HHS Public Access

Author manuscript

Brain Behav Immun Integr. Author manuscript; available in PMC 2024 July 19.

Published in final edited form as:

Brain Behav Immun Integr. 2024 April ; 6: . doi:10.1016/j.bbii.2024.100060.

Protocol for a pilot study assessing a virtual mindfulness intervention for postpartum African American women

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Abstract

Elevated perinatal depressive symptoms are more common among disadvantaged African American women, and they are almost four times as likely to have postpartum posttraumatic stress compared to white women. For new mothers, depressive symptoms and posttraumatic stress can lead to negative parenting, poor mother-infant bonding, and delayed infant development. For African American women, a culturally adapted mindfulness-based intervention offers great potential as an acceptable approach to reduce psycho-behavioral symptoms and improve mother-infant interactions (i.e., bonding). Additionally, it is critical that mindfulness interventions consider time constraints of new mothers, provide accessible intervention delivery, address parenting, and consider the challenges of caring for an infant. Given these considerations, we describe a pilot research protocol in which we evaluate a culturally adapted mindfulness program: *Mindfulness for African Americans Postpartum* (MAAP). The intervention is based upon Kabat-Zinn's Mindfulness Based Stress Reduction program, but is adapted to include culturally relevant concepts of spirituality, inter-dependence, self-empowerment, and storytelling, which are salient to African American culture. To accommodate the needs of new mothers, a certified mindfulness interventionist delivers each session virtually using Zoom. The investigation uses a randomized controlled design in which African American women within 12 months of giving birth are randomized either to the MAAP intervention or to an Education Program. The primary aim is

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Declarations of interest

None.

CRediT authorship contribution statement

Lindsey Garfield: Writing – review & editing, Writing – original draft, Validation, Resources, Project administration, Methodology, Investigation, Funding acquisition, Formal analysis, Data curation, Conceptualization. **Linda Witek Janusek:** Writing – review & editing, Writing – original draft, Supervision, Resources, Methodology, Investigation, Funding acquisition, Formal analysis, Data curation, Conceptualization. **Herbert L. Mathews:** Writing – review & editing, Writing – original draft, Supervision, Resources, Methodology, Investigation, Funding acquisition, Data curation, Conceptualization. **Natalie N. Watson-Singleton:** Writing – review & editing, Writing – original draft, Methodology, Investigation, Funding acquisition, Data curation, Conceptualization.

to determine the extent to which the MAAP intervention decreases maternal psycho-behavioral symptoms (perceived stress, depressive symptoms, anxiety, poor sleep, posttraumatic stress, and fatigue) and improves mother-infant bonding. A secondary aim is to explore the effects of MAAP on proinflammatory cytokines and oxytocin. Culturally adapted mindfulness interventions delivered virtually will make mindfulness more accessible and meaningful to populations, like African American new mothers, who are at higher risk for postpartum mood disorders and poor infant outcomes.

Keywords

Digital Mindfulness; Postpartum African American Women; Psycho-Behavioral Symptoms; Proinflammatory Cytokines; Oxytocin

Background

Postpartum mood disorders

New mothers may experience an overwhelming array of emotions during the postpartum period (Iwanowicz-Palus et al., 2021; Rai et al., 2015). These emotions may range from intense feelings of joy and love to loneliness, guilt, and depression (Finlayson et al., 2020). In combination with postpartum biological changes, psychosocial changes, and stressors, such as sleep deprivation, postpartum mothers may have an increased risk of postpartum mood disorders (Iwanowicz-Palus et al., 2021; Baattaiah et al., 2023). Postpartum mood disorders range from maternal blues, depression, anxiety, post-traumatic stress, to maternal psychosis (Rai et al., 2015; Garapati et al., 2023). Estimates suggest up to 50% of new mothers experience postpartum psycho-behavioral symptoms (stress, depressive symptoms, anxiety, poor sleep, posttraumatic stress, and fatigue) related to mood disorders (Chung et al., 2004; Beck, 1996; Moses-Kolko and Roth, 2004). Moreover, postpartum mood disorders may be present years after giving birth, (Putnick et al., 2020; Vliegen et al., 2014) with many women not receiving a diagnosis or treatment for these conditions (Marcus et al., 2003).

On average, 19% of new mothers report elevated postpartum depressive symptoms, (Minkovitz et al., 2005) with onset occurring 4–6 weeks postpartum and symptom duration lasting 1–3 years postpartum (Putnick et al., 2020; Vliegen et al., 2014; APA, 2013; Gavin et al., 2005). Postpartum posttraumatic stress occurs in 9.5% of women experiencing a traumatic childbirth (Milosavljevic et al., 2016). This form of stress is characterized by re-experiencing the event, avoiding stimuli related to the birth, and having negative thoughts (APA, 2013). Mothers who experience postpartum posttraumatic stress and elevated depressive symptoms, are more likely to experience further negative outcomes including parental stress, (Leigh and Milgrom, 2008) and negative parenting practices, (Field, 2010; Forcada-Guex et al., 2011) which may place their infant at risk for delayed development (Steer et al., 1992; Field et al., 2006; Pierrehumbert et al., 2003). Mothers with depressive symptoms are also at risk for impaired mother-infant interactions, (McLearn et al., 2006; Poehlmann and Fiese, 2001; McIntosh et al., 2004) which can lead to insecure bonding and poor parenting behaviors (Taylor et al., 2005). Such behaviors manifest as decreased responsiveness to their infant and insecure attachment relationships (McLearn et al., 2006;

Poehlmann and Fiese, 2001; McIntosh et al., 2004). In addition, mothers with depressive symptoms have elevated risk for cardiovascular disease, immunosuppression, fatigue, and negative health behaviors (e.g., poor diet, drug/alcohol abuse, and poor sleep) (Poudevigne and O'Connor, 2006; Kendall-Tackett, 2005; Mussolino, 2005; Johnston et al., 2004; Corwin et al., 2005). Thus, these women need interventional assistance.

Postpartum depression and posttraumatic stress in African American women

Elevated postpartum depressive symptoms are far more common among disadvantaged African American women (40–60% vs 19% national average), (Giscombe and Lobel, 2005; Williams et al., 1997; McLoyd, 1998; Liu and Tronick, 2013) and they are almost four times more likely to have posttraumatic stress (13.4% vs 3.5%), compared to white women (Seng et al., 2011). Additionally, postpartum mood disorders are more common in women who deliver a low birth weight or preterm infant (Singer et al., 1999; Kersting et al., 2004; Trumello et al., 2018). African American women are twice as likely to have a low birthweight (LBW) infant (13.2% vs 7%) (Hamilton et al., 2015) and 1.6 times more likely to have a preterm infant (16.3% vs 10.2%) compared to white women (Martin et al., 2015). This places African American women at high risk for postpartum mood disorders (Chung et al., 2004; Younger et al., 1997). Moreover, African American women with postpartum mood disorders are at high risk for negative mother-infant interactions, which jeopardize infant emotional, motor, and mental development (Singer et al., 1999; Rahman et al., 2002; Lyons-Ruth et al., 1986; Martins and Garffan, 2000). These findings emphasize the profound impact that psycho-behavioral symptoms may have on the future health of African American women and their infants.

The need for mindfulness for postpartum African Americans

Mindfulness Based Stress Reduction (MBSR) is a structured program used to teach mindfulness strategies to reduce physical and psychological symptoms of stress (Grossman et al., 2004). Ample evidence demonstrates MBSR to be a means by which to self-regulate emotions and to provide life-long skills that can be practiced anytime or anywhere (Davis and Hayes, 2011). Interviews and focus groups demonstrate that African American women believe that mindfulness interventions need to be culturally adaptated (Proulx et al., 2018; Watson-Singleton et al., 2019). Key cultural adaptations of mindfulness include using African American women as interventionists and providing course material that use written and artistic expressions of African American culture. Other adaptations include incorporating storytelling that resonates with African Americans' experience, fostering a sense of community among research participants, and including self-empowerment strategies (Watson-Singleton et al., 2019). Yet, existing mindfulness programs are rarely culturally adapted for African American populations.

Several studies evaluated mindfulness-based interventions for perinatal women. For example, a pilot study, not specific for African American women, demonstrated that mindfulness decreased stress, depressive symptoms and anxiety in mothers with infants in the neonatal intensive care unit (NICU) (Mendelson et al., 2018). Another study, also not specific for African American mothers, included mindfulness as part of an educational program for mothers of infants in the NICU. The findings of that study revealed that

mindfulness improved maternal psycho-behavioral symptoms (Mendelson et al., 2018; Petteys and Adoumie, 2018; Marshall et al., 2019). Other researchers reported several challenges when investigating whether mindfulness-based interventions reduced stress and depression in pregnant African American women (Zhang and Emory, 2015; Dutton et al., 2013). Those challenges were high attrition, decreased attendance, unacceptance of mindfulness as a secular practice, and stigma associated with revealing psycho-behavioral symptoms (Dutton et al., 2013). African American women were also hesitant to recommend mindfulness due to lack of congruence with their spirituality (Woods-Giscombe). Thus, there is a need for culturally adapted MBSR interventions to be meaningful and acceptable to African American women (Proulx et al., 2018; Watson-Singleton et al., 2019; $author1$ et al., 2014).

Digital mindfulness for perinatal women

Perinatal mindfulness programs need to accommodate a new mother's schedule, which centers on the care of their newborn, and for some, the care of other children. A growing body of research support the success of teaching mindfulness on a digital platform (Garfield and Watson-Singleton, 2020; Mrazek et al., 2019). A systematic review and meta-analysis of 13 randomized controlled trials (N = 1373 women) evaluating the efficacy of digital-based mindfulness interventions for pregnant women found digital-based mindfulness to significantly reduce anxiety and depressive symptoms, but not symptoms of stress (Mrazek et al., 2019). Yet, of the limited studies evaluating digital mindfulness for perinatal women, some investigators report attrition and lack of participant engagement as barriers to success (Mefrouche et al., 2023; Osborne et al., 2023; Goetz et al., 2020). For example, a self-guided online mindfulness course for pregnant women that consisted of ten interactive sessions experienced a high non-completion rate (Zhang et al., 2023). In contrast, another study of a self-guided online mindfulness program for postpartum women experienced an 84% completion rate. That study found mindfulness to reduce depression, anxiety, and pregnancy-related anxiety symptoms, as well as to improve infant temperament and developomental behavior (Goetz et al., 2020). A smart-phone based mindfulness intervention consisting of readings, recordings of guided practice, videos, and push reminders reported a lower dropout rate (35%) and significant reductions in maternal anxiety and depression compared to an attention control group (online health consultation) (Krusche et al., 2018). Although these findings are encouraging, lack of participation and engagement are key concerns when digital interventions are used for perinatal women (Sun et al., 27 2021). This may be due to the often self-guided nature of digital apps and websites, which may lack video and/or contact with an interventionist (Davis et al., 2022; Cuijpers et al., 2019). Creating an online intervention with components that encourage participation, engagement, sense of community, and interactions between the interventionist and participants would offer a more acceptable and engaging intervention.

Inflammation and oxytocin as plausible mediators of stress reduction

Increased inflammation and reduced oxytocin levels may play a role in stress-related symptoms, and interventions (e.g. mindfulness) may reduce psycho-behavioral symptoms by modifying inflammatory and/or oxytocin pathways. This notion is supported by ample evidence which demonstrates that psychological stress induces elevations in

proinflammatory cytokines, and (Shim et al., 2017; Liu et al., 2017) elevated inflammation is found in pregnant African American women with depressive symptoms (Liu et al., 2017; Connor and Leonard, 1998). Stress, (Cassidy-Bushrow et al., 2012) depressive symptoms, (Selye, 1984) anxiety, (Dantzer et al., 1999) poor sleep, (Michopoulos et al., 2017) posttraumatic stress, (Irwin and Opp, 2017) and fatigue (Gola et al., 2013) are linked to inflammatory processes through the hypothalamic pituitary adrenal (HPA) axis and the kynurenine tryptophan pathway. It is possible mindfulness will reduce behavioral symptoms through attenuating inflammation. Emerging data show mindfulness reduces proinflammatory cytokine levels in non-postpartum samples, (Lacourt et al., 2018; Witek Janusek et al., 2019; Black and Slavich, 2016) including reductions in the levels of the proinflammatory cytokines IL-6 and TNF-alpha (Witek-Janusek et al., 2008; Bower et al., 2015; Jedel et al., 2014; Rosenkranz et al., 2013) Further, MBSR participants who exhibit reductions in TNF alpha and lL-6 also report reductions in stress, depressive mood, fatigue, and sleep disturbance (Lacourt et al., 2018; Black and Slavich, 2016).

Oxytocin is released in response to positive social interactions, vaginal stimulation, labor progression, and lactation (Creswell et al., 2012). In contrast, negative emotions, anxiety, and pain inhibit the release of oxytocin (Gimpl and Fahrenholz, 2001; Uvnas-Moberg et al., 2005). Oxytocin promotes maternal behaviors (Gimpl and Fahrenholz, 2001; Uvnas-Moberg and Petersson, 2005; Altemus et al., 2001, 1995; Uvnas-Moberg, 2003; Uvnas-Moberg and Carter, 1998; Pedersen et al., 1982) and facilitates bonding between mother and child (Heinrichs and Domes, 2008; Bales and Carter, 2003; Carter, 1998; Carter et al., 2005). For example, high levels of oxytocin associate with increased maternal gaze, vocalization, positive affect, and touch (Cushing and Carter, 2000; Feldman et al., 2007). In contrast, low levels of oxytocin are linked to altered patterns of mother-infant interactions including less touch, (Levine et al., 2007) Oxytocin down-regulates the adrenal and behavioral response to stress (Uvnas-Moberg et al., 2005; Feldman et al., 2012; Engelmann et al., 2004; Taylor et al., 2006) Oxytocin is inversely related to stress, (Machatschke et al., 2004) depressive symptoms, (Jezova et al., 1995) anxiety, (Purba et al., 1996) poor sleep, (Windle et al., 1997) posttraumatic stress, (Lancel and DNeumann ID, 2003) and fatigue (Garfield et al., 2019). We previously identified that low oxytocin levels are associated with increased postpartum depressive symptoms and posttraumatic stress (Lancel and DNeumann ID, 2003; Tops et al., 2007). Others report low oxytocin levels are associated with higher maternal psycho-behavioral symptoms (Purba et al., 1996) (e.g., stress, (Machatschke et al., 2004) depression, (Jezova et al., 1995) and anxiety). For African American women, low oxytocin levels are associated with increased depressive symptoms (Tops et al., 2007; Garfield et al., 2015). Moreover, oxytocin has demonstrable anti-inflammatory effects (Garfield et al., 2014; Jankowski et al., 2010; Carter et al., 2020) It is possible that mindfulness may reduce psycho-behavioral symptoms in postpartum African American women through inflammatory and/or oxytocin pathways.

Study intervention development—We developed the *Mindfulness for African Americans Postpartum* (MAAP) intervention by drawing from the 8-week Kabat-Zinn MBSR program as well as the recommended cultural adaptations to mindfulness for African Americans (Proulx et al., 2018; Watson-Singleton et al., 2019). The MAAP program is 8

weeks long (1 hr/wk) and the weekly session topics are based upon those of the Kabat-Zinn MBSR program. Each week focuses on learning more about mindfulness exercises and practicing mindfulness together. Mindfulness is taught using exercises such as mindful eating, sitting mindfulness, being present, yoga, mindful prayer, and working with emotions.

We adapted the MAAP program by using African American writings/illustrations, fostering storytelling, building space for self-empowerment, and using spiritual-based activities to develop mindfulness skills (Carter, 2014). The MAAP also emphasizes community building among study participants, which is an important cultural value that can promote intervention engagement and retention. Each session addresses a culturally relevant concept, as outlined in the Methods. In addition to these cultural adaptations, the program addresses parenting and considers the challenges of caring for an infant.

The MAAP intervention uses Zoom technology to teach mindfulness virtually. This approach provides greater accessibility and convenience for postpartum mothers, as it reduces time, transportation, and, for many, childcare barriers. Virtual mindfulness sessions also increase the opportunity for African American women to complete the program in their own comfortable and familiar surroundings. An interventionist conducts the group synchronous Zoom sessions using the video option. This approach cultivates trust with the interventionist, promotes individual motivation, and reduces attrition.

Methods

Study design

This pilot study compares an 8-week *Mindfulness for African Americans Postpartum* (MAAP) intervention to an 8-week Educational Program (active comparison group). The Educational Program is matched with respect to the delivery format, frequency, and duration of the MAAP intervention. The study is ongoing. Participants are randomized to either the MAAP intervention or the Educational Program.

Study aims

The primary aim is to determine the extent to which the MAAP intervention decreases maternal psycho-behavioral symptoms and improves mother-infant bonding. We hypothesize that the MAAP intervention, when compared to the Education Program, will reduce behavioral symptoms (perceived stress, depressive symptoms, anxiety, poor sleep, posttraumatic stress, and fatigue). Further, MAAP is hypothesized to improve mother-infant bonding. A secondary aim is to explore the effects of MAAPI on proinflammatory cytokines and oxytocin. We hypothesize that participants completing the MAAP intervention will exhibit reduced salivary proinflammatory cytokines and increased salivary oxytocin levels as compared to participants completing the Education Program.

Setting

Both MAAP and the Educational Program (control condition described below) are delivered online (i.e., virtual group synchronous sessions by Zoom). A certified mindfulness interventionist facilitates each session. After enrollment, participants attend eight weekly

one-hour Zoom sessions. Data collection includes completion of online questionnaires. Face-to-face meetings are scheduled with a member of the research team to collect saliva samples at weeks 1, 4, and 8. These face-to-face encounters are at an agreed upon location, such as the collaborating medical center or the participants' home. Due to the face-to-face encounters, all participants reside within the Chicagoland metropolitan area.

Participants

Participants are women over the age of 18 years who identify as African American, and who speak and read English at or above a 5th grade level. The women will have given birth to an infant within the past 12 months. They also are asked to be willing to comply with study procedures, provide saliva samples, have access to a smart phone, and agree to download the Zoom app. Exclusion criteria include use of immune altering medications (e.g. steroids) or diagnosis of an immune altering disease.

Sample size

For each study aim, a prospective power analysis estimated that a sample size of N=40 (20/group) will achieve 80% power. Based on our pilot and published data, (Woods-Giscombe and Black, 2010; Feldman and Eidelman, 2004; Groer and Morgan, 2007;Putnam) the effect size was estimated at 0.70 for anxiety, 0.45 for prenatal stress and 0.8 for sleep quality, 0.40 for depressive symptoms, and 0.36 for proinflammatory cytokines. A sample of 40 will give 80% power to detect a difference as small as 0.5 ng/ml in plasma IL-6 (0.36 ×1.4 SD) and 0.81 ng/ml in plasma TNF (0.36 ×2.24 SD), 0.6 units (0.40 ×1.5 SD) in depressive symptoms, 22.5 units (0.45 ×50.0 SD) in prenatal stress, and 0.58 units (0.8 ×0.72 SD) in sleep quality, at α=.05. Variables tested will be adjusted for control variables assumed to explain 15% of variance in outcomes. For HLM analyses, power was calculated via Optimal Design Software (Witek Janusek et al., 2013). A sample of 40 will have 80% power to detect an effect size of 0.72 using a longitudinal design with three observations, assuming orthogonal design and random effects covariance structure. For multivariate regression models, a sample of 40 achieves 80% power to detect an R (Rai et al., 2015) of 0.16, attributable to predictor variables (F-test, $\alpha_{=}$.05 two-tailed).

Recruitment

We use three approaches to recruit participants, all of which have Institutional Review Board (IRB) approval. The first is a multistep process that uses the institution's Epic database (permission was obtained from the institution's Medical Director). A list of names, addresses, and phone numbers of women who meet study criteria is reviewed. Potential participants are mailed recruitment materials consisting of an introductory letter from the Medical Director, a letter from the principal investigator (PI), and a recruitment flyer. Those receiving the letters who want to opt out of any further study communication are instructed to leave a phone or text message at the research office number. Two weeks after mailing the letters those who do not opt out, receive a text message, followed up by a phone call. Any potential participant who does not respond to the text message or phone call are contacted one more time via text and phone. If no response, further communication from the study ceases. Interested participants who call or text the study office are further screened for

eligibility and given an explanation of the nature and purpose of the study. Informed consent is obtained at a face-to-face appointment.

A second approach is to recruit participants in person. Members of the research team, unit nurses, or physicians identify potential participants from the unit's daily census report. [We received a waiver of consent and HIPAA for the identification of potential research participants.] Women identified from the census report are approached, introduced to the research study, and given a recruitment flyer with the study contact information. Those expressing interest in learning more about the study are asked if a member of the research team could call or visit them in their hospital room to explain the study. If a potential participant reaches out to the study via phone, text, or email a member of the study team responds to answer questions and to provide additional information about the study. All participants provide informed consent at a face-to-face appointment.

The third recruitment approach uses social media. The study recruitment flyer describing the study's purpose and study contact information is posted on the Instagram and Facebook page of the PI and the University. Members of the research team respond to calls, emails, or texts from interested individuals.

Randomization

Randomization employs an electronic randomization list, using a block size of four participants. The MAAP intervention and Educational Program have a fixed time of eight weeks, and run continuously. This provides an eight-week period for recruitment of a minimum of four participants to ensure two to four participants per group. Research team members, including the PI, who obtain informed consents, are blinded to the randomization list. After obtaining informed consent, the participant is assigned to the appropriate group. Blinding the participant is not possible as the MAAP group includes mindfulness exercises and stress reduction. All analyses will be performed without knowing group assignments.

Intervention condition - MAAP

The MAAP intervention is based upon that of Jon Kabat-Zinn (Optimal Design for Longitudinal and Multilevel Research, 2011). MAAP is 8 weeks long (1 hr/wk) and includes the following weekly topics: 1) Tasting Your Life, 2) Seeing and Believing, 3) The Scent of Roses, 4) When Life Hurts, 5) Hearing Your Own Cries, 6) Embracing Inner Peace, 7) Holding On, 8) Welcoming Stillness. In addition, the MAAP program is adapted to be culturally relevant to African American postpartum women with each session addressing a culturally relevant topic. Those topics are: (1). Creating a Community, (2) Role of African American Mothers, (3) Relationship Between Prayer and Mindfulness, (4) Relationship Between Pediatric Healthcare Providers and Mothers, (5) Racism and Unique Stressors Experienced by African American Mothers, (6) Inner Strength and Validating African American Voices, (7) Self-Empowerment and Personal Power, and (8) Acknowledgement of Today. African American women randomized to the MAAP group receive a program workbook (5th grade level) containing objectives, weekly MAAP activities, and video mindfulness practice links. The MAAP intervention manual details protocols for each session.

Intervention fidelity and integrity

Intervention fidelity is maintained by using strategies set by "Best Practices and Recommendations from the NIH Behavior Change Consortium" (Kabat-Zinn, 1996) including trained provider, delivery of treatment, receipt and enactment of treatment skills. All cohorts receive the intervention by trained mindfulness facilitators (not the PI) who identify as women of color. The interventionist uses a standardized session-by-session workbook. At the start of each MAAP cohort, the interventionist reviews program objectives, content, and delivery approaches to ensure equivalence and prevent "decay" of delivery over time. The interventionist ensures transfer of skills by asking questions, discussing material, and monitoring skill development at each class.

Intervention integrity is maintained using mechanisms that satisfy Dane and Schneider's five dimensions of intervention integrity: adherence (extent to which program objectives are met), quality of delivery (interventionist effectiveness), exposure ("dosage"), participant responsiveness (engagement), and program differentiation (Bellg et al., 2004). Exposure and participant responsiveness is monitored by recording attendance at sessions. Due to the online nature of the intervention, crossover between groups is not possible as participants are given a specific Zoom link for their assigned group. Subjects are requested not to enroll in any other stress reduction or mind-body programs during the study.

Control condition - educational program

The 8-week Educational Program is matched in duration, frequency, delivery method, and data collection to the MAAP intervention. Like MAAP, it is delivered using online/Zoom weekly classes. Weekly session topics are: 1) Perineum and Incision Injury, 2) Safe Sexual Practices, 3) Understanding Infant Feeding Methods, 4) How to Communicate Effectively with your Child's Health Care Providers, 5) Healthy Eating, 6) Infant Changing and Baths 7) Infant Safety at Home, and 8) Utilizing Support from Family and the Community. An expert perinatal clinician/educator leads the Education Program sessions. Fidelity is similar to that described above for the MAAP intervention. Content is set and delivered consistently across cohorts. Subject receipt is monitored by attendance. Sessions do not include content on stress reduction (yoga, meditation, etc.).

Increasing compliance and decreasing attrition

Multiple culturally adapted strategies are used to maximize subject recruitment and retention (Yang et al., 2017; Liu et al., 2013). Mindfulness sessions incorporate the concepts of spirituality, self-empowerment, and interdependence (State-Trait Anxiety Inventory for adults, 1983; Spielberger et al., 1970). Additionally, the MAAP workbook is specific to African American women, including writings and artistic expressions by African American women and use of images of African American women in meditation/yoga poses (Liu et al., 2013). Further, research team members are trained in culturally-based strategies for subject retention and follow-up. Informed consent is obtained at a private location determined by the participant. Participants may choose their home, their family members' home, or the medical center. We encourage participants to have a family member or friend present during the informed consent process. At weeks 1, 4, and 8 participants answer questionnaires, provide saliva samples, and receive a $50 gift card (total amount is $150).

Another strategy employed is the integration of technology into the communication, intervention delivery, and outcome assessment. Our study phone line has texting ability and multiple research team members have access to respond to participants. Phone messages are recorded and emailed to the research team. Participants are sent weekly reminders of their Zoom session with the Zoom link and then again at the time of their Zoom session. This makes attending the Zoom sessions more flexible as participants attend from their phone by clicking a link received by a text. Our Zoom link for each cohort remains the same throughout the eight weeks to make joining the Zoom session easier. We also use texting to set up the three face-to-face contacts for saliva collection. Participants who miss a session are texted or called to determine the reason for their absence and address any concerns that may inhibit participation in the project.

Measures

Table 1 summarizes the outcome measures and times of their measurement. Measures are obtained for both the MAAP and the Educational Program at baseline, week 4, and week 8 (study conclusion). Women complete study questionnaires through a secured online platform and make an appointment with a member of the research team for collection of saliva. Study questionnaires are self-administered. Primary outcome variables are stress, depression, anxiety, post-traumatic stress, sleep, fatigue, mindfulness, and mother-infant bonding. Oxytocin and proinflammatory cytokines are measured in saliva as secondary outcomes.

Data and safety monitoring plan

Mindfulness is a low-risk, non-invasive intervention. A data and safety monitoring plan is in place to monitor unexpected adverse events. We anticipate any adverse events to be related to mental health. Participants answer questionnaires that may bring up their birth experience or their newborn's health. Additionally, during the mindfulness sessions, conversations may include birth experiences and discussions about newborn healthcare. Questionnaires assessing depressive symptoms are scored within 48 hours and any participants scoring "at risk" will be contacted via phone and screened for suicidal ideations. Any participant who reports suicidal ideation are assessed for immediate danger to themselves or others and emergency services are called and sent to their home if needed. Participants without suicidal ideation are provided resources. These resources may include mental health provider contact, emergency mental health resource line, help in setting up a mental health appointment, and an option for a member of the study team to discuss this finding with a participant family member or friend.

A second possible adverse event is loss of confidentiality. To decrease this risk, the study procedures ensure integrity and accuracy of data and protection of confidentiality of participant data. All questionnaires are labeled with the study participant's identification (ID) code and no identifying information. Questionnaires are de-identified and entered into a digital file. Demographic, identifying data, and participant consents are securely stored in a locked file cabinet located in a locked office and a secured building. Saliva samples are labeled with the participant ID and no identifying information. Additionally, during the mindfulness and education sessions, participants introduce themselves with their first names

only to protect confidentiality. Participants are not required to have their video on or show their face during Zoom sessions.

Data analysis

Variables tested will be adjusted for control variables assumed to explain 15% of variance in outcomes. All variables will be evaluated and data transformations done as needed. Descriptive exploratory analyses of each variable will be made at each time point via T-tests, Wilcoxon Rank Sum tests, Pearson Chi Square tests, or Fisher's exact tests, as appropriate. A Dunn-Sidak correction will control for experiment-wise Type I error. To determine the extent to which the MAAP intervention improves maternal psycho-behavioral symptoms and birthing-parent/infant bonding we will use growth curve analysis (HLM), (Witek-Janusek and Mathews, 1999) based on full maximum likelihood estimation. HLM models longitudinal data by allowing random effects to account for repeated measures on participants over three times, and to evaluate change in trajectories over time. HLMs allow for analysis of unbalanced data across time points, increasing power and reducing bias (Oxytocin enzyme immunoassay kit, 2006). HLMs treat time as a continuous variable letting both time-variant and time-invariant covariates to be included in the model. Both linear and quadratic association will be explored using likelihood ratio test of nested models. Random effects covariance indices will be examined for association between intercept and slope parameters. Non-nested models will be compared using Akaike (Raudenbush and Bryk, 2002) and Bayesian (Hedeker, 2004) Information Criteria. HLM analysis will evaluate the effects of the MAAP intervention on change in proinflammatory cytokines and oxytocin levels. Models will control for maternal age, gestational age at delivery, and infant age at enrollment.

Discussion

The postpartum period is a critical time when women undergo physical, psychological, and relationship transitions. Although childbirth is considered a joyous life event, postpartum women face many stressors related to the demands of caring for an infant, accompanied by sleep disturbance, fatigue, and emotional challenges (Akaike, 1974). Compared to white women, disadvantaged African American women are more vulnerable during the postpartum period with greater risk for depressive disorders and posttraumatic stress (Giscombe and Lobel, 2005; Williams et al., 1997; McLoyd, 1998; Liu and Tronick, 2013). (Seng et al., 2011) To address these concerns, this study enrolls African American women to determine the extent to which a virtual mindfulness (MAAP) program improves their psycho-behavioral well-being (stress, anxiety, depression, sleep, and fatigue) and fosters mother-infant bonding. Additionally, the salivary levels of proinflammatory cytokines and oxytocin are measured in an exploratory fashion. For the comparison group, women receive an 8-week Education Program matched in frequency and duration and led by a health professional. The MAAP and Education sessions are delivered virtually using Zoom, allowing video face-to-face engagement with the interventionist.

Our protocol enrolls women up to the first 12 months after birth. Although the postpartum period has typically been defined to be the first 6 weeks after birth, more recently the

American College of Obstetricians and Gynecologists extended this period to the first year after birth (Schwarz, 1978). Supporting this extended view of the postpartum period, a recent study identified overload as the most frequent stressor, which was significantly higher at 9–12 months than at 5–8 months or at 13 months or more postpartum (Horowitz and Damato, 1999). Moreover, a prospective multisite study of white women reported that one in five women experienced incident depression within the first year after birth (Eckert, 2020). These findings highlight the necessity to address the mental health needs of women beyond the immediate weeks after birth

There are several strengths of this study protocol. A major strength is that the MAAP intervention is delivered online by a certified mindfulness interventionist, making it more feasible and accessible for busy new mothers, who may not have the time nor means to travel to or attend an in-person program. In addition, an online intervention offers a scalable approach with greater clinical utility for clinicians to prevent and manage postpartum behavioral symptoms. In-person care restrictions during the COVID pandemic spurred growing interest and use of digital platforms for the remote delivery of mental health care (Walker and Murry, 2022). Although still in its infancy, emerging work in pregnant women suggests digitally based mindfulness interventions benefit maternal mental health. For example, a study conducted in China found smartphone-based self-guided mindfulness training improved depressive symptoms and reduced anxiety in at risk pregnant women. Unfortunately, this approach had a high dropout rate (Krusche et al., 2018). To increase participant retention, these same investigators offered a self-guided mindfulness program using a video and audio delivery method (i.e., WeChat) for pregnant women (12–20 weeks gestation). This approach demonstrated improved retention and a significant reduction in depression, anxiety, and pregnancy-related anxiety symptoms, compared to the usual perinatal care group (Goetz et al., 2020). The MAAP intervention used in our protocol offers real-time engagement via Zoom with a certified mindfulness interventionist (as opposed to a self-guided approach), which may provide additional benefit through video engagement with the interventionist.

Few studies have evaluated mindfulness interventions for postpartum African American mothers. Focusing on African American women and tailoring the MAAP intervention to be culturally relevant to African American new mothers addresses disparities in postpartum mental health. The adaptation of the MAAP intervention was based on prior evidence and expert opinion. As adapted, the intervention is more acceptable and consistent with the experiences and values of African American women, who view person-centered, strength endorsement interventions in a positive manner (Carter, 2014). Prior studies find that African Americans report perceived barriers to traditional MBSR interventions, such as lack of consideration of their culture, stigma related to mental health disorders, and extensive time commitment (Tebeka et al., 2021). African American women more commonly experience postpartum depressive symptoms, (Giscombe and Lobel, 2005; Williams et al., 1997; McLoyd, 1998; Liu and Tronick, 2013) and they are almost four times as likely to have posttraumatic stress compared to white women (Seng et al., 2011). Thus, it is important to find effective interventions to address postpartum behavioral symptoms in African American women.

An important strength of this study is the exploration of proinflammatory cytokines and oxytocin in response to the MAAP intervention. Proinflammatory cytokines are increased in response to psychological stress (Connolly et al., 2021) and may engender depressive symptoms and fatigue (Watson et al., 2016; Ravi et al., 2022; Sawyer, 2021). Oxytocin is not only important for the establishment of mother-infant bonding, (Xia et al., 2022) but also has anti-inflammatory activity (Jankowski et al., 2010). Although proinflammatory cytokines and oxytocin will be measured, the small sample size prevents any mediational analyses to determine whether these biomarkers mediate changes in psycho-behavioral symptoms in response to MAAP. Nevertheless, the knowledge gained from this study will inform future studies that investigate biologic pathways whereby mindfulness-based interventions might improve perinatal psycho-behavioral symptoms. Further, knowledge of proinflammatory cytokines and/or oxytocin response to MAAP may lead to novel markers to identify mothers at risk, allowing targeting of these women early-on and providing ways to monitor intervention effectiveness. Another strength of this study is the use of an active comparison condition (i.e., an Education Program). Most past studies that evaluated mindfulness for perinatal women are limited by use of a non-active control condition, primarily usual perinatal care. In contrast, this study compares the online MAAP intervention to an online Education Program that uses the same delivery method matched in frequency and duration. In addition, such a design provides additional control for attention from a health care provider.

There are several limitations to this study protocol. One limitation is the potential for difficulty in recruitment, which stems from multiple factors. First, participation in this study requires a considerable time commitment, and this may be especially problematic for postpartum mothers engaged in the care of an infant. Second, the targeted sample is African American women. The literature indicates African Americans are often hesitant to participate in a research study (Corwin et al., 2003). To enhance recruitment, the protocol includes multiple recruitment strategies. To date, sending recruitment letters to potential participants identified through the Medical Center Epic database has been most successful. In contrast, approaching women during their postpartum hospitalization is not as successful. Another limitation is the large variance in the time since the mother gave birth (i.e., up to one year postnatal) and study enrollment. To mitigate this potential confounder, infant age will be considered in the data analysis. Finally, psycho-behavioral symptoms are assessed by self-reported measures, which are subject to social desirability bias. This may be particularly the case for the measure used to assess mother-infant bonding. Observational methods are considered the gold standard to assess mother infant interactions. However, the additional training, equipment, and time for in-person observations makes this approach prohibitive for this pilot study.

Future directions

The findings from this pilot study can guide future large-scale studies investigating innovative digital approaches to improve the mental health of African American mothers. For example, the experience gained from this study can be used to identify effective strategies to recruit, engage, and retain African American mothers in studies evaluating digital interventions to reduce psycho-behavioral symptoms. Additionally, identifying

characteristics of participants who complete the MAAP program versus those who do not can inform changes or enhancements to the MAAP intervention. For instance, if women who complete the study are found to report a higher socioeconomic status than those who do not complete the study, modifications can be made to increase engagement of participants from lower socioeconomic backgrounds. Lastly, findings related to the potential role of inflammatory mediators and oxytocin may suggest biological mechanisms worthy of pursuing in future studies aimed at understanding psycho-biological mechanisms of mindfulness.

Offering mindfulness using a digital platform has potential to reach underserved new mothers who are most in need of mental health preventive care. Such an approach overcomes the many barriers and challenges women face as they navigate new motherhood and the responsibilities of parenthood. Digital mindfulness adapted for the unique needs of perinatal women offers the real possibility of widespread use in perinatal centers. Consistent with this goal, an inter-professional team is piloting an innovative perinatal mental health prevention intervention designed to increase access and appeal of mindfulness. That perinatal care model incorporates Mindfulness-Based-Cognitive Therapy for Perinatal Depression using a telehealth platform, making mindfulness more accessible for perinatal women within a standard perinatal care setting (Scatliffe et al., 2019).

Conclusion

Digital technology offers African American women greater access to effective interventions, like mindfulness. This delivery approach reduces barriers related to time, transportation, and allows mothers to learn mindfulness in the comfort of their home. Unlike self-guided virtual mindfulness programs, synchronous group Zoom sessions add the benefit of creating a community of women. Additionally, the video delivery of mindfulness by a certified mindfulness interventionist fosters trust with the interventionist, promoting individual motivation, and reducing attrition. It is essential to make high quality mindfulness programs available, and emerging work shows virtual mindfulness can reduce depression and anxiety in pregnant women (Goetz et al., 2020). Reducing barriers to mindfulness and adapting mindfulness to resonate with African American culture and values can benefit a population burdened by stress-related erosion of maternal health and poor infant outcomes.

Funding

This work was supported by the National Institutes of Health, National Institute for Nursing Research grant number K23NR019101.

Declaration of Competing Interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Lindsey Garfield reports financial support was provided by National Institute of Nursing Research. If there are other authors, they declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Table 1

Description and timing of assessment for study questionnaires and biological measures.

Demographic Questionnaire at Baseline only
Demographic and health behaviors. Demographic and health information are obtained by questionnaire and medical records. The goal is to obtain genetic (family history), biologic (history of medical disorders), and potential covariates (marital status, income, social support, age of infant). A summary of labor and birth are assessed by review of infant medical records (i.e., mode of delivery, induction, labor medication (e.g., oxytocin), use of pain medication). Subject health behaviors (e.g., breastfeeding, smoking, substance misuse, & exercise) are also assessed.
Maternal Questionnaires at Baseline, 4 weeks, 8 weeks
Parental Stress. Parental perception of the stress related to parenting their infant is measured using the Parental Stressor Scale *(PSS).* PSS is an 18 item 5-point instrument used to measure the positive and negative themes in parenting (Dane and Schneider, 1998). Good internal consistency of the PSS was found across a range of samples (Berry and Jones, 1995; Pontoppidan et al., 2018).
Postpartum Depressive Symptoms. The Center for Epidemiologic Studies Depression Scale (CESD) (Algarvio et al., 2018) is used to measure frequency of depressive symptoms. It is a self-report measure consisting of 20 depressive symptom items, rated on a 4-point Likert scale. Scores range from 0 to 60. Higher scores indicate more depressive symptoms. Scores >16 indicates elevated depressive symptoms (Younger et al., 1997). Cronbach's alphas range from.87 to.91 in minority postpartum women (Radloff, 1977; Yang et al., 2017).
Anxiety. State anxiety is measured with the state anxiety sub-scale of the State-Trait Anxiety Inventory (STAI) (Liu et al., 2013; State-Trait Anxiety Inventory for adults, 1983). The state sub-scale includes 20 items, found to be sensitive to changes in anxiety. Numerous reliability and validity studies of the STAI have been conducted (Liu et al., 2013; State-Trait Anxiety Inventory for adults, 1983). The coefficients range from.16 to.53. Cronbach's alphas range from.85 to.95 (Liu et al., 2013; State-Trait Anxiety Inventory for adults, 1983; Spielberger et al., 1970).
Posttraumatic Stress. The Perinatal PTSD Questionnaire (PPQ) is used to measure the extent to which participants experience post-traumatic stress symptoms in response to their birth experience (Garfield et al., 2015; DeMier et al., 1996; Callahan et al., 2006; Callahan and Hynan, 2002). PPQ has 14 yes-no items that measure intrusive thoughts (e.g., bad dreams of giving birth), avoidance or numbing (e.g., inability to remember parts of the hospitalization), and increased arousal (e.g., increased irritability or anger). The "yes" answers are summed. Cronbach's alpha was.83, and test-retest reliability over 2–4 weeks was.92 (Garfield et al., 2015).
Sleep. Sleep quality is measured by the Pittsburgh Sleep Quality Inventory (PSQI). The PSQI has a global score of 0–21 and 7 subscales. In perinatal birthing-parents, Cronbach α ranges from 0.72 to 0.78 (Quinnell and Hynan, 1999).
Fatigue. Fatigue is measured by the Multidimensional Fatigue Symptom Inventory Short Form (MFSI-SF). MFSI-SF measures overall fatigue in 5 domains (general, emotional, physical, mental, and vigor). Factor analysis shows good fit for the 5 factors. Internal consistency ranges from 0.87 to 0.96 (Skouteris).
Mindfulness. The Five Facets of Mindfulness Questionnaire (FFMQ) is used to assess mindfulness (Research Support, 2009). These facets include: observing, describing, acting with awareness, non-judging of inner experience, nonreactivity to inner experience (Research Support, 2009). The FFMQ utility with Black individuals is established with an internal consistency ranging from 0.60 to 0.86 (Stein et al., 2004).
Infant Questionnaires at Baseline, 4 weeks, 8 weeks
Birthing-parent/infant bonding. The Mother-to-Infant Bonding Scale is an 8 item self-rating questionnaire designed to assess the feelings of a birthing-person towards their new baby. This scale has strong reliability with a strong correlation of scores at 3 days and 12 weeks postpartum. It also has an inverse correlation with the EPDS. Cronbach alpha is.71 (Baer et al., 2008; Watson-Singleton et al., 2017).
Salivary Measures at Baseline, 4 weeks, and 8 weeks
Cytokine Production & Measurement: Saliva samples are collected for cytokine measurement using a salivette collection technique. Samples are frozen at − 80°C for batch analysis (Poehlmann and Fiese, 2001). IL-6 and TNF-alpha are measured in duplicate by ELISA (Yoshida et al., 2020). Sensitivity is < 0.7 pg/ml for IL-6, and <3.9 pg/ml for TNF. Intra assay variability is <7%.
Oxytocin Measurement. Salivary oxytocin is analyzed by ELISA. Detection levels are 15.6 pg/ml to 1000 pg/ml with sensitivity as low as 11.7 pg/ml (Toivo et al., 2023). Intra-assay coefficient of variability range from 5% to 10% with an inter-assay coefficient of variability of 4.6–8.6%.