Pilot Testing PRE-CARE to Address Unmet Social Needs for Preschoolers with Inattention and/or Hyperactivity

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1 List of Abbreviations

Abbreviation	Abbreviation definition
ADHD	Attention Deficit/Hyperactivity Disorder
BU	Boston University
BMC	Boston Medical Center
CHW	Community Health Worker
WECARE	**W**ell Child Care, **E**valuation, **C**ommunity, Resources, **A**dvocacy, **R**eferral, **E**ducation
PRE-CARE	**PRE**schooler care, **C**ommunity resources, **A**dvocacy, **R**eferral, **E**ducation

2 Protocol Summary

Title:	Pilot testing PRE-CARE to address unmet social needs for preschoolers with inattention and/or hyperactivity
Population:	60 English and Spanish-speaking primary caregivers of preschool aged children with symptoms of inattention and/or hyperactivity, with or without a previous clinical diagnosis of ADHD
Intervention:	"PRE-CARE": Bachelors-level interventionist-delivered low intensity, family-centered screening, referral, and patient navigation program adapted from the WE CARE program
Objectives:	To develop an early intervention strategy targeting unmet social needs for low-income families of preschool-age children with emerging ADHD.
Design/Methodology:	An adaptive randomized, controlled pilot study.
Total Study Duration:	Approximately 1 year
Subject Participation Duration:	12 months (assessment timepoints at baseline, 3 months, 6 months, and 12 months)

3 Background/Rationale & Purpose

3.1 Background Information

Attention-Deficit/Hyperactivity Disorder (ADHD) is one of the most common chronic conditions in childhood, most often beginning in the preschool years.[1,2] While ADHD is in part heritable, social and environmental determinants contribute significantly to its development and expression.[3] Socioeconomic disadvantage and associated social adversities emerge as strong risk factors for ADHD as early as the preschool years.[4–9] These stressors predict more severe illness, poor functioning, inferior response to treatments, and worse outcomes.[10] Therefore, addressing unmet social needs - such as food insecurity, housing instability, and lack

of quality child care - could be a powerful early intervention for preschool-age children with ADHD symptoms, altering the life course of this chronic condition.

However, there is a critical gap in understanding how unmet social needs influence ADHD illness trajectory; the degree to which individual needs impact ADHD risk; and whether addressing remediable unmet social needs in young children with ADHD symptoms could reduce the socioeconomic disparity in ADHD outcomes. Adapting an intervention to target preschoolers with emerging ADHD, who are typically first identified in primary care, could significantly impact symptoms and functioning, as well as improve clinical outcomes in this crucial developmental stage. This highlights the need for intervention methods in preschool aged children that account for social, economic, and environmental stressors, including low income, low parental education level, housing instability, food insecurity, single parenthood, prenatal smoking and illicit drug use, community violence, parental incarceration, and familial mental illness. Using the framework for the NIH stage model for behavioral interventions, we have developed an intervention to identify and alleviate unmet social needs in families of young children with emerging ADHD symptoms.

Dr. Arvin Garg, pediatrician and pioneer in the field of addressing unmet social needs as part of medical care, has shown that a low intensity, family-centered screening and referral program (WE CARE) at well infant visits is feasible and can increase receipt of resources for unmet social needs (e.g. food, transportation, and parent education).[11] Others have shown that a similar intervention paired with navigation to services (i.e. assistance from staff to find and access resources) could improve general child health.[12] The American Academy of Pediatrics now recommends social needs screening and referral to community resources at well child visits.[13] Adapting this strategy to target preschoolers with emerging ADHD, who are typically first identified in primary care, could significantly impact clinical symptoms and disease trajectory during a critical developmental period, and yet a time when there are few known effective treatments. Therefore, our overarching goal is to develop and pilot test a novel early intervention strategy targeting remediable unmet needs for families of low-income, preschool-age children with inattention and/or hyperactivity symptoms, which could be a sign of emerging ADHD.

We conducted in-depth interviews with parents of preschool aged children with emerging ADHD symptoms to gain a deeper understanding of how unmet social needs affect symptoms and functioning in young children with ADHD and intervention preferences. Using this rich data from families and guided by experts, we have developed an intervention by adapting the WE CARE screening and referral model originally developed for well infant visits. We have adapted WE CARE in several key domains: for a new target population (preschoolers with emerging ADHD), incorporating new content (e.g., needs particular to this age group and disease, such as special education and parent mental health care), and primary outcome (ADHD symptoms). Our new intervention is called PRE-CARE (**PRE**schooler care, **C**ommunity resources, **A**dvocacy, **R**eferral, **E**ducation), and includes three core components: (1) screening for unmet needs, (2) providing families with written resource sheets listing community-based referrals tailored to their needs, and (3) providing families with family navigation support to assist them with connecting to community resources. This study will be conducted in compliance with the

protocol, applicable regulatory requirements, and BMC/BU Medical Campus Human Research Protection policies and procedures.

3.2 Rationale and Purpose

The goal of this proposed study is to pilot test a novel treatment model (PRE-CARE) addressing unmet social needs for families of preschool-age children with ADHD symptoms. We will conduct an adaptive, pilot randomized controlled trial (RCT) of the intervention with parents of 60 low-income children age 3-5 (36-71 months) with ADHD symptoms in order to: optimize intervention delivery; field test study logistics (e.g., recruitment, enrollment, randomization, retention); explore putative intervention mechanisms; and obtain estimates of study parameters to plan an appropriately powered RCT of the intervention. The PRE-CARE intervention is adapted from WE CARE, a screening and referral intervention that has been shown to be feasible and effective in addressing the family psychosocial stressors of low-income families seen in pediatric medical homes. Given the negative impact that socioeconomic stressors can have on the health and development of young children with ADHD symptoms, tailored interventions such as PRE-CARE may serve as a vital early intervention strategy to promote long-term well-being.

4 Objectives

4.1 Study Objectives

Our aim is to enroll 60 subjects (30 intervention, 30 control). Because this is a pilot study, it is not fully powered to detect differences between groups. Our main objectives are as follows:

- Field test study logistics: We will record the number of families approached, screened, ineligible, refusing participation, and enrolled; rate of recruitment and referring provider/site; intervention attrition and study retention; adverse events; and collect participant feedback via detailed exit interviews.
- Optimize intervention delivery: We will collect process measures for intervention optimization including the number of contacts and length of time per contact, referrals made and resources received, time to resolution of each unmet need, and participant feedback.
- Explore putative intervention mechanisms: We will do this via participant exit interviews and parent-report questionnaires. We will power a future study for detection of target engagement using the parameters obtained. Our proposed measures of target engagement are unmet social needs (decrease expected); parent stress (decrease expected); parent activation (increase expected), and child/parent mental health service use (increase expected). These may change based on formative work and participant feedback.

4.2 Study Outcome Measures

4.2.1 Primary Outcome Measures

Primary outcomes include the following clinical outcomes:

- ADHD Symptoms (ADHD-RS-IV Preschool Version)
- Child Psychiatric Symptoms (Child Behavior Checklist 1.5-5)

Secondary outcomes include the following measures of unmet social needs, treatment access and utilization, parent activation, parent mental health/stress, adverse childhood experiences, and feasibility/acceptability:

- Unmet Social Needs Outcomes (Children's Health Watch Vital Signs and National Survey of Children's Health pertaining to all unmet needs in the PRECARE Screener).
- Adverse Childhood Experiences (CYW ACE-Q)
- Parental Depression (PHQ-9)
- Parental ADHD (ASRS-v1.1)
- Global Perceived Stress (PSS)
- Parenting Stress (PSI-SF)
- PRE-CARE Feasibility and Acceptability Questionnaire
- Semi-structured in-depth exit interviews with parent/guardians on feasibility/acceptability

Process outcomes include the following measures of study and intervention processes:

- ***Recruitment and enrollment statistics*** (number of parent/guardians referred and from which clinic, contacted, screened, eligible, refused participation, enrolled, dropped out of study or intervention early and why, and completed intervention)
- ***Contacts with parent/guardians*** (number, frequency, modality, length)
- ***Referrals made*** (including agencies, date of referral, and parent/guardian vs. staff referral)
- ***Resources accessed*** (including specific resource accessed, resource category, date accessed)
- ***Needs resolved*** (date at which a participant indicates they no longer need help with a need and why)

5 Study Design

This study is a pilot randomized control trial. Participants are parents of preschool aged children between the ages of 3-5 years old with either an ADHD diagnosis OR with a score ≥ 80th percentile on the Preschool Version of the ADHD Rating Scale-IV. Potentially eligible participants will be referred to the study team by pediatric providers via the electronic medical record (EMR), or identified via EMR screening. Following eligibility screening, informed consent, and completion of baseline questionnaires, participants will be randomly assigned to treatment methods of either the interventional treatment (PRE-CARE) or control treatment (care as usual). All participants will be sent baseline and follow-up questionnaires to complete either electronically via REDCap, in-person with an RA using pencil/paper, or verbally with an RA (depending on participant preference). Participants randomized to PRE-CARE will also complete feasibility and acceptability measures including an exit interview.

Participants assigned to the PRE-CARE arm will be asked to complete the PRE-CARE self-report screener including 16 questions that assess 14 social needs categories (childcare, employment, housing, food, parent education, utilities, public benefits, tax filing, child education, child healthcare, child behavioral/mental health services, child after school activities, parent healthcare, and parent mental health services). Following completion of the screener, they will meet with a BA-level interventionist (either in person or virtually via videoconference) in which the interventionist will review the screening responses with the participant and assess in more detail what help is needed and possible. The interventionist will provide the participant with a Family Resource Booklet (physically and/or electronically) containing written resources corresponding to the 14 categories reflected on the PRE-CARE screener. The interventionist will provide the participant with any additional care coordination and referral support needed to ensure that the family is able to access needed community resources. Meetings will be scheduled bi-weekly, with additional contact as needed, until three months have passed. If the needs and issues require longer than three months to resolve, participants may continue their intervention period even after three months have passed in order to complete all the ongoing support. Participants may also end their intervention period before three months have passed if they no longer need support and all needs have been resolved. Interventionists will provide PRE-CARE participants with their contact information and serve as an available resource to support families throughout the duration of the intervention period.

Participants assigned to the control condition will receive care as usual within their pediatric primary care practice. At many Boston Medical Center-affiliated pediatric practices, this involves social needs screening at medical visits with provision of resources and referral to integrated behavioral health providers for assistance with short term treatment and referrals to other behavioral health services as needed. There will be no research staff-initiated contact with control subjects between baseline and follow up questionnaires. If control subjects contact research staff we will follow standard clinical or BMC procedures depending on the nature of the contact or concern. If they call to ask about a resource (e.g., obtaining food), we will provide information about BMC services or community organizations that could help with that resource. For most concerns both clinical and social, we will direct them to their primary care provider's office for additional support. If there is a safety concern we will follow our safety protocol, as in the intervention group as well.

Participants in the intervention arm will communicate with primary care providers about referrals completed, and enter this information into the medical record. Furthermore, participants may already have been referred to resources prior to enrollment in the study. In that case, interventionists will communicate with usual care providers and staff to be sure they are aware of the family's participation, and coordinate accordingly on the provision of needs. Families in the intervention arm or in the control arm will NOT be restricted on what they can access in the clinical setting.

6 Potential Risks and Benefits

6.1 Risks

(a) Subjective discomfort. In pilot testing, participants may experience discomfort speaking to an RA and discussing experiences they choose to share regarding their child's and their own unmet needs and treatment. All participants will be reminded that they can decline to answer any questions if they so choose.

(b) Breach of confidentiality. As with any research setting, a breach of confidentiality is possible. Participants' identifying information will not be included in the analytic dataset or publication, therefore the risk to participants' confidentiality is minimized.

(c) Intervention burden. Subjects may feel that the intervention or research measures are time consuming or that scheduling is burdensome. Every effort will be made to diminish burden for subjects. Burden of the intervention is part of what we will be testing in this pilot study.

6.2 Potential Benefits

The goal of the study is to diminish the impact that unmet social needs create for families with preschool aged children with ADHD. Participants may directly benefit by receiving this new intervention, which has been developed based on both quantitative and qualitative formative work, and is an adapted version of WE CARE, an existing, evidence-based social needs intervention.[14] Participants in the intervention arm will have the opportunity to be connected with resources using a strategy that has been specifically tailored to the needs of families with preschoolers who have inattention and/or hyperactivity symptoms. Participants in both arms will have access to their clinic's usual care pathway. In some cases, for participants on waiting lists for specialty care, they would receive this intervention as well as the clinical measures while they are waiting, when they would otherwise not receive any support or care from the clinic. Additionally, participants in both arms will complete standardized psychiatric questionnaires (the CBCL for ages 1.5-5 and ADHD-RS-IV Preschool Version) that could help clinical care and can be shared with providers via the EMR with permission of parents. Additionally, the information collected from this study will be used to refine the intervention, which we are testing as a method of improving ADHD symptoms in preschoolers. By being in the study, participants are helping investigators learn if this intervention could improve ADHD in preschoolers.

6.3 Analysis of Risks in Relation to Benefits

The risk to participants in this study is quite minimal, as they include potential subjective discomfort through discussing social needs that are unmet, potential for subject burden, and potential breach in confidentiality. Conversely, the potential benefits to being involved in this study are substantial. Although Boston Medical Center Pediatrics and its affiliated pediatric practices generally have social needs assessment and care coordination available (control arm), PRE-CARE is designed to be a more comprehensive and tailored form of screening and referral for this population, and the research assessments will provide more detailed emotional and behavioral symptom information than is typically available in a primary care setting. Thus, participants have the opportunity to directly benefit from the study, besides the benefit to

society of testing a new intervention to improve ADHD symptoms in preschoolers, who are generally more difficult to treat than older children with ADHD.

7 Study Subject Selection

7.1 Subject Inclusion Criteria

In order to be eligible to participate in this study, an individual must meet all of the following criteria:

1. Legal guardian and primary caregiver of a child aged 36-71 months
2. Legal guardian or primary caregiver is age 16 years or older
3. Child receives pediatric care at Boston Medical Center or at one of the participating Boston HealthNet clinics
4. Able to understand informed consent procedures in English or Spanish
5. Participant has a child aged 36-71 months with an ADHD diagnosis, OR one elevated total or subscale score at the 80th percentile on the ADHD-Rating Scale-IV Preschool Version. 80th percentile cut-offs on the ADHD-Rating Scale-IV Preschool Version are as follows:
    - For male children, a total score ≥ 25 OR subscale score (inattention and/or hyperactivity) ≥ 12
    - For female children, a total score ≥ 13 OR subscale score (inattention and/or hyperactivity) ≥ 6 for female children

7.2 Subject Exclusion Criteria

There are no specific exclusion criteria for this study. We have chosen not to exclude families already receiving other ADHD services because they might also benefit from the intervention.

8 Study Intervention

Participants will receive the 1:1 PRE-CARE social needs navigation intervention with specific content and delivery strategy which was developed based on 1) quantitative analyses of the association between unmet social needs and ADHD symptoms in a large-scale nationally representative sample of children age 3-5, and 2) in-depth qualitative interviews with parents/guardians of preschoolers with inattention and/or hyperactivity symptoms to identify mechanisms by which unmet social needs exacerbate ADHD symptoms and functioning.

Based on an enhanced WE CARE model, the PRE-CARE intervention includes:

1. **Screening.** Parent-report screening for remediable, unmet social needs.
2. **Resource Packet.** Provision of packet of resource sheets (“Family Resource Booklet”) detailing local community-based resources to address these needs, with needs that respond to family's requests highlighted.
3. **Resource Navigation.** Navigation to resources, care coordination, and parent support provided by a trained bachelors-level interventionist who is a member of the research study staff.

The planned duration of the intervention will be until:

1. All needs have been addressed,
2. Family requests termination of the program, OR
3. Three months have passed

Intervention Part 1, **Screening.** First, parents will complete the PRE-CARE screener. The screener is designed as a parent-report, to be filled out either on paper or electronically using a link sent via text or email using Twilio and REDCap to our REDCap intervention database. If needed, the interventionist can read the questions out loud to the parent and record their answers. The social needs screening questions (which can be seen in full as an attachment to this IRB application) inquire about the following needs using the original WE CARE questions, due to their validity and effectiveness as shown in other studies: childcare, employment, housing, food, parent education, and utility bill payment ease. The PRE-CARE screener also assesses the following additional social needs categories: access to public benefits, paying taxes, school services/special education, parent mental health, parent physical health, child behavioral health, and extracurricular activities. The screener asks two questions about each need assessed. First, it asks whether there is a need or a risk (i.e., "Do you have trouble paying your heating/cooling, water or electricity bill?"). Next, if the answer is yes, there is a follow up question about whether the participant would like help with that particular item ("If yes, would you like help with this?"). Following administration of the PRE-CARE screener, the interventionist will review the participant's responses in order to tailor the referral/resource provision phase of the intervention.

Intervention Part 2, **Resource Packet.** The interventionist will physically give (or send by email and/or regular mail if they are not meeting with the parent in person) a Family Resource Booklet. All families in the intervention arm will receive the full booklet, with written resources for all categories of needs assessed in the PRE-CARE screener.[15] The Family Resource Booklet lists 3-5 community resources for each category of need, including a brief description of the services provided by the community agency, contact information, cost, location, and eligibility details. Interventionists will highlight in the resource booklet the areas that particularly address the needs indicated by families. Along with the resource booklet, the interventionist will provide participants with their own contact information. Resource guides will be updated regularly to ensure that they remain up to date and most helpful to participants.

Intervention Part 3, **Resource Navigation.** Interventionists will discuss further with families the details of specific needs indicated during screening in order to best tailor assistance provided. Based on this conversation, the interventionist may offer more intensive support navigating to certain resources for families where it is needed. Interventionists will have a companion Navigation Resource Booklet that includes workflows and algorithms to assist with referral decisions for families. The level of interventionist involvement will be based on the family's particular needs, community resources available, and a shared decision-making process between the interventionist and family. For example, some participating parents may choose to

simply contact agencies listed in the Family Resource Booklet on their own, and not request any further support from the interventionist. Other families may want more assistance contacting and accessing community resources. In these cases, the interventionist may place referrals, coordinate services, or contact community agencies and providers on behalf of the family to inquire about resources.

As a default, the interventionist will offer follow-up meetings with the participating caregiver (either in-person, by phone, or via videoconference) every two weeks until three months have passed since the randomization date. The interventionist may end the intervention period later for the participant whose needs require longer than three months to resolve. The interventionist may also end the intervention period earlier than three months for the participant if all needs mentioned by the participant have been resolved. All forms of interventionist contacts (in-person appointments, emails, phone, and text message exchanges) and community resources placed on behalf of participating families will be documented in the participant's electronic medical record and logged by the interventionist in the study record. Interventionists will also log the length of time per contact. At each contact, interventionists will also inquire about resources received since last contact, and about whether additional help is needed for that need, or other (even new) needs. They will also ask for feedback about resources received and our process for helping families. Contacts will vary in time length (e.g., 5-10 minute calls vs. 1 hour long meetings) depending on the needs of each family.

9 Study Procedures

Intervention Delivery:

PRE-CARE will be delivered by a research staff member with a minimum of a Bachelors-level degree who has experience working with low-income parents of children with ADHD. The research staff will be trained by Dr. Spencer, the study PI, using the protocol below, to deliver the intervention. During the intervention period, research staff who are serving as interventionists will meet weekly with Dr. Spencer for supervision and feedback for quality improvement.

Intervention Delivery Optimization:

Based on the experiences and feedback of subjects and staff and process measures collected, we will amend our study protocol as needed in order to optimize intervention delivery throughout the study and prepare for a fully-powered RCT.

The Family Resource Booklet component of PRE-CARE intervention will be reviewed and updated by research staff at least every 2-4 weeks to ensure that all listed agencies are currently active, and that the listed contact information and eligibility criteria is accurate. RAs will remove or revise the resources in the Family Resources Booklet throughout the trial based on participant feedback. We request to be able to make these changes without protocol modifications in order to be most responsive to participant feedback and changes in the landscape of community resources, without modifying the core intervention components.

Intervention Training:

All interventionists will first view a series of short, pre-recorded training videos about the WE CARE social needs screening model created by Dr. Arvin Garg's research group. The videos take up to 2 hours to view. Then, the PI, Dr. Andrea Spencer, will also conduct at least 4 hours of intervention training in workshop format with the research staff members conducting the intervention. The training curriculum will cover intervention procedures; the basics of ADHD in preschool-age children; the basics of social needs screening; principles of shared decision-making; community, hospital, and government social service and referral resources; the basics of advocacy for special education services; and motivational interviewing.

Participant Recruitment:

Participants will be recruited from the Boston Medical Center (BMC) Primary Care and Specialty Care Pediatric Clinics (including Developmental Behavioral Pediatrics, Pediatric Neurology, and Child Psychiatry), the BMC Family Medicine clinic, and affiliated Community Health Center, The Dimock Center. The PI will ensure that the proper approval from the director of each clinical service or health center is in place prior to beginning recruitment at each clinic. Referrals will come from 4 possible mechanisms: 1) direct provider referral from providers in the above departments; 2) self-referrals (e.g., word of mouth); 3) use of the electronic medical record (EPIC or CDW) to identify participants seen by providers in the above departments; and 4) use of referral queues to the above departments to identify participants. These recruitment strategies are outlined in more detail below.

1) **Direct provider referral.** The research team will work with physicians and clinicians to ensure that they are aware of this research opportunity in order to facilitate their ability to refer potential participants to the study team. We will advertise the study to staff/faculty by making announcements about the study at staff meetings and discussing the study with providers. The research team may also send an email to faculty or health care providers in the above mentioned Departments with information about the study as well as the contact information for the study team. Potential participants identified by clinical staff can be given research staff contact information. Interested caregivers can be given a business card which details study staff name, phone number, email address, so they can call to learn more information about the study. Potential participants identified by clinical staff can also be given a study flier, which will detail the purpose of the study, eligibility criteria, and research staff contact information. Interested caregivers will be able to call the phone number or contact the email address for the research team included on these advertisement materials in order to learn more information about the study. In addition, providers may request that study staff call the parent/guardian to invite them to participate. To refer patients to the study for study staff to contact, providers will send a message via Epic In-Basket to the study PI, research staff member, or to the Epic ADHD Pool, which goes to research staff. Messages are linked to patients charts including contact information and patient name.

2) **Self referral.** Parents who call on their own because they have heard about the study from another person or have viewed the study flyer can be screened by research staff. The study

flyer will detail the purpose of the study, eligibility criteria, and research staff contact information. Interested patients will be able to call the phone number or contact the email address for the research team included on these advertisement materials in order to learn more information about the study. IRB approved advertisements/fliers may be posted throughout Boston Medical Center or its network of affiliated behavioral health clinics with permission. IRB approved advertisements may also be placed in newspapers.

3) **Electronic medical record.** The research team may also utilize the Clinical Data Warehouse (CDW) or Epic (BMC electronic medical record) to identify 3-5 year olds with ADHD or inattention/hyperactivity symptoms who may be eligible for the study. Members of the research team will reach out to these patients' care providers to ask if the patient may be appropriate for this research study, and if they grant permission for research staff to contact the patient's guardian to invite them to participate in the study. This process of viewing patient medical records will only be used as a way to ask providers if they feel it appropriate to invite a patient and guardian to participate. It will not be used to directly contact potential participants without permission from their treating providers. With the provider's approval, the research staff will use one of several ways to invite these patients to participate.

1. The research team may ask the provider's permission to meet the patient and parent/guardian at an upcoming appointment with their provider, at which the provider can ask the guardian and patient if they would be willing to talk with research staff to learn more about the study.
2. The research team may call the parent/guardian to provide additional information about the study, review eligibility criteria, and invite them to participate. If research staff call, they will inform the parent/guardian that their provider wanted them to know about this opportunity, and that they can decline participation without affecting their clinical care at BMC. Research staff will explain the study further and perform additional screening for those interested.
3. The research team may send a letter to the parent/guardian's home describing the study and inviting the parent/guardian to participate. If research staff send a letter, this letter will inform them that their provider wanted them to know about this opportunity, and that they can call to decline participation or they may receive a phone call to provide more information and invite them to participate (see above).

4) **Referral Queues.** Parent/guardians of potential participants referred electronically to any of the above clinics for attention or hyperactivity concerns may be invited to participate. Research staff will routinely review the following referral queues in the electronic medical record: Child and Adolescent Psychiatry, Pediatric Integrated Behavioral Health, and Developmental and Behavioral Pediatrics. These referral queues are lists of patients referred to each service by providers at Boston Medical Center and affiliated pediatric practices. Research staff will request permission from either the clinic director, medical director, or designated clinical provider responsible for triaging referrals before reaching out to patients identified by reviewing referral queues. This will take the place of contacting the referring provider for permission, given that providers may be from a practice outside of the main hospital who are not aware of the study.

When they call, staff will make clear to patients that their participation in the study will not affect their wait time nor the care they receive from the clinic.

Upon calling the study staff for scheduling or being called, interested participants will be asked to complete a brief screening interview to determine eligibility using the phone script provided with this IRB application.

Participant Consent Procedures:

Participants will have the option to complete the informed consent procedures either: In person at Boston Medical Center (BMC); In person at their home (2 research staff will travel to the participant's home); or remotely via videoconferencing or telephone with research staff. Paper copies of the adult consent form can be read and signed, or participants will be able to access an electronic version of these forms and can sign via REDCap. Research staff will conduct the informed consent process with the parent/guardian, which will include a detailed description of the eligibility determination, randomization, active intervention, control condition, and expectations for participation. Participants will be also told that they are free to take breaks and/or terminate the consent process or study visit at any time. Potential participants will be told that they do not have to answer any questions that they do not want to answer or that make them uncomfortable. Participants will be told that reports of research results will not specifically identify them. Participants will be informed that they will be compensated upon completion of baseline assessments ($100) and also upon completion of follow-up assessments at 3, 6, and 12 months post baseline (additional $100 per time point), but not for other study activities (including the clinical interview or intervention sessions). Signed consent will be obtained prior to collection of any research data. The consent form will detail a section on participant Right to Re-Contact. Participants can opt to participate in the study but not be re-contacted.

Participants completing the electronic REDCap form will provide an e-signature typing in their name and date, or drawing their signature on the screen (phone, computer, or tablet/iPad) with their finger, mouse, surface pen, etc. Parent or legal guardian consent will be required to participate in the study. Study staff members are trained in Boston University Medical Campus (BUMC) IRB policy and will closely follow consent procedures as outlined by the BUMC IRB. Potential subjects will be provided the consent document which details the background, purpose and procedures of the study. The study details will be reviewed with potential participants who will be given the opportunity to ask questions about the study and their participation. All participants will be given, mailed or emailed an unsigned copy of the consent form for their records. They may additionally be given, mailed or emailed a copy of their signed consent form, if requested.

If a participant indicates that they are interested in participating in the study, but cannot schedule a study visit to complete the informed consent procedures, or have previously missed their scheduled study visit, participants will have a period of 3 months to decide their participation and schedule a study visit. After the 3-month period, interested participants will be required to be re-screened as eligibility criteria may have changed. Research study staff will then re-administer the screening procedure to determine study eligibility.

As this study will enroll Spanish-speaking participants, the consent form will be translated into Spanish by the BMC interpreter services. The consenting process and interviews will be conducted in Spanish by fluent Spanish speakers or with the assistance of professional interpreters.

Participants can either read themselves or be read the consent form by a member of the research staff. After reviewing the consent form, all participants will be delivered the Assessment of Capacity, a teach-back process to ensure his/her understanding of the project, the purpose and procedures involved, and the voluntary nature of his/her participation. Those who have difficulty answering the items on the capacity questionnaire will have the study re-explained by research staff with a focus on aspects they did not understand. Those who demonstrate understanding of the study and voluntarily agree to participate will be asked to sign the Informed Consent Form.

Baseline Assessment

If the caregiver consents to participate, they will proceed to complete the baseline assessments. Assessments can be completed at the same time as the informed consent, or at another time, at the convenience of the participant. All study assessments can occur in person at BMC, in person at the participant's house, or remotely through REDCap survey links, whichever is most convenient and appropriate for the patient. If needed, the interventionist can read the questions out loud to the parent and record their answers over Zoom or telephone. Participants will not be excluded if they cannot read and answer questionnaires themselves, nor will they be excluded if they do not have access to the necessary technology or internet required to complete surveys electronically. If participants are willing, research staff will read the questions and answer choices to them over the phone, Zoom, or in person, and make note of their responses in the study file. Participants who prefer to complete the surveys online will be sent REDCap survey links to their emails or mobile phone (through Twilio, a third party web service that enables REDCap for SMS text survey link distribution) following informed consent and will be encouraged to complete the baselines surveys within 48 hours of consent.

Randomization Procedures

Once a caregiver gives consent to enroll in the study, they will be provided with a unique ID number and this ID number will be connected to their identifiable data (access to identifiable data will be limited to only research staff members and investigators listed on the IRB). Once consent and baseline assessment are completed, the caregiver/family will be randomized. Participants will be randomized to either the PRE-CARE intervention or to the care as usual control condition through the computerized randomization feature of REDCap. If a participating caregiver has multiple eligible children, they will be randomized by family. Randomization will be stratified by primary language (English and Spanish). Due to the nature of the intervention, we will not be able to blind study participants or research assistants serving as interventionists. Study assessments will be completed by parents independently, but if assistance is needed, it will be provided by a separate research staff member who is not the interventionist.

After the random assignment has been generated in REDCap, research staff will contact participants by phone to share their assignment, and with their permission, also inform the clinical care team of the study assignment. If a participant is randomized to the PRE-CARE intervention, research staff will then schedule their first study visit with the family. Research staff will aim to schedule this first study visit as soon as possible, preferably within one week of the date that the random assignment was generated. If a participant is randomized to care as usual, the parent will be advised to follow up with their clinical providers to determine the next steps for their child's treatment according to the standard of care at their clinical site. Clinical providers will also be advised that the family has been randomized to care as usual. Results of psychometric tools (i.e., CBCL 1.5-5 and ADHD-RS-IV-Preschool Version) will be shared with providers for all families with permission of the participating parent. Research staff will not contact the families in the control condition again until the time of follow-up assessments at 3, 6, and 12 months following completion of baseline assessments.

Study Intervention (PRE-CARE)

Research staff will then ask participants to complete the PRE-CARE questionnaire prior to their scheduled study appointment. The preference is for participants to complete the PRE-CARE questionnaire electronically via a REDCap survey link. If a participant agrees to this and is comfortable with using the electronic survey technology, the RA will send them the link to the screener by email or text message. If the participant prefers to complete the questionnaire on paper, they can do so at the time of the first scheduled study visit. Lastly, if a participant has any difficulties with reading and/or would strongly prefer for the questionnaire to be administered verbally, the research staff will verbally ask the participant the PRE-CARE questions via phone or videoconference prior to the time of the first study visit. Research staff will note method of administration in our REDCap database. If participants have not completed the questionnaire prior to their study visit, interventionists will have them complete it at the beginning of their first intervention session.

Participants will be informed that the first study visit will last up to 60 minutes if necessary and acceptable to the participant. The first study visit will consist of the following: (1) parent self-report completion of the PRE-CARE social needs screener (if not already completed electronically in REDCap prior to the time of the study visit) and interventionist review of responses, (2) distribution of Family Resource Booklet, with areas of specified need highlighted; and (3) targeted resource navigation. The study intervention is described in detail in the "study intervention" section of this application.

Control Intervention (“Care as usual”)

Families randomly assigned to the control condition will continue to receive care as usual, which in the Boston Medical Center system includes screening for social needs annually at well-child visits as recommended by the American Academy of Pediatrics, followed by provision of information as needed by the family. Families will also be offered the opportunity to make research assessments available to their primary care physician for best continuity of care.

Parent-Reported Study Assessments

In addition to the baseline assessments, all 60 participants (30 intervention and 30 control) will complete follow-up assessments at 3, 6, and 12 months following the completion of baseline assessments. Follow-up assessments can be completed in person at the research office, in the participant's home, or remotely by phone or videoconference.

Participants in the intervention arm only will also be invited to participate in an in-depth exit interview once their intervention period is complete in order to collect feedback on the intervention content and strategy and explore putative intervention mechanisms. If participants refuse to participate in the exit interview, but complete the survey assessments, they will still be compensated.

At any of the assessment timepoints, if participants refuse to complete select questions in the assessments, but answer most questions, they will still be compensated.

It is anticipated that in some cases, two primary caregivers will desire to be part of the intervention. Other adult family members involved in primary caregiving may also participate in any intervention sessions as long as the consenting primary caregiver is present for all sessions and is the only one completing all intervention assessments.

At baseline, participants will complete a Contact Information form that details their preferred mode of contact for completion of follow-up assessment (email, phone, mail). At each subsequent time point, RAs will refer to the contact information form and send reminders (via email, phone, or text message, based on preference) to the participant to complete their follow-up assessments every 4 days for at least 2 weeks (or until the assessment is complete). RAs will run weekly reports off REDCap to see which participants have not completed their assessments. If a participant has not completed their assessment after 2 weeks, the RA will call the participant to complete the assessment over the phone. At each of the follow-up timepoints (3, 6, and 12-months after baseline), RAs should stop reminder calls to participants 8 weeks after the participant was initially contacted to complete the assessment.

Research Staff-collected Process Outcomes

Research staff will collect and analyze process measures throughout the intervention period in order to optimize intervention delivery. They will record:

1) ***Contacts:*** Each contact with a parent/guardian (intervention or control) including the date, time, person who initiated contact, length of time per contact, and modality of contact (e.g. phone, zoom, in person);
2) ***Referrals made*** (including agencies, date of referral, and parent/guardian vs. staff referral)
3) ***Resources accessed*** (including specific resource accessed, resource category, date accessed)
4) ***Needs resolved*** (date at which a participant indicates they no longer need help with a need and why, e.g. they received help or they no longer need help or needed help does not exist)

Throughout the study, research staff will also maintain a record (counts only) of the number of:

1) Potential participants identified, by which recruitment strategy, and from which clinic;

2) Potential participants screened ineligible;
3) Potential participants eligible but refusing participation;
4) Participants dropping intervention before its end with reason if known;
5) Participants dropping out of the study before its end with reason if known.

Electronic Medical Record

Additionally, charts of the children whose parents/guardians are participating will be accessed in order to collect utilization data directly from their electronic medical records (EMRs) including the following data for each child whose parent has participated (intervention and controls):

1) Number of medical encounters, encounter providers, and diagnoses during the intervention period
2) Prescribed medication prior to and during the intervention period
3) Other diagnoses in the medical record
4) Documented referrals to other specialty services or community agencies and referring provider

Safety Assessment

If study staff learn of any acute safety concerns, such as current thoughts about suicide, self-harm, or intent to harm others, abuse, neglect, or other reportable conditions, research study staff will interrupt study activities and utilize the Safety Assessment form to assess parent or child risk. Research staff will probe participants about frequency and severity of the concern to identify participants and their child who may be at immediate risk and require further intervention. Upon completion of the Safety Assessment, research staff will contact the study PI who will conduct a brief acute safety assessment over the phone, zoom, or in person. PI will then utilize clinical judgment to determine further course of action.

Payment

Participants will be compensated $100 for the baseline assessments and for each of the 3 outcome assessments, for a total of $400 possible for completing all study assessments. Participants will not be compensated for their participation in the PRE-CARE intervention, only for completion of study assessments.

Removal of Participants

All instances of study drop out will be documented using the Premature Termination form on REDCap, including reason for dropout, who decided the participant would drop out (participant, study staff or PI), and whether the drop out resulted from burden of intervention, study assessment, or another reason. Withdrawn participants will be encouraged to continue to participate in study assessments throughout the 1-year follow-up period in order to optimize the intention-to-treat assessment design. Participants may withdraw voluntarily at any time for any reason. Withdrawn participants will be encouraged to participate in an exit interview to provide feedback on why the intervention did not work for them and suggestions for improvement. Participants may withdraw voluntarily at any time for any reason. Participants

will also be informed during the consent process that information already collected as part of the study will remain in the study record even if they later withdraw. There are two types of participant withdrawal: "intervention withdrawal" and "study withdrawal".

1. **Intervention withdrawal:** A participant drops out of the PRE-CARE intervention (either because they are no longer interested or because the study PI feels the intervention is no longer appropriate), but still provides the research team with post-intervention data by completing assessments at the follow-up timepoints and exit interview. Intervention withdrawal would be defined as one or more of the following: Family declines to respond to PRE-CARE screening questions; family refuses to engage with the interventionist in a discussion about unmet needs; for family decline to accept the Family Resource Booklet. If a participant responds to screening questions, discusses needs with the interventionist, and accepts the Family Resource Booklet, but declines only the optional resource navigation component of the intervention, this would not constitute an intervention withdrawal.
2. **Study withdrawal:** A participant (or provider on behalf of participant) explicitly communicates that they are no longer interested in being a part of the study at all, including future assessments and compensation. Cases of intervention withdrawal are not automatically considered to be study withdrawal unless the participant specifically states that they never wish to be contacted again by the study, or if the study investigator deems any future contact would be inappropriate.

Participants may be removed if:

1. If the study investigator or treating provider feels the study is negatively impacting the participant's health or wellbeing resulting in increasing severity of illness that is clinically assessed as such by the study PI. The interventionist and study PI will have weekly meetings/supervision to evaluate study progress, and discuss and address any concerns about participant risk. Any cases of a parent reporting that either their child's ADHD symptoms or their own parental mental health symptoms are worsening will be assessed clinically and study PI will determine whether the participant should be removed from the study and whether an adverse event or unanticipated problem should be filed.
2. If the participant presents with clinically determined safety risk to self or others.

Zoom Videoconferencing

Participants will have the option to complete any parts of the intervention and study via Zoom Video Communications software. Zoom Video Communications is a remote conferencing services company that provides remote conferencing services, that combines video conferencing, screen sharing services, online meetings, chat, and mobile collaboration, with both audio and video communication options. We will use a BMC Zoom account which is HIPAA compliant. Participants can use zoom via their phone, computer, or tablet/Ipad. Intervention sessions will not be recorded. We will audio record only the final exit interview, with the permission of the participant, using a digital voice recorders or audio recording programs on our BMC encrypted study laptops. Participant's video feed in zoom will not be recorded during

this process. Once the interview is complete, the audio will be saved and coded with the subject unique identifiers, only connected to identifiers (PHI) via a separate, password-protected, master code. The audio file will be saved directly from the audio recorder or audio recording program on a secure, password protected server at Boston Medical Center (BMC) to which only designated individuals have access, thus providing a secure environment for all project data.

It is vital for the research team to provide a remote videoconferencing option to participants receiving the intervention for public health reasons. This will not only enable research teams to continue conducting vital research work during pandemics such as COVID-19, but will also allow patients to receive psycho-social and educational interventions and health care services that counteract many logistical and financial barriers. This includes access to care barriers, including distance to health care facilities, financial burden of transportation to health care facilities, financial burden of arranging childcare, and health conditions/pandemics that may prevent patients from leaving their homes.

10 Assessment of Safety and Data Safety Monitoring Plan (DSMP)

10.1 Definitions

The following definitions will be used in the assessment of safety:

Adverse Event (AE) is defined as an event or group of events together that pose potential physical, emotional, legal or financial risk that is/are plausibly related to the research intervention and/or research procedures. Thus, AEs in this study could include any substantial or significant changes to the participant's mental health and symptoms, abnormal or harmful behaviors, suicidal behavior or attempts, or breach in the protection of participant data or breach of confidentiality because they are plausible in regards to our study intervention/procedures. We will document such AEs, whether or not considered related to the participants' participation in the research. The investigator or designee will make a determination regarding relatedness to the study intervention and/or procedures. We will not track physical signs and symptoms, abnormal lab results, new diagnoses, etc. as AEs.

Serious Adverse Event (SAE) is any adverse event that

(1) results in death;
(2) is life-threatening;
(3) results in inpatient hospitalization or prolongation of existing hospitalization;
(4) results in a persistent or significant disability/incapacity;
(5) results in a congenital anomaly/birth defect; or
(6) based upon appropriate medical judgment, may jeopardize the subject's health and well-being and requires hospitalization, other mental health or medical stabilization, child protection services or other higher level of care

Life-threatening means that the event places the subject at immediate risk of death from the event as it occurred.

Unanticipated Problem is defined as an event, experience or outcome that meets **all three** of the following criteria:

- is unexpected; AND
- is related or possibly related to participation in the research; AND
- suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

Possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research

Unexpected means the nature, severity, or frequency of the event is not consistent with either:

- the known or foreseeable risk of adverse events associated with the procedures involved in the research that are described in (a) the protocol–related documents, such as the IRB-approved research protocol, any applicable investigator brochure, and the current IRB-approved informed consent document, and (b) other relevant sources of information, such as product labeling and package inserts; or
- the expected natural progression of any underlying disease, disorder, or condition of the subject(s) experiencing the adverse event and the subject's predisposing risk factor profile for the adverse event.

10.2 Safety Review

The Principal Investigator will be ultimately responsible for the overall conduct of the study including ensuring that any Adverse Events are recorded and reported according to BUMC IRB policy. If adverse events, unanticipated problems or study deviations arise, then the academic institution's Institutional Review Board (IRB) will be notified using an Adverse Event Form. If the adverse event is an unanticipated problem, it will be reported to the IRB within 7 days of its identification. The principal investigator will also report the findings to the NIH program staff. The NIH will be informed of any actions taken by the IRB as a result of their continuing review.

Security or inadvertent confidentiality breaches as well as suspected child maltreatment or other events that require mandated reporting will be recorded as adverse events. The study team has a detailed safety protocol in place to address child maltreatment, mental health emergencies, and other related safety concerns as they arise. We will continually monitor whether and how often the protocols are needed and, once activated, if they function as expected. If they do not, that will also be considered an adverse event and will be assessed as an unanticipated problem. No other Adverse Events/Serious Adverse Events are anticipated – any that arise and meet the definition of an unanticipated problem will be reported to the IRB in compliance with the IRB reporting policies.

Data Safety Monitoring Board

In addition, because this project includes an intervention intended to impact clinical outcomes, the inclusion of a Data and Safety Monitoring Plan and Board is appropriate. The Data and Safety Monitoring Board (DSMB) will include an independent group of experts on child behavioral health, clinical trials, and biostatistics, who will advise and monitor the project with the study principal investigator (PI). None of the members will directly supervise, report to, or directly collaborate with the PI. The following three members will serve on the DSMB:

1) **Rheanna Platt MD, MPH,** Assistant Professor in Department of Child and Adolescent Psychiatry, Johns Hopkins University/Johns Hopkins Bayview Medical Center
2) **Sarabeth Broder-Fingert, MD,** Vice Chair for Research in Pediatrics, University of Massachusetts Medical School
3) **Radley Christopher Sheldrick, PhD**, Research Associate Professor of Health Law, Policy, and Management at the Boston University School of Public Health

The DSMB will meet every six months (+/- 30 days for flexible scheduling). Its primary responsibilities will be to:

1) Review and evaluate the accumulated study data for participant safety, study conduct and progress, and efficacy; and
2) Make recommendations concerning the continuation, modification, or termination of the trial.

In this proposed project, the DSMB will consider study-specific data and any concerns for poor clinical outcomes among patients in a particular randomization condition. As part of their responsibility, DSMB members will ensure the timeliness, completeness, and accuracy of the data submitted to them for review. Members will ensure submitted data are sufficient for evaluation of the safety and welfare of study participants. The DSMB will also assess the performance of overall study operations and any other relevant issues, as necessary.

Specific items to be reviewed by the DSMB will include:

- Interim/cumulative data for evidence of study-related adverse events;
- Interim/cumulative data for evidence of efficacy according to pre-established statistical guidelines;
- Data quality, completeness, and timeliness;
- Adequacy of compliance with goals for recruitment and retention, including those related to the participation of women and minorities;
- Adherence to the protocol;
- Factors that might affect the study outcome or compromise the confidentiality of the trial data; and
- Factors external to the study such as scientific or therapeutic developments that may impact participant safety or the ethics of the study.

After each meeting of the DSMB, members will meet without the study PIs and provide them with a written letter of recommendations.

10.3 Reporting Plans

The Principal Investigator at BMC/BU Medical Campus will report Unanticipated Problems, safety monitors' reports, and Adverse Events to the BMC/BU Medical Center IRB in accordance with IRB policies:

- Unanticipated Problems occurring at BMC/BU Medical Campus will be reported to the IRB within 7 days of the investigator learning of the event.
- Reports from safety monitors with recommended changes will be reported to the IRB within 7 days of the investigator receiving the report.
- Adverse Events (including Serious Adverse Events) will be reported in summary at the time of continuing review, along with a statement that the pattern of adverse events, in total, does not suggest that the research places subjects or others at a greater risk of harm than was previously known.
- Reports from safety monitors with no recommended changes will be reported to the IRB at the time of continuing review.

10.4 Stopping Rules

Study contacts will be stopped if there is an acute and immediate concern for the safety of a parent or child. This would include the revelation of current abuse, neglect, suicidal or homicidal ideation. In addition, participants may choose to withdraw from the study at any point and for any reason.

11 Data Handling and Record Keeping

11.1 Confidentiality

All survey information will be collected from participants using a unique ID. Participants may complete surveys on paper, and the data will then be entered by research staff into a data base built with Research Electronic Data Capture (REDCap), a secure, HIPPA compliant web-based application hosted by BMC. Participants will have the option of entering data directly into the research database, which allows for direct electronic data capture under the participant's unique ID. The REDCap software allows researchers to design and implement study surveys for collecting, storing, retrieving, and manipulating data electronically. The data is stored in a secure database via an encrypted connection, and is immediately available to the investigator for analysis by a statistical package.

Downloaded data will reside on a secure, password protected server at Boston Medical Center (BMC) to which only designated individuals have access, thus providing a secure environment for all project data. Study data will be automatically backed up on a nightly basis. Files stored on BMC servers will be protected by electronic 'firewalls' that restrict access to designated users.

Any paper questionnaires (if participants prefer to complete it on paper in person) and source documents will be kept in study binders and stored in a locked cabinet, in a locked

office, in the BMC Psychiatry Research Center. Only the PI and psychiatry research staff will have access to this area. The "Master Code" linking subject IDs to identifiers will be password protected, only accessible to study staff, and will be located on a HIPAA-compliant, BMC controlled computer, in a folder on the secure BMC network that meets BMC standards for the storage of PHI. Survey data and qualitative interviews will be linked through the unique ID. Participant identifying information will not be collected for data analysis purposes.

The exit interviews will be audiotaped, with subjects' permission, using a digital voice recorders or audio recording programs on our BMC encrypted study laptops. We will not be collecting any personal identifiable information from participants during the exit interview. If a participant accidentally mentions identifying information on the audio recording, this identifying information will be removed from the audio file and transcription. All participants will be reminded that they can decline to answer any questions if they so choose. Each digital audio file will be coded with subject unique identifiers, only connected to identifiers (PHI) via a separate, password-protected, master code. These files will be stored on a password-protected, encrypted BMC network. The coded audio file will additionally be sent to a BMC privacy office approved commercial service for transcription, or transcribed by a member of the research staff. For participants who are completely the intervention remotely through videoconference software (Zoom), their interviews with be audio recorded only. Once the interview is complete, the audio will be saved and coded with the subject unique identifiers, only connected to identifiers (PHI) via a separate, password-protected, master code.

All data for study purposes will be managed using the Boston University Medical Campus' installation of REDCap data collection system, a software tool developed at Vanderbilt University and made available through the Clinical and Translational Science Awards network (CTSAs). To help protect and secure the data stored in REDCap's database, the software application employs several methods to protect against malicious users who may attempt to identify and exploit any security vulnerabilities in the system. Access to the REDCap data entry website will be based on permissions granted by username and password which will be managed by the Boston University Clinical and Translational Sciences Institute for the Medical Campus Office of Information Technology (OIT). Only authorized study members will be able to enter or view data. The login information (username) of the person submitting the information, the date and time submitted, and other navigational information will be automatically obtained and stored in the database.

Boston University's installation of REDCap is HIPAA compliant. Information posted on forms will be electronically encrypted using secure socket layering (SSL) encryption technology so that only the intended recipient can decode the data. Data will reside on a secure, password protected server at Boston University Medical Center (BUMC) to which only designated individuals have access, thus providing a secure environment for all project data. The database will be automatically backed up on a nightly basis. Files stored on BUMC servers will be protected by electronic 'firewalls' that restrict access to designated users. Restrictions and permissions to update the database will be controlled through the REDCap web application.

Because the server will be part of the BUMC network NT domain, only connections from users authenticated from the domain controller are accepted, thus providing a secure environment for all Center data. Specifically, the policy for computer systems security implemented at BUMC:

- Provide physical security of data. All central systems are physically secured behind locked doors with access restricted to key personnel in the OIT. Access through the primary door is also protected by an alarm system that is tied directly into the on-site central emergency response security control center. Written policies exist for contingencies to provide access to the room to those not explicitly authorized.
- Provide virtual security via connectivity. Internal access to all systems is done via Microsoft Challenge Handshake Authentication Protocol. With the exception of internet provider-based services, external client access must first gain access to the internal network before connecting to the systems. This connection is initiated via a Virtual Private Network connection using Point-to-Point Tunneling Protocol or through the University's modem pool which require Kerberos authentication.

All data are protected with disaster recovery via several methods:

- Hardware redundancy: Several stages of redundancy exist at the hardware level to minimize failure: dual-redundant power supplies exist on each disk array; hot-spare disk is configured to automatically self-heal in the event of a disk failure in the array; emergency power generators ensure a 100% electrical uptime; and uninterrupted power supplies present the systems with conditioned steady-state power.
- Data backup: The data are backed up on a regular schedule. All tapes are moved off-site on a daily basis and are stored in a fire-proof safe. Cycle-time of backups is approximately two months with the exception of a yearly archive which is retained for a one-year period.
- Data Security: All data are stored on NT File Systems with password-protected files and directories.

The BUMC REDCap Server has implemented a mix of preventive and detective security measures:

- Two factor authentication required for both admin and user access
- Require a password change every quarter for users
- Server is placed behind data center firewall
- Requires two-factor authentication and only permits for specific admin(s) that need to access the server
- Inform PIs that they need to remove investigators who are no longer involved, and periodically (ideally quarterly) review accounts
- Server is protected by intrusion prevention measures (firewalls/snort)
- Server is part of change management and vulnerability management programs to ensure server is patched within 30 days of vulnerability notification

Twilio is a third-party web service that provides the functionality for researchers to send REDCap survey invitations via SMS text messaging. When a BU REDCap admin enables Twilio for a REDCap project, BU REDCap verifies that the Twilio Request Inspector has been

disabled. This setting ensures that survey participants' phone numbers do not get permanently logged on Twilio's servers, but instead remain securely in the BU encrypted REDCap server.

If the study staff learns of any acute safety concerns, such as current thoughts about suicide, self-harm, or intent to harm others, abuse, neglect, or other reportable conditions, investigators may need to break confidentiality to prevent this harm from happening. Participants are made aware of this during the consenting process. Study staff will abort study procedures and take the necessary steps to keep the participant and child from harm. The study Principal Investigator will be immediately notified by pager. Children or parents may be referred for emergency evaluation at the Boston Medical Center Psychiatric Emergency Services or at the Boston Emergency Services Team (BEST) located near the hospital. We also may contact treating health care providers to be sure they are aware of the risk identified. In addition, if research staff identify any concern for current abuse or neglect, they will page the study investigator who must report this to the Department of Children and Families.

11.2 Source Documents

This study will utilize REDCap (Research Electronic Data Capture), a software toolset and workflow methodology for electronic collection and management of clinical and research data, to collect and store survey data. REDCap will be utilized to collect and store data obtained through surveys and assessments. The Boston University School of Medicine Research Department will be used as a central location for data processing and management. REDCap provides a secure, web-based application that provides an intuitive data manipulation interface, custom reporting capabilities, audit trail functionality, real-time data monitoring/querying of participant records, and variations of data exporting/importing. Paper questionnaires and source documents will be kept in study binders and stored in a locked cabinet, in a locked office, in the BMC Psychiatry Research Center. Only the PI and psychiatry research staff will have access to this area.

The exit interviews will be audio recorded on a digital voice recorder or through an audio recording programs on our BMC encrypted study laptops, and the audio recordings will be transcribed by a commercial transcription service. The interviewer may also take notes throughout the intervention and exit interview and these notes may also serve as source documents for study data. The recordings, transcriptions, and notes will be stored in a locked file cabinet. Electronic versions of the transcriptions will be password protected and stored on a secure network. The transcriptions and notes will be retained for at least seven years after the completion of the study and will be destroyed after the publication of the final journal article that uses this data. The audio files will be destroyed after they have all been transcribed.

11.3 Study Records Retention

Survey data and study notes will be retained for at least seven years after the completion of the study and will be destroyed after the publication of the final journal article that uses this data.

12 Statistical Plan

12.1 Study Hypotheses

Our hypothesis is that reducing unmet social needs will lead to improved ADHD symptoms via multiple mechanisms, including: 1) reduced child and parent stress; 2) increased parent empowerment and activation, and 3) improved connection to needed mental health care.

12.2 Sample Size Determination

Based on Dr. Spencer's mentorship team's past experience optimizing interventions, we believe that intervention testing and iterative improvement with 30 intervention participants will be adequate to create an optimized intervention ready for study in a fully powered RCT. We will not estimate effect size, since this can be misleading in a pilot study. To power a future RCT we will obtain within-group standard deviation of continuous outcome measures and correlation over time of outcome measures at baseline and follow up. Since group means on continuous variables typically begin to stabilize around 15 participants per group, the proposed sample size of 30 participants per group, even after 25% attrition, will allow us to evaluate the potential of the intervention while remaining within the budgetary parameters.

12.3 Statistical Methods

Because this is a pilot study, it is not fully powered to detect differences between groups. Because of emerging consensus that group-to-group comparisons in a pilot study are invalid and misleading, estimating effect size is not one of our study objectives. However, our goal will be to obtain estimates of study parameters to inform power calculations for a subsequent study, including the following:

- Within-group standard deviation of each continuous primary and secondary outcome measure as well as each measure of target engagement; and
- Correlation over time of each outcome measured at baseline and follow-up.

Furthermore, our collection and analysis of process measures will be used to inform changes to the intervention throughout the pilot study in order to optimize its delivery for a future RCT.

13 Ethics/Protection of Human Subjects

This study is to be conducted according to applicable US federal regulations and institutional policies (which are based in federal regulations, guidance, and ICH Good Clinical Practice guidelines).

This protocol and any amendments will be submitted to the Boston Medical Center and Boston University Medical Campus IRB, for formal approval of the study conduct. The decision of the IRB concerning the conduct of the study will be made in writing to the investigator. A copy of the initial IRB approval letter will be provided to the sponsor before commencement of this study.

All subjects for this study will be provided a consent form describing this study and providing sufficient information for subjects to make an informed decision about their participation in this study. The consent form will be submitted with the protocol for review and approval by the IRB. The consent of a subject, using the IRB-approved consent form, must be obtained before that subject is submitted to any study procedure. Consent will be documented as required by the IRB.

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15 Appendix

Schedule of Events

Domain/measure	**Informant**	**Assessment Time Point (Month) Intervention Period (0-3+ months)**			
		0	**3 (Post-intervention)**	**6**	**12**
Family Background					
Background Socio-demographic Questionnaire	Parent	X			
Unmet Social Needs Questionnaire and Adequacy of Resources	Parent	X	X	X	X
Child Symptoms, Adverse Experiences, and Treatment Utilization					
Child Behavior Checklist 1.5-5	Parent	X		X	X
ADHD Rating Scale, Version IV (ADHD-RS-IV), Preschool Version	Parent	X	X	X	X
CYW Adverse Childhood Experiences Questionnaire (ACE-Q) Child	Parent	X			X
Parent Symptoms, Activation and Treatment Utilization					
Patient Health Questionnaire (PHQ-9)	Parent	X	X	X	X

Adult ADHD Self Report Scale (ASRS-v1.1)	Parent	X	X	X	X
Perceived Stress Scale (PSS)	Parent	X	X	X	X
Parenting Stress Index-Short Form (PSI-SF)	Parent	X	X	X	X
Intervention Feasibility, Acceptability, and Content					
PRE-CARE Exit Interview – *PRE-CARE condition only*	IE (via Parent)		X		
PRE-CARE Feasibility and Acceptability Form - *PRE-CARE condition only*	Parent		X		
Interventionist Post-Session Summary Form - *PRE-CARE condition only*	RA	X	X		
Premature Termination Form	RA	X	X		