STUDY PROTOCOL AND STATISTICAL ANALYSIS PLAN

Full Title: Addressing Racial Disparities in Autism Diagnosis and Treatment: Translating Peer-to-Peer Support into a Clinical Setting

Institution: University of Maryland, Baltimore

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Justification, Objective, & Research Design

Specific Aims

Aim 1. Deliver Parents Taking Action to caregivers of Black children with developmental delays on a waitlist for an autism or developmental evaluation. Parent Leaders (parents of children 9+ years and older with autism) will deliver the program to 20 caregivers of waitlisted children (ages 8 and younger). We include children referred for autism or developmental concerns, as well as older children, due to concerns about late and/or inaccurate referrals of Black children.

Aim 2: Assess the feasibility, acceptability, and short-term outcomes of Parents Taking Action with a clinical sample. We will measure pre/post changes in child (challenging behaviors) and caregiver outcomes (parenting stress; depression; and family functioning, including social support); and evaluate intervention process measures (acceptability and fidelity). We hypothesize the intervention will be acceptable and feasible and improve child and caregiver outcomes.

Design

Phase 1: We will expand our advisory group to include Brown on the Spectrum (BOS) and SOM representatives and other relevant stakeholders. This group will advise us on local service needs and potential barriers and facilitators for implementation. We will continue to consult with this group throughout the research process.

Phase 2: To address Aim 1, we will identify and train four additional Parent Leaders (parents of children ages 9 years or older with autism). SOM clinical staff will identify eligible children and their families as they are added to the waitlist. The clinical team will also accept referrals internally from UM providers. We will send a letter from the research team leaders to potential participants via email (if available) and mail. The letter will let potential participants know that a research team member will be calling them about the study. The letter will also provide the research team's contact information, along with more study information. If participants are interested in the study, the research team member will go through the informed consent and intake processes. The research team will match Parent Leaders with caregivers, and provide caregivers with case management for housing and other needs.

Phase 3: To achieve Aim 2, we will evaluate program outcomes. Intervention participants will complete measures at three time points. Additionally, the Parent Leaders will complete weekly fidelity checklists. At the end of the program, we will interview intervention participants and Parent Leaders (separately) about the program, in order to obtain in-depth qualitative data on intervention acceptability and feasibility. We hypothesize Parents Taking Action 1) will be acceptable and feasible; 2) will reduce problem child behaviors, parent stress and depression; and 4) will improve family functioning.

Phase 4: We will complete data analyses, prepare manuscripts and conference presentations for peer review, and draft external grant proposals.

Study Procedures

This protocol involves two groups of human subjects: Parent Leaders (caregivers of older children with autism who deliver the intervention) and intervention participants (caregivers of children on an autism or developmental evaluation waitlist). The procedures for these groups are described below.

Parent Leaders Procedures

Once Parent Leaders consent to join the study, they will engage in a training program led by the research team. After they complete the training, they will be matched with intervention participants and deliver the 12-week program. Parent Leaders will provide two types of data. First, at each intervention session, the Parent Leader will complete a fidelity checklist to ensure the program is being delivered as intended. A member of the research team will also observe the Parent Leader during two sessions per participant and complete the fidelity checklist. Second, Parent Leaders will participate in a one-on-one interview after the program is complete. These interviews will occur in private conference rooms at the UMB School of Social Work and be led by research staff; or by video conference/phone as needed.

SSW staff will match Parent Leaders with eligible families. Parent Leaders can generally accommodate two to three families each at a given time; thus, recruitment will be ongoing such that Parent Leaders can serve approximately five families each over the one-year research period. In order to participate in the final interviews, we will also obtain informed consent from Parent Leaders.

Intervention Participants Procedures

We will recruit potential intervention participants through local waitlists for a developmental or autism evaluation. (Children, particularly toddlers, who ultimately receive an autism diagnosis are often referred initially for developmental concerns.) To be eligible, participants must be the primary caregiver of a child eight years old or younger; and, identify their child as Black or African American. SOM clinical staff led by Dr. Charina Reyes will identify eligible children and their families from UMB's Developmental-Behavioral Pediatrics waitlist. We will also provide flyers to local providers, including general pediatricians, with Dr. Reyes' name (if providers can send a secure referral through Epic) or the research team information (for potential participants to contact the team directly). Dr. Reyes will share the names and contact information of potential participants in a SharePoint Excel file only available to the research team which includes researchers from SOM and SSW. The research team will mail and email letters to potential participants the SOM clinical team identifies. The letter will provide the research team's contact information, and also notify the potential participants that a research team member will call them in the next week. All staff will follow strict protocols to protect the confidentiality of participant information, described in subsequent sections of this protocol. When the research team contacts potential participants, they will screen for the inclusion criteria described above before going through the informed consent and intake processes.

Research team staff will meet eligible potential participants in a private place and review the study information sheet in detail. Once the potential participant expresses comprehension of the risks and benefits of the research and agrees to participate, research staff will ask the participant to give verbal consent. The study staff will then request participants to complete baseline data (described below).

Participants will receive $50 when they complete the questionnaires after completion of module 1 and another $50 when they complete the final questionnaires and interview.

NOTE: As needed, we will complete meetings and intervention delivery remotely. We will use secure video conferencing software (e.g., Webex, available through UMB) which allows phone-in or video joining options. For data collection, we will send participants secure Qualtrics links (a survey software available at UMB) to complete surveys. We will conduct and record interviews using video conferencing software (e.g., Webex).

Duration of Participation

Parent Leaders will be required to participate in 30-32 hours of training of Parents Taking Action Program, led by research staff. The Parent Leaders will work one-on-one with intervention participants to deliver two six-week modules (12 weeks total). Each Parent Leaders will be matched with approximately 4-5 caregivers each. Given it is not necessary for intervention participants' sessions to run concurrently, it is possible that Parent Leaders will deliver the intervention to their assigned caregivers through April 2021. We aim to hold the Parent Leaders post-intervention interviews in April 2021. These interviews will last approximately 60 minutes.

Three-time points measures (pre, post-module 1, and post-module 2) will take approximately one hour each for participants to complete. Post-intervention interviews with research staff will last approximately 60 minutes. We will use the same questionnaires for the three time points.

As noted above, as needed, we will hold the Parent Leader Training and intervention virtually.

Sample Size and Data Analysis

A convenience sampling method is appropriate for testing the feasibility and acceptability of this pilot trial. We aim to recruit additional 4 Parent Leaders and 20 intervention participants for this study. We will recruit potential intervention participants through waitlists for developmental or autism evaluations. (Children, particularly toddlers, who ultimately receive an autism diagnosis are often referred initially for developmental concerns.) To be eligible, participants must be the primary caregiver of a child eight years old or younger; and, identify their child as Black or African American.

Quantitative Data Analyses

Based on a power analysis ($\alpha = .05$; effect size = .3; main outcome: parenting stress), we project a sample of 20 families adjusted for 10% attrition. We will use Generalized Estimating Equations (GEE) to analyze changes over time in parenting stress, caregiver depression, child behavior, and family functioning. Since we have three time points of data collection, we will use a commonly used method in repeated measures design, complete case analysis, to validate intervention effects (Bell, Fiero, Horton, & Chiu-Hsieh, 2014). In our study, we will consider baseline and T1 data (following completion of Module 1) a complete set. Furthermore, we will follow the manuals of our measures for protocols for missing data at the item level. For those measures without such guidance, we will use the Markov chain Monte Carlo multiple imputation method to address item-level missing data.

Qualitative Data Analyses

We will digitally record interviews and create an initial codebook based on the semi-structured interview guides. We will then analyze audio transcripts in NVivo 11 and code using open and axial coding processes. Consistent with grounded theory method (Corbin & Strauss, 2008), we will consult field notes, quantitative data findings, and research and program staff as themes emerge. We will actively seek responses not fitting the dominant themes (disconfirmatory responses) in order to understand the diversity of informants' perspectives. Dr. Dababnah and her research team will consult with Dr. Reyes on final codes and themes until we reach consensus.

Data Integration

To aid our interpretation of the data, we will compare our data findings by reporter (e.g., Parent Leader versus caregiver acceptability) as well as type (e.g., qualitative versus quantitative caregiver acceptability).

Surveys/Questionnaires

1. Pre-post survey including demographic questionnaire and service use form, Nisonger Child Behavior Rating Form, Autism Parenting Stress Index, Center for Epidemiological Studies-Depression, Family Outcomes Survey-Revised
2. Post-intervention Social Validity Questionnaire
3. Weekly Procedural Fidelity Checklist Self-Assessment for Promotora Home Visits
4. Post-intervention Interview Guides for Parent Leaders and Parent Leaders

Duration of Expected Completion

1. Pre-post survey: 1 hour
2. Social Validity Questionnaire: 5 minutes
3. Weekly Procedural Fidelity Checklist Self-Assessment for Promotora Home Visits: 5 minutes
4. Post-intervention Interview Guides for Parent Leaders and Parent Leaders: 1 hour

Audio or Video Recording

We will audio record the post-intervention interviews to ensure we accurately capture their responses for our data analyses. Audio files will be saved using anonymous identifiers, rather than names or other identifiable information. Further, individuals will be instructed to not share their or their children's names in the interviews. The audio files will be professionally transcribed. Research staff will verify the transcript for accuracy and remove any identifying information that was unintentionally shared. Audio files will be deleted once transcripts are verified for accuracy.

Intervention Description

Parents Taking Action is an intervention originally developed to increase service access and knowledge among low-income Latino children with autism and their families (Magaña, Lopez, & Machalicek, 2017). In a previous study, we worked closely with our community advisory board to make cultural adaptations to the manual for use in Baltimore with a majority Black population. We adapted the program to deliver

content in two six-week modules (12 weeks total). The first module introduces topics on typical child development, autism and other developmental delays, common interventions and other methods to address child needs, parent stress and depression, and advocacy. The second module presents more advanced methods to improve social communication, reduce challenging child behaviors, and increase social support. We also provide participants with social work services to address challenging life circumstances, such as housing instability and food insecurity.

Participant Selection

The study is open to adults (18+) of any gender, race or ethnicity, provided they meet the inclusion criteria specified below. We will not target any vulnerable populations.

Inclusion Criteria:

1. [Parent Leaders Participant] Parent or other primary caregiver of a child age nine years or older with autism or other developmental disability
2. [Intervention Participant] Parent or other primary caregiver of a child age eight years or younger on waitlist for autism or developmental concerns
3. [All Participants] Identifies self or child as Black or African American

Recruitment

Intervention Participants

We will recruit potential intervention participants through waitlists for developmental or autism evaluations at UMB Developmental-Behavioral Pediatrics and other local clinics. (Children, particularly toddlers, who ultimately receive an autism diagnosis are often referred initially for developmental concerns.) We will recruit participants using two methods:

1) Distribute flyers describing the study to local clinics with autism or developmental evaluation waitlists as well as to primary care providers. The flyers will provide information for potential participants to contact the study team directly; or for providers to refer potential participants to Dr. Reyes securely through Epic.

2) Dr. Reyes will review her clinic's (UMB Developmental-Behavioral Pediatrics) waitlist to determine eligible participants. In addition, Dr. Reyes and Co-I Dr. Badawi will also review potential participants referred to them securely through Epic, to identify potential participants for research team to contact. The names and contact information will be added to a secure file on SharePoint. Before making initial contact, the study team will mail letters via postal mail and email that describe the study, notify caregivers that a research team will be contacting them, and provide the research team's contact information. Future telephone contacts with potential participants will begin by the research team referring to previous contacts.

Parent Leaders

SSW study staff will recruit potential Parent Leaders primarily through our existing Autism Advisory Group and other local contacts. The PI (Dr. Dababnah) and a program manager will meet each Parent Leaders in person to determine if they meet eligibility criteria and discuss Parents Taking Action and the

research process. Parent Leaders will be paid for their time delivering the intervention, and thus will need to fill out paperwork to be compensated through UMB.

Measures to Prevent Coercion

Our research team will discuss the study with individuals who approach us directly through our flyers or through providers at the Developmental-Behavioral Pediatrics Clinic), or with those to whom we have sent an initial letter describing the study. We will explain that their participation is completely voluntary and then can withdraw from study at any time without penalty. Neither their participation in the study, nor a decision to withdraw, will not impact any services they may receive at the University of Maryland, Baltimore and/or University of Maryland Medical System. The statements regarding individuals' participation and right to withdraw are reiterated in the study information sheet, which will be reviewed with each participant.

Text of Advertisement

Maryland Parents Taking Action

Did you know that Black and African American children receive an autism diagnosis much later than white children?

This means that they often miss out on early intervention and other important services.

Parents Taking Action supports mothers, fathers and other primary caregivers in Maryland whose child is:

❏ Black or African American

❏ 8 years old or younger

❏ On the waitlist for an autism or developmental evaluation

Maryland PARENTS TAKING ACTION supports parents to develop skills to communicate and play with their children, manage challenging child behaviors, and advocate for needed services.

Maryland PARENTS TAKING ACTION is led by trained Parent Leaders, who themselves are parents of Black children with autism or other developmental disabilities.

The free program meets for two hours weekly for 12 weeks. It's one-on-one and meets when caregivers want!
Caregivers will receive up to $100 for answering questions before, during and after they participate in the program, which will help us understand how the program is working.

If you a provider, please contact Charina Reyes, MD through Epic to refer any potential participants.

If you are a caregiver, or want more information, please contact our study team at autismstudy@ssw.umaryland.edu or call 443-509-2550.

Research Related Risks

When appropriate, we have listed the risks separately for intervention participants and Parent Leaders:

Risk for Intervention Participants
1) There is an unlikely risk for emotional distress resulting from completing the questionnaires. We believe the frequency of this risk is low. We will minimize this risk by ensuring participants have referrals to trained social workers, psychologists and other mental health professionals who are knowledgeable about resources in the community for children with autism and their families. We also will maintain a list of other community resources for participants to access. (See Resources Guide attached under "Additional Documents.") Finally, we have created a safety plan (see "Safety Plan" under "Additional Documents") for those participants who experience distress due to completing the questionnaires and/or participating in the parenting program.

2) As with any program involving parents, there is the possibility participants will disclose child abuse or neglect, or the possibility of hurting oneself or others. All individuals named on this protocol are mandated to report suspected or documented child abuse or neglect to Child Protective Services. If an intervention participant disclosed child abuse or neglect to a Parent Leader, or the Parent Leader observes such abuse, then the Parent Leader will immediately report this to PI (Sarah Dababnah) who will report to Child Protective Services. Participants' disclosure of harm to oneself or others is also immediately reportable. Such instances, thus, would result in disclosure of personal information to the appropriate authorities. The contact information for these authorities can be found in the "Safety Plan" (see "Additional Documents"). These are the only instances in which research staff will disclose personal information about a participant in this research to individuals not involved in the study.

Risks for both Parent Leaders and Intervention Participants
1) There is a risk of loss of data confidentiality. We believe this risk is low. We will minimize this risk by maintaining strict confidentiality protocols to protect participants' identities, which we explain subsequently in the "Privacy of Participants" and "Confidentiality of Data" sections. In summary, first, we will use unique identifiers on paper and digital files. Only a linking file will connect names and other identifying information to study information. Second, we will remind participants to not use identifiable information in their responses to the questionnaires or the interviews. However, if they do, research staff will remove this identifiable information from study documents. Third, we will remind all groups involved in this research that confidentiality is expected. (These groups include intervention participants, Parent Leaders, and the Autism Advisory Group. The latter group will not be involved directly with the research; however, it is possible they will refer potential Parent Leaders and/or intervention participants to the study.)

2) There is the possibility of a rare breach of privacy when completing the questionnaires and/or participating in the interviews. We will minimize this risk by providing participants with private spaces to complete the questionnaires and participate in the interviews, as described in the section "Privacy of Participants."

Potential Benefits and Alternatives

Potential Benefit to Participants

Participants might not directly benefit from their participation in the research. However, the "Parents Taking Action" program may benefit intervention participants by helping them to learn new methods to

work with their children and/or to advocate for services for their children with autism. The research may benefit Parent Leaders by offering them free training in an empirically supported parenting program, and support to deliver the program to a pilot group of caregivers.

Importance of Knowledge to be Gained

There are few interventions in general for caregivers of children who are in the waiting list, and little research on interventions appropriate for low-income and Black and African American families. The knowledge gained from this study will contribute to efforts to pilot a promising intervention, "Parents Taking Action," for Black and African American parents of children with suspected autism.

Balance of Risks to Benefits

We believe the risks to participants are minimal and reasonable with respect to the benefits to improve service options for caregivers of children on a waiting list.

Alternatives

Participation in the research is voluntary and the alternative is not to participate in the research.

Withdrawal of Participants

Researchers have the right to withdraw subjects if they have an unanticipated reaction from completing the questionnaires or participating in the parenting programs. We believe these circumstances will be extremely rare. If participants have an unanticipated reaction from completing one set of questionnaires, they will not complete subsequent sets of questionnaires or interviews. Also, participants have the right to withdraw from the research at any time without penalty. If research participants inform research staff they wish to withdraw from the study, subsequent data collection will cease.

Privacy of Participants

All staff will follow strict protocols to protect the confidentiality of participant information and their privacy throughout the research process. We will send informational letters about the study to potential participants before we contact them by phone. Once intervention participants agree to participate in the study, participants will be given a private space at UMB SSW to complete questionnaires or set up a time to administer the questionnaires in participants' homes. Research staff will be available to ask questions, but otherwise give participants privacy to complete the measures. Similarly, post-intervention measures for the intervention participants will be administered by research staff either in participants' homes or in private offices at UMB SSW. Post-intervention interviews with Parent Leaders and intervention participants will take place in private spaces at UMB SSW or another private location of the participant's choice (e.g., participant's home).

NOTE: As needed, we will conduct meetings (e.g., explaining informed consent) and intervention delivery remotely. We will use secure video conferencing software (e.g., Webex, available through UMB) which allows phone-in or video joining options. For data collection, we will send participants secure Qualtrics links (a survey software available at UMB) to complete surveys. We will conduct and record interviews using video conferencing software (e.g., Webex).

Location

Research staff will provide research information on their office phones in private offices or meet in person in their private office at UMB SSW or in participants' homes. When meeting or speaking on the phone at UMB SSW, research staff will close their office door to ensure conservation are private.

Environmental Stressors

We do not believe there are significant environmental stressors from this research.

Confidentiality of Data

Research staff will create a unique identifier for each participant. A file linking this identifier with participants' names and other information will be maintained on a password-protected computer at UMB SSW.

Hard Copy Data (Questionnaires)
All paper data collected from participants will be labeled with their unique identifiers, rather than names. Participants will be directed to not enter names on the questionnaires, as the unique identifier will substitute for their names. Hard copies will be stored in the PI's office in a locked filing cabinet in her locked office, located at 525 West Redwood Street, Baltimore. If needed, we will collect questionnaires using Qualtrics (a secure survey software available through UMB). Please see next section about protection of electronic data for storage of any data collected through Qualtrics.

Electronic Data (Interviews)
Research team members will interview participants on their experience with the parenting program. Participants will be instructed to not provide their name or other identifiable information while the digital audio recorder is on. If they do share identifiable information, this information will be removed from the transcripts. Audio recordings and transcripts will be saved using participants' unique identifiers. Audio recordings will be deleted once the transcripts are verified for accuracy. These data, along with data input from the quantitative measures described above, will be stored in password-protected files on a password-protected server. Only Dr. Dababnah and her designated research team members at UMB will be able to access folders with these data.

Data Storage and Access

Hard copy data will be secured in the PI's locked office in a locked file cabinet. These hard copies will not contain any identifying information. If a participant unintentionally adds identifiable information on the forms, they will be blacked out by research staff.

Electronic data will be secured on password-protected computers within password-protected folders.

Only members of the research study team will have access to the data. Data analysis results will be shared with funders in the aggregate.

Payment/Reimbursement

Payment/reimbursement to participants will be for time and effort. We will pay parents up to $100 to complete measures related to the parenting program. They will receive $50 when they complete the questionnaires after completion of module 1; another $50 when they complete the final questionnaires and interview.

Protected Health Information (PHI)

We will use the patient name, address, phone number, parent's/ guardian's name and email to contact potential participants about the study. The date of their scheduled appointment, if within University of Maryland, will also be obtained to determine when they will be seen for their developmental or autism evaluation. PHI is only needed for recruitment purposes, and HIPAA only applies to that portion of the study. We will not access PHI in other stages of the study.

Informed Consent Process

Once an individual indicates interest in the study, research staff will meet with them privately to discuss their eligibility and the information sheet in detail. Once an individual indicates comprehension of the risk/benefits of the voluntary research, individuals will be asked to verbally consent to participate in the study. If participants wish, they can take the information sheet home and think about their participation before they verbally agree to participate. Participants will be provided with a copy of the information sheet containing all of the information on their rights as a research participant, as well as contact information for the PI and IRB.

Only research staff listed on IRB protocol will obtain informed consent. The consent process will take place in private office at UMB SSW, or in participants' homes, where potential participants can meet with research staff to seek clarification or ask questions prior to agreeing to take part in the research.

NOTE: As needed, we will review the informed consent process with potential participants remotely. We will use secure video conferencing software (e.g., Webex, available through UMB) which allows phone-in or video joining options.

The participants will meet individually with research staff to discuss the study prior to agreeing to participate in the research. Staff will seek clarification that participants understand the information sheet before beginning research procedures. Participants will be informed they can withdraw at any time, for any reason.

Waiver of Documentation of Consent

The only record linking the subject and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality. We note that we do have a master linking file in electronic form, which links participants' names with anonymous identifiers. Only some people on our research team have access to the password-protected electronic linking file. However, the only paper document linking the subject and research would be the consent form. This signed informed consent document would contain participants' names and would constitute an additional risk to loss of confidentiality. All participants will receive a copy of the information sheet with their rights as subjects. The research team will document the participants' verbal consent to take part in the study.