A Pilot Study of a Sequential Multiple Assignment Randomized Trial Aimed at Reducing Depressive Symptoms among Home Visiting Clients

The Home Visiting Applied Research Collaborative (HARC) advances innovative methods in home visiting research and the translation of findings into policy and practice.

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Background and Project Aims

Depression is common among perinatal (i.e., pregnant individuals and new mothers with a child < 1 year) families enrolled in home visiting (HV) services.[1, 2] Home visiting (HV) programs have increasingly integrated depression screening into their standard operating procedures, which has allowed programs to identify individuals who could benefit from mental health services and supports. For HV clients exhibiting more severe symptoms of depression, referral to a community mental health or primary care provider is often conducted. Effective interventions for treating perinatal depression among HV clients have also been developed that are integrated into HV workflows.[3-5] HV clients exhibiting mild to moderate depressive symptoms are at elevated risk for developing perinatal depression, with the Mothers and Babies (MB) intervention having demonstrated efficacy in preventing the onset of perinatal depression and reducing depressive symptoms among HV clients.[6-8]

Precision HV—defined as HV that differentiates what works, for whom, and in what contexts--has gained increasing attention in recent years.[9] A precision HV approach moves away from a "one size fits all" approach to tailoring HV services based on client needs. A similar precision approach can be used when conceptualizing how to optimally implement enhancements to HV services, including those focused on addressing perinatal depression. To illustrate, despite the success of MB in preventing the onset and worsening of perinatal depression among HV clients, not all women receiving MB exhibit improvements in their mental health. As such, an emerging area of inquiry for our MB research team was to develop tailored intervention delivery and content that provided the optimal amount intervention content and type of delivery modality to promote improved mental health outcomes for perinatal individuals receiving MB.

As an initial attempt to conduct a personalized, precision approach to MB implementation, we conducted a pilot study that used a sequential, multiple assignment, randomized trial (SMART) design[10] to test the effects of MB among perinatal individuals enrolled in HV programs. This pilot study aimed to establish the feasibility and acceptability of delivering different permeations of the MB intervention to perinatal individuals in HV programs. The specific objectives of our HARC Pilot Study were to:

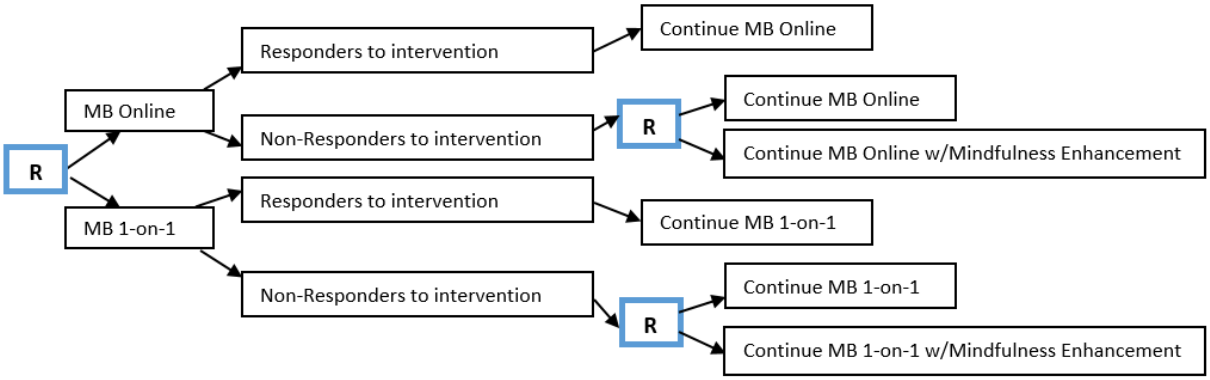
1. Pilot test the use of ecological momentary assessment (EMA)[11] data collection with HV clients to obtain real-time data on mood and stress
2. Pilot test randomization procedures for our SMART design
3. Develop and pilot test the delivery of additional mindfulness content in response to HV clients' self-reported mood and/or stress
4. Translate EMA text messages and MB mindfulness content into Spanish

Methods

Study Design

We used a SMART design in which all HV clients initially were randomized to receive the online version of MB ("eMB") or the individualized version of MB ("MB 1-on-1"). Women who exhibited low mood or happiness and/or high anxiety after beginning the intervention, as determined by their responses to EMA text messages, were intended to be re-randomized with half the "non-responders" in each arm assigned to continue to receive eMB or MB 1-on-1, while the other half of non-responders received the same delivery modality along with additional mindfulness content and MB text message reinforcements. Figure 1 depicts our SMART design.

Figure 1. SMART Design randomization for responders and non-responders



Study Participants and Recruitment Procedures

Three HV programs participated in this pilot study as partners and referral sites. The HV programs had been previously trained on MB and had experience delivering MB to HV clients. HV programs were located in Illinois and Indiana and represented Healthy Families America, Healthy Start, and Parents as Teachers HV models. Pregnant individuals and new mothers who were English or Spanish-speaking, receiving services at one of the participating HV programs, and were enrolled in HV for less than six months were eligible for study enrollment. Clients meeting these initial criteria were approached by home visitors to ask their permission to share their contact information with the research team. A member of the research team subsequently contacted the client by phone or text message to explain the research study, ascertain interest, and send a Research Electronic Data Capture (REDCap)12, 13 link to those expressing interest in the study. In REDCap, informed consent was obtained and subsequently clients completed the Beck Depression Inventory II (BDI-II)14 and the Maternal Mood Screener (MMS).15 Individuals who scored >11 on BDI and who did not meet criteria for major depressive episode (MDE) on the MMS were eligible for study participation. For individuals who were excluded due to MDE, a list of mental health resources was provided and the client's home visiting program was notified.

We received 19 referrals, of whom nine (47%) were eligible and were enrolled. The mean age of participants was 27.8. Of the nine enrolled participants, six identified as White and three as other when asked to report their racial identity; five participants identified as Hispanic/Latina. All participants were postpartum with an average age of eight months for their child. Four participants were enrolled in a program that used the Healthy Families model, four in Healthy Start, and one in Parents as Teachers.

Intervention Arms

MB 1-on-1. MB 1-on-1 is a manualized 9-session intervention divided into four modules. An introductory 1-session module establishes key concepts related to stress, monitoring one's mood, and ways our mood influences internal thoughts and external environment. Subsequently, there are modules that correspond with key cognitive-behavior elements: pleasant activities (Module 2, Sessions 2-3), thoughts (Module 3, Sessions 4-6), and social support (Module 4, Sessions 7-9). Each session lasts 20-25 minutes. Home visitors are instructed to deliver MB sessions in-person, by phone, or via telehealth (e.g., Zoom, Skype).

Mothers and Babies Online Course (eMB). The eMB intervention consists of 8 sessions with content that is largely similar to MB 1-on-1. Specifically, eMB consists of the same four modules and core cognitive-behavioral content found in MB 1-on-1. The eMB includes informational pages, short audio/video clips, images of infants and pregnant women, and worksheets for participants to enter personalized information in response to the psychoeducational lesson content. It differs from MB 1-on-1 in that a) there are no interactive discussions between facilitator and client, b) clients control the pace by which they review online content, and c) clients can review online content as many times as they like. The research team performed weekly checks to track session completion and after a participant completed an online session the research team recorded completion in HealthySMS--a web-based platform used by the research team in previous MB studies.

Participants enrolled in the study were initially randomized to either MB 1-on-1 or eMB. Four participants were randomized to receive MB 1-on-1 and five participants were randomized to receive eMB.

EMAs and SMART Randomization

EMAs. Each MB session (1-on-1 or eMB) was recorded as completed in HealthySMS. For MB 1-on-1 participants, home visitors were trained on HealthySMS to record session completion while for eMB participants, a member of the research team monitored and recorded session completion in HealthySMS. Once a MB session was recorded as completed in HealthySMS, the system released EMAs and collected EMA responses. Specifically, after the receipt of the 1st MB 1-on-1 or eMB intervention session, HealthySMS sent three EMA text messages every day for three weeks or until a client had completed their 3rd MB 1-on-1 or eMB session. Each EMA text message asked the participant to report on their mood on a 1-9 scale (1= worst possible mood, 5 = average mood, 9 = best possible mood). The same EMA text message also asked the participant to rate their happiness and anxiety on a four-point scale using EMA questions previously validated to assess these affective outcomes,16 with higher ratings indicating more happiness or anxiety. We created a mean mood, happiness, and anxiety score that averaged a participant's rating in each area (mood, happiness, anxiety) across all their responses. These EMA responses were used to determine intervention "responders" and "non-responders", used for purposes of re-randomization. Individuals scoring <7 on mood, <2.5 on happiness, and >2.5 on anxiety were considered non-responders.

SMART Randomization. Among the five participants initially randomized to the eMB arm, all five were "responders" to the intervention and therefore continued receiving eMB. Therefore, no participants initially assigned to the eMB arm were re-randomized to receive eMB with enhanced content. Among the four participants initially randomized to the MB 1-on-1 arm, one was deemed a "responder" to the intervention and continued receiving MB 1-on-1. The remaining three participants dropped out of their HV program. As such, none of the participants initially randomized to the MB 1-on-1 arm were re-randomized to receive MB 1-on-1 with enhanced content.

Data Collection: Client Mental Health Outcomes

Study participants completed three self-report surveys: baseline (pre-intervention), immediately before re-randomization (mid-intervention), and immediately after intervention completion (post-intervention). All surveys were completed via REDCap. Data collection was limited to demographics and three primary mental health outcomes. Depressive symptoms were assessed via the BDI-II,17 anxiety symptoms were measured via the Generalized Anxiety Disorder 7-item scale (GAD-7),18 and perceived stress was measured with the 10-item Perceived Scale (PSS-10).19 At post-intervention, clients were also asked about acceptability and usefulness of text messages, ecological momentary assessments, and enhanced content.

Results

Aim 1: Pilot test using EMA data collection with HV clients to obtain real-time data on mood and stress

Prior to this pilot study, our research team had not attempted to collect EMA data from HV participants. We received responses to EMAs from all nine enrolled participations, indicating at a more basic level that HV participants can access EMA text messages and respond to these text messages when prompted. Across the six participants who received any intervention content, our EMA response rate was 48% (range 0%-65%), indicating that just under half of the EMA text messages were responded to by study participants.

Aim 2: Pilot test randomization procedures for our SMART design

SMART designs require that decisions be made related to (1) selecting tailoring variable(s) to "trigger" re-randomization, (2) cutoffs for the tailoring variables to determine response/non-response to the intervention, and (3) appropriate time points for determining response/non-response. Related to selecting tailoring variables, we reviewed multiple potential constructs and ultimately selected mood, happiness, and anxiety as three variables that were associated with intervention content that would be most appropriate to determine participants' response to MB 1-on-1 or eMB. We used previous MB data and published literature to establish cutoffs for each tailoring variable (mood, happiness, and anxiety). We also selected between intervention sessions 3 and 4 as the time point for determining intervention response. This time point was selected, as it corresponds with the completion of one-third of the "base" intervention content, which was deemed an appropriate length of time for determining if a participant was responding favorably to the intervention.

Although these decision rules were established, we were not able to re-randomize participants since all study participants either did not meet our established cutoffs for "non-response" or disengaged from their HV program before their 4th MB session when re-randomization was due to occur. Table 1 illustrates the mean EMA scores for each tailoring variable, along with the range of average EMA scores for each variable.

Table 1. EMA scores among pilot study participants (n=9)

	Cutoff for Re-Randomization	Mean (SD) EMA Score	Range of EMA Average Scores
Mood	<7.0	7.7 (1.8)	7-9
Happiness	<2.5	3.4 (.85)	1-4
Anxiety	≥2.5	1.6 (.85)	1-4

Aim 3: Develop and pilot test the delivery of additional mindfulness content in response to HV clients' self-reported mood and/or stress

We were able to successfully develop additional mindfulness content intended to be used as part of the enhanced eMB or MB 1-on-1 intervention among individuals who were non-responders based on their EMA ratings. This additional content was developed as a series of text messages that contained strategies on using mindfulness approaches to help manage stress and to promote participants engagement in core MB skills. Some text messages contained embedded links to external content (e.g., worksheets, videos). As noted above, because none of our study participants were eligible for re-randomization, we were not able to deploy this mindfulness content during our pilot.

Aim 4: Translate EMA text messages and MB mindfulness content into Spanish

Data collected by the National Home Visiting Resource Center indicated that Spanish is the primary language for 15% of families enrolled across 15 evidence-based HV models.20 As such, we accomplished the final aim of our HARC pilot by translating our EMA text messages and mindfulness content into Spanish to allow our team to engage Spanish-speaking families during our pilot study and in subsequent projects.

Additional Results

Prior to this pilot study, our team had only delivered MB via in-person modalities—either MB 1-on-1 or MB group. Thus, another goal of this project was to determine the acceptability and feasibility of having HV clients engage in an online (eMB) modality. We found that all participants randomized to the eMB study arm logged into the eMB site and viewed at least one lesson. Participants viewed between 3-7 lessons, with 80% of participants also accessing or downloading one or more resources that was linked to in an eMB session. We also found that all participants engaged with the eMB platform by typing in at least one tailored response to questions asked during sessions.

Conclusions and Future Directions

Our pilot study was able to establish useful infrastructure that will serve as preliminary data for future research. In particular, we were able to (1) establish the feasibility of collecting EMA data from HV clients, (2) develop mindfulness content that can serve as supplemental content for intervention non-responders, (3) translate intervention materials into Spanish to allow for greater intervention reach, and (4) develop randomization procedures—including selection of tailoring variables and their cutoffs—necessary for a SMART study design. We were also able to establish preliminary feasibility of using the eMB modality among HV clients.

Our pilot study was not without challenges, however. First, recruitment was hindered by staff turnover and competing programmatic demands related to the COVID-19 pandemic. Many families approached by HV programs also declined to provide their contact information for eligibility screening, due, in part to families not wanting to participate in screening activities knowing that they may not meet eligibility criteria for study participation. We also received feedback from HV programs that some clients were reluctant to be assigned to a study arm that was not their preference. Second, we were limited in our ability to test our re-randomization procedures for several reasons. Our small sample size meant that we had fewer potential participants available for our re-randomization procedures. Additionally, our enrolled participants either did not meet criteria for re-randomization or disengaged from their HV programs. Although we felt the tailoring variables we

selected—i.e., mood, happiness, and anxiety—were appropriate metrics of client responsiveness to the MB intervention, it is possible that other constructs such as perceived stress or depressive symptoms are more appropriate. A larger sample size may have also allowed us to see greater variability in our tailoring variables, and future work should continue to explore the potential appropriateness of these variables for the purposes of identifying intervention responders.

Our EMA response rate of 48% also warrants review as we plan future studies. Because we requested EMA responses multiple times per day over a period three weeks, we had established a priori that only 30% of EMAs would need to be completed to allow us to have sufficient data to generate average mood, happiness, and anxiety ratings to judge our "responders" and "non-responders". All respondents except for one in our pilot study met this 30% threshold. However, it is possible that sending fewer EMAs to participants would have resulted in a higher response rate and also minimized participant burden.

The long-term goal of this project is to move from a "one size fits all" model for MB delivery to an adaptive intervention tailored to HV clients. Although our initial goal was to use our HARC pilot as a springboard to a R01 application, we believe a more appropriate next step will be the submission of a R21 or R34 application that will allow us to better identify intervention responders/non-responders and pilot our re-randomization procedures.

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