

Study Title: Evaluating Screening Adherence Between Moment for Parents App and Attention Control

Unique Protocol Id: R43MH130293

Protocol Version: 1.0

Version Date: December 4, 2025

Principal Investigators:

Marianna Kerppola

Poisera, Inc.

CEO

team@momentforparents.com

(734) 210-1120

Dr. Maria Muzik

University of Michigan

Professor of Psychiatry and Obstetrics & Gynecology

mmuzik@umich.edu

734-764-0231

Sponsor / Funding Agency

National Institute of Mental Health (NIMH)

SBIR Phase I Grant Number: *R43MH130293*

Background:

Problem to be Solved Maternal mood and anxiety disorders (MMADs) are the number one complication of pregnancy. Depression symptoms appear in 16-37% of pregnant women^{1,2} and anxiety symptoms in 14-54%.³⁻⁵ Pregnant women with untreated MMADs are at higher risk for maternal morbidity, preterm birth, and postpartum MMAD.⁶⁻⁹ Adverse outcomes for their children include low birth weight, developmental delays, and psychiatric disorders.⁸⁻¹¹ Further, postpartum MMADs contribute to adverse childhood experiences,¹¹⁻¹³ including suboptimal parenting^{13,14} and maternal suicide.⁷ Untreated MMADs lead to 115,000 additional days spent in the hospital, 85,000 emergency department visits, and 72,000 missed well-child visits each year.¹⁵ Overall, undetected and untreated MMADs have a high health burden.

Current MMAD Screening Practices Pregnant women are inadequately screened with 50-65% of women with MMAD symptoms never diagnosed.^{16,17} The American College of Obstetrics and Gynecology (ACOG) recommends at least one screening in the perinatal period.¹⁸ Yet one in five pregnant women report never being screened by a healthcare clinician.¹⁹ Even when screened, MMADs remain undetected because mothers do not trust clinicians due to fear of judgment, stigma, or even loss of parental rights.²⁰⁻²²

Current MMAD Treatment Practices MMADs are temporary and treatable^{3,30} with therapy, such as cognitive behavioral (CBT), interpersonal (IPT), acceptance and commitment (ACT), and dialectical behavior (DBT) therapies, and medications. Yet women with MMAD symptoms face multiple barriers to treatment. Mental health stigma and provider distrust prevent help-seeking behavior,³¹ particularly for Black and Latina women, who are half as likely to receive MMAD treatment than white women.^{32,33} Further, obstetric clinicians are inadequately trained about treatment options^{20,34,35} and inconsistent in their treatment practices.^{35,36}

Perinatal Access Programs (PAPs), established in over 30 states, increase access to MMAD treatment by employing behavioral health clinicians (BHCs) to deliver immediate psychiatric care and coordinate long-term treatment via phone.^{37,38} MC3 Perinatal (MC3), the Michigan PAP, successfully reduced MMAD scores by 50% for 103 women, according to preliminary MMAD symptom analysis. As with other PAPs,³⁷ MC3 improved access to MMAD treatment with 57% percent meeting MMAD clinical criteria; 47% were African-American and 53% on public insurance. Yet PAPs have not eliminated underdiagnosis. Even Massachusetts Child Psychiatry Access Program for Moms, the first established PAP, reaches less than 10% of the presumed women with MMADs.³⁷

Gap in Knowledge The US Preventive Services Task Force identified MMAD monitoring as an urgent unmet need.^{39,40} Women who could benefit from PAPs and other existing effective MMAD interventions⁴¹⁻⁴³ cannot be identified because individual risk profiles are unknown,⁴⁰ and MMAD onset spans from pregnancy to 36 months postpartum.⁴⁴⁻⁴⁶ Without longitudinal MMAD monitoring, treatment cannot be delivered to women who need it.

Given 95% of 18-49-year-old women own a smartphone,⁴⁷ mobile health (mHealth) apps can affordably deliver health interventions at scale, including to marginalized individuals, when developed with inclusive design practices.^{48,49} Twelve commercially available mHealth apps claim to address MMADs, yet none have been scientifically validated to effectively monitor or treat MMADs.^{50,51} Another 22 academia-developed mHealth apps either prevent, screen, or treat MMADs, some proving to be feasible and acceptable by samples of <100 perinatal women.^{52,53} Yet none are proven to engage mothers beyond 3 months, a small fraction of the MMAD risk timeframe. *Evidence is required to validate that mothers will adhere to longitudinal MMAD monitoring.*

Research Questions:

- Does the Moment for Parents app and chatbot experience increase mental health screening adherence over three months?
- What patterns (e.g., demographic, sociographic, etc) exist among the users who engage with the app longitudinally?

Purpose: This study will evaluate if pregnant and postpartum women complete mental health screening while engaging with the fully developed Moment for Parents app and chatbot. We will conduct a two-arm pilot RCT to evaluate screening adherence between the Moment for Parents intervention (n=80) and control (n=80) over 3 months. Findings will inform the design in a fully powered randomized controlled trial (RCT) in Phase II SBIR study.

Objectives: (1) evaluate screening adherence differences between the two arms, (2) understand Moment for Parents app engagement and feedback patterns among participants; (3) use this information to determine if a chatbot can longitudinally engage pregnant women to facilitate continuous MMAD symptom monitoring.

Methods:

Eligibility

Inclusion criteria:

- Women who are pregnant or up to 1 year postpartum
- Age 18 years or older
- Lives in the United States
- Owns a smartphone with internet access
- Proficient in English

Exclusion criteria:

- Not female
- Not currently pregnant or more than 1 year postpartum

- Younger than 18 years old
- Does not live in Michigan
- Does not own a smartphone with internet access
- Not proficient in English

Design

This is a pilot randomized control trial to evaluate if the Moment for Parents app motivates higher mental health screening compared to a control version of the app.

Participants in the **chatbot intervention arm** will use the Moment for Parents app with the chatbot as developed in Aim 1. In this arm, participants will read articles and engage in chatbot conversations about pregnancy, motherhood, and mental health. When a participant starts using the app, she will choose a “Journey” to support her emotional well-being. Journeys are composed of an average of 8 lessons. Each lesson includes an article, a chatbot-guided reflection, and occasionally, a meditation. Lessons take about 5 minutes to complete. Women rate lesson satisfaction on a 5-point Likert scale. Journeys cover topics such as:

- Cultivating resilience
- Enhancing social support networks
- Improving communication with clinicians
- Increasing mindfulness, non-judgment, and acceptance of feelings
- Strengthening the mother-child bond
- Decreasing feelings of isolation, depression, and anxiety
- Establishing self-care patterns
- Increasing knowledge around parenting and child development
- Preparing for labor and delivery

Each day, the app will send a push notification inviting the participant to continue the next lesson in the Journey. When the user clicks on the push notification, it will initially ask the participant about her mood. Then, it will offer different ways to process the selected mood (e.g., venting, meditating, or journaling). If the user selects one of these activities the app guides them through completing the activity.

If it's time for the user to complete a mental health screening, the app algorithm will incorporate the PHQ-9 and GAD-7 questions into the mood check-in. including sensitive topics, such as trauma history, mental illness, and social support.

The Moment for Parents chatbot does not use the PHQ-9 and GAD-7 results in its algorithms in selecting topics delivered to the user. As such, the Moment for Parents app does not serve as an intervention for any possible MMAD symptoms. It does not claim to prevent, diagnose, or treat any medical conditions. Instead, it provides general wellness information in an interactive, conversational form that feels like talking to a well-informed friend.

The Moment for Parents chatbot is an innovative approach to overcome social desirability and

self-presentation biases by turning sensitive conversations into validating, empathetic experiences for women. The chatbot conversations provide psychosocial support for perinatal women, while simultaneously monitoring for MMAD symptoms. These chatbot conversations yield an interactive and personalized experience. We hypothesize that this interactive and personalized experience will engage women more often, thereby giving more opportunities to deliver the mental health screenings.

Participants in the **attention control arm** will use a modified Moment for Parents app without the chatbot. Weekly push notifications invite participants to read an article about what's happening during their current week of pregnancy and/or postpartum. These articles focus on baby development and general advice about what symptoms to expect at each stage of pregnancy and postpartum. As in the chatbot intervention arm, the app algorithm will deliver the weekly mental health screening within the chatbot conversation.

In both arms, the PHQ-9 and GAD-7 mental health screeners will be used. Participants in both arms will be prompted to complete a PMD screen more frequently than in the current standard of care (i.e., only once perinatally).

Positive Screening Procedures

When a participant screens positively for symptoms of depression, anxiety, and/or suicidality via PHQ-9 and GAD-7 in either arm, a Moment for Parents Application Programming Interface (API) will immediately alert MC3 Perinatal and the UM study team (i.e., Dr. Muzik (PI), a perinatal psychiatrist and Medical Director of the MC3 Perinatal Program, and Dr. Menke, the behavioral health consultant and licensed clinical psychologist on the MC3 Perinatal team) via secure email, including contact information for the participant with possible symptoms (i.e., first names, email, phone number, address and emergency contact if available).

If the participant endorsed suicide risk, Dr. Menke will immediately contact (M-F 9-5) the participant for safety assessment, conduct a state-of-the-art suicide risk assessment (i.e., Safety Planning Intervention) and, if appropriate, facilitate immediate psychiatric care based on standard suicide protocol (i.e., patient monitored by family or staff and brought to emergency services). In such cases, the participant will not be left unsupervised until seen in the psychiatric emergency room. Dr. Menke will report back to the PI, Dr. Muzik, a perinatal psychiatrist and Medical Director of the MC3 Perinatal Program, who can further support the psychiatric disposition. Dr. Muzik will be continuously accessible via a pager system and cell phone. Should the participant refuse hospitalization, and it is deemed necessary, the clinicians will engage police and authorities in ensuring safe transport to the nearest psychiatric emergency room for further in-person assessment. If it is deemed that the participant is not an imminent suicide risk, the participant will complete an intake and be offered services in the MC3 Perinatal program.

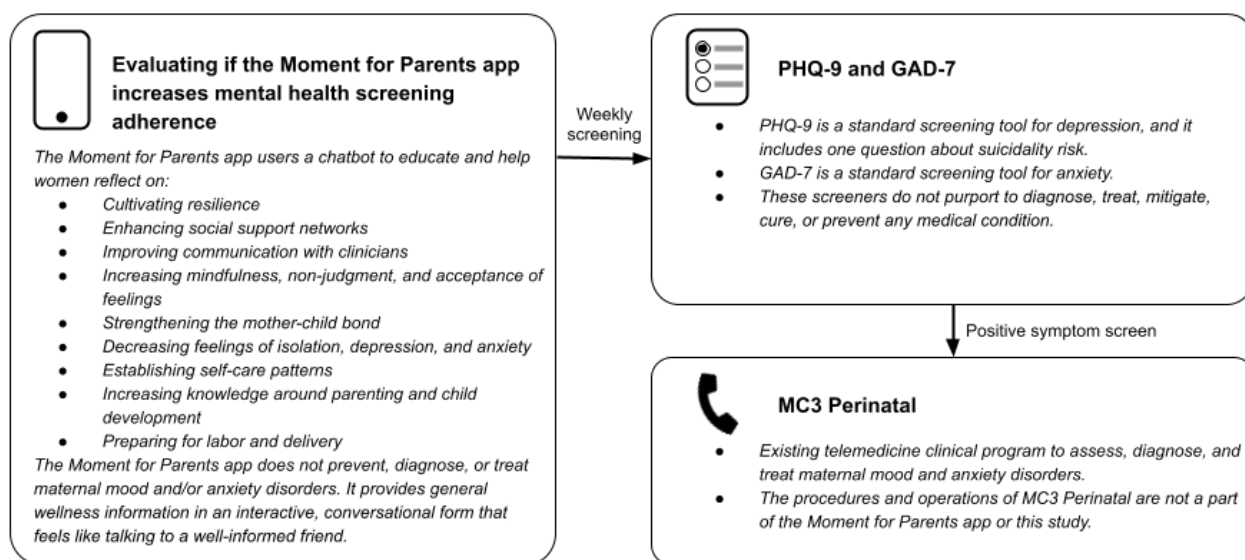
If the participant screened positively for depression and/or anxiety, a MC3 Perinatal BHC will contact the participant within 24 hours (M-F 9-5) of screening and be offered services in the MC3 Perinatal program. If the participant is interested, The BHC describes the program to the

participant, thus engaging her, and then completes an assessment. The assessment includes a standard psychiatric assessment (including re-evaluation of presence/absence of suicidality, psychosis, and coherent thinking and behaviors), and subsequent disposition to short-term evidence-based practices, or connection to long-term care depending on the severity of presentation, and participants' preference. Types of evidence-based interventions provided include Cognitive Behavioral Therapy (CBT), Dialectic Behavioral Therapy, Acceptance and Commitment Therapy, Interpersonal Therapy, Motivational Interviewing, Early Relational Health, and Infant Mental Health principles.

The Moment for Parents platform will connect to MC3 Perinatal programming, an existing clinical program. MC3 Perinatal is not a component of the Moment for Parents app. MC3 Perinatal procedures and/or operations will not be a part of the research or data analysis. MC3 Perinatal are monitored by an existing IRB.

Study Diagram

The following diagram illustrates the relationship between the Moment for Parents app, the mental health screening, and MC3 Perinatal.



Randomization Procedure

Randomization will be achieved using permuted block randomization, which allows us to randomly allocate participants into arms, while maintaining balance between arms (i.e., race, mental health history, race, gestational age). We will use a block size of 10. Randomization will be automatically assigned at the enrollment website and will avoid possible bias due to knowledge of block size. Since all data is collected through a website or app, no blinding of assessors is necessary.

Survey Procedure

One week after a participant downloads the app (both arms), we will contact them via in-app message, email, and SMS, inviting them to complete a four-question survey. The questions are adapted from a product-market fit survey developed by Sean Ellis.⁵⁴ The questions are:

1. How would you feel if you could no longer use Moment for Parents?
 - a. Very disappointed
 - a. Somewhat disappointed
 - a. Not disappointed
2. What type of people do you think would most benefit from Moment for Parents?
3. What is the main benefit you receive from Moment for Parents?
4. How can we improve Moment for Parents for you?

Participants who do not respond to the survey will receive weekly reminders until the end of the study period.

Interview Procedure

We will identify participants who respond “Very disappointed” to Question 1, as this group is most likely to represent individuals who find the app highly valuable. Then, we will contact these participants via e-mail and SMS, inviting them to participate in a virtual interview about their experience with the Moment for Parents app. We will offer participants a \$30 e-gift card incentive for completing the interview.

The goal of these interviews is to better understand who is engaging most meaningfully with the app and why. We aim to explore whether there are shared characteristics, experiences, or needs among participants who report high satisfaction with the app. By identifying patterns in who is benefiting most, we hope to gain insight into what drives deeper engagement and perceived value.

We are intentionally focusing on this subset of participants rather than interviewing all users. In Aim 1, when we invited all participants to interview, we found that interviews with disengaged users often yielded limited insight, as the majority had not used the app enough to provide meaningful feedback. This targeted approach allows us to more effectively explore the factors contributing to positive user experiences.

Interviews will take place remotely and be conducted via Zoom. These will be single-session interviews without any follow-up. All women will have the option to decline participation in the interview. We will record and transcribe each interview using Fathom and then use inductive thematic analysis to code each interview. After confirming the accuracy of the interview transcription, we will delete the audio recording and any identifying information in Fathom. Participants who complete the interview will receive a \$30 gift card to Amazon via email or SMS.

At the beginning of each interview, the interviewer will request the following for safety purposes:

- The participant's current location

- The participant's emergency contact

This information will be recorded in a temporary document, so it is available should the interviewee require crisis support during the interview (see Crisis Protocol for more details on these procedures). The information will be deleted at the end of the interview.

Recruitment and Consent Process

Pregnant women will be recruited from:

- obstetric clinics
- partnerships with doula agencies, prenatal yoga studios, birth education classes, and other providers supporting perinatal women
- public spaces, such as libraries and coffee shops
- internet-based strategies (e.g., email/newsletters, social media, community postings).

Only research personnel will be communicating with interested women via email. A research personnel email contact will be provided for study-specific questions.

All promotional materials will include a URL and/or QR code directing women to an enrollment website informing them about the study. Women will self-recruit by downloading the Moment for Parents app and entering their:

- First name
- Email address
- Phone number
- Due date (confirming she is <24 weeks of gestation)
- Month and year of her birthday (confirming she is <18 years old)
- County and zip code (confirming she lives in Michigan)
- Race
- Ethnicity
- Annual income
- Household size
- Mental health history

Downloading the app and entering this information demonstrates that she owns a smartphone with internet access and is proficient in English.

Next, the app will prompt the user to allow location permissions on their phone. This is the prompt provided to the user about location permissions:

You can get mental health support during this study if you need it. Because this support is limited to individuals living in Michigan, we request that you turn on your location permissions to confirm that you are eligible for these services.

We are requesting “approximate location”, which does not track the user’s precise location, but rather triangulates the user’s proximity to cell towers. This allows us to confirm that the

participant is physically in Michigan. We are requesting “foreground access”, which means that the user’s location will only be tracked “while using the app.” When location permissions are activated, our backend will collect their latitude and longitude, along with a timestamp. If the user denies location access, the individual is not eligible for this study.

If an individual is eligible for the study, she will be directed to an electronic consent document form within the app. Individuals who want to participate must select “I agree to participate.” Completing this step is considered the end of the enrollment process.

If an individual does not meet enrollment criteria, she will be directed to a screen explaining she is ineligible for the study.

Incentives

Participants who complete the interview will receive a \$30 e-gift card. E-gift cards will be provided through Tango card, where participants can choose their preferred gift card. Here is a list of e-gift card options available through Tango card:

<https://www.tangocard.com/reward-catalog?rewardcategory=gift+card>. Gift cards will be provided within 48 hours of completing the survey or interview.

All participants will be entered into a raffle to win one of 4 \$50 e-gift cards (also from Tango). We will draw the raffle winners once all 160 participants have completed the study, then email the winners with a link to the gift card.

Outcome Measures

Measures

- a. PHQ-9 and GAD-7 screening adherence over 3 months
- a. Responses to product-market fit survey questions described above
- b. Qualitative feedback via interviews

Statistical Design and Power

This 3-month pilot randomized controlled trial (RCT) tests the hypothesis that women using the Moment for Parents app will adhere to screening at twice the rate of those in the control arm. It will also help determine the optimal design of a Phase II RCT.

In this pilot RCT, we will (1) test differences between PHQ-9 and GAD-7 screening adherence in both arms and (2) examine baseline predictors of retention and patterns of engagement in both arms. Knowledge of baseline predictors of retention will determine other factors to manipulate in assigning women to groups, e.g. oversampling women with a history of mental illness or elevated baseline symptoms.

The pilot RCT sample size (Moment for Parents intervention, n=80 and attention control, n=80) was determined by logistical concerns, such as time available to recruit and enroll participants, yet it will allow us to detect large differences in screening adherence between groups.

1. Evaluating screening adherence in Moment for Parents intervention and control arms

We will examine if women in the Moment for Parents arm complete more PHQ-9 and GAD-7 screenings than the control. We will count the total number of PHQ-9 and GAD-7 screenings completed during the study while ignoring the timing of the responses. We will test differences between the arms, using Poisson regression with the number of PHQ-9 and GAD-7 screenings completed as the dependent variable and chatbot arm as the main predictor, controlling for age of the participant, race, mental health history, gestational age, and annual income. We expect that women in the chatbot arm will respond to the PHQ-9 and GAD-7 at twice the rate of those in the control arm. Using a two-sided Type I error of 0.05, a total of 160 women randomized 1:1 to chatbot intervention (n=80) or attention control (n=80) will have 84% power to detect a doubling in the response rate based on Poisson regression methods (G*Power version 3.1.9.7).⁸⁰ We will also explore different distributions, including negative binomial and zero-inflated Poisson, and choose the distribution that best fits the data. We will present adjusted response rates and the difference between the two groups with 95% confidence intervals (CI) and p-value. Unlike other studies where dropping out of the study results in missing data, collecting data through the Moment for Parents app will be complete because we will know at each time point if a screen was completed.

Next, we will estimate the length of time that women adhere to PHQ-9 and GAD-7 screens in chatbot and control arms, using survival analysis. The starting point for the survival analysis will be when the participant enrolls in the study and completes the first PHQ-9 and GAD-7 screen, and the endpoint will be when she completes her final PHQ-9 and GAD-7 screen. There will be no censoring because, as explained above, we will know at each timepoint whether the screen was completed. We will examine survival curves in each group with the Kaplan-Meier method and report median survival times with 95% CI for each group.

2. Examining baseline predictors of retention and patterns of engagement between Moment for Parents intervention and control arms

Understanding predictors of engagement will inform the optimal design for the Phase II RCT. We will use Cox proportional hazards regression to examine predictors, including mental health history and baseline PHQ-9 and GAD-7 score. As above, the starting point will be when the participant enrolls in the study and completes the first PHQ-9 and GAD-7 screen, and the endpoint will be when she completes her final PHQ-9 and GAD-7 screen. The proportional hazards assumption will be tested for each predictor by including the interaction between the predictor and time. If the interaction term is significant, we will include it in the final model to account for the non-proportional hazards. For each predictor, we will report the odds ratio with 95% CI.

Next, we will use a generalized linear mixed-effects model with a logit link for the binary outcome of whether the participant completed the PHQ-9 and GAD-7 at each of the 12 weeks of the study. Due to the exploratory nature of the study, we will use graphical techniques to examine the data, by plotting the fitted model over time.⁸⁰ First, we will plot the fitted model for the overall sample. Next, we will plot fitted models for chatbot and control arms and other relevant groups (e.g., those with positive baseline PHQ-9 and GAD-7 score vs. those without and those with a history of mental illness vs. those without). Plots will be examined for group differences. Through this graphical analysis, we expect to find groups of users with different

patterns of use. For example, there could be an “early adopters” group who complete screens for the first few weeks and then drops out. Other possible patterns are “infrequent responders”, who will complete screens less frequently, but continue throughout the study. In addition, there will be “compliers” who complete screens every week throughout the study. We will be able to detect relationships between groups based on mental health history and baseline mental health scores if they are strongly associated with these groups.

Data Management

Moment for Parents will obtain the following app usage data from participants who enroll in the study:

- Demographics, including week of gestation, age, race, ethnicity, annual income, household size, and previous mental health history
- Number of chats started and completed
- Number of meditations opened and played
- Number of articles opened and read
- PHQ-9 and GAD-7 screening results
- Number of chats, meditations, and or articles saved, indicating content that users found helpful
- Engagement rate, which measures the average number of activities completed in the app (e.g., chats, meditations, and/or articles) per active user over daily, weekly, or monthly intervals.
- Retention rate, calculated as the proportion of active users relative to the total number of enrolled users.
- Total number of enrolled users of the Moment for Parents app.
- Total number of active users, defined as those who have completed at least one activity in the app (i.e., chat, meditation or article) in the past seven days.

Data Sharing (collection and analysis)

Moment for Parents will store de-identified data in a password-protected cloud-based system (i.e., Google Drive) only accessible to research personnel. Women’s and Infant’s Mental Health/Zero to Thrive (WIMH/Z2T) research personnel will only have access to de-identified data.

Data Storage

App Usage and PHQ-9 and GAD-7 Data: App usage data will be obtained via the Moment for Parents app. Data collected via the Moment for Parents app will be stored securely in a HIPAA-compliant data warehouse on Amazon Web Services (AWS) that was developed by Moment for Parents. Backend app usage data will be obtained by Moment for Parents from the AWS data warehouse. When a participant screens positively for symptoms of depression, anxiety, and/or suicidality, Moment for Parents will automatically send participant contact information (first name, email, phone number, and emergency contact info) and which

symptoms were identified by the PHQ-9 and GAD-7 (i.e., depression, anxiety, and/or suicidality) to MC3 Perinatal via secure email. The secure email is sent using an application programming interface (API) developed by the Moment for Parents team, thus requiring no human handoff. The MC3 BHC can only access the secure email via password.

Survey Data: The product market fit survey data will be collected in a Paperform survey linked to a participant's enrollment ID and stored in Google Drive. Once data collection is complete, the survey data will be exported and enriched with user profile information from the AWS participant database, including:

- Week of pregnancy
- Age
- Zip code
- Race
- Ethnicity
- Number of children
- Mental history
- Annual income
- Household size
- Number of chats completed during 30-day period
- PHQ-9 and GAD-7 scores during 30-day period

Once the data above is incorporated, the participant ID will be deleted to de-identify the data.

Interview Data: Interview data will be obtained through a Zoom interview audio recording conducted by Moment for Parents research personnel. Audio recordings will be transcribed via Fathom. All data will be de-identified by Moment for Parents to ensure confidentiality. Moment for Parents will store data in a password-protected cloud-based system (i.e., Google Drive) only accessible to research personnel. WIMH/Z2T research personnel will only have access to de-identified transcripts (i.e., WIMH/Z2T research personnel will not have access to audio recordings).

Identifiable Information: This study will collect participant's email and phone number, both considered individually identifiable sensitive data. This data is stored in a password-protected AWS database developed and maintained by the Moment for Parents team.

Data Analysis

Quantitative (e.g., descriptive statistics, correlations, regressions) and qualitative (e.g., thematic analysis) will be conducted. App usage and survey data will be analyzed by the Moment for Parents research personnel using R or comparable statistical software. Interview transcripts will be coded using inductive thematic analysis, a qualitative method where data patterns or themes are identified naturally, without preexisting codes.

Risk to Subjects

Level of Risk: This study involves no more than minimal risk to participants.

- There is minimal risk of breach of confidentiality since identifiable information will be collected once a participant has agreed to the electronic consent form.
- There is minimal risk of breach of confidentiality for those who participate in an interview. These participants will be audio recorded, so there is a risk of loss of confidentiality.
- There is a small risk that topics and questions posed by the Moment for Parents chatbot, including the PHQ-9 and GAD-7 screening questions, could make a participant feel uncomfortable.
- There is a small risk that participants who receive services from the MC3 Perinatal program may experience psychological discomfort answering questions or during assessment and therapy sessions.

Risk Mitigation

Personally identifiable information, including a participant's name, email address, and phone number, is collected once a participant has agreed to the electronic consent form. This information is stored in a separate, encrypted database on AWS. WIMH/Z2T research personnel will only have access to de-identified data.

Participants who participate in an interview agree in the consent form that their audio can be recorded. Only authorized research personnel on this application will be granted access to the data.

Our study includes pregnant women who may experience a range of stressors, including mental health problems, socioeconomic challenges, relational problems, medical complications, and a variety of traumatic exposures. Uncomfortable emotions and/or issues may be surfaced through conversations with the chatbot. However, we believe this constitutes only minimal risk, as participants can skip any questions they do not want to answer or end the conversation with the chatbot at any time. The Moment for Parents app also offers strategies to engage in mindfulness, self-regulation, and self-care.

Mental health symptoms may be surfaced through the PHQ-9 and GAD-7 screeners, and women may be made more aware of their distress. At any point in the research study, each woman has the option of not answering questions on the screener, as well as ending her study participation completely. These options are made explicit to women during the consent process. We believe that the provision of the PHQ-9 and GAD-7 screener constitutes only minimal risk in that it parallels current routine prenatal care practice, where standardly depression and anxiety screeners are given at the initial prenatal visit.

Users may experience psychological discomfort answering questions or during MC3 Perinatal assessment and therapy sessions. WIMH/Z2T have selected tools that are standardly employed

in the field, and these have been observed to be safe and have not elicited significant distress or discomfort among participants. We do not expect the discomfort to be greater than that experienced during routine psychological services.

Potential Benefits to Subjects

All women participating in the proposed research will receive more mental health screenings and more rapid treatment support than in the current standard of care, thereby improving the likelihood that they will get needed treatment for MMADs. Chatbot conversations are educational in nature. All women participating in the study will receive more educational material related to MMADs, which will improve help-seeking behavior.

Dissemination of Results and Publication Policy

All data will be de-identified. Quantitative data will be presented in its aggregate form and any direct quotes shared from interviews will be de-identified. Results will be used for publications, reports, grant applications, and to inform the next phase of the study.

References

1. Woods SM, Melville JL, Guo Y, Fan MY, Gavin A. Psychosocial Stress during Pregnancy. *Am J Obstet Gynecol* [Internet]. 2010 Jan [cited 2020 Dec 3];202(1):61.e1-61.e7. Available from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2811236/> PMID: PMC2811236
2. Lee AM, Lam SK, Sze Mun Lau SM, Chong CSY, Chui HW, Fong DYT. Prevalence, course, and risk factors for antenatal anxiety and depression. *Obstet Gynecol*. 2007 Nov;110(5):1102–1112. PMID: 17978126
3. Yonkers KA, Vigod S, Ross LE. Diagnosis, pathophysiology, and management of mood disorders in pregnant and postpartum women. *Obstet Gynecol*. 2011 Apr;117(4):961–977. PMID: 21422871
4. Vesga-López O, Blanco C, Keyes K, Olfson M, Grant BF, Hasin DS. Psychiatric disorders in pregnant and postpartum women in the United States. *Arch Gen Psychiatry*. 2008 Jul;65(7):805–815. PMID: PMC2669282
5. Rubertsson C, Hellström J, Cross M, Sydsjö G. Anxiety in early pregnancy: prevalence and contributing factors. *Arch Womens Ment Health*. 2014 Jun;17(3):221–228. PMID: 24442712
6. Grote NK, Bridge JA, Gavin AR, Melville JL, Iyengar S, Katon WJ. A meta-analysis of depression during pregnancy and the risk of preterm birth, low birth weight, and intrauterine growth restriction. *Arch Gen Psychiatry*. 2010 Oct;67(10):1012–1024. PMID: PMC3025772
7. Admon LK, Dalton VK, Kolenic GE, Ettner SL, Tilea A, Haffajee RL, Brownlee RM, Zochowski MK, Tabb KM, Muzik M, Zivin K. Trends in Suicidality 1 Year Before and After Birth Among Commercially Insured Childbearing Individuals in the United States, 2006-2017. *JAMA Psychiatry*. 2020 Nov 18; PMID: PMC7675215
8. Jarde A, Morais M, Kingston D, Giallo R, MacQueen GM, Giglia L, Beyene J, Wang Y, McDonald SD. Neonatal Outcomes in Women With Untreated Antenatal Depression Compared With Women Without Depression: A Systematic Review and Meta-analysis. *JAMA Psychiatry*. 2016 Aug 1;73(8):826–837. PMID: 27276520
9. McKee K, Admon LK, Winkelman TNA, Muzik M, Hall S, Dalton VK, Zivin K. Perinatal mood and anxiety disorders, serious mental illness, and delivery-related health outcomes, United States, 2006-2015. *BMC Womens Health*. 2020 Jul 23;20(1):150. PMID: PMC7376899

10. Santos IS, Matijasevich A, Barros AJD, Barros FC. Antenatal and postnatal maternal mood symptoms and psychiatric disorders in pre-school children from the 2004 Pelotas Birth Cohort. *J Affect Disord* [Internet]. 2014 Aug 1 [cited 2021 Jul 20];164(100):112–117. Available from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4051989/> PMID: PMC4051989
11. Muzik M, Borovska S. Perinatal depression: implications for child mental health. *Ment Health Fam Med*. 2010 Dec;7(4):239–247. PMID: PMC3083253
12. Turney K. Pathways of disadvantage: Explaining the relationship between maternal depression and children's problem behaviors. *Soc Sci Res*. 2012 Nov;41(6):1546–1564. PMID: 23017973
13. Letourneau NL, Dennis CL, Benzies K, Duffett-Leger L, Stewart M, Tryphonopoulos PD, Este D, Watson W. Postpartum depression is a family affair: addressing the impact on mothers, fathers, and children. *Issues Ment Health Nurs*. 2012 Jul;33(7):445–457. PMID: 22757597
14. Muzik M, Morelen D, Hruschak J, Rosenblum KL, Bocknek E, Beeghly M. Psychopathology and parenting: An examination of perceived and observed parenting in mothers with depression and PTSD. *J Affect Disord*. 2017 Jan 1;207:242–250. PMID: PMC5107117
15. Luca DL, Margiotta C, Staatz C, Garlow E, Christensen A, Zivin K. Financial Toll of Untreated Perinatal Mood and Anxiety Disorders Among 2017 Births in the United States. *Am J Public Health*. 2020 Jun;110(6):888–896. PMID: PMC7204436
16. Ko JY, Farr SL, Dietz PM, Robbins CL. Depression and treatment among U.S. pregnant and nonpregnant women of reproductive age, 2005–2009. *J Womens Health* 2002. 2012 Aug;21(8):830–836. PMID: PMC4416220
17. Byatt N, Levin LL, Ziedonis D, Moore Simas TA, Allison J. Enhancing Participation in Depression Care in Outpatient Perinatal Care Settings: A Systematic Review. *Obstet Gynecol*. 2015 Nov;126(5):1048–1058. PMID: PMC4618720
18. American College of Obstetricians and Gynecologists' Committee on Obstetric Practice. Screening for Perinatal Depression. *Obstet Gynecol*. 2018;132(5):5.
19. Bauman BL. Vital Signs: Postpartum Depressive Symptoms and Provider Discussions About Perinatal Depression — United States, 2018. *MMWR Morb Mortal Wkly Rep* [Internet]. 2020 [cited 2020 Dec 3];69. Available from: <https://www.cdc.gov/mmwr/volumes/69/wr/mm6919a2.htm>

20. Byatt N, Simas TAM, Lundquist RS, Johnson JV, Ziedonis DM. Strategies for improving perinatal depression treatment in North American outpatient obstetric settings. *J Psychosom Obstet Gynaecol*. 2012 Dec;33(4):143–161. PMID: 23194018
21. Kingston DE, Biringer A, Toosi A, Heaman MI, Lasiuk GC, McDonald SW, Kingston J, Sword W, Jarema K, Austin MP. Disclosure during prenatal mental health screening. *J Affect Disord*. 2015 Nov 1;186:90–94. PMID: 26233318
22. Dennis CL, Chung-Lee L. Postpartum depression help-seeking barriers and maternal treatment preferences: a qualitative systematic review. *Birth Berkeley Calif*. 2006 Dec;33(4):323–331. PMID: 17150072
23. Kim JJ, Silver RK, Elue R, Adams MG, La Porte LM, Cai L, Kim JB, Gibbons RD. The experience of depression, anxiety, and mania among perinatal women. *Arch Womens Ment Health*. 2016;19(5):883–890. PMID: 27188618
24. Wenzel ES, Gibbons RD, O'Hara MW, Duffecy J, Maki PM. Depression and anxiety symptoms across pregnancy and the postpartum in low-income Black and Latina women. *Arch Womens Ment Health* [Internet]. 2021 May 10 [cited 2021 Jul 15]; Available from: <https://doi.org/10.1007/s00737-021-01139-y> PMID: 33970310
25. La Porte LM, Kim JJ, Adams MG, Zagorsky BM, Gibbons R, Silver RK. Feasibility of perinatal mood screening and text messaging on patients' personal smartphones. *Arch Womens Ment Health*. 2020 Apr;23(2):181–188. PMID: 31203440
26. Fayers P. Item Response Theory for Psychologists. *Qual Life Res* [Internet]. 2004 Apr 1 [cited 2021 Sep 2];13(3):715–716. Available from: <https://doi.org/10.1023/B:QURE.0000021503.45367.f2>
27. Gibbons RD, Weiss DJ, Frank E, Kupfer D. Computerized Adaptive Diagnosis and Testing of Mental Health Disorders. *Annu Rev Clin Psychol* [Internet]. Annual Reviews; 2016 Mar 28 [cited 2021 Jul 21];12(1):83–104. Available from: <https://www.annualreviews.org/doi/10.1146/annurev-clinpsy-021815-093634> PMID: 26651865
28. Gibbons RD, Weiss DJ, Kupfer DJ, Frank E, Fagiolini A, Grochocinski VJ, Bhaumik DK, Stover A, Bock RD, Immekus JC. Using computerized adaptive testing to reduce the burden of mental health assessment. *Psychiatr Serv Wash DC*. 2008 Apr;59(4):361–368. PMID: PMC2916927
29. Beiser D, Vu M, Gibbons R. Test-Retest Reliability of a Computerized Adaptive Depression Screener. *Psychiatr Serv Wash DC*. 2016 Sep 1;67(9):1039–1041. PMID: PMC5033509

30. Weissman MM, Pilowsky DJ, Wickramaratne PJ, Talati A, Wisniewski SR, Fava M, Hughes CW, Garber J, Malloy E, King CA, Cerda G, Sood AB, Alpert JE, Trivedi MH, Rush AJ, STAR*D-Child Team. Remissions in maternal depression and child psychopathology: a STAR*D-child report. *JAMA*. 2006 Mar 22;295(12):1389–1398. PMID: 16551710
31. Ward E, Wiltshire JC, Detry MA, Brown RL. African American Men and Women's Attitude Toward Mental Illness, Perceptions of Stigma, and Preferred Coping Behaviors. *Nurs Res* [Internet]. 2013 [cited 2021 Jun 14];62(3):185–194. Available from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4279858/> PMCID: PMC4279858
32. Kozhimannil KB, Trinacty CM, Busch AB, Huskamp HA, Adams AS. Racial and Ethnic Disparities in Postpartum Depression Care Among Low-Income Women. *Psychiatr Serv* [Internet]. 2011 Jun [cited 2024 Jan 22];62(6):619–625. Available from: http://psychiatryonline.org/doi/abs/10.1176/ps.62.6.pss6206_0619
33. Taylor J, Gamble CM. Suffering in Silence [Internet]. Center for American Progress. [cited 2021 Jun 14]. Available from: <https://www.americanprogress.org/issues/women/reports/2017/11/17/443051/suffering-in-silence/>
34. Byatt N, Biebel K, Lundquist RS, Simas TAM, Debordes-Jackson G, Allison J, Ziedonis D. Patient, provider, and system-level barriers and facilitators to addressing perinatal depression. *J Reprod Infant Psychol* [Internet]. Routledge; 2012 Nov 1 [cited 2020 Dec 3];30(5):436–449. Available from: <https://doi.org/10.1080/02646838.2012.743000>
35. Palladino CL, Fedock GL, Forman JH, Davis MM, Henshaw E, Flynn HA. OB CARES--The Obstetric Clinics and Resources Study: providers' perceptions of addressing perinatal depression--a qualitative study. *Gen Hosp Psychiatry*. 2011 Jun;33(3):267–278. PMID: 21601724
36. Kim JJ, La Porte LM, Adams MG, Gordon TEJ, Kuendig JM, Silver RK. Obstetric care provider engagement in a perinatal depression screening program. *Arch Womens Ment Health*. 2009 Jun;12(3):167–172. PMID: 19277845
37. Byatt N, Straus J, Stopa A, Biebel K, Mittal L, Moore Simas TA. Massachusetts Child Psychiatry Access Program for Moms: Utilization and Quality Assessment. *Obstet Gynecol*. 2018 Aug;132(2):345–353. PMCID: PMC6059997
38. Lifeline4Moms Network Members [Internet]. UMass Chan Medical School. 2020 [cited 2022 Mar 16]. Available from: <https://www.umassmed.edu/lifeline4moms/Access-Programs/network-members-us/>

39. US Preventive Services Task Force, Curry SJ, Krist AH, Owens DK, Barry MJ, Caughey AB, Davidson KW, Doubeni CA, Epling JW, Grossman DC, Kemper AR, Kubik M, Landefeld CS, Mangione CM, Silverstein M, Simon MA, Tseng CW, Wong JB. Interventions to Prevent Perinatal Depression: US Preventive Services Task Force Recommendation Statement. *JAMA*. 2019 Feb 12;321(6):580–587. PMID: 30747971
40. O'Connor E, Senger CA, Henninger M, Gaynes BN, Coppola E, Soulsby Weyrich M. Interventions to Prevent Perinatal Depression: A Systematic Evidence Review for the U.S. Preventive Services Task Force [Internet]. Rockville (MD): Agency for Healthcare Research and Quality (US); 2019 [cited 2020 Dec 3]. Available from: <http://www.ncbi.nlm.nih.gov/books/NBK537819/> PMID: 30807060
41. Tandon SD, Leis JA, Mendelson T, Perry DF, Kemp K. 6-Month Outcomes from a Randomized Controlled Trial to Prevent Perinatal Depression in Low-Income Home Visiting Clients. *Matern Child Health J* [Internet]. 2014 May [cited 2021 Jul 20];18(4):873–881. Available from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3871944/> PMCID: PMC3871944
42. Zlotnick C, Tzilos G, Miller I, Seifer R, Stout R. Randomized controlled trial to prevent postpartum depression in mothers on public assistance. *J Affect Disord*. 2016 Jan 1;189:263–268. PMCID: PMC4641029
43. Dimidjian S, Goodman SH, Felder J, Gallop R, Brown AP, Beck A. Staying Well during Pregnancy and the Postpartum: A Pilot Randomized Trial of Mindfulness Based Cognitive Therapy for the Prevention of Depressive Relapse/Recurrence. *J Consult Clin Psychol* [Internet]. 2016 Feb [cited 2021 Jul 20];84(2):134–145. Available from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5718345/> PMCID: PMC5718345
44. Putnick DL, Sundaram R, Bell EM, Ghassabian A, Goldstein RB, Robinson SL, Vafai Y, Gilman SE, Yeung E. Trajectories of Maternal Postpartum Depressive Symptoms. *Pediatrics*. 2020;146(5). PMID: 33109744
45. Park M, Brain U, Grunau RE, Diamond A, Oberlander TF. Maternal depression trajectories from pregnancy to 3 years postpartum are associated with children's behavior and executive functions at 3 and 6 years. *Arch Womens Ment Health* [Internet]. 2018;21(3):353–363. Available from: <https://doi.org/10.1007/s00737-017-0803-0> PMID: 29340801
46. Ahmed A, Bowen A, Feng CX, Muhajarine N. Trajectories of maternal depressive and anxiety symptoms from pregnancy to five years postpartum and their prenatal predictors. *BMC Pregnancy Childbirth*. 2019 Jan 14;19(1):26. PMCID: PMC6332639

47. Demographics of Mobile Device Ownership and Adoption in the United States [Internet]. Pew Research Center: Internet, Science & Tech. [cited 2021 Jul 20]. Available from: <https://www.pewresearch.org/internet/fact-sheet/mobile/>
48. Veinot TC, Mitchell H, Ancker JS. Good intentions are not enough: how informatics interventions can worsen inequality. J Am Med Inform Assoc JAMIA [Internet]. 2018 May 16 [cited 2021 Jun 11];25(8):1080–1088. Available from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7646885/> PMID: PMC7646885
49. López L, Green AR, Tan-McGrory A, King R, Betancourt JR. Bridging the digital divide in health care: the role of health information technology in addressing racial and ethnic disparities. Jt Comm J Qual Patient Saf. 2011 Oct;37(10):437–445. PMID: 22013816
50. Zhang MW, Ho RC, Loh A, Wing T, Wynne O, Chan SWC, Car J, Fung DSS. Current status of postnatal depression smartphone applications available on application stores: an information quality analysis. BMJ Open [Internet]. 2017 Nov 14 [cited 2021 Aug 6];7(11):e015655. Available from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5695478/> PMID: PMC5695478
51. Feldman N, Back D, Boland R, Torous J. A systematic review of mHealth application interventions for peripartum mood disorders: trends and evidence in academia and industry. Arch Womens Ment Health [Internet]. 2021 Apr 30 [cited 2021 Aug 6]; Available from: <https://doi.org/10.1007/s00737-021-01138-z> PMID: 33929636
52. Hussain-Shamsy N, Shah A, Vigod SN, Zaheer J, Seto E. Mobile Health for Perinatal Depression and Anxiety: Scoping Review. J Med Internet Res [Internet]. 2020 Apr 13 [cited 2021 Aug 6];22(4):e17011. Available from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7186872/> PMID: PMC7186872
53. Dol J, Richardson B, Murphy GT, Aston M, McMillan D, Campbell-Yeo M. Impact of mobile health interventions during the perinatal period on maternal psychosocial outcomes: a systematic review. JBI Evid Synth. 2020 Jan;18(1):30–55. PMID: 31972680