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Perinatal depression prevention through home visitation: a cluster randomized trial of mothers and babies 1-on-1

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Abstract Postpartum depression is highly prevalent in low-income women and has significant health effects on mother and child. This pilot study tested the effectiveness of the newly adapted Mothers and Babies (MB) 1-on-1 intervention. A cluster randomized trial was conducted with 8 programs using trained home visitors to deliver MB 1-on-1 and 6 delivering usual home visiting. One hundred twenty pregnant women not experiencing major depression were enrolled. Outcomes were assessed at baseline and 3- and 6-months postpartum. The rate of change in depressive and anxiety symptoms between groups was significant at 6 months, but not 3 months. No statistically significant differences between groups were found on secondary outcomes except perceptions of social support at 6 months. There was variability in use of MB skills, with fewer women using cognitive restructuring techniques. Although larger studies should be conducted, MB 1-on-1 appears promising in using home visitors to deliver a cognitive behavioral intervention to women at risk for postpartum depression.

Keywords Perinatal depression · Intervention · Home visiting

Introduction

Postpartum depression is a serious mental health disorder that poses significant health and mental health risks for mothers and their infants, creating two generations of suffering and increased risk for ongoing intergenerational transmission (Gaynes et al., 2005; National Research Council and Institute of Medicine, 2009; Weissman et al., 2016). One of the most common pregnancy-related health complications, women who experience postpartum depression are more likely to develop recurrent mood disorders over the life course, including increased risk for suicide attempts and mortality, as well as impaired attachment and parenting and long-term consequences for family well-being (Meltzer-Brody & Stuebe, 2014). Postpartum depression has been linked to developmental delays among infants of depressed mothers, including social interaction difficulties, attachment insecurity, and cognitive impairments (e.g., Grace et al., 2003; Sohr-Preston & Scaramella, 2006). Research has also shown less frequent use of preventive health services among mothers with postpartum depression (e.g., well-child visits and timely immunizations), as well as greater use of ambulatory and in-patient services for illness and injury (Chung et al., 2004; McLearn et al., 2006; Minkovitz et al., 2005).

The prevalence of postpartum depression has been estimated at 10–22% and disproportionately affects low-income women of all racial and ethnic groups, with a 20% prevalence rate consistently found among women of lower socio-economic status (Evans et al., 2001; Gaynes et al., 2005; Moses-Kolko & Roth, 2004; Segre et al., 2007). Studies indicate that rates of subthreshold depressive symptoms among low-income women are 30–45% (Howell et al., 2005; Mora et al., 2009)—double the rates of women of higher socio-economic status; these disparities exist

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irrespective of race, ethnicity, or geography (Bennett et al., 2004; Dolbier et al., 2013; Holzman et al., 2006). Despite these striking disparities, low-income women are less likely to receive mental health services in the perinatal period (pregnancy through child's first year) than their more affluent counterparts, due to a variety of factors including stigma related to mental health services and lack of access to community-based mental health providers—the latter being particularly salient in rural communities (Abrams et al., 2009; Leis et al., 2011). The public health need for mental health interventions outside of mental health settings is crucial to reduce health disparities across generations. These interventions need to include depression prevention interventions given the sizable number of women with subthreshold depressive symptoms who are at risk for developing major depressive disorder. Moreover, subthreshold depressive symptoms are associated with many of the same negative maternal and child health outcomes as major depression (Cuijpers et al., 2004; O'Hara & McCabe, 2013; Wagner et al., 2000). This article describes a randomized controlled effectiveness trial of one such postpartum depression prevention intervention, Mothers and Babies, delivered in home visiting settings with at-risk pregnant women.

Mothers and Babies (MB) is a manualized perinatal depression prevention intervention tailored to the specific needs and issues during the perinatal period, addressing both maternal mood and stress as well as mother-infant attachment. Based on both cognitive-behavioral theory and attachment theory, with emphasis on psychoeducation, the MB Course encourages a "healthy management of reality" approach wherein participants shape their daily experiences by noticing and attending to their internal reality (cognitive and emotional experiences) and external reality (environment and circumstances) by increased engagement in pleasant activities and positive social contacts within the context of environmental challenges they may have little control over (Le et al., 2015). MB has shown efficacy in preventing the onset of postpartum depression and worsening of depressive symptoms as well as improved mood management among perinatal women compared to women receiving usual care through a series of randomized controlled trials in prenatal care, pediatric primary care, and home visiting (Le et al., 2011; Leis et al., 2015; McFarlane et al., 2016; Muñoz et al., 2007; Tandon et al., 2011, 2014) when MB is delivered in a group format by mental health professionals. The most recent of these RCT's have been conducted in home visiting settings (McFarlane et al., 2016; Tandon et al., 2011, 2014).

MB was adapted into an individual intervention in response to barriers related to the implementation of groups, such as transportation and childcare, and rural settings. While the MB group intervention continues to be widely used, our research team adapted the MB group curriculum into an individual intervention for use in settings where pregnant women and new mothers and infants access services. Mothers and Babies 1-on-1 (MB 1-on-1) is a 12-session curriculum in which each session is delivered in 15–20 min segments, allowing for incorporation into another visit type (e.g., home visiting, prenatal care). A detailed description of the MB 1-on-1 adaptation process and initial feasibility testing is described in another manuscript (Tandon et al., 2018).

Home visiting is a service delivery strategy wherein trained individuals (e.g., social workers, nurses, early childhood education specialists) meet regularly in-home with pregnant women and women with young children (typically through age 3–5, depending on the model), to assess family needs and provide services or referrals related to maternal health, child health, parenting practices, child development and school readiness, and economic self-sufficiency (U.S. Dept. of Health Resources and Services Administration). Home visitation programs exist in all 50 states, and are funded through a variety of sources including federal, state, and county maternal and child health programs, boards of education, community-based organizations, and philanthropy. Over the past decade, home visiting models have been rigorously evaluated for effectiveness in impacting desired outcomes; of the 20 home visiting models currently shown to be evidence-based, Healthy Families America and Parents as Teachers, the home visiting models used in this study, perform well across multiple outcome domains (Avellar et al., 2016; Sama-Miller et al., 2017).

Within the Affordable Care Act legislation, the Maternal, Infant, and Early Childhood Home Visiting Program (MIECHV) provides nation-wide funding and oversight (Social Security Act, section 511 [42 U.S.C.711]), identifying maternal mental health as a benchmark outcome. As such, HV programs have increasingly integrated depression screening into standard operating procedures to determine whether a HV client has elevated symptoms or major depressive disorder and are responsible for addressing positive screens via in-house strategies or referrals to community resources. Rates of major depressive disorder among women in HV programs are around 15% (Ammerman et al., 2010) while rates of subthreshold depressive symptoms have been found among 45–50% of HV clients (Ammerman et al., 2009; Chazan-Cohen et al., 2007; Duggan et al., 2007; Tandon et al., 2005). For the most part, positive screens are followed by referral to an off-site mental health clinic for intervention only for women who meet criteria for major depressive disorder.

Several interventions aimed at *treating* depression among women in HV programs have been developed and empirically tested within the context of HV service deliv-

ery. Most notably, In-Home Cognitive Behavioral Therapy (IH-CBT), has been proven effective in achieving a high rate of depressive episode remission when delivered by licensed master's-level social workers over 15 one-hour in-home sessions, compared with control participants who received standard home visitation on its own (Ammerman et al., 2011, 2013). Beeber et al., (2010) implemented a culturally adapted version of Interpersonal Psychotherapy (IPT) among Latina immigrants with infants or toddlers, via 11 in-home sessions delivered by master's-level psychiatric nurses followed by five booster visits by Spanish language interpreters; results showed a significant decrease in depressive symptom severity among intervention participants compared to women receiving usual home visiting services alone. In both cases, these interventions required clinical mental health staff and lengthy additional sessions—options which may not be available or acceptable to all HV programs and clients. Segre et al., (2015) implemented six Listening Visits, either in home visits or OB-GYN office visits, delivered by home visitors or OB clinic staff. Listening Visits focused on empathic listening, collaborative problem solving, and assessment of need for additional mental health treatment. Results indicated that women receiving the Listening Visit intervention experienced reduced depression symptom severity and improved quality of life as compared to women receiving standard home visiting or prenatal services.

Given the large number of low-income perinatal women in HV programs exhibiting subthreshold depressive symptoms but not major depressive disorder, there is, therefore, prime opportunity to implement *preventive* interventions such as Mothers and Babies. This manuscript describes and shares results from a randomized controlled trial examining the efficacy of MB 1-on-1 implemented by home visitors with prenatal clients. Our main hypotheses were that receipt of MB 1-on-1 would result in a greater reduction in depressive symptoms and onset of fewer new cases of major depressive disorder when compared with receipt of usual HV services. We also hypothesized that the core CBT skills found in MB 1-on-1 would lead to greater reductions in anxiety symptoms and perceived stress among women receiving the intervention. Our secondary hypotheses focused on examining MB 1-on-1's impact on outcomes related to core CBT skills taught in the curriculum. We hypothesized that women receiving MB 1-on-1 would exhibit greater improvements in outcomes related to MB's three CBT modules: pleasant activities, thoughts, and contact with others. Finally, we hypothesized that greater dosage of MB 1-on-1 would result in greater reductions in depressive symptoms among women receiving the intervention.

Method

Research setting

Training

In partnership with the Illinois Governor's Office for Early Childhood Development, HV programs in Illinois were invited to attend one of three regional trainings on MB 1-on-1 in 2014. HV supervisors and staff from 19 HV programs participated in 1.5 day group trainings, led by the lead author, to learn basic cognitive-behavioral theory concepts, the MB 1-on-1 curriculum content, and the process for implementing the intervention in conjunction with delivering home visits (e.g., positioning of the MB session within the home visit agenda, alignment with the goals of the visit, modeling concepts for clients). Immediately after training and prior to this RCT, home visitors and their agency supervisors received biweekly supervision for 6 months from the lead author to support learning and promote intervention fidelity. Implementation fidelity was assessed on a session-by-session basis using a self-report tool tied to the specific content, asking providers (1) whether all of the session content was delivered to the client, (2) whether the client understood the content, (3) whether the client was engaged in learning the content, and (4) whether the client completed their personal project between sessions, as well as an open-ended question prompting details about challenges and successes encountered. In December 2014, 14 of these HV programs agreed to participate in a RCT where HV program sites were randomized to implement usual home visiting services or home visiting as well as MB 1-on-1.

Home visiting sites

All participating HV programs used either the Healthy Families America (HFA) (n = 9) or Parents as Teachers (PAT) model (n = 5)—both of which are included on the list of evidence-based HV models (Sama-Miller et al., 2017).

Healthy Families America and Parents as Teachers: Designed to promote positive parent–child relationships and healthy attachment via strengths-based, family-centered, culturally sensitive, and reflective practice, HFA enrolment targets parents facing challenges such as single parenthood, low income, childhood history of abuse and other adverse child experiences, and current or previous issues related to substance abuse, mental health issues, or domestic violence. Individual HFA sites are given latitude to select specific characteristics of the target population they plan to serve, while enrolling prenatally or within

3 months of birth and offering services through the child's fifth birthday (HFA National Office 2018). PAT aims to impact parenting knowledge, attitudes, behaviors and family well-being to advance the child's developmental trajectory, through home visits that focus on three areas of emphasis—parent–child interaction, development-centered parenting, and family well-being. The PAT model requires that providers deliver one-on-one home visits, group connections, health and developmental screenings for children, and linkages and connections for families to needed resources. PAT provider organizations select the specific characteristics and eligibility criteria of the target population they plan to serve (e.g., families at risk for child abuse, first-time parents), providing services to families in pregnancy through kindergarten entry (Parents as Teachers National Center 2018). Both HFA and PAT encourage sites to implement enhancement services, such as Mothers and Babies, that impact the specific needs of their target population.

Participants

Study inclusion and exclusion criteria were: (a) pregnant at time of referral and enrolment in the study, (b) English or Spanish speaking, (c) 18 years or older, and (d) no major depressive disorder. Between December 2014–June 2016, 201 pregnant women were referred to the research team from participating HV programs. Details regarding participant eligibility, randomization, and flow are presented in Fig. 1. Home visiting programs were randomized to act as intervention or control sites, using a modified constrained randomization process in which we addressed imbalance between study arms with respect to the key cluster level variables of home visiting model (HFA, PAT), program location/population density (urban, rural), and primary race/ethnicity of clients served by a HV program. Randomization schemes were simulated using these variables and we randomly selected one scheme using a random number generator. Of the 201 women referred, we were unable to contact 18. Among the 183 screened for eligibility, 120 were enrolled into the study. Most women who did not enroll in the study were not pregnant (n = 23), refused study participation (n = 13), were under 18 years of age (n = 11), or had major depression (n = 11). Four women were ineligible because they moved out of their HV program's service area after being referred to the study. Given that women in HV are eligible for HV services based on criteria such as being a single parent, social isolation, and living in poverty, we chose not to exclude women on the basis of a depression screener score since these same risk factors for HV program inclusion are highly predictive of major depression onset (O'Hara & Swain, 1996; Dennis & Dowswell, 2013). Of the 120 women enrolled in the

study, 54 were enrolled in HV programs randomized to receive the MB 1-on-1 intervention, and 66 were enrolled in HV programs randomized to deliver usual HV services.
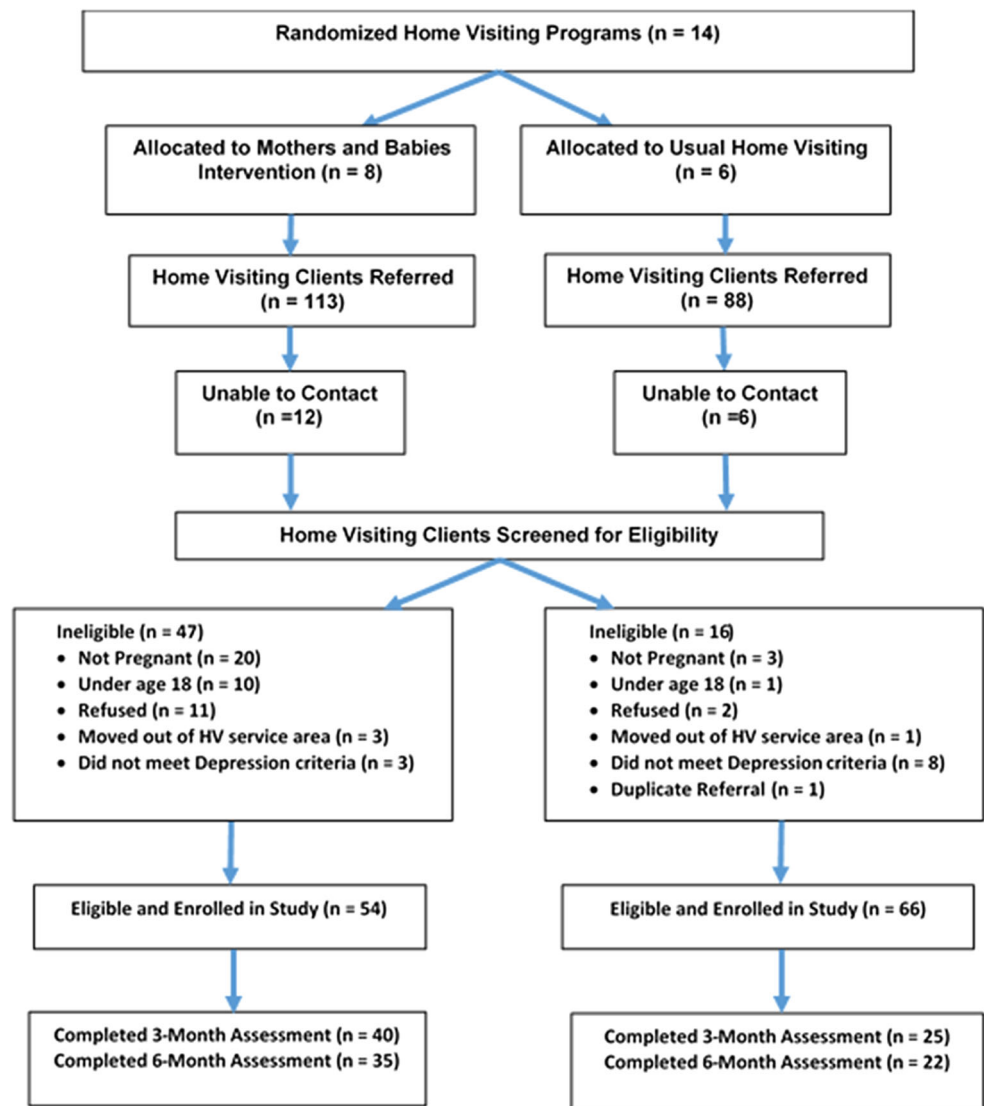
Data collection procedures

Home Visitors sent a referral form with contact information for an eligible participant to the research coordinator. The coordinator contacted these women to introduce the study, answer questions about participation, and ascertain interest in study participation. For women interested in the study, the research coordinator obtained informed consent by telephone or set up an appointment to meet with the participant in person. Participants consented by phone were mailed a copy of their consent form. All study procedures were approved by the Northwestern University Institutional Review Board and informed consent was obtained from all participants included in the study.

Participants were surveyed at three time points: baseline, 3 months postpartum, and 6 months postpartum. The research coordinator or research assistant conducted follow-up assessments over the telephone or in person via pen-and-paper surveys. Study participants were compensated with a $20 gift card for each completed survey. Data were manually entered into REDCap (Research Electronic Data Capture) and periodically audited to ensure accuracy over the course of the project. Of the 54 women enrolled in the intervention arm, 74% (n = 40) completed the 3-month follow-up assessment and 67% (n = 36) competed the 6-month follow-up assessment. Of the 66 women enrolled in the usual care arm 38% (n = 25) completed the 3-month follow-up and 33% (n = 22) competed the 6-month follow-up.

Measures

Our primary study outcomes were depressive symptoms and onset of new cases of major depression. The latter represented an important outcome for this preventive intervention, although we anticipated that the small number of cases would not allow for statistical testing of differences between study arms. Depressive symptoms were assessed using the Beck Depression Inventory II (BDI; Beck et al., 1996). The BDI-II is a 21-item self-report checklist that measures the existence and severity of depressive symptoms consistent with DSM-IV symptom criteria. Major depressive disorder was assessed using the Mood Module of the Structured Clinical Interview for DSM-IV, Non-Patient Research Version (SCID; First et al., 2002). Stress and anxiety were secondary outcomes that the CBT-informed MB intervention was hypothesized to impact. We used the 10-item Perceived Stress Scale (PSS-10; Cohen & Williamson, 1988; Remor 2006) to assess the

Fig. 1 Participant flow diagram


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Randomized Home Visiting Programs (n = 14)
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Allocated to Mothers and Babies          Allocated to Usual Home Visiting
Intervention (n = 8)                     (n = 6)
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Home Visiting Clients Referred           Home Visiting Clients Referred
(n = 113)                                (n = 88)
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Unable to Contact                        Unable to Contact
(n =12)                                  (n =6)
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Home Visiting Clients Screened for Eligibility
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Ineligible (n = 47)                      Ineligible (n = 16)
• Not Pregnant (n = 20)                  • Not Pregnant (n = 3)
• Under age 18 (n = 10)                  • Under age 18 (n = 1)
• Refused (n = 11)                       • Refused (n = 2)
• Moved out of HV service area (n = 3)   • Moved out of HV service area (n = 1)
• Did not meet Depression criteria (n = 3)  • Did not meet Depression criteria (n = 8)
                                         • Duplicate Referral (n = 1)
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Eligible and Enrolled in Study (n = 54)  Eligible and Enrolled in Study (n = 66)
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Completed 3-Month Assessment (n = 40)    Completed 3-Month Assessment (n = 25)
Completed 6-Month Assessment (n = 35)    Completed 6-Month Assessment (n = 22)
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level to which an individual considers her life stressful and how controllable a person appraises her life. To assess anxiety, we administered the Generalized Anxiety Disorder 7-item scale (GAD-7; Spitzer et al., 2006), which is a widely used self-report measure of anxiety symptoms. At each time point we assessed mental health treatment utilization, including both counseling and medication, via self-report.

The skills taught in MB 1-on-1 were hypothesized to lead to improvements in outcomes related to the three CBT modules: pleasant activities, thoughts, and contact with others. Engagement in pleasant activities was assessed using an adapted 25-item version of the Pleasant Events Schedule (PES; MacPhillamy and Lewinsohn 1982) that included pleasant events relevant for low-income pregnant women. To assess changes in thought patterns, we used the Experiences Questionnaire (EQ; Fresco et al., 2007), which is designed to measure decentering and rumination. The EQ has demonstrated strong internal consistency in examining effects of interventions that incorporate cognitive restructuring techniques (Fresco et al., 2007). We used the Medical Outcomes Study Social Support Survey (MOS-SSS; López & Cooper, 2011; Sherbourne & Stewart, 1991) to assess participants' perceived social support. This 19-item survey includes an overall functional social support index, as well as four functional support subscales: affectionate, emotional/informational, tangible, and positive social interaction. Another core MB concept is promoting mood regulation; as such, we assessed mood regulation using the Negative Mood Regulation Scale (NMRS; Catanzaro & Mearns, 1990; Catanzaro & Greenwood, 1994), a 30-item scale that assesses what an individual believes she can do when feeling disappointed or experiencing a negative mood.

We assessed intervention participants' use of MB skills using items developed by study investigators that ask, on a

5-point Likert scale (5 = every day, 1 = not at all), how often core skills taught in the curriculum were used in the last 30 days. Demographic data were collected at baseline and included age, race, current marital status, employment status, educational attainment, weeks pregnant, and number of previous births. All primary and secondary outcomes were measured at baseline and both follow-up assessments with the exception of the SCID that was administered only at the 3 and 6-month assessments.

Study conditions

Usual home visiting

Women in HV programs randomized to the usual home visiting arm received home visiting services in accordance with standard HFA or PAT program protocols. Usual home visiting for the two HV models that comprised our study sites, calls for home visits to occur, at minimum, on a bi-weekly basis. Women receiving usual home visiting were not proscribed from receiving any activities other than MB, including mental health referrals.

MB 1-on-1

Women in HV programs randomized to MB 1-on-1 received usual HV services in addition to the 12-session MB 1-on-1 curriculum. MB 1-on-1 was delivered in person by a home visitor trained on MB during regularly scheduled home visits. Each of the 12 MB sessions is designed to be delivered in 15–20 segments; home visitors have autonomy to deliver MB content at any point during a home visit. Sessions 1 and 2 provide an introduction to the MB curriculum and frame the curriculum as a stress management program that is beneficial to all women who are about to experience a role change (i.e., giving birth). Sessions 3–11 are divided into three separate modules, each consisting of three sessions that focus on each of the curriculum's core CBT concepts: pleasant activities, thoughts, and contact with others. Session 12 provides a course review and planning for ongoing use of MB skills in daily life. Each session contains didactic instruction on core content as well as interactive activities for the home visitor to conduct with a client. A personal project designed to facilitate practice of MB skills between sessions is assigned at the end of each session. MB sessions were delivered in English or Spanish, depending on the language preference of the client.

Data analysis

We followed intention to treat principles whereby participants were included in follow-up analysis regardless of participation in the Mothers and Babies intervention or usual home visiting services. Differences between participants in the intervention and usual care groups at baseline were determined using Fisher's exact test for categorical variables with small cell sizes, Chi square tests for categorical variables without small cell sizes, and independent samples t tests for continuous variables. The effect of intervention on our primary outcome (depressive symptoms) and secondary outcomes were estimated using separate mixed effects linear regression for each outcome. The regression model included fixed effects for condition (intervention vs. usual care), time, condition by time interaction and random effects for participant (to account for non-independence of measures for the same participant over time), and cluster. Analyses of primary and secondary outcomes were conducted using SPSS 24.0 (IBM Corp 2016), with the MIXED procedure to run the multilevel (mixed effects) models. Exploratory dosage analyses were conducted for women receiving the MB 1-on-1 intervention to examine changes in BDI-II scores between baseline and the 6-month postpartum assessment; dosage was categorized as "low" (0–6 MB sessions) or "high" (7+ MB sessions). To assess major depressive disorder, we calculated the percentage of intervention and control participants who met criteria for MDD at 6 months postpartum. For each MB skill, we calculated the percentage of intervention participants who indicated they used the skill "every day", "most of the days" or "over half the days" in the last 30 days.

Results

Figure 1 illustrates participant flow using the CONSORT diagram. Eight HV programs were randomized to deliver Mothers and Babies and six HV programs were randomized to usual home visiting. Table 1 presents participant characteristics by study arm. Both groups were diverse racially and ethnically, as over 60% of participants in both groups were African American or Latina. Most women were single or separated and were not working at time of study enrollment. There were two significant between-group differences in participants' characteristics at baseline, with intervention participants being significantly younger ($p < .01$) and first-time mothers ($p < .01$); both variables were entered as covariates in each multilevel model. At the time of enrolment and baseline assessment completion, participants were typically reaching the end of the second trimester or entering the third trimester [M

Table 1 Participant demographic characteristics at baseline by study group

Baseline characteristics	Intervention (n = 54)	Usual care (n = 66)	P value
Age (mean, SD)	22.5 (3.7)	29.1 (5.9)	< .01
Race (N, %)			
African American	18 (33)	29 (44)	.06
Latina	21 (39)	11 (17)	
White	10 (19)	23 (35)	
Other	4 (8)	3 (4)	
Marital status (N, %)			.43
Single or separated	34 (63)	46 (70)	
Married	6 (11)	11 (17)	
Living with partner or engaged	14 (26)	9 (13)	
Employment status (N, %)			.05
Not currently working	35 (65)	54 (82)	
Working part-or full-time	19 (35)	12 (18)	
Educational attainment (N, %)			.78
< High school degree	18 (33)	19 (29)	
High school degree/GED or beyond	36 (67)	47 (71)	
Weeks pregnant (mean, SD)	29.9 (6.2)	26.5 (7.1)	.22
First time mother (N, %)	32 (59)	13 (20)	< .01

(SD): 28.04 (6.9) weeks], with no statistically significant between group difference. There were no statistically significant differences at the 3- or 6-month postpartum assessments between women who completed assessments and those lost to follow-up for either the intervention or control groups. Fewer than 5% of study participants reported receipt of mental health treatment at the 3 or 6 month postpartum assessment.

Table 2 presents the means and standard deviations on the BDI-II and GAD-7 at all three time points. Within the intervention group, scores decreased between baseline and 3 months postpartum, with further reductions found at 6 months postpartum. In contrast, depressive symptom levels among control group participants were roughly similar at baseline and 6 months postpartum. There was not a statistically significant difference in the rate of change in depressive symptoms between intervention and control group participants at 3 months postpartum (unstandardized coefficient = − 1.56, z = .− 87, P = .38), although there was a significant difference between study groups at 6 months (unstandardized coefficient = − 5.99, z = − 2.39, P < .05). A similar pattern was found for anxiety symptoms, with significant differences in symptom-level changes between baseline and 6 months postpartum (unstandardized coefficient = − 4.45, z = − 3.13, P < .01), but no changes between baseline and 3 months postpartum (unstandardized coefficient = 1.91, z = 1.13, P < .35). No significant differences were found from baseline and 3 or 6 months postpartum between groups on perceived stress. At the 6-month postpartum assessment, 4 of 22 (18%) women receiving usual care met criteria for MDD compared with 2 of 35 (6%) women in the intervention condition.

Figure 2 shows results of our dosage analysis. Women receiving a low dose of the MB intervention (n = 15) showed little symptom relief between baseline [M (SD):

Table 2 Scores on the beck depression inventory-II (BDI-II) and generalized anxiety disorder 7-item (GAD-7) at each study time point by study group

	BDI-II score [mean (SD)]		GAD-7 score [mean (SD)]	
	Intervention	Usual care	Intervention	Usual care
Baseline[a]	10.1 (7.3)	12.1 (10.1)	5.9 (4.6)	6.9 (5.9)
3-month postpartum follow-up[b]	7.1 (5.8)	8.6 (8.7)	4.8 (5.1)	6.5 (5.9)
6-month postpartum follow-up[c]	6.4 (7.9)	12.4 (11.1)	3.7 (4.7)	8.2 (5.8)

[a]Intervention n = 54, usual care n = 66

[b]Intervention n = 40, usual care n = 25
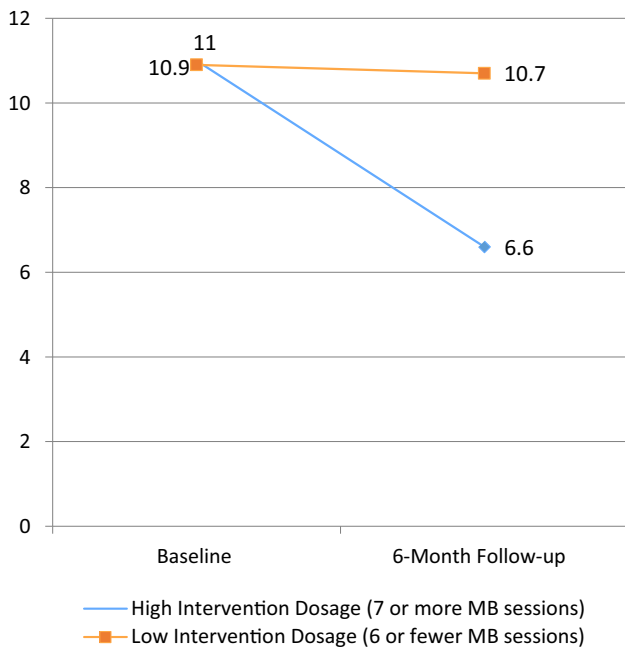
[c]Intervention n = 36, usual care n = 22

Fig. 2 Mean BDI-II scores at baseline and 6 months postpartum for women receiving low (n = 15) and high (n = 20) intervention dosage

10.9 (6.6)] and 6 months postpartum [M (SD): 10.7 (11.0)]. Women receiving a high dose of the intervention (n = 20), however, exhibited greater symptom relief between baseline [M (SD): 11.0 (8.1)] and 6 months postpartum [M (SD): 6.6 (5.9)].

When examining our secondary outcomes that align with core MB components, changes in mood regulation, engagement in pleasant activities, or decentering did not differ by group from baseline to either follow-up time point. However, the groups differed in perceptions of social support from baseline to the 6-month postpartum assessment (unstandardized coefficient = .61, z = − 2.44, P < .05). Table 3 reports on MB skill use by intervention participants. Almost two-thirds of intervention participants reported keeping track of their mood at least half of the

days in the last month when asked at their 3-month postpartum assessment, although this percentage dropped to 53% at 6 months postpartum. There was greater engagement in pleasant activities and contact with supportive individuals, with 75–81% of intervention participants reporting doing pleasant activities and contacting supportive individuals at follow-up assessments. The use of cognitive restructuring techniques was the least commonly endorsed of the core MB skills, with only 50 and 47% of intervention participants indicating that they used two or more of the techniques at least half of the days in the last month, when assessed at 3 and 6 months postpartum.

Discussion

Home visiting programs were randomized to deliver usual HV services or their standard of care in addition to the Mothers and Babies 1-on-1 intervention to prenatal clients. Women receiving MB 1-on-1 exhibited decreases in our primary outcome of depressive symptoms between baseline and 3 months postpartum, with a further decline exhibited at 6 months postpartum. There was a significant intervention effect on depressive symptoms between groups at our 6-month postpartum assessment. There was also a significant effect on anxiety symptoms at 6 months postpartum. Women receiving a higher dosage of the intervention appeared to show greater symptom relief between baseline and 6 months postpartum. However, we did not find statistically significant differences on perceived stress or key hypothesized mechanisms of the intervention except for perceived social support.

This is the first study to test the adapted, 1-on-1 version of MB. Our results are similar to RCTs of the MB group modality, which have demonstrated positive effects in reducing depressive symptoms among women at risk for developing perinatal depression (Le et al., 2011; McFarlane et al., 2016; Muñoz et al., 2007; Tandon et al., 2011,

Table 3 Mothers and babies skill use by intervention participants at 3- and 6-month postpartum assessments

Over the past month, how often have you…	% indicating every day, most days, or half of the days at 3 month postpartum assessment[a]	% indicating every day, most days, or half of the days at 6 month postpartum assessment[b]
Kept track of your mood	65	53
Engaged in pleasant activities	78	75
Used 2 or more of: thought interruption, worry time, time projection, or self-instruction to counter negative thought patterns	50	47
Talked to or contacted someone who has been a positive support to you or your baby?	80	81

[a] n = 40

[b] n = 36

2014). MB 1-on-1 may have important pragmatic implications for HV programs and other service providers that could benefit from integrating an intervention aimed at preventing the onset and worsening of depressive symptoms among perinatal populations. Specifically, MB 1-on-1 removes the need to provide transportation or childcare to women attending group-based intervention sessions. Although these costs are typically modest, and some HV programs may not find them to be fiscal or logistical barriers to using the MB group model, a group-based perinatal intervention also requires that enough pregnant women are receiving services and interested in receiving a group-based intervention at a single point in time. Thus, some smaller HV programs may inherently be better suited for an intervention that can be delivered individually to a pregnant woman or new mother, such as MB 1-on-1.

Another potential advantage of MB 1-on-1 is the use of home visitors as interventionists, especially given the low rate of mental health service access among low-income women (Abrams et al., 2009; Leis et al., 2011), and the growing population of high-risk women receiving home visitation. A systematic review of perinatal depression preventive interventions (Dennis & Dowswell, 2013) found that interventions delivered by both professionals and lay individuals appeared to reduce the risk of developing depressive symptoms. This review also notes that despite the encouraging findings when using lay interventionists, the majority of empirically tested interventions used professionals such as social workers or nurses. Our study's use of lay health professionals is innovative as home visitors already have a relationship with, and are delivering services to, perinatal women. As such, MB 1-on-1 has the potential to be highly cost-effective via its use of home visitors who are trained to integrate the intervention into the course of existing service contacts with their pregnant and recently delivered clients. This type of "self-contained" intervention that does not rely on linkages to external mental health services *or* bringing in an external intervention facilitator also builds the capacity of home visitors to understand and address stress and depression with their clients.

Study strengths and limitations

Strengths of this study include our randomized design, diverse sample of low-income women, and use of lay health workers—i.e., home visitors—to deliver our cognitive-behavioral intervention. Recent federal initiatives such as the Maternal, Infant, and Early Childhood Home Visiting (MIECHV) program allow HV programs to use up to 25% of funding to implement model enhancements such as MB 1-on-1. Thus, by engaging home visitors as intervention facilitators, MB 1-on-1 has great potential to be scaled to other HV programs across the country that are interested in augmenting their core model with mental health enhancements given the prevalence of women at risk for developing postpartum depression in HV.

There are three main limitations that must be considered in interpreting our study findings. First, our study suffered from large rates of attrition, thereby limiting our sample size of women with complete data at our two follow-up assessments. One of the contributing factors to our attrition is related to the macro-level forces influencing HV in Illinois during our assessment follow-up period. Many HV programs faced severe budget cuts due to a state budgetary impasse, which resulted in most participating sites reducing staff or even temporarily closing, thereby fragmenting relationships clients had with their HV program and also affecting their responsiveness to engage in ancillary activities such as participating in our study assessments. These budgetary issues appeared to disproportionately affect our usual care sites. It is important to note that despite our attrition rates, there were no statistically significant differences in demographics of responders and non-responders for either our control or intervention group at either follow-up assessment, thereby minimizing concerns of a systematic bias in our sample. The trend in our primary outcome of depressive symptoms also indicates the potential impact of MB 1-on-1 irrespective of the usual care condition, as mean depressive symptom scores declined from baseline to 3 months postpartum, with further declines in symptoms at 6 months postpartum. This trend mirrors findings from the most recent RCTs of the MB group model (McFarlane et al., 2016; Tandon et al., 2014). Our dosage data are also useful for this pilot study as they illustrate improvements in depressive symptoms among women receiving greater intervention exposure. Second, although we were interested in examining MB 1-on-1's impact on the core CBT skills that are the hypothesized mechanisms driving changes in depressive and anxiety symptoms, this study was not designed or powered to test for mediation. Building on the current study, we are now conducting a larger RCT of MB 1-on-1 that is adequately powered to test these mediational pathways. Third, because all participating HV programs were trained on MB prior to randomization, it is possible that home visitors at usual care sites used some MB content with women enrolled in the control arm despite instructions to wait to deliver the intervention until these women completed their 6-month follow-up assessment. When queried at the end of the study, no home visitors reported formally delivering the MB curriculum to women in the usual care arm, although it remains possible that some home visitors could have used MB terminology during the course of their regular home visits.

Future directions

Recent years have seen calls for increased perinatal depression screening by the U.S. Preventive Services Task Force (2016) and the American Academy of Pediatrics (Earls & The Committee on Psychosocial Aspects of Child and Family Health, 2010). Although perinatal depression screening has been widely integrated into HV programs and other settings that serve perinatal women—e.g., community health centers, prenatal clinics, pediatric primary care—increased screening has not translated into increased receipt of mental health services, particularly for women exhibiting subthreshold depressive symptoms since most specialized mental health providers focus primarily on women meeting criteria for major depressive disorder. This study provides preliminary evidence that a brief intervention delivered by lay health workers is effective in reducing depressive and anxiety symptoms among women who have subthreshold depressive symptoms during pregnancy. Although we conducted this study in the context of HV programs, MB 1-on-1 is a highly portable intervention that could be considered for use in a variety of non-mental health settings that serve perinatal women.

Maternal psychosocial well-being in the postpartum period is critically important in promoting the self-regulation and adaptive functioning of infants and toddlers, which, in turn are robust predictors of future child health and development (Glover 2014; O'Connor et al., 2013). Typically, interventions to promote positive parenting in the postpartum period target parents already depressed or children exhibiting early signs of conduct problems. We believe that HV, and enhancements to these programs like Mothers and Babies, could greatly reduce the burden on postpartum health care providers to provide treatment-focused services. Because of HV programs' rapid growth in the number of clients served throughout the last decade (Sama-Miller et al., 2017), HV serves as an important, and growing, setting for preventive interventions that have a significant two-generation public health impact on postpartum maternal mental health and young child development, which is important for all concerned.

Compliance with ethical standards

Conflict of interest S. Darius Tandon, Erin A. Ward, Jaime L. Hamil, Cindy Jimenez, and Mya Carter declare that they have no conflict of interest.

Human and animal rights and Informed Consent All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Informed consent was obtained from all patients for being included in the study.

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