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6-Month Outcomes from a Randomized Controlled Trial to Prevent Perinatal Depression in Low-Income Home Visiting Clients

S. Darius Tandon, Ph.D.,

Johns Hopkins University School of Medicine, Department of Pediatrics, 200 North Wolfe Street, Baltimore MD 21287; standon@jhmi.edu; Phone: 41-614-5281

Julie A. Leis, Ph.D.,

Johns Hopkins University School of Medicine

Tamar Mendelson, Ph.D.,

Johns Hopkins University Bloomberg School of Public Health

Deborah F. Perry, Ph.D., and

Georgetown University

Karen Kemp, MSW

Johns Hopkins University School of Medicine

Abstract

Objectives—Perinatal depression (PD) has negative consequences for mothers and children and is more prevalent among women of low socioeconomic status. Home visitation programs serve low-income pregnant women at risk for PD. This study tested the efficacy of a group-based cognitive behavioral intervention (Mothers and Babies Course; MB) in reducing depressive symptoms and preventing the onset of perinatal depression among low-income women enrolled in home visitation.

Methods—A randomized controlled trial was conducted. Seventy-eight women who were pregnant or had a child less than 6 months of age and who were assessed as at risk for PD were randomized to the MB intervention or usual home visiting services. Depressive symptoms were assessed at baseline and 1-week, 3- and 6-months post-intervention; depressive episodes were assessed with a clinical interview at the 6-month follow-up.

Results—Depressive symptoms declined at a significantly greater rate for intervention participants than usual care participants between baseline and 1-week, 3 months, and 6 months post-intervention. At the six-month follow-up, 15% of women who received the MB intervention had experienced a major depressive episode as compared with 32% of women receiving usual care.

Conclusions—Integrating mental health interventions into home visitation appears to be a promising approach for preventing PD. Cognitive behavioral techniques can be effective in preventing depression in perinatal populations and treating it.

Keywords

Perinatal depression; depression; prevention; home visiting; African American; African-American; low-income

Introduction

Perinatal depression (PD) affects 10–15% of childbearing women (1–2). Defined as major depression occurring during pregnancy or the first 12 months postpartum (3) PD is the most frequent form of maternal morbidity following delivery (4), making it a major public health concern. Women from lower socioeconomic status have been found to be at elevated risk for PD, with some studies showing that depressive symptoms are twice as prevalent among low-income pregnant women as those women of higher socioeconomic status (5–6). The negative consequences associated with PD for the mother, her infant, and the mother-child relationship are well established (7). PD is commonly under-recognized and undertreated, however. Only half of women with PD are estimated to receive any type of mental health evaluation or treatment (8), with this number decreasing to less than one-quarter among women diagnosed with depression during pregnancy (9).

Given the negative consequences of PD and the limited success in linking women with needed treatment, a growing number of randomized controlled trials (RCTs) aimed at preventing PD have been conducted, yielding mixed results (10–22). These RCTs have varied in terms of sample characteristics, sample size, recruitment sites, inclusion and exclusion criteria, and interventionist background and training. The interventions studied in these RCTs also had different theoretical frameworks, although most studies used cognitive-behavioral therapy (10,17,18) or interpersonal psychotherapy (21–22) approaches. Most interventions also included psychoeducation and instruction on how to manage PD, strategies for seeking or enhancing social support, and information on infant development, the process of pregnancy, and childbirth. Three studies showed significant reductions in depressive symptoms (14,17,21) while three found lower rates of new depressive episodes (16,21,22). Another study found reductions in depressive symptoms and fewer new cases of clinical depression among intervention participants, but only for primiparous women (15).

The previous RCTs aimed at preventing PD are limited in respect to two significant design characteristics. First, only roughly half of these studies included structured diagnostic interviews to assess new depressive episodes. Second, depressive symptom or episode outcomes were typically assessed only shortly after intervention completion, with only five studies conducting follow-ups at six months post-intervention or beyond (10,16–19). Of these studies that examined depression outcomes at six months post-intervention or beyond, only Lara et al (16) found an intervention effect. Their study, which enrolled women 26 weeks pregnant, found a lower cumulative incidence rate of major depression when combining new cases of depression at six weeks and four to six months postpartum. Previous RCTs were conducted in hospital or community clinic settings. Stronger intervention effects may be anticipated in settings that afford more structured and consistent contact with women, such as home visitation programs.

Home visitation programs for at-risk mothers and their infants have proliferated in recent years making home visitation one of the largest avenues through which perinatal women come to the attention of service providers. This expansion of home visitation will increase in the coming years given the authorization of a federal maternal, infant, and early childhood home visiting initiative (MIECHV) created by the Patient Protection and Affordable Care Act (23). Although home visitation models and targeted outcomes vary, they typically enroll women prenatally with services continuing until a child reaches two to five years of age. Home visitation models include both direct service and referrals, and focus largely on maternal health during pregnancy and childbirth, preparing the home for a new baby, establishing connections between families and preventive health care providers (e.g., prenatal care, pediatric primary care), and promoting infant development. Home visitation programs typically enroll women most vulnerable to poor maternal and child health

outcomes. As such, home visitation programs serve large numbers of women with depressive symptoms with some studies reporting rates of about 50% (24–27).

Despite the large number of women presenting to home visitation programs with depressive symptoms, few interventions have addressed PD among home visitation clients, with previous studies focused on treatment of PD rather than prevention (28,29). To address this notable gap, our team has developed a program of research aimed at preventing PD among home visitation clients. We built on the RCTs conducted by Muñoz et al. (18) and Le et al. (17) that used a CBT-based group intervention—the Mothers and Babies Course (MB Course). The MB Course is a manualized intervention that promotes healthy mood management by teaching participants how to increase the frequency of thoughts and behaviors that lead to positive mood states. Results of a small RCT in a hospital setting with 41 low-income, pregnant Latinas at high risk for PD indicated that 14% of women participating in the MB Course developed a new onset of major depression by the end of the first postpartum year compared to 25% receiving usual care (18). In Le et al.'s (17) RCT conducted in a prenatal care clinic with 217 low-income Latinas, women participating in the MB Course had lower depressive symptoms one week after the last intervention session than women receiving usual prenatal care.

This manuscript reports on the outcomes of a RCT conducted in four home visitation programs in [*deleted for blind review*] in which women were assigned to receive either the MB Course or usual home visitation services. We report on the efficacy of the MB course in reducing depressive symptoms at one week, three months, and six months post-intervention. We also discuss intervention efficacy in preventing the onset of major depressive disorder. Building on a previous report (30), which described preliminary outcomes from this RCT, the current manuscript includes a larger sample size (i.e., a fourth home visiting program). Also, and of considerable significance given the limited number of previous PD prevention trials that have examined outcomes at six months post-intervention or beyond, this manuscript presents self-reported depressive symptom data and results of clinical interviews used to assess major depressive episodes at six months post-intervention.

Methods

Sample

The sample consisted of 78 women and included both pregnant women and women with a child less than six months old who were enrolled in one of four [*city deleted for blind review*] home visiting programs. The study coordinator contacted women by phone to screen them for study eligibility. We used the CES-D (31) to screen for current depressive symptoms and the Maternal Mood Screener (MMS) (32) to assess current and lifetime major depressive episode. The MMS is a self-report checklist to assess depressive episodes using DSM-IV criteria that has shown good concordance with diagnostic interviews (33,34).

Women with elevated depressive symptoms (CES-D ≥ 16) and/or a lifetime depressive episode but who were not currently exhibiting a depressive episode were eligible for study participation. Women experiencing a depressive episode were referred to the clinical supervisor at the home visiting program who initiated further assessment and referral to mental health treatment.

Recruitment took place between October 2009 and March 2010. Details of the flow of participants can be seen in Figure 1. Of the 307 women we attempted to contact, 188 (61%) were screened. Of those women screened, 66 (35%) did not meet eligibility criteria and 2 (<1%) met criteria but declined participation. The remaining 120 women were randomized. Individuals were randomized by the study coordinator using a random number table. Of the

61 women assigned to the intervention group, 41 (67%) enrolled in the study while among the 59 who were assigned to the control group, 37 (63%) enrolled. Across both groups, the most common reason for not enrolling in the study after randomization was our inability to sustain phone contact due to participants' moving and/or having all available phone numbers disconnected. However, no statistically significant differences were found on maternal age, pregnancy status (i.e., prenatal vs. postpartum), number of previous pregnancies, or race/ethnicity between randomized women who enrolled and did not enroll in the study for both the intervention and control groups.

Assessments

Depressive symptoms—At baseline, one-week, three months, and six months post-intervention we assessed depressive symptoms using the second version of the Beck Depression Inventory (BDI-II) (35). 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. The BDI-II has been widely used in perinatal depression research and has excellent internal reliability (Chronbach's α s ranged from .88 to .93 across the time points). Surveys were read aloud and administered via group administration. If a study participant did not attend the scheduled group administration, the study coordinator administered the survey individually. Study participants were compensated \$20 cash for each completed survey.

Depressive episodes—We administered the Structured Clinical Interview for DSM-IV Axis I Disorders Research Non-Patient Version (SCID-I) at six months post-intervention to assess new cases of perinatal depression (36). The SCID-I is a semi-structured interview for diagnosing DSM-IV Axis I disorders. Study participants were compensated an additional \$25 for completing the SCID. The SCID was administered individually to study participants by a licensed clinical social worker who was blind to participants' group assignment; this clinician was not involved in intervention delivery.

The [deleted for blind review] Institutional Review Board approved all study procedures. All participants provided informed consent prior to completion of the baseline assessment.

Intervention

Intervention participants received standard home visiting services plus the adapted 6-session version of the Mothers and Babies Course (MB Course), consisting of six two-hour intervention sessions delivered weekly in a group format by either a licensed clinical social worker or clinical psychologist. The six sessions were divided into three two-session modules that mapped onto core CBT concepts: pleasant activities, thoughts, and contact with others. Each session contained didactic instruction on core content, along with activities and group discussion. The activities and group discussion focused largely on introducing and practicing the use of core skills (e.g., strategies to reduce harmful thought patterns, ways to effectively ask for support). In keeping with the CBT orientation of the intervention, at the end of each session a personal project was assigned which asked participants to practice using one or more of the skills taught during the session. The format for each session remained constant: general announcements, review of key concepts from previous session, review of personal projects, introduction of new material, and introduction of personal projects.

Because the MB Course had previously been implemented with perinatal Latinas in a hospital OB/GYN clinic (18) and prenatal care clinic (17), study investigators conducted formative research with home visiting programs to adapt the MB Course for a new setting (i.e., home visiting programs) and new population (i.e., low-income African American

women). Based on feedback received from home visiting programs, we condensed the content of the intervention into six rather than eight weeks to facilitate greater attendance. The 6-week version contained the same number of contact hours (12 hours) and retained all core intervention elements found in the 8-week version. Fidelity of adaptation from the original model was checked by one of the program's developers (see *deleted for blind review*, 37) for additional details regarding intervention adaptation).

Home visitors were asked to reinforce group material for five to ten minutes during each of their regularly scheduled home visits with intervention participants. To facilitate this reinforcement, study investigators developed laminated index cards for home visitors. One side of the index card summarized key intervention points while the other side outlined the personal project that study participants were asked to complete between intervention sessions. Booster sessions were conducted at 3-months and 6-months post-intervention. These sessions focused on reinforcing key content from intervention sessions, discussing challenges group participants had applying intervention skills in their lives, and brainstorming approaches to facilitate subsequent use of these skills. As an example, group participants were asked to share their experiences scheduling and completing pleasant activities for themselves (e.g., talking with a friend, reading scripture) along with pleasant activities with their babies (e.g., singing a lull-a-bye). If a participant experienced challenges with scheduling or completing pleasant activities, the group facilitator asked other participants to share strategies they used to overcome similar challenges.

Intervention participants were provided with transportation, childcare (if needed), and a meal at each session. To ensure attendance at each intervention session, the study coordinator attempted to contact each participant twice by phone and once by email prior to a session. Clinicians leading intervention groups were trained to fidelity on the MB Course prior to implementation and received weekly supervision from a masters-level clinical psychologist who had previous experience leading MB groups (17). This weekly supervision involved a review of the fidelity observation form completed by the study coordinator who attended all intervention sessions that documented whether clinicians did not cover, adequately covered, or excellently covered key session components.

The intervention was delivered to five different groups of participants across the four home visiting sites. The number of participants per group ranged from six to nine. Across intervention groups, the mean number of sessions attended was 4.5 (SD = 1.36, range 1–6) and there were two modes, with 12 participants attending five and six sessions, respectively. Most intervention participants (78%) attended at least one booster session and 51% attended both. Home visitors conducted weekly reinforcements with 71% (29/41) of study participants, with an average of 3.0 reinforcements conducted (max = 5). Across all sessions, clinicians adequately or excellently covered 84% of key session components.

Usual Care

All women randomized to the usual care condition received standard home visiting services plus a packet of information on perinatal depression.

Retention

Of the 41 women in the intervention group, 40 (98%) completed the one-week post-intervention assessment and all 41 completed the 3- and 6-month post-intervention assessments. Of the 37 women in the control group, all 37 completed the one-week post-intervention assessment, 35 (95%) completed the 3-month assessment, and 34 (92%) completed the 6-month assessment.

Data Analysis Plan

Differences between participants in the intervention and usual care groups at baseline were determined using χ^2 and Fisher's exact tests (one-sided) for categorical variables and independent sample t tests for continuous variables. The effect of the intervention on depressive symptoms was estimated using mixed effects linear regression. The regression model included fixed effects for condition (intervention vs. usual care), time, site (i.e., home visiting program), an intervention X time interaction term that examined the rate of change over time between the two intervention conditions, and a random effect for participant to account for non-independence of scores for the same participant over time. Exploratory analyses were conducted to examine effects of intervention dosage on changes in mean depressive symptoms at our follow-up time points. These dosage analyses defined high intervention dosage in various ways, attempting to determine whether number of intervention sessions, number of booster sessions, and number of home visitor reinforcements independently or additively produced more favorable outcomes for intervention participants. The effect of the intervention on cases of depression assessed by the SCID at the 6-month follow-up was tested with χ^2 tests. All analyses were conducted using Stata version 11 (38).

Results

Demographic Characteristics

At baseline, participants ranged in age from 14 to 41 with a mean age of 24.1 (SD = 6.1) years. Overall, the majority of the women in the sample were African American (83.1%), single (78.2%), and were not currently working (72.4%). Over half had a high school degree or GED (59.7%). Approximately one third (28.2%) of the sample was pregnant, and approximately two thirds (71.8%) were postpartum. The current child was the first child for 27.6% of women. No statistically significant differences were found between participants in the intervention and usual care groups at baseline on any demographic characteristics (Table 1).

Change in Depressive Symptoms

Table 2 presents the means and standard deviations on the BDI-II at all four time points. Within the intervention group, scores decreased from baseline to each follow-up while within the usual care group, scores remained approximately the same. A formal test of the effect of the intervention on depressive symptoms indicated that depressive symptoms declined at a significantly greater rate for intervention participants than usual care participants between baseline and 1-week (unstandardized coefficient = -6.07 ; $z = -2.96$; $P < 0.01$; $d = -0.64$), 3 months (unstandardized coefficient = -5.91 ; $z = -2.87$; $P < 0.01$; $d = -0.62$), and 6 months (unstandardized coefficient = -6.94 ; $z = -3.35$; $P < 0.001$; $d = -0.73$) post-intervention (Table 3). No intervention or control group participants reported any antidepressant use or receipt of mental health services (e.g., psychiatrist, psychologist) between baseline and 6-month follow-up. We did not find any statistically significant differences in mean depressive symptom score changes at our follow-up time points when comparing participants receiving different levels of intervention dosage (data available from first author upon request).

Depressive Episodes

At six months post-intervention, 11 of 34 (32.4%) women receiving usual care were assessed as having a depressive episode compared with 6 of 41 (14.6%) women receiving the MB Course ($\chi^2 = 3.33$, $P = .07$, effect size (ϕ) = .21).

Discussion

The findings from this RCT suggest that a cognitive-behavioral intervention integrated into home visitation programs can prevent the worsening of depressive symptoms among low-income perinatal women. Women receiving the MB Course exhibited a decrease in depressive symptoms at each study follow-up, with intervention effects strongest at the 6-month follow-up. To our knowledge, this study is the first randomized controlled trial to document the effectiveness of a perinatal depression preventive intervention on depressive symptoms at six months post-intervention. Moreover, no previous trials have demonstrated an enduring preventive effect on depressive symptoms across multiple time points post-intervention.

We also found a trend toward fewer women in the intervention group developing a depressive episode at six months post-intervention, as determined by a structured clinical interview. The 14.6% incidence rate for developing a depressive episode among intervention participants approximates the incidence rate for postpartum depression among general populations, suggesting that depression risk in our intervention group of women at elevated risk for postpartum depression had been reduced to normal community rates (1,2). Given the low incidence of depressive episodes, obtaining statistically significant results in depression prevention trials is challenging without very large sample sizes (39). However, the current study and previous trials of the MB Course (18) reveal clinically meaningful trends in preventing new depressive episodes in the perinatal period. Smaller trials such as the current study also facilitate the estimation of an intervention effect size, which will aid in the development of a subsequent, larger-scale randomized controlled trial. Moreover, multiple smaller trials advance the rigorous study of prevention outcomes via meta-analytic approaches (39).

This study is the first to attempt to prevent perinatal depression among participants enrolled in home visitation programs. Studies have indicated high rates of depression among home visiting program enrollees, but few depressed perinatal women in these programs receive needed mental health treatment (24,27). Reasons for low treatment rates include mental health stigma, mistrust of mental health providers, and practical challenges to accessing services (e.g., transportation, child care) (40). The limited success in linking depressed perinatal women with treatment services argues for a shift in focus to prevention services. Home visitation programs can serve as an ideal setting for embedding depression prevention interventions given the large number of women served by home visitation programs—many of whom are at elevated risk for perinatal depression (24–27). One such strategy for integrating depression prevention interventions into home visitation is through the Patient Protection and Affordable Care Act's MIECHV initiative which allows each jurisdiction to allocate up to a quarter of their funding for promising practices.

Preventive interventions such as the MB Course also offer an advantage in that they are not framed as mental health treatments but rather as courses to enhance coping skills; thus, they are far less likely to be perceived by clients as stigmatizing. As seen in this study, home visitors—who have an existing relationship with study participants—are also able to reinforce key intervention messages during the course of their 1-on-1 home visits, thereby creating a multimodal approach to delivering intervention content. In our experience, we did not encounter difficulty engaging clients in the program, they greatly enjoyed participating in the groups, and they expressed disappointment when the sessions ended. A warm, friendly atmosphere at the group sessions—including food—appeared to contribute to clients' positive experience. At the booster sessions, group members reported staying in contact with one another.

The primary limitation of this study is the absence of an active control condition. Resources were not available to be able to conduct a structured clinical interview at our three-month follow-up. As a result, another limitation is the administration of a structured clinical interview to assess depressive episodes at only the six-month follow-up. Given the episodic nature of depression, some study participants may have had an episode at only the three-month follow-up, potentially underestimating the number of new depressive episodes in each study group. We also had limited ability to study the effects of intervention dosage on study outcomes given our relatively small sample size. Interestingly, our exploratory analyses did not suggest that greater intervention exposure resulted in more robust improvements in depressive symptoms. Given this study's focus on establishing the efficacy of the MB Course in home visitation programs, we believe that future studies will be better positioned to examine thresholds for intervention dosage effects.

Study limitations are offset by several notable strengths, including the use of a randomized control design; excellent retention rates; measurement of intervention fidelity; and a high level of attendance by intervention participants. This study also benefitted from multiple follow-up assessment points, including a six-month post-intervention follow-up. Few other perinatal depression prevention trials have incorporated a six-month follow-up, with the present study being the first to demonstrate an intervention effect on depressive symptoms at this more distal time point. The present study also used a structured clinical interview to assess depressive episodes at six months post-intervention. Many previous PD prevention trials have not used a structured clinical interview, with only one study (16) finding a statistically significant difference and a previous trial of the MB intervention (18) yielding a clinically significant difference between intervention and control groups in new cases of major depressive disorder.

In conclusion, these findings suggest that a brief cognitive-behavioral intervention integrated into home visitation programs can successfully prevent the worsening of depressive symptoms, with sustained effects seen at six-months post-intervention. Given the pernicious effects of maternal depression on child development, parenting practices, and child preventive health care utilization, interventions to prevent perinatal depression onset are warranted. As home visitation programs proliferate in the coming years through federal legislation such as the Patient Protection and Affordable Care Act MIECHV program, interventions such as the MB Course that can be integrated into home visitation have considerable potential to be taken to scale. Perinatal depression preventive interventions conducted in home visitation should also examine the effects of intervention exposure on program retention and engagement, given previous research (41, 42) that has identified psychosocial risk factors such as depression as barriers to program engagement.

Future experimental studies should be undertaken with geographically and ethnically diverse home visitation populations to further establish the efficacy of the MB Course. Although challenging given the resources needed and increased respondent burden, future research should strive to include structured clinical interviews to determine major depression diagnosis at all follow-up time points. More formal dosage analyses using statistical techniques such as complier average causal effects are also needed to generate more precise estimates of intervention effects based on intervention dosage. Future studies should examine the long-term preventive effects on depressive symptoms and incidence of major depression given the paucity of research documenting sustained effects of interventions with perinatal populations. These studies would ideally also include long-term follow-up assessments that examine intervention effects on maternal parenting practices and infant and young child emotional and behavioral problems.

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Figure 1.
Participant flow diagram

Table 1

Participant demographic characteristics at baseline by intervention group

Baseline Characteristics		Intervention (n=41)	Usual Care (n=37)	P Value
Age, (mean, SD)		24.4 (6.4)	23.8 (5.9)	.65
Race (N, %)				
	African American	33 (82.5)	31 (83.8)	.99
	Caucasian	5 (12.5)	4 (10.8)	
	Other	2 (5.0)	2 (5.4)	
Marital status, (N, %)				
	Single	31 (75.6)	31 (83.8)	.37
	Married	10 (24.4)	6 (16.2)	
Employment status, (N, %)				
	Unemployed	28 (70.0)	27 (75.0)	.25
	Working full-time	5 (12.5)	7 (19.4)	
	Working part-time	7 (17.5)	2 (5.6)	
Educational attainment, (N, %)				
	< High school degree	15 (37.5)	16 (43.2)	.10
	High school degree/GED	9 (22.5)	14 (37.8)	
	> High school degree/GED	16 (40.0)	7 (18.9)	
Pregnancy status				
	Prenatal, (N, %)	12 (29.3)	10 (27.0)	.83
	Postpartum, (N, %)	29 (70.7)	27 (73.0)	
Weeks pregnant (among women enrolled prenatally) (mean, SD)		27.3 (9.8)	28.6 (6.8)	.75
Child age in weeks (among women enrolled postpartum) (mean, SD)		12.6 (6.3)	12.0 (7.3)	.77
First time mother (N, %)				
	Yes	11 (27.5)	10 (27.8)	.98
	No	29 (72.5)	26 (72.2)	

Table 2

Scores on the BDI-II at each wave by intervention group

BDI-II score, mean (SD)	Intervention	Usual Care
Baseline ^a	16.3 (8.7)	13.4 (10.2)
1-week post-intervention ^b	11.7 (10.1)	14.8 (8.4)
3-months post-intervention ^c	9.1 (10.2)	12.2 (10.5)
6-months post-intervention ^d	8.9 (9.2)	13.2 (10.1)

Abbreviations: BDI, Beck Depression Inventory.

^aIntervention n=41, Usual care n=37^bIntervention n=40, Usual care n=37^cIntervention n=41, Usual care n=35^dIntervention n=41, Usual care n=34

Table 3

Results of the mixed effect linear regression model

	Coefficient (SE)	<i>z</i>	Effect size (<i>d</i>)
Condition (intervention vs usual care)	2.91 (2.12)	1.37	0.31
1 week post-intervention	1.46 (1.48)	0.99	0.15
3-months post-intervention	-1.21 (1.51)	-0.80	-0.13
6-months post-intervention	-0.45 (1.52)	-0.30	-0.05
Condition x 1 week post-intervention	-6.07 (2.05)	-2.96 ^a	-0.64
Condition x 3-months post-intervention	-5.91 (2.06)	-2.87 ^a	-0.62
Condition x 6-months post-intervention	-6.94 (2.07)	-3.35 ^b	-0.73

^a
 $p < 0.01$.^b
 $p < 0.001$