Advancing Perinatal Mental Health and Well-Being: The DC Mother-Infant Behavioral Wellness Program Study Protocol and Statistical Analysis Plan

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RESEARCH PROTOCOL

TITLE: **Advancing Perinatal Mental Health and Wellbeing: The DC Mother-Infant Behavioral Wellness Program**

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BACKGROUND

THE BURDEN OF STRESS, DEPRESSION AND ANXIETY IN PREGNANCY

Mental health (MH) disorders, including stress, depression, and anxiety (hereafter referred to as *maternal distress*), are the most common complication of pregnancy, affecting up to 25% of women in the prenatal period and/or first postpartum year.[1] Stark disparities exist, with almost 40% of low-income women who are Black/of African Descent suffering from maternal distress during pregnancy.[2] These disparities extend to the stress, anxiety and depression[3]triggered by giving birth amid a COVID-19 pandemic that has exacted a heavier toll[4] among people of color[5]in the U.S. Pilot data from our Project RESCUE study indicate that high levels of anxiety, depression and stress experienced by pregnant women in DC more than doubled from the pre- to the post COVID-19 era. Repercussions of these pregnancy-related MH disorders are widespread and longstanding.[6] Beyond their potentially devastating effects on the pregnant woman and her fetus (e.g., preterm labor, fetal growth restriction, low birthweight – leading causes of infant mortality) and the associated postpartum (e.g., attachment dysregulation, low self-efficacy) and newborn complications (e.g., prematurity), the personal, familial and societal impact is further magnified by known health repercussions across the child's lifespan,[7] and even across generations. [8-23] Future pregnancies in the mother and her adult offspring may also be compromised, perpetuating this enormous public health problem.[6]In a recent study of *well-resourced pregnant women with low-risk pregnancies,* we investigated the impact of prenatal stress, depression, and anxiety on *in vivo* human fetal brain growth using advanced non-invasive MRI tools. We reported for the first time that almost 30% of these pregnant women reported high levels of stress that was associated with impaired fetal brain growth, both global and regional (hippocampus and cerebellar)[24] and disturbances in fetal brain function.[25] These alarming findings highlight the need for effective screening and intervention programs to improve MH in pregnant women and optimize infant outcomes, which we plan to address in the current proposal, building on our pilot data that indicates early, effective interventions lessen toxic maternal stress, anxiety and depression.

There are major ***barriers to treatment*** for low-income women who are Black/of African Descent who develop pregnancy-related MH complications.[26] These include *under-detection* of mental illness, significant *psychosocial stressors*, and *lack of integrated health and mental health care*. In an extensive recent report using a *human centered design* (see below).[27] The DC-Primary Care Association (DC-PCA) cited transportation, housing insecurity, food insecurity, childcare, disrespectful care providers, and poor communication with providers as potent barriers to care. These results corroborate those from our own pilot efforts in which psychosocial stressors emerge as potent and persistent barriers to care. These barriers highlight the need to develop, implement and evaluate evidence-based models of care that aim to: (1) increase screening for prenatal and postpartum maternal distress, (2) provide more immediate access to culturally-adapted, evidence-based interventions (that include both prevention and treatment) to decrease risk for maternal distress, and (3) increase coordination of care among various perinatal providers. Of note, one of the authors of the DC-PCA report is a co-investigator on our proposal, and the report's key recommendations (novel technologies; care coordination) are embedded in our research strategy.

Washington, DC, provides a useful model for evaluating strategies aimed at improving the detection of, and intervention for, pregnancy-related mental health needs in low-income women who are Black/of African Descent and their offspring for several reasons. First, the District of Columbia (DC) is a relatively small and circumscribed area, with stark socioeconomic and healthcare disparities. Second, low-income Black/of
African Descent communities are largely concentrated in the northeast and southeast of the district (Fig 1).
Maternal health care outcomes in the U.S. are among the worst in the developed world, and the DC maternal[28] and infant[29] mortality rates are among the highest in the nation. Recent reports from the Centers for Disease Control (CDC)[28,30] highlight the deep racial disparities in maternal health care in DC. Maternal mortality in DC overall is 50% higher than the national average[30], yet white women in DC have the *lowest* maternal mortality in the nation.[28,30] These disparities persist even when controlling for education and income,[31] reflecting a deeper set of issues related to distrust, poor access, communication, and resource information. According to the 2018 DC Perinatal Health and Infant Mortality Report, about 50% of women who are Black/of African Descent enter prenatal care only in the 2nd or 3rd trimester, if at all. [29] Only 36% of Medicaid recipients in DC attend the recommended number of prenatal visits,[32] and < 50% have postpartum visits.[32] Women of color, particularly those living in poverty, are less likely to proactively seek help for stress, anxiety, and depression.[33] **These alarming statistics are corroborated by a local survey of the delivery centers partnering in this proposal**. Recently, access to pregnancy-related care in DC was further compromised with the closure of two maternity centers in predominantly low-income AA areas.

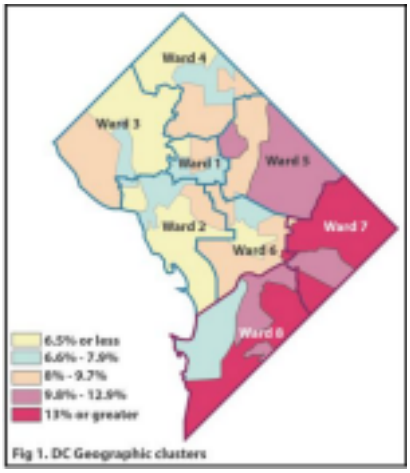


Fig 1. DC Geographic clusters

Aim 1: We will refine an individualized plan to integrate patient navigation and a culturally adapted cognitive behavioral (CBT) intervention for low-income pregnant women who are Black/of African Descent, designed to increase recruitment and retention within the healthcare community system.
Aim 2: Through a two-arm prospective randomized controlled design, women who are subthreshold and threshold risk for prenatal stress, depression and/or anxiety will participate in one of two interventions: (a) usual care: existing prenatal intervention; or (b) patient navigation plus adapted CBT, and peer support group, per patient preference.

PRELIMINARY STUDIES

Stress, depression, and anxiety are the most common complications of pregnancy, with enormous racial disparities in prevalence and care. Prevalence of these disorders is almost two-fold higher among pregnant low income Black/of African Descent women[2,34] who, paradoxically, also face the greatest obstacles to mental health care. These racial disparities are particularly striking in DC. Yet MH disorders remain seriously under-detected in part due to poor implementation of recommended screening protocols. The CDC reports that about 60% of women with depression go undiagnosed, and among those that are diagnosed about 50% go untreated because of limited access to treatment, cost, medical mistrust, and stigma.[35,36] As low-income women who are Black/of African Descent experience multiple psychosocial stressors, it is also imperative to screen for stress alongside depression and anxiety. In this proposal, we plan to partner with stakeholders within low-income Black/of African Descent communities[37] to develop and implement strategies that reduce these obstacles to screening, and to provide necessary follow-up resources, via navigation and evidence-based interventions, that are tailored for expectant low-income women who are Black/of African Descent.

After identifying women at risk, the next major knowledge gap lies in the optimal engagement and retention within treatment programs: Which optimal navigation tools connect and retain women in the healthcare system? As MH conditions during pregnancy may impact the behavioral and neurodevelopmental outcome of the offspring, what is the best way to monitor these infants to detect early signs of these complications, and to intervene early? Will the integration of maternal postpartum MH monitoring with the infant's well-baby checks provide benefit? A third gap in care is the absence of MH interventions for women *at risk (subclinical)* for

maternal distress. Most clinical trials focus on women who meet "threshold," based on DSM-5 criteria, for *clinical* depression or anxiety then evaluate the effectiveness of a *treatment* for this group. However, mothers' elevated depressive symptoms (i.e., "subthreshold" or subclinical depression that would not be diagnosed) can also have negative consequences for infants' and young children's development.[38] Therefore, it is necessary to provide more immediate access to evidence-based, *preventive* interventions for *all* women seeking prenatal care to decrease risk for future maternal distress, which are both acceptable and adapted to meet the contextual realities of low-income women who are Black/of African Descent. CBT interventions are effective for preventing and treating perinatal depression;[39,40] adapting these CBT interventions to address not only depression but also stress and anxiety will further address the psychosocial needs of our target population. A culturally tailored CBT

to manage pregnancy-related and psychosocial stress among these women may improve detection rates as well as implementation and adherence to interventions. Furthermore, studies have shown that when MH services are co-located within the settings in which women are already receiving care, women are more likely to use those services.[41] Our own pilot studies find that more women are likely to use services that are co-located, and our AA context experts advocated for this "one-stop shop" approach. Several overlapping strategies for overcoming these obstacles and filling these critical knowledge gaps are proposed. We will test whether Patient Navigation optimizes case identification and retention, and reduces psychosocial barriers, when delivered with a culturally adapted CBT intervention in an integrated obstetric-psychiatric-pediatric care model (Fig 2). We will measure the outcomes in terms of case identification, engagement and retention, as well as maternal, pregnancy, and infant outcomes, including standardized measures of infant temperament, behavior and development until age one year.

Fig 2. Integrated Care Model

Few PCORI-funded studies (Li NCT02371356,[42] Silverstein NCT03221556,[43] Tandon NCT02979444)[44] have addressed pregnancy-related MH; each distinctly differs from our current proposal. Most importantly, none focuses exclusively on low income women who are Black/of African Descent. The first study (Li) compares the efficacy of different treatments (and no treatment) on fetal outcomes (mortality/morbidity, prematurity and birthweight). The second study (Silverstein) focuses on CBT as a first-line treatment, which enrolls 230 women both prenatal and postpartum, with its primary outcome the effect on maternal depressive symptoms. The third study (Tandon) evaluates whether having paraprofessional home visitors lead the Mothers and Babies group prevention is more efficacious than providing usual care. Our proposal has distinct and important differences from these ongoing studies. **We focus on early identification, both *prevention* and *treatment*, as well as engagement and retention of a large intervention group (N=700), and include both mothers and infants in our outcomes.** While maternal report of child outcomes is measured in the Silverstein study, there is no independent evaluation of the infant's attachment, temperament and development as is done in our study. In addition, all three studies focus only on depression, unlike ours which includes the more pervasive and co-occurring problems of prenatal maternal stress and anxiety. Lastly, our study also includes patient navigation, which addresses the multiple needs reflecting important social determinants among low-income Black/of African Descent perinatal women.

A major limitation of previous large community-based trials is the failure to sustain the benefits of the trial in the community after completing the trial. A number of factors align to support the success and **sustainability** of this proposal. First, is the team of investigators, experts drawn from all the disciplines relevant to the issues targeted (discussed below). Second, is the integration of embedded patient and community stakeholders at the center of this proposal (see below). Third, is the support from leadership at the hospitals and community centers where the work will occur. In addition, our proposal harnesses momentum. The timing of this proposal coincides with a surge of other local and national initiatives calling for prioritization of pregnancy-related health care. On a national level, the importance of implementing and sustaining pregnancy-related MH screening has been endorsed by a number of important agencies, including the *American College of Obstetrics and Gynecology*[45,46] (ACOG, see letter) *American Psychiatry Association (APA),*[47,48] and *American Academy of Pediatrics* (AAP, see letter). On a local DC government level, insufficient MH screening and lack of referral resources[49] are now recognized as critical unmet perinatal health burdens, and maternal and infant health has been identified as a priority. Our PCORI project closely aligns with the mission and milestones of a substantial investment from the

A. James & Alice B. Clark Foundation towards the Clark Parent & Child Network (Limperopoulos, co-director) to bolster the quality and capacity of perinatal health for low-income families in Washington, DC, and includes many of the same key stakeholders as this PCORI proposal. Since 2018, *DC Mayor Muriel Bowser* has hosted annual Maternal and Infant Health Summits including politicians, health providers, community workers and DC residents to explore strategies to improve perinatal health and address racial disparities in birth outcomes; the 2020 Summit highlights the transformational nature of our five-year, Clark-funded project.[29] The DC City Council recently passed legislation requiring the formation of a Maternal Mental Health Task Force to address disparities in perinatal health, health care access, and infant outcomes.[29] Likewise, the *Department of Health Care Finance* (DHCF) has convened a Perinatal Collaborative comprising managed care organization representatives and other relevant stakeholders charged with monitoring maternal and infant health care efforts. This year (2020), Deborah Perry, PhD is conducting the DC Perinatal Needs Assessment, funded by the DC Department of Health, to examine how racism adversely affects the decisions of women who are Black/of African Descent to access prenatal care services. Dr. Perry and her team have already gathered data from 22 multidisciplinary health providers who are knowledgeable about the services, systems, barriers to care experienced by women who are
Black/of African Descent in Wards 5, 7, and 8, the most impoverished parts of DC. The team is currently recruiting 40 women who are Black/of African Descent to further assess these structural issues. This report will be ready by the end of 2020 and will enrich our understanding of the contextual barriers to care for women who are Black/of African Descent in DC (D. Perry, see letter). In recent years, the DHCF and *DC Department of Behavioral Health* have focused on improving maternal MH, particularly homing in on integrating screening efforts in pediatric primary care settings, an important aspect of this proposal (see below). Lee Beers, MD (co-I) leads the *Community Mental Health CORE (Collaboration, Outreach, Research and Equity*), and created screening toolkits and other resources to screen for perinatal mood and anxiety disorders in pediatric primary care (Appendix A). Finally, Catherine Limperopoulos, PhD (co-PI) leads the *DC Perinatal Mental Health Consortium* which has successfully formed a joint collaborative of local community partners from obstetrics, psychiatry and pediatrics to develop perinatal screening and intervention strategies to improve behavioral health in pregnant women and infants. The logical next step is to move this work into the obstetric setting, recognizing that depression during pregnancy is the strongest predictor of postpartum depression.[43, 44] Huynh-Nhu Le, PhD (co-PI) and Aimee Danielson, PhD (co-I), led efforts in 2017-2019 to implement a screening process for perinatal depression and anxiety in obstetrical settings. The DC-PCA conducted in-depth interviews of women who are Black/of African Descent in DC to better understand the barriers to pregnancy care, and to identify opportunities for intervention. They recently published their findings and developed a roadmap for action.[27] Two of the women who were in this report are part of the context experts team (n=6 in the DC-PCA's Maternal Health Equity Action Lab) and from April to July 2020 participated in 6 focus groups with our research team to inform and co-create all aspects of the screening and intervention arms of this study. These women are all now part of the Patient Stakeholder group, known as Moms' Collective WISDOM (see below). We have further capitalized on this important initiative from the DC-PCA report by incorporating many of the recommendations into our proposal, and by recruiting one of the two lead authors and director of Policy at the DC-PCA (Patricia Quinn, Co-lead of our Stakeholder Engagement Core) and a patient stakeholder (Shanae Bond), a postpartum doula and lactation specialist, and one of the context experts in the Equity Action Lab, who has actively participated in the focus groups, into our research team.

RESEARCH DESIGN AND METHODS

Overall Research Design

Methods:

Specific Aim 1: Refinement of the intervention arm, integrating patient navigation with prevention and treatment interventions already has begun with input from the context experts/focus groups from April to July 2020. This process will continue through a systematic, multi-step process driven by the SEC during the first year of the study to further refine the individual roles of patient navigator and interventions. We remain wholly committed to continuing this stakeholder-driven and iterative process to define the specifics of the final research questions and the final intervention. The process will be completed by the first year of the study. They

represent a broad array of local stakeholder expertise See Leadership Plan (Table 1). All members of the Core will be reimbursed for their service.

Specific Aim 1.a. Development and refinement of the patient navigator (MCS) role. The Patient Navigation elements were developed in collaboration with our Stakeholder Engagement Core using the feedback and guidance from the patient stakeholders during our focus groups. The patient navigators, "Maternity Care Specialists," are humans (rather than e-navigation) whose role should be to provide "personalized care" - support, resources, and referrals to address psychosocial issues that arise during the perinatal period.

Specific Aim.1. b. Refinement of the adapted CBT Interventions: The proposed content of the stress management interventions (prevention, treatment) were co-created by the patient stakeholder group, will now be reviewed with the providers for further refinement (Table 1, Appendix C). Also, five meetings of the entire Stakeholder Engagement Core and four consultations with the National Advisory Board over the study's first year will provide additional opportunity for feedback and refinement. The process will follow a rapid cycle quality improvement with refinement after focus group sessions to finalize the intervention components, including patient navigation, prevention, treatment and peer support group components.

Specific Aim 1.c. Refinement of the "Virtual Mommy Meet Ups": Created and co-led by the context experts, these peer support group interventions will be reviewed in consultation with the National Advisory Board for further refinement and adaptation to the current study (Table 1, Appendix C).

Specific Aim 2: Through a two-arm prospective randomized controlled design, women who are subthreshold and threshold risk for prenatal stress, depression and/or anxiety will participate in one of two interventions: (a) existing prenatal intervention/usual care/UC; n=350, Group 1); (b) patient navigator, n=350 (Group 2).

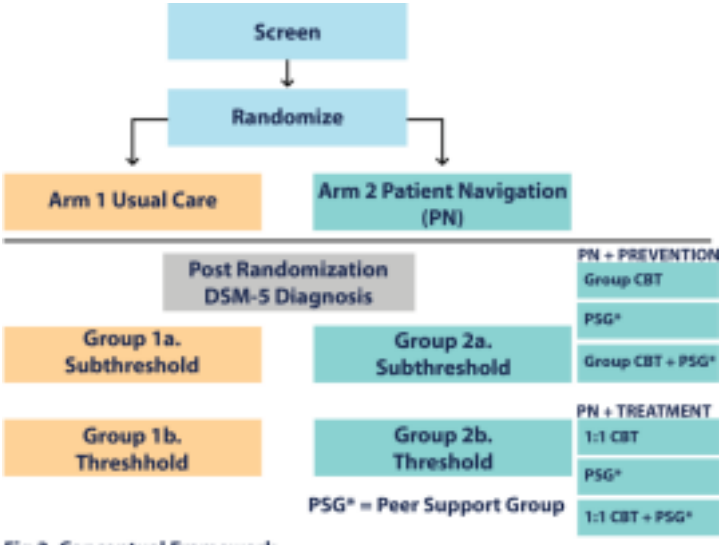


Fig 3. Conceptual Framework

Randomization: We estimate an existing total population of 4,000 women within the delivery center network that would be eligible for participation. Due to budgetary constraints, we assume a 25% working population (n=1,000) available for screening of which, based on our prior RCTs, 70% (n=714) will consent to screen. Of these, we anticipate 2% of women (n=14) will screen in the critical risk category (imminent risk for harm to self or other and need immediate crisis intervention at the site where they are receiving care) and will be excluded. Therefore, we anticipate consenting and randomizing 700 women (1:1) to one of two arms: (Aim 2) (a) existing prenatal intervention/usual care/UC; n=350, (Group 1); (b) patient navigator, n=350 (Group 2). Following randomization all women in either arm will participate in a diagnostic interview based on DSM-V criteria to 'self-select' themselves into 1 of 2 groups (i.e., 'threshold' or 'subthreshold'). *Threshold* includes women who meet criteria for depression or anxiety based on DSM-V diagnostic criteria. *Subthreshold* includes all other women who do not meet DSM criteria. We anticipate 70% (n=245) of women to present as '*subthreshold*' risk with the remaining 30% (n=105) to comprise the '*threshold*' group. Women in the patient navigator arm (Group 2a) can choose to participate in group-based *preventive* interventions based on: (1) a culturally adapted CBT (in person within prenatal care site or virtual given COVID); (2) peer support group (virtual); or (3) both. Women in the *threshold* risk group (Group 2b) at baseline warrant treatment interventions and will be invited to participate in: (1) culturally adapted CBT (individual, in person or virtual given COVID); (2) peer support (virtual); or (3) both. Women in this more severe risk group may be referred for psychiatric treatment if warranted. Randomization lists will be generated by the study statistician using a permuted block design and uploaded to a HIPAA compliant, password-protected website (REDCap) allowing for patient randomization at the time of registration in the data collection system.

Table 1. Overview of Interventions

Intervention	PREVENTION (+Patient Navigation)	TREATMENT (+Patient Navigation)	PEER SUPPORT (+Patient Navigation)
Participants	Subthreshold	Threshold	All
Modality	Group	Individual	Group
Number of sessions	8 (6 prenatal; 2 postpartum boosters)	12 (8 prenatal; 4 postpartum boosters)	12
Open vs. closed	Closed	Closed	Open

Measurement Outcomes and their

psychometrics are detailed in Appendix E. Although we consider stress, anxiety and depression measures in our target population as equally important, for this project we will clarify that stress as measured by the Perceived Stress Scale[50] (PSS) will be considered as the primary outcome. Our recent studies have shown that prenatal stress is prevalent among expectant mothers (27%) as measured by the PSS and is associated with impaired fetal brain development[3] and an increased risk for wide-ranging cognitive, and social behavioral problems in the off-spring of these women at 12-18 month neurodevelopmental testing. Secondary outcomes considered will be reductions in perinatal depression (EPDS) and anxiety (GAD-7), rate of program adherence to pre-/postnatal mental health treatment, rate of pregnancy complications (e.g., bleeding, infection), healthcare utilization (e.g., cost of care [U.S. dollars]), and infant outcomes (e.g., neurodevelopment, mother baby dyad attachment, etc.). Our secondary outcomes are perinatal depression and perinatal anxiety. The Edinburgh Postnatal Depression Scale[51] (EPDS) is generally expressed as a rate with traditional clinical cut-off points for minor or major depression set at 9/10 or 12/13, respectively. Thus, we assess clinical meaningfulness as the change in pre- vs. post-intervention proportion above the selected threshold (depressed) to the post proportion below. Participants scoring below the threshold are thought to have demonstrably improved. Previous research has shown a 4-point drop using the Reliability Change Index to be adequate in assessing a reduction in maternal depression. Thus, a pre-intervention null EPDS rate of depression (EPDS score of 14/15, depressed), and a post-intervention depression rate of 15 suggests 413-450 subjects provide approximately 80% power, alpha=0.05, two-tailed, to detect a statistically significant reduction in maternal depression. Any further decrease in EPDS score from a 4-point decrease to 5-point, etc. will increase our study power and therefore require fewer subjects.

Recruitment and Eligibility Criteria:

***Procedure at each recruitment site**:* After consulting with the clinical staff, a trained clinical research coordinator (CRC) from Children's National Hospital (CNH) will approach patients during their visit (T1, Appendix E) to determine their interest in the study and to confirm eligibility. Following informed consent, the CRC will ask the patient to complete the identified screening tools for stress, depression, and anxiety, and for static risk factors for perinatal MH disorders, including prior experience of trauma, personal, familial MH history, and interpersonal violence, at multiple time points (Table 2; Appendix E). The proposed screening will include the following measures: the EPDS,[51] the GAD-7,[52] the PSS[50] along with risk factors questions regarding MH history, trauma, and interpersonal violence. Participants determined to be at "critical risk" via "yes" responses to both item 10 (suicidality) on the EPDS and screening question "Today I'm having difficulty with depression, anxiety, anger, or frightening thoughts" warrant an immediate on-site risk assessment and psychiatric emergency consultation, per standard of care available in each of the study sites and are ineligible for the study (Appendix B). Participants will be randomized into UC or Intervention. At T2, a team psychologist will perform a structured clinical interview to divide participants into two subgroups: (1) *subthreshold*: women who currently do not meet criteria for major depression or anxiety, or *threshold*: women meeting criteria for depression and/or anxiety. Follow-up visits will assess maternal depression, anxiety, and stress at T3-T9. Maternal risk and protective

Table 2. Prenatal, postpartum and pediatric follow-up

Screening	What (where)	Timing
T1	2nd OB visit (OB)	<20 weeks
T2	Structured Clinical Interview	20-24 weeks
T3	Glucose screening (OB)	24-28 weeks
T4	Hospital registration visit (OB)	30-34 weeks
T5	Last OB visit (OB)	40 weeks
T6	Postpartum visit (OB)	2 or 6 weeks
T7-T9	Pediatric well-baby visits	2, 6, 12 months
T10	Infant neurodevelopmental assessment	12 months

factors will be assessed at T3 and T6 (PDRQ only).
Eligibility: Inclusion criteria include:
(a) Black/of African Descent;
(b) pregnant (gestational weeks ≤ 28 weeks),
(c) age 18-45;
(d) English proficient;
(e) receiving services in one of the four study sites above;
(f) low-income: i.e., receiving Medicaid
(g) subthreshold or threshold risk for maternal distress (stress, depression, and/or anxiety); and
(h) able to provide consent.

Exclusion criteria include: (a) age <18; (b) currently under the influence of a substance(s); (c) experiencing psychosis; (d) critical (clinical) risk: actively suicidal or homicidal; e) not Black/of African Descent; and (f) planning to deliver outside DC.

To honor the heterogeneity of Black participants, once participants who self-identify as Black/of African Descent enroll in the study, we will also capture data about their country of birth and years in the U.S. if not born in the U.S. We will use questions to further characterize their ethnic heritage, adapted from "My Family's Cultural Background," part of the National Institute of Child Health and Human Development Study of Early Child Care and Youth Development. These questions include:

1. Describe your African heritage (e.g., African American, African Caribbean, Kenyan, Nigerian, South African, Ethiopian, Other (describe)_____.
2. Of the groups checked, what is the primary group that describes your ethnic heritage other than American? _____.
3. What national or cultural heritage do you most identify with?
   - ❏ My American (U.S.) heritage
   - ❏ My other heritage (named in Question #2)
   - ❏ Both my American and my other heritage about equally
   - ❏ Don't know

Data Collection and Storage

Data will be maintained in a secure database system (REDCap), housed on the Children's National Research Institute (CNRI) server, which will be used to track enrollment in the study, enter patient information, and enter/store questionnaire data. The REDCap database system is a password protected research database available to CTSA institutions. The REDCap data server is located behind the CNRI firewall and is protected against intrusion. Access to these data is limited to only those designated by the co-PIs. All hard copy data will be stored in locked file cabinets in a secure suite within the Developing Brain Institute at Children's National. Only study team members will have access to these files, and all will be trained in the importa nce of keeping files secure and confidential.

Statistical Considerations

Analysis Plan: To evaluate the impact of expanded care (Aim 2) on maternal MH and maternal-infant outcomes, we will compare outcomes across the two randomized treatment groups (1) Group 1 (UC) vs. (2) Group 2 (PN). Analyses will be considered as intent to treat. Given the longitudinal design of the study, we anticipate missing data during follow-up. Missing data rates per participant will be calculated per measure (e.g. GAD-7, PSS, etc.) with > 10% missing data considered for multiple imputation. Rates of maternal outcomes (e.g. infection, severe bleeding), pregnancy complications (e.g., pre-term delivery, gestational diabetes) will be compared using chi square or unconditional logistic regression. Healthcare utilization will be compared using repeated measures mixed models allowing for participant intra-correlation. The prevalence of depression, anxiety, etc. will be compared using unconditional logistic regression. Three analysis strategies are planned to assess the effect of treatment on depression (e.g. EPDS), anxiety (e.g. GAD-7) and stress (e.g. PSS). Analysis 1: compare the overall impact of Group 1 vs. Group 2; Analysis 2: assess the impact of overall impact of treatment in addition to

assessing risk groups (e.g. *subthreshold*/2a, *threshold*/2b) nested within Group 2; and Analysis 3: utilize the Analysis 2 framework (e.g. *subthreshold*/2a, *threshold*/2b nested within Group 2), but further assess the impact of Group 2 choices of (1) peer support only, and/or (2) adapted CBT. Initial group comparisons will focus on baseline characteristic using t-tests, chi-square, etc. to determine which characteristics may need inclusion within multivariate models (MV). Analyses 1-3 will utilize a latent growth model approach (LGM) to assess trajectories of rates of depression, anxiety, and stress until the end of the 12 postpartum-month study period. Models will focus on the effect of treatment (Group 1 vs. Group 2), time (9 visits for mothers), time (group by time interaction to assess whether trajectories differ between groups over time. Analyses 2 and 3 will include nesting terms for risk subgroup (*threshold* vs. *subthreshold*) and group 2 choices (peer support, adapted CBT, peer support + adapted CBT). Statistically significant covariates from univariate group comparisons (e.g. maternal age, GA, etc.) will be included as necessary. A two-sided p-value of 0.05 will be considered significant for all analyses.

Adequacy of the Sample: Sample size estimates were conducted using PASS15 based on Aim 2 (Group 1 vs. Group 2). All tests assume α= 0.05, β=.20, two-tailed. For the primary outcome of stress (PSS), a-priori results suggest a mean PSS prior to intervention ranges from approximately 10-21 (SD= 4.5-6.5). For our MCID (minimally clinically important difference), we chose a distributional approach of ½ the pre-intervention SD. Published literature suggests a 2.15 to 2.75 decrease in PSS score represents the MCID. Thus, we estimate an MCID equal to a 2-point decrease (15%) in total PSS score following intervention. This MCID of 2-points was derived via a simulation using published estimates assuming an average pre-intervention mean total PSS score of 14.50 (SD=4.72), a post-intervention total mean PSS score of 12.14 with risk subgroup nesting) using a repeated measures latent growth modeling approach. For Aim 2, secondary outcome were reduction in depression (EPDS) and anxiety (GAD7), a pre-intervention null rate of depression (EPDS score of 14/15, depressed) or anxiety (GAD7 score of 15-19, moderate/severe), and a post-intervention depression rate of 15% suggests 413-450 subjects (200-225 pe group) provides approximately 80% power, two-tailed, to detect a statistically significant reduction in maternal depression or anxiety. Any further decrease in EPDS or GAD7 from baseline (≥ 4-point decrease) will increase our study power and require fewer subjects.

STUDY POPULATION

We propose to prospectively screen 1,000 low-income pregnant women who are Black/of African Descent and 18-45 years of age using standardized screening tools for stress (Perceived Stress Scale [PSS]), anxiety (Generalized Anxiety Disorder 7-item Scale [GAD-7]), and depression (Edinburgh Postnatal Depression Scale [EDPS]) with the expectation of identifying 700 women eligible for enrollment into the intervention (Fig 5). Screening and enrollment will occur at three large D.C.-based delivery centers: George Washington University Hospital (GW), Howard University Hospital (HU) and Unity Health Care, a community outpatient health center.

Eligibility: Inclusion criteria include: (a) Black/of African Descent ; (b) pregnant (gestational weeks ≤ 28 weeks), (c) age 18-45; (d) English proficient; (e) receiving services in 1 of 4 study sites above; (f) low-income: i.e., receiving Medicaid (g) subthreshold or threshold risk for maternal distress (stress, depression, and/or anxiety); and (h) able to provide consent.

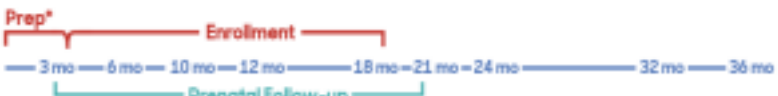
Exclusion criteria include: (a) age <18; (b) currently under the influence of a substance(s); (c) experiencing psychosis; (d) critical (clinical) risk: actively suicidal or homicidal; e) not Black/of African Descent; and (f) planning to deliver outside DC.

HUMAN SUBJECTS

Recruitment:

Recruitment will occur at three large D.C.-based delivery centers: George Washington University Hospital (GW), Howard University Hospital (HU) and Unity Health Care, a community outpatient health center. Low-income pregnant women who are Black/of African Descent will be identified through the obstetric clinics at these sites. Trained clinical research coordinators from CNH will review and sign consents with participants in person at their obstetric visit and enroll participants

Fig 5. Study Timeline



once the
consenting process is complete. As these will be adult participants with the ability to sign consent on their own behalf, assent and parental permission do not apply. Parental permission will apply at T10 (12 months postpartum) at which time participants will provide parental consent for their infants to complete a standardized neurodevelopmental assessment.

Consent:

The informed consent process will be initiated at the second prenatal visit.

It will be conducted in a private clinic room. Informed consent will be obtained from participants prior to the initiation of any research study activities. The consent form will supplement, not replace, dialogue between participants and research personnel.

Additional consent procedures that will be followed by the study team include:

●The informed consent document will be approved by each site's IRB/IRB of record; the study participants must sign a consent that has both a current IRB approval stamp and that reflects the most recent version of the research protocol.

● Potential participants will be allowed ample time to review the document and encouraged to ask questions.

●Copies of the consent document will be given to participants for their records.

●A study investigator will be available to answer any questions that arise during the informed consent process.

● Potential participants will be given as much time as they desire to decide whether or not to participate.

RISKS AND SIDE EFFECTS

Breach of Confidentiality. The primary risk to participating in this study is breach of confidentiality. While there are no known psychological risks to subjects when completing interviews or completing standardized psychological questionnaires, the questions may make the subjects feel uncomfortable in that they ask about their psychological health. Patients will be assured both verbally and in the written consent form that they can skip any questions that they do not wish to answer.

Severe stress, depression, anxiety and/or suicidality. We may identify patients who are severely depressed, stressed, anxious and/or suicidal during recruitment, screening, and/or while participating in the study. The research team will address the potential risk of increased suicidality in this study by following the guidelines for risk management protocols delineated by NIMH.[53] First, the CRCs who will have contact with participants will receive extensive training in crisis intervention and suicide risk assessment by the Dr. Le (co PI) and Dr. Danielson (co-investigator & lead of the Perinatal Mental Health Core). They will be trained to look for behavioral signs of depression (e.g., participant looks sad, seems upset or disturbed by the material, has blunted or flat affect, etc.). Second, participants will be told at the beginning of the study that confidentiality will be broken if participants are currently suicidal. These participants will be referred to mental health resources immediately following the study session to minimize embarrassing or humiliating the participant in question.

Should suicidality be identified at the first screening in the study (i.e. those who meet "critical risk" at Time 1), we will implement a suicide prevention plan to assess immediate risk for harm and secure treatment. If a participant endorses anything other than "never" (0) on item #10 "The thought of harming myself has occurred to me" on the EPDS or endorsement on a screening question: "Today I'm having difficulty with depression, anxiety, anger, or frightening thoughts", the following questions will be asked: 1) Do you think about killing yourself? If the answer is "Yes," then a follow up question is asked: 2) When was the last time you thought about killing yourself? If the answer is within the last month, the CRC will follow the risk protocol designated at each site for suicide screening, contacting the appropriate people on site for appropriate follow up care. Additionally, if there is risk of the participant hurting others (expressing thoughts of harming another), the CRC will follow the same protocol as listed above. This participant would not be eligible for the study.

Should suicidality be identified during the course of the study (T2-T10), the CRC will immediately contact the perinatal mental health (MH) specialist assigned to that study site, Dr. Danielson (co-investigator)

or Dr. Le (co-PI), and the Patient Navigator (PN) assigned to this participant. The Perinatal MH specialist, Drs. Danielson or Le, will conduct an assessment of the participant's suicidality risk in person or by telephone. These mental health professionals will work closely with the PN, research team, and study sites to develop a safety plan, which may involve referral back to the
Perinatal MH specialist (i.e., if the participant was already receiving CBT intervention), or Emergency Department at a nearby hospital for evaluation for psychiatric hospitalization. All participants will be given the number to the National Suicide Prevention Hotline and additional resources in the D.C. area. Drs. Danielson and Le are licensed psychologists in Washington, D.C. Dr. Danielson, founder and director of the Women's Mental Health Program at MedStar Georgetown University Hospital, specializes in women's perinatal mental health and regularly sees clients in this program. Her clinical practice focuses on treating mood and anxiety disorders in pregnancy and postpartum, as well as supporting women through the transition to motherhood. Dr. Danielson regularly assesses for suicidality in her clinical practice. Dr. Le has conducted several clinical research studies with mothers at high risk for depression and supervises clinical graduate students who see many depressed patients, requiring suicidality assessments. In addition, each of the four study sites has a standard protocol for dealing with these situations, including making appropriate referrals as necessary, which will be reviewed prior and quarterly throughout study implementation. The CRC also will inform the co-PIs and on-site clinicians and patient navigators. A similar protocol for follow up would be instituted for patients at risk for hurting others.

Child abuse. Participants will be told (verbally and in writing) during the informed consent process that we are required to report any instances of child abuse or neglect. If participants report information that suggests the possibility of child abuse or neglect, a clinician will be available by phone to evaluate the potential risk for the presence of child abuse. If risk for child abuse is suspected, a clinician will discuss the situation with the participant, and inform the participant of the advisability of making a report to the Child Protective Services (CPS), and tell them that the clinician is required to contact CPS. If, upon inquiry, there is no evidence of child abuse, the participant will be given a list of emergency numbers to be used if this should become necessary in the future.

BENEFITS

This study has the potential for both direct (and indirect) benefit to low-income women who are Black/of African Descent and of childbearing age who are suffering from stress, depression and anxiety. These data will illustrate if the interventions (PN, adapted CBT and/or peer support groups) are successful in increasing engagement and retention in the healthcare system, reducing risk for maternal distress and improving maternal and/or infant health and behavior outcomes. In addition, study participants will benefit from extra monitoring during their pregnancy and interventions that target their level of risk severity, providing appropriate follow-up mental health care. During postpartum care, mothers and babies may benefit from maternal interventions as well as neurodevelopmental assessments for the baby through 12 months of life.

Importance of Knowledge to be Gained

Stress, depression and anxiety during pregnancy are under-studied public health issues that have significant consequences on population health outcomes. The ultimate long-term goal of this research is to elucidate the risk factors for maternal stress, anxiety and depression during pregnancy and postpartum among low-income African American women. If we demonstrate the effectiveness of these interventions (navigation and adapted CBT – both prevention and treatment, peer support groups), there will be opportunities to expand such services to manage perinatal mental health distress in other obstetrics and pediatric settings, where women are more likely in their lifetimes to seek health care for themselves and for their children. The potential reach of the findings is great locally, nationally and internationally.

OUTSIDE CONSULTANTS/COLLABORATORS

None.

CONTRACTUAL AGREEMENTS

Huynh-Nhu Le, PhD – George Washington University (Subcontract)
Loral Patchen, PhD – MedStar Washington Hospital Center "MHRI" (Subcontract)

Jennifer Keller, MD – George Washington University/Medical Faculty Associates/OB: (Subcontract)
Kristin Atkins, MD – Howard University (Subcontract)

COSTS TO SUBJECTS
None.

CONFLICTS OF INTEREST
None.

CONFIDENTIALITY

All protected health information will be de-identified prior to analysis and reporting in compliance with HIPAA regulations and CNMC institutional policies. All protected health information collected will be linked to a study ID code. The study ID code will be assigned by the investigator. The linkage key and the PHI will be maintained separately in locked file cabinets in a locked office accessible only by study staff. The database will be password protected and accessible only by study staff. No PHI will be stored on thumb drives. PHI will be stored for three years following the completion of the study also in locked file cabinets in a locked office accessible only by study staff. Data will be disposed of according to CNMC institutional standards three years after the completion of the study.

SUBJECT COMPENSATION
Focus groups will be conducted before the RCT study. The purpose of these virtual focus groups is to elicit additional feedback on the interventions (patient navigation, peer support group, and prevention and treatment) from relevant stakeholders (women of Black/African descent) with lived experiences with maternal distress, health and/or mental health experiences in the DC area. Each participant will be paid $50 for their time. Participants will include the context experts team (n=6 in the DC-PCA's Maternal Health Equity Action Lab) who previously participated in 6 focus groups with our research team and other women in the DC area.

Table 1. Participant compensation (N=700)

Time in Study	Timing	Measurement	Location	Participant Fee
T1	<20 weeks (2nd OB visit)	Maternal self-report measures	OB	$15
T2	20-24 weeks	Structured Clinical Interview	OB	$20
T3	24-28 weeks (glucose visit)	Maternal self-report measures	OB	$20
T4	30-34 weeks (hospital registration paperwork)		OB	$20
T5	40 weeks (last OB visit)		OB	$20
T6	2 or 6 weeks PP (Pediatric well visit/Ped)		Ped	$30
T7	2 months PP (Ped)		Ped	$30
T8	6 months PP (Ped)		Ped	$30
T9	12 months PP (Ped)		Ped	$30
T10	12 month PP	**Baby:** Bayley Scales of infant/toddler development	Children's National Hospital	$60
Total per participant in UC for measure compensation T1-T10 (n=350)				**$275**
Total per participant in Patient Navigation + Prevention (8 sessions: $10/session for transportation = $80) + $275 measure compensation (n=245)				**$355**
Total per participant in Patient Navigation + Treatment (12 sessions: $10/session for transportation = $120) + $275 measure compensation (n=105)				**$395**

All participants will be compensated for their time in answering questionnaires, as listed above, from T1 to T9. At T10,

Women in both the intervention arm (prevention and treatment) will be compensated for transportation to attend their sessions at the OB site ($10/session; PN-Prevention at 8 sessions = $80; PN-Treatment at 12 sessions=$120).

To facilitate retention for participants in the study, incentives will be offered at three time points with increasing amount over time. In total, participants who receive UC only will receive $275. Participants randomized in to INT (Prevention) condition (n=245) will receive an additional $160 and to INT (treatment) condition (n=105) will receive an additional $120.

FACILITIES AND EQUIPMENT

All study procedures will take place at CNH, GW, HU and Unity.

SAFETY ASSESSMENTS AND REPORTING

All suspected adverse reactions to study observations that are both serious AND unexpected will be reported to the IRB.

ETHICAL CONSIDERATIONS

Ethical Standard

The study team will ensure that this study is conducted in full conformity with the Regulations for the Protection of Human Subjects of Research codified in 45 Part 46 of the Code of Federal Regulations, Children's National Policies and Procedures and Good Clinical Practices.

Institutional Review Board (IRB)

The protocol, informed consent form(s), recruitment materials, and all participant materials will be submitted to the Children's National, HU andGW IRBs for review and approval. Approval of both the protocol and the consent form will be obtained before any participant is consented. Any change to the protocol, consent, recruitment materials and participant information sheets or letters will require IRB approval before implementation and use. The IRBs will determine whether previously consented participants need to be re-consented and whether consent of more than one parent is required for minors.

The IRBs will be notified of study team updates via an amendment. Reports from regulatory oversight bodies will be submitted at the time of the continuing review or with another applicable IRB transaction.

Other study events (e.g., protocol deviations, unanticipated problems) will be submitted per the Children's National, HU and GW IRB Reportable Events Module.

Maintaining Subject Privacy

Every effort to protect subject privacy and confidentiality will be maintained, including using a private area for consenting, and immediately de-identifying data and the secure storage of all data.

Maintaining Study Data Confidentiality

Participant confidentiality is strictly held in trust by the participating investigators, their staff, the sponsor and their agents. Therefore, the study protocol, documentation, data, and all other information generated will be held in strict confidence. No information concerning the study or the data will be released to any unauthorized third party without prior written approval of the sponsor.

The sponsor representatives and regulatory authorities (e.g., IRB, OHRP) may inspect all documents and records required to be maintained by the investigator. The study team will permit access to such records.

The study participant's contact information will be securely stored at each study site for internal use during the study. At the end of the study, all research records will be stored in a secure location for the time period dictated by the sponsor and institutional regulations.

The research data will not include the participant's contact or identifying information. Rather, individual participants and their research data will be identified by a unique study identification number. The study data entry and study management systems used by research staff will be secured and password protected. At the end of the study, all study databases will be archived at Children's National.

Study Support and Conflicts of Interest

Salary support for this study is provided by Patient-Centered Outcomes Research Institute (PCORI) and Children's National Developing Brain Institute. REDCap® support is provided by The Clinical and Translational Science Institute (CTSI) at Children's National. All key study personnel will follow the Human Research Protections Program Investigator, Study Staff, and Family Member Conflicts of Interest (COI) Policy.

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