Adverse events are classified as serious or non-serious. A ***serious adverse event*** is any AE that is:

- fatal
- life-threatening
- requires or prolongs hospital stay
- results in persistent or significant disability or incapacity
- a congenital anomaly or birth defect
- an important medical event

All adverse events that do not meet any of the criteria for serious should be regarded as ***non-serious adverse events***.

We do not anticipate any serious adverse events, given the behavioral nature of this study.

Non-serious adverse events including emotional distress, are possible. This may include possible feelings of discomfort in answering questions about themselves or their family, their child's autism diagnosis, and discussing structural racism, and/or systemic inequities.

7.2.4 Pharmacokinetics (if applicable)

n/a

7.2.5 Biomarkers (if applicable)

n/a

7.3 Study Procedures

7.3.1 Study Schedule

Eligibility (Time 1): Child participants without a confirmed diagnosis of autism will participate in a diagnostic evaluation for autism (Approximately 3 hours) to confirm study eligibility and collected baseline developmental data.

Visit 0 (Day 1): Participants will be randomized to study condition. (Approximately 5 minutes)

Visit 1 (Day 7): Phone or Zoom call (Approximately 10 minutes for Condition A, and 1 hour for Condition B).

Visit 2 (Day 14): Phone or Zoom Call (Approximately 10 minutes for Condition A, and 1 hour for Condition B)

Visit 3 (Day 30): Phone or Zoom Call (Approximately 10 minutes for Condition A, and 1 hour for Condition B)

Visit 4 (Day 60): Phone or Zoom Call (Approximately 10 minutes for Condition A, and 1 hour for Condition B)

Visit 5 (Day 180): Phone or Zoom Call (Approximately 10 minutes for Condition A, and 15 minutes for Condition B)

Time 2 (18 months): All participants local to NC will complete a follow up developmental evaluation (approximately 3 hours), following the same protocol at Time 1.

7.3.2 Informed Consent

Informed consent will be conducted with a study coordinator via telephone prior to signing. Once participant questions are answered, they will be sent the consent form electronically to review and sign.

7.3.3 Screening

Screening will be completed by the study coordinator during their first phone call with the interested participant. Caregivers are determined based on their participation and provision of consent for their child in the parent study.

Screening involves confirming the following:

1) Is the participant over the age of 18?

2) Is their child Black/African-American?

3) Do they have consistent access to a personal phone and or internet connection at home?

4) Are they able to read and converse in English?

7.3.4 Recruitment, Enrollment and Retention

Participants will be drawn from three primary pieplines:

1. Participants family units will be recruited from an ongoing study at Emory University (herein referred to as the "parent study"). Participants (Black toddlers <3yo) in the parent study will complete a diagnostic evaluation for autism spectrum disorder during their initial study visit. Those who meet diagnostic criteria for autism will be eligible to enroll in the present study. Study staff from the parent study will give eligible participants a 1-page document that provides a summary of the EASE study, and a link to a Qualtrics form (Permission to Contact form)

where they can share their desire to be contacted to learn more about the study and provide their contact information.

Participants who complete the online survey will be contacted by study staff at UNC. During this phone call, study staff will describe the study, answer questions, and administer the screening survey. Participants who choose to enroll will review the consent form and sign the consent form electronically.

2. Families local to North Carolina. Family units with a participant child with a new diagnosis of autism (in the last month). Families will complete a Permission to Contact form where they can share their desire to be contacted to learn more about the study and provide their contact information. Eligible families will then be consented.

3. Families local to North Carolina. Family units with a participant child who is awaiting a diagnostic evaluation will be invited to participate in a diagnostic evaluation through the study team (T1). If their evaluation results in a positive diagnosis of autism, they will remain in the study and continue to Visit 0.

7.3.5 Study Visits

Visit Time 1 (T1): Diagnostic Evaluation for Autism

- Autism Diagnostic Observation Schedule -2 (*ADOS-2*)
- Mullen Scales of Early Learning (Mullen)
- Adaptive Behavior Assessment System, Third Edition (ABAS-3)
- Diagnostic Clinical Interview

Visit 0 (Day 1):

- Participants will be randomized to condition.
- All participants will complete the General Well-Being Schedule (Online via Qualtrics, approx 5 minutes).

Visit 1 (Day 7):

Condition A: Educational Materials

- Collect Distress Thermometer (Phone call, approx 5 minutes)

Condition B: Family Navigation

- Collect Distress Thermometer (via phone or Zoom, approx 5 minutes)
- Family Navigation Session (via phone or Zoom, approx 1 hour)

Visit 2 (Day 14):

Condition A: Educational Materials

- Collect Follow-Up Distress Thermometer (Phone call, approx 5 minutes)

Condition B: Family Navigation

- Collect Follow-Up Distress Thermometer (via phone or Zoom, approx 5 minutes)
- Family Navigation Session (via phone or Zoom, approx 1 hour)

Visit 3 (Day 30):

Condition A: Educational Materials

- Collect Follow-Up Distress Thermometer (Phone call, approx 5 minutes)

Condition B: Family Navigation

- Collect Follow-Up Distress Thermometer (via phone or Zoom, approx 5 minutes)
- Family Navigation Session (via phone or Zoom, approx 1 hour)

Visit 4 (Day 60):

Condition A: Educational Materials

- Collect Follow-Up Distress Thermometer (Phone call, approx 5 minutes)

Condition B: Family Navigation

- Collect Follow-Up Distress Thermometer (via phone or Zoom, approx 5 minutes)
- Family Navigation Session (via phone or Zoom, approx 1 hour)

Visit 5 (Day 180):

Condition A: Educational Materials

- General Well-Being Schedule (Online via Qualtrics, approx 5 minutes).

Condition B: Family Navigation

- General Well-Being Schedule (Online via Qualtrics, approx 5 minutes).
- Feasibility of Intervention Meausre (FIM) (Online via Qualtrics, approx 5 minutes)
- Intervention Appropriateness Measure (IAM) (Online via Qualtrics, approx 5 minutes)
- Acceptability of Intervention Measure (AIM) (Online via Qualtrics, approx 5 minutes)

Monthly data collection:

- Initiation of intervention/waitlist data will be collected via Qualtrics survey for all participants (approx 5 minutes).

Visit Time 2 (T2 – 18 months): Developmental Follow Up Visit

- Autism Diagnostic Observation Schedule -2 (*ADOS-2*)
- Mullen Scales of Early Learning (Mullen)
- Adaptive Behavior Assessment System, Third Edition (ABAS-3)
- Diagnostic Clinical Interview

7.3.6 End of Study and Follow Up

Participants will complete a final comprehensive diagnostic evaluation at 18 months. Those whose are recruited from the Emory site will complete this evaluation at Emory, and data will be shared through a data-sharing agreement.

7.3.7 Removal of Subjects

- Participants can withdraw voluntarily from the study at any time.
- There are almost no conditions in which participants will be withdrawn early by the research team. Participants can withdraw freely at any time.
- Participants in the FN condition will be offered up to 4 navigation sessions. If families wish to stop receiving navigation sessions before their 4th session, this will not necessitate a complete withdrawal from the study.

7.4 Statistical Method

7.4.1 Statistical Design

Aim 1a: Time to initiation of intervention (date 2 - date 1 in number of days) will be analyzed using a Cox Proportional Hazards Survival Regression.

Aim 1b: Developmental outcomes (e.g., cognitive skills, adaptive skills, autism symptom severity) will be compared between the 2 conditions using an independent samples t-test, controlling for sex, age, and developmental scores at baseline.

Aim 2: Caregiver well-being will be compared between the 2 conditions using a multiple regression model, controlling for sex, age, and developmental scores, as appropriate.

Aim 3: Scores on the AIM, FIM, and IAM will averaged individually for each measure. Higher scores indicate greater acceptability, appropriateness, and/or feasibility. Mean scores for each measure will be compared to the scale mean (3) using an independent samples t-test to determine are meaningfully different than a neutral rating.

7.4.2 Sample Size Considerations

Using estimates from previous Family Navigation (FN) literature, power analysis using the powerSurvEpi package in R suggests that we are powered at .8 to find a hazard ratio of 1.7 or

greater with a sample size of 86 (n=43 per group), assuming conservatively that 60% of our sample initiate intervention before 18 months. This is reasonable given that previous literature using FN to expedite autism diagnoses, a similar outcome, has reported hazard ratios ranging from 2 - 3.5**.** For tests of mean difference, we are powered at .8 to detect a medium effect size (d =.6).

7.4.3 Planned Analyses

7.4.3.1 Primary Analyses

Aim 1a: Time to initiation of intervention will be analyzed using survival analysis methods. Time to event is defined as the number of days between the referral/eligibility date (Date 1) and initiation of the intervention (Date 2). Participants who do not initiate the intervention during the observation period will be censored at the end of follow-up.

Differences in time to initiation of intervention between the Family Navigation (FN) group and the standard of care control group (Educational Materials; EM) will be evaluated using the log-rank test. Additionally, a Cox Proportional Hazards regression model will be used to estimate the effect of FN relative to EM while accounting for time to event.

The primary effect of interest is the hazard ratio comparing FN to EM. In the Cox regression model, effects will be quantified using hazard ratios with corresponding 95% confidence intervals. A hazard ratio greater than 1 indicates a higher likelihood of initiating the intervention at any given time for participants receiving FN compared to EM, whereas a hazard ratio less than 1 indicates a lower likelihood. A hazard ratio equal to 1 indicates no difference between groups.

Model assumptions, including proportional hazards, will be evaluated using standard diagnostic methods.7.4.3.2 Secondary Objectives Analyses, if applicable

Aim 1b: Developmental outcomes (e.g., cognitive skills, adaptive skills) will be compared between the 2 conditions using multiple regression, controlling for sex, age, and developmental scores at baseline.

Aim 2: Caregiver well-being will be compared between the 2 conditions using multiple regression, controlling for sex, age, and developmental scores.

Aim 3: Items for the AIM, FIM, and IAM sub-scales will averaged for each measure. Higher scores indicate greater acceptability, appropriateness, and/or feasibility. Mean scores for each measure will be compared to the scale mean (3) using a one-sample t-test to determine are meaningfully different than a neutral rating.

7.4.3.3 Analysis of Subject Characteristics

7.4.3.4 Interim Analysis (if applicable)

No plan for this.

7.4.3.5 Health economic evaluation, if applicable

Not applicable.

7.4.3.6 Other

7.4.4 Subsets and Covariates

Subgroup analysis - Sex

Covariates – Age at study entry

7.4.5 Handling of Missing Data

We assume missing data in this study will be missing at random. The survival model we proposed will accommodate for missing data.

8. Trial Administration

8.1 Ethical Considerations: Informed Consent/Assent and HIPAA Authorization

Informed Consent: Informed consent will include a conversation via phone with study staff to review study procedures, possible benefits and risks, protections against possible risks, and participant compensation. All participants will complete informed consent before enrolling in the study. Participants will be informed that they can revoke their consent at any time. Participants will review and sign the consent form via DocuSign and provide an electronic signature. To avoid coercion, participants will be e-mailed links to the consent forms after finishing their informed consent call and asked to sign them at their convenience (i.e., not while on the phone with study staff which could increase the risk of feelings of coercion). Participants will also be reassured that participation in this study will not affect their enrollment or compensation for the parent study. Participants will be offered additional time to speak with study staff if needed after reviewing the consent form on their own.

Compensation: Participants will be compensated for their participation in the study. All participants will be compensated $25 for the completion of online forms at their initial visit (Visit 0) and again at their final visit (Visit 5), totaling $50.

Participants who complete qualitative interviews (~15/condition) will be compensated an additional $50.

8.2 Institutional Review Board (IRB) Review

This study has been approved by the UNC IRB on 9/5/2023. Any protocol modifications will be submitted to the IRB for approval before implementing changes in the study. If the IRB determines that participants need to be informed of protocol modifications, an updated consent form will be created and participants will be asked to sign it before continuing participation in the study.

8.3 Subject Privacy, Confidentiality & Data Management

Data protection: Data will be stored on a university-sponsored HIPPA-compliant cloud-based server (Microsoft OneDrive) and surveys linked using an anonymous id number. Participant data will only be accessible to study staff who have completed human subjects research training (e.g., CITI training) and approved by the University IRB. Access to all study data will be password-protected. To protect confidentiality, study IDs will be assigned as participants enroll. Identifying information (e.g., participant names, addresses, dates of birth) will be saved separately from all other coded data which will utilize study IDs. One document will exist that links study IDs with participant identity. This document will be stored separately on the virtual drive (OneDrive). No study data will be added to the participant's medical record.

8.4 Deviations/Unanticipated Problems

This study has been deemed non-human subjects research, as the intervention is benign and presents no more than minimal risk to participants.

8.5 Data Collection

Data collection is the responsibility of the research staff, under the supervision of the PI. The PI is responsible for ensuring the accuracy, completeness, legibility, and timeliness of the data reported.

Survey data will be collected via Qualtrics, an online data collection platform using a secure UNC account. Qualitative data will be collected via audio recordings of telephone or video calls. Audio files will be kept until transcription and data analysis are complete, at which point, they will be destroyed.

All participants will be assigned a unique study ID that will be used in place of identifying information on study documentation. We will maintain one master document with linkage codes to the identifiers in a password-protected file that is only accessible by research staff. All data (including video and audio files) will be stored on a secure, HIPAA-compliant network accessible only by IRB-approved research staff.

Study documents will be retained for the longer of 3 years after closeout or 5 years after final reporting/publication. These documents may be retained for a longer period, however, if required by local regulations.

8.6 Data Quality Assurance

Study staff and PI will meet weekly throughout the study to monitor study progress and quality control. Family navigators will attend training with the PI, which will cover the information in the study manual. Additionally, navigators will meet with the PI bi-weekly for supervision to ensure fidelity to the intervention. Monthly audits will be completed on all survey data to identify any missing data or errors so that they can be remedied.

Qualitative interviews will be transcribed by trained research staff. Transcriptions will be audited by a second staff member to check for accuracy. Any discrepancies will be reviewed and resolved by the PI.

8.7 Study Records

Study records include:

- Consent forms
- Electronic survey responses
- Audio recordings from qualitative interviews
- Video recordings from family navigation sessions

8.8 Access to Source

Access to study records will be limited to IRB-approved members of the study team. The investigator will permit study-related monitoring, audits, and inspections by the IRB and

University compliance of all study-related documents (e.g. source documents, regulatory documents, data collection instruments, study data etc.).

8.9 Data or Specimen Storage/Security

Data will be collected in 3 formats; (1) survey data (2) video data, and (3) audio data.

(1) Survey data will be collected via Qualtrics, a secure online portal. The survey data will be collected in a de-identified manner, with participants entering their study ID at the start of each survey. Survey data will be downloaded from Qualtrics and saved on the UNC OneDrive server.

(2) Video data will be collected via Zoom. Video calls between participants and the family navigator will be recorded live. Files will be saved to the Family Navigators computer hard drive and then transferred to OneDrive for long-term storage. Once transferred to OneDrive, they will be deleted from the hard drive.

(3) Audio data will be collected via an audio recorder. Audio files will be downloaded from the recorder directly to OneDrive for long-term storage. Audio files will be deleted from the audio recorder once they have been uploaded to OneDrive and checked for accuracy.

All data collection and storage formats (e.g., Qualtrics, OneDrive) are password-protected and only accessible to IRB-approved study staff.

8.10 Retention of Records

To comply with the requirements of the IRB, study records are maintained for at least six (6) years after completion of the research.

8.11 Study Monitoring

The study will be monitored internally by the PI.

8.12 Data Safety Monitoring Plan

This study does not involve more than minimal risk. There is no formal Data and Safety Monitoring Plan.

8.13 Study Modification

Study modifications will be approved by the PI. Desired modifications will be submitted to the IRB for approval. Once approved, the study protocol will be updated, and changes will be implemented.

8.14 Study Discontinuation

This study may be temporarily suspended or prematurely terminated if there is sufficient reasonable cause. Written notification, documenting the reason for study suspension or termination, will be provided by the suspending, or terminating party to study participants, investigator, funding agency, and regulatory authorities. If the study is prematurely terminated or suspended, the Principal Investigator (PI) will promptly inform study participants, the Institutional

Review Board (IRB), and sponsor/funding agency and will provide the reason(s) for the termination or suspension. Study participants will be contacted, as applicable, and be informed of changes to study visit schedule.

Circumstances that may warrant termination or suspension include, but are not limited to:

- Determination of unexpected, significant, or unacceptable risk to participants (although unlikely, due to minimal risk involved in this study)
- Demonstration of efficacy that would warrant stopping
- Insufficient compliance of study staff to the protocol (ie, significant protocol violations)
- Data that are not sufficiently complete and/or evaluable
- Determination that the primary endpoint has been met

The study may resume once concerns about safety, protocol compliance, and data quality are addressed, and satisfy the funding agency and IRB.

8.15 Study Completion

A participant is considered to have completed the study if they complete visits 0 through 5 (i.e., Baseline through 6-month follow-up). The end of the study is defined as the completion of the 6-month follow-up shown in the study schedule (Section 7.3.1).

8.16 Conflict of Interest Management Plan

The independence of this study from any actual or perceived influence is critical. Therefore, any actual conflict of interest of persons who have a role in the design, conduct, analysis, publication, or any aspect of this trial will be disclosed and managed. Furthermore, persons who have a perceived conflict of interest will be required to have such conflicts managed in a way that is appropriate to their participation in the trial. The UNC IRB has established policies and procedures for all study group members to disclose all conflicts of interest and will establish a mechanism for the management of all reported dualities of interest.

8.17 Funding Source

This study is funded by NIH NCATS K12TR004416-03.

8.18 Publication Plan

This study will comply with the NIH Public Access Policy, which ensures that the public has access to the published results of National Institutes of Health (NIH) -funded research. It requires scientists to submit final peer-reviewed journal manuscripts that arise from NIH funds to the digital archive PubMed Central upon acceptance for publication.