Preventing maternal mental health disorders in the context of poverty: pilot efficacy of a dyadic intervention

Pamela Scorza, ScD; Catherine Monk, PhD; Seonjoo Lee, PhD; Tianshu Feng, PhD; Obianuju O. Berry, MD, PhD; Elizabeth Werner, PhD

BACKGROUND: The United States Preventive Services Task Force recommends that clinicians provide or refer pregnant and postpartum women who are at an increased risk of perinatal depression to counseling interventions. However, this prevention goal requires effective interventions that reach women at risk of, but before, the development of a depressive disorder.

OBJECTIVE: We describe a pilot efficacy trial of a novel dyadic intervention to prevent common maternal mental health disorders, that is, Practical Resources for Effective Postpartum Parenting, in a sample of women at risk of maternal mental health disorders based on poverty status. We hypothesized that Practical Resources for Effective Postpartum Parenting compared with enhanced treatment as usual would reduce symptoms of maternal mental health disorders after birth.

STUDY DESIGN: A total of 60 pregnant women who were recruited from obstetrical practices at Columbia University Irving Medical Center were randomized to the Practical Resources for Effective Postpartum Parenting (n=30) or enhanced treatment as usual (n=30) intervention. The Edinburgh Postnatal Depression Scale, Hamilton Depression Rating Scale, Hamilton Anxiety Rating Scale, and Patient Health Questionnaire were used to compare maternal mood at 6 weeks, 10 weeks, and 16 weeks after delivery.

RESULTS: At 6 weeks after delivery, women randomized to Practical Resources for Effective Postpartum Parenting had lower mean Edinburgh Postnatal Depression scores ($P=.018$), lower mean Hamilton Depression scores ($P<.001$), and lower mean Hamilton Anxiety scores ($P=.041$); however, the incidence of postpartum mental disorders did not differ by treatment group.

CONCLUSION: The Practical Resources for Effective Postpartum Parenting, which is an intervention integrated within obstetrical care, improves subclinical symptomology for at-risk dyads at a crucial time in the early postpartum period; however, our study did not detect reductions in the incidence of postpartum mental disorders.

Key words: maternal mental health disorders, postpartum depression, prevention

Introduction

The clinical approach to common perinatal mood and anxiety disorders—preferably termed maternal mental health disorders (MMHDs)[1]—is shifting from the need to treat to the imperative to prevent. MMHDs are among the most common complications of pregnancy and the postpartum period, affecting 1 in 7 women, and it is well established that they can result in adverse short- and long-term effects on both the woman and child. Negative effects even persist beyond the offspring's life course, with intergenerational effects clearly demonstrated.[2] The national economic costs of not treating these disorders from conception to the first postpartum year is estimated at $7.5 billion.[3] The United States Preventive Services Task Force (USPSTF) recently published a systematic review of primary care–relevant interventions to prevent perinatal depression, defined as a major or minor depressive episode during pregnancy or up to 1 year after childbirth,[4] and recommended that "clinicians provide or refer pregnant and postpartum persons who are at increased risk of perinatal depression to counseling interventions."[5]

This prevention goal requires effective interventions that reach women at risk of, but before, the development of a depressive disorder. One intervention that was included in the USPSTF systematic review is a novel dyadic prevention intervention, that is, Practical Resources for Effective Postpartum Parenting (PREPP). A previous randomized control trial of PREPP in a sample of 54 pregnant women with subthreshold symptoms of depression showed that PREPP was associated with a statistically significant reduction in depressive and anxiety symptoms at 6 weeks after delivery.[6]

Rates of depression are higher for those living in poverty, with almost 50% of low-income mothers of infants and young children having depression.[7] Women who live in poverty often have a combination of low maternal education, young maternal age at childbirth, single parenthood, minority group status, substance use, increased stressful life situations, and challenges accessing mental healthcare, all leading to a higher risk of MMHDs and poor developmental outcomes in the offspring.[8,9] In this second trial of PREPP, reported here, we asked whether PREPP reduces MMHD symptoms in a sample of women living in poverty and subsequently at high risk of MMHDs given the psychosocial context of their lives.

A key challenge of the USPSTF-recommended prevention strategy is the access to mental healthcare, specifically to prevention interventions. Distressed and burdened pregnant women in particular face logistical hurdles and time constraints related to attending an additional specialty healthcare appointment at another location. Stigma presents another barrier for some women to

Cite this article as: Scorza P, Monk C, Lee S, et al. Preventing maternal mental health disorders in the context of poverty: pilot efficacy of a dyadic intervention. Am J Obstet Gynecol MFM 2020;2:100230.

2589-9333/$36.00

https://doi.org/10.1016/j.ajogmf.2020.100230

AJOG MFM at a Glance

Why was this study conducted?

The United States Preventive Services Task Force recommends that clinicians provide or refer pregnant and postpartum women who are at an increased risk of perinatal depression to counseling interventions. This report tests the efficacy of a dyad-focused preventive perinatal psychotherapy intervention, Practical Resources for Effective Postpartum Parenting (PREPP), in women at high risk of perinatal mental health disorders based on poverty status.

Key findings

PREPP reduced depressive and anxiety symptoms at 6 weeks after delivery in low-income urban women—a key time point for identifying postpartum depression (PPD) during the postpartum visit. Overall depressive and anxiety symptomology was low across the sample, and no differences were found in the incidence of PPD or anxiety across the groups.

What does this add to what is known?

Consistent with previous findings, PREPP, which is a brief psychotherapy intervention integrated into obstetrical care, leads to modest reductions in subdiagnostic symptomatology in women at risk of maternal mental health disorders based on income level.

seek and accept mental healthcare. Colocated and collaborative care models, many oriented to embedding mental healthcare within obstetrical (OB) practices, are innovative approaches to addressing these challenges, although to date the focus of these models is on treatment vs prevention.[10,11] For this trial of PREPP, intervention sessions were provided in person and adjunctive to women's standard OB care.

Typically, specialized services for mothers and newborns are in separate hospitals. Independent foci on the mother or child overlook the 2-generation orientation of the perinatal period and the importance of maternal-infant interactions to maternal well-being.[12–15] Several interventions used to treat MMHDs include the bidirectional feedback between maternal mood and fetal and infant behavior: The Nurse Family Partnership,[16] Circle of Security,[17,18] and Minding the Baby[19,20] have shown positive parenting and life course outcomes. However, each is lengthy and demanding, none is integrated into existing OB services, and none specifically targets prevention of MMHDs. Of the few existing MMHD prevention interventions and services for at-risk women in the perinatal period, none incorporates the exceptionally close associations between mother and infant functioning and behavior or the leverage this dyadic, mother-infant orientation to engage women in care. In our view, a dyadic approach conceptualizes maternal depression as a potential disorder of the mother-infant dyad, such that change in one member affects the other—for example, increased ease with parenting strategies leading to better infant sleep and improved maternal sleep.

PREPP enrolls pregnant women at risk of MMHDs late in pregnancy, is integrated within OB visits, and considers the mother-fetus and infant as a dyad. The intervention provides psychoeducation, mindfulness and self-reflection skills, and parenting skills. Here, we report a pilot efficacy trial of PREPP in a sample of 60 pregnant women living in poverty (ClinicalTrials.gov NCT02121496). We hypothesized that PREPP would cause a statistically significant reduction in symptoms of MMHDs after birth and would reduce the incidence of postpartum depression (PPD) compared with enhanced treatment as usual (ETAU).

Materials and Methods

Study procedures

Women were recruited and screened for eligibility for this randomized controlled trial by telephone between 20 and 28 weeks' gestation. Between 34 and 38 weeks, eligible participants came to a research area in the hospital to provide an informed consent and complete mood assessments by self-report and interviewer administration (Assessment 1). Once enrolled, participants also met with the clinical psychologist who informed them of their treatment group assignment as dictated by a computer-generated random assignment schedule. Participants who were assigned to the PREPP group received their first session of PREPP, whereas those in the ETAU group were given information about PPD, a brief clinical mood assessment, and a referral for treatment if requested by the participant or deemed appropriate by clinical evaluation. Between 18 and 36 hours after giving birth, all participants were visited by a research assistant who collected medical information about their delivery. Those in the PREPP intervention received their second treatment session with the psychologist. At 2 weeks after delivery, participants in the PREPP group received a check-in telephone call from the psychologist with whom they had been working, to encourage the use of PREPP skills through motivational interviewing. Those in the ETAU group received a brief check-in call from the research assistant. At 6 weeks after delivery, all participants returned to the research area in the hospital to complete mood assessments (Assessment 2). Women in the PREPP group received their final PREPP session at this time whereas those in ETAU were again given information about PPD and were clinically assessed and referred to treatment when appropriate. At 10 weeks after delivery, participants were contacted by telephone and completed mood assessments via telephone (Assessment 3). At 16 weeks after delivery, mood assessments were again administered in person in the research area within the

hospital (Assessment 4). A schedule of the participants' PREPP intervention sessions, ETAU sessions, and research assessment sessions is presented in Figure 1.

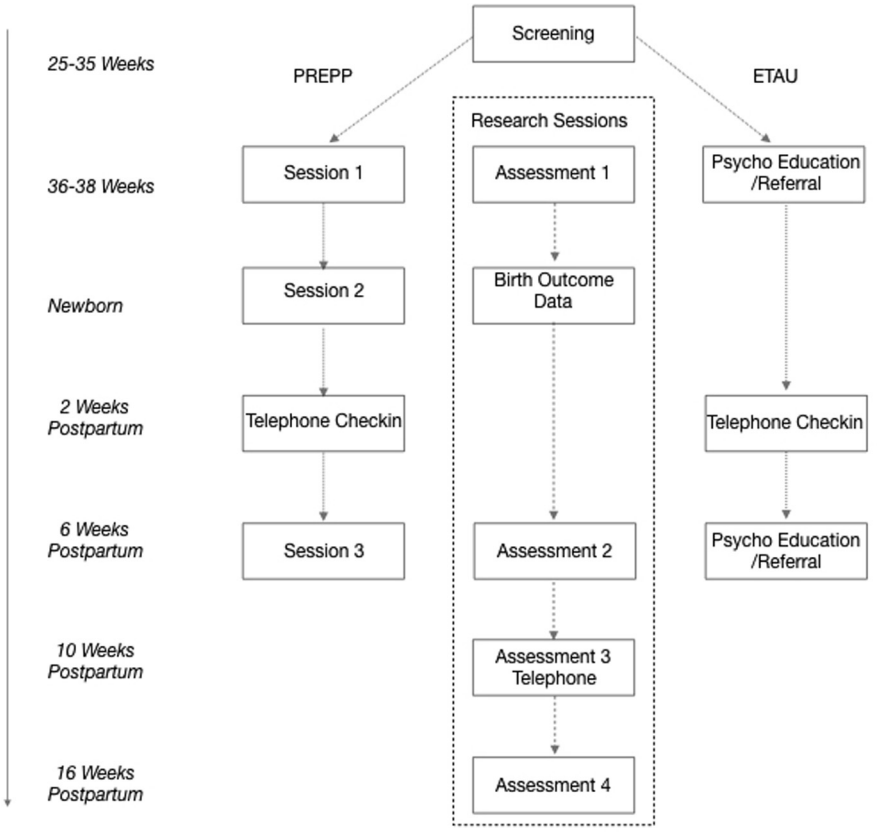
Recruitment

Participants were drawn from the OB practice at the Audubon Clinic, part of the Ambulatory Care Network of the NewYork-Presbyterian Hospital, part of the Columbia University Irving Medical Center, and other affiliated OB practices. Potential participants were screened by telephone between 20 and 28 weeks' gestation. The screening process was explained to them and an oral consent to answer screening questions was documented. Eligible subjects were invited to a face-to-face interview between 28 and 32 weeks' gestation during which they provided an informed written consent and completed self-report questionnaires and interviews. Those who met the inclusion and exclusion criteria were randomized into the 3-session trial. Ethical approval for this study was provided by the New York State Psychiatric Institute Institutional Review Board.

Inclusion and exclusion criteria

The inclusion criteria were 18 to 45 years old; a healthy, singleton pregnancy; receipt of standard prenatal care; English speaking; and living in poverty as defined as follows: (1) salary indicated to be "near poor, struggling" (200% of national poverty levels)—≤$47,700 annually for a family of 4, based on self-report—or (2) having met the income criteria for Medicaid. The exclusion criteria were multifetal pregnancy, pregnancy or birth complications including any infant NICU admission, giving birth before 37 weeks' gestation, smoking or alcohol or illicit drug use during pregnancy, and receiving psychological or psychiatric care, including psychopharmacology. The Mini-international Neuropsychiatric Interview (MINI), a brief structured clinical interview,[21] was used to screen out mental disorder comorbidity during the initial in-person screening (meeting criteria for major depressive disorder, bipolar disorder, suicidal intent, substance use, psychosis).

FIGURE 1
PREPP, ETAU, and research sessions



ETAU, enhanced treatment as usual; *PREPP*, Practical Resources for Effective Postpartum Parenting.
Scorza et al. Pilot efficacy of a dyadic intervention to prevent MMHDs. AJOG MFM 2020.

Treatment conditions: Practical Resources for Effective Postpartum Parenting and enhanced treatment as usual

Practical Resources for Effective Postpartum Parenting intervention

PREPP enrolls pregnant women at risk of MMHDs and consists of 3 sessions performed within OB prenatal and postnatal appointments by a PhD-level study psychologist called a "coach." The sessions' content is described below:

Mindfulness and self-reflection skills (sessions 1–3). Two mindfulness-based tools aim to (1) aid women in returning to sleep after waking at night and (2) help them to cope better when their babies are distressed or inconsolable. In particular, adapted from Dimidjian and others,[22–24] we provide iPod Touches with recordings of progressive muscle relaxation and other mindfulness exercises and instruct participants in taking a mindful walk, using all of one's senses for observation. PREPP uses supportive psychological interviewing to explore women's past and current social relationships and consider how these affect the woman's thoughts and reactions to the fetus and baby. In this way, the intervention harnesses the mother-fetus or infant dyadic orientation of the childbearing period, facilitating the capacity to reflect on one's own and other's states, which has been associated with more sensitive caregiving.[19,25]

Parenting skills (sessions 1–3). Following Pinilla and Birch[26] and Barr et al,[27] coaches teach and engage women in using 5 specific infant

TABLE 1
PREPP session overview

PREPP sessions	Components
Session #1 34–38 wk gestation In person at the clinic 60 min	• Establish alliance. • Self-reflection practices in the context of learning about the patient's unique history and life circumstances. • Sleep skills, mindfulness. • Psychoeducation. • Infant-carrying techniques (use an infant doll to practice swaddling and carrying). • Distribute materials: PREPP pamphlet, iPod Touch with mindfulness audio files, infant carrier, and swaddling blanket.
Session #2 18–36 h after delivery In person at the hospital 30 min	• Review PREPP pamphlet. • Practice relevant techniques and skills: ○ Swaddling ○ Carrying ○ Mindfulness
Motivational interviewing 2 wk after delivery On the phone 15–30 min	• Inquire about the mother and infant well-being and maternal mood. • Assess the use of specific skills. • Discuss challenges of caring for the newborn.
Session #3 6 wk after delivery In person at the clinic 60 min	• Practice self-reflection through inquiry about the maternal mood and mother and baby well-being. • Assess the use of skills. • Review skills where necessary.

PREPP, Practical Resources for Effective Postpartum Parenting.

Scorza et al. Pilot efficacy of a dyadic intervention to prevent MMHDs. AJOG MFM 2020.

behavioral techniques to reduce infant fuss and cry behavior and promote sleep: (1) "focal feeds," (2) accentuating differences between day and night, (3) lengthening latency to the middle of the night feeding time, (4) carrying infants for at least 3 hours a day, and (5) learning to swaddle the baby.[26,28–30] In session 2, participants practice the caregiving techniques with a life-size doll and receive a carrier and swaddling blanket to use with their babies.

Psychoeducation (sessions 1–3). Coaches review childbearing hormone level changes, baby blues, and infant cry patterns. This knowledge is meant to inform realistic expectations and focus on fostering positive infant attributions and caregiving sensitivity.

To increase accessibility for patients, the 3 in-person sessions are scheduled to coincide with standard medical visits: (1) 34 to 38 weeks' gestation (third trimester ultrasound), (2) at the hospital after delivery (delivery), and (3) 6 weeks after delivery (6-week well-baby visit). The psychologist also contacts the participants by telephone at 2 weeks after delivery and, using motivational interviewing techniques, encourages the use of PREPP skills and answers specific participant questions. The sessions' content is presented in Table 1, and more details are included in the PREPP manual available from the authors upon request.

Control condition: enhanced treatment as usual

ETAU participants meet with the research personnel 3 times (aligned with PREPP sessions 1, 2, and 3), receiving "usual care" with enhanced support for finding treatment. At the first contact, lasting 30 minutes, they are given information about PPD, a brief clinical assessment, and a referral for treatment if requested or deemed necessary by the psychologist. At 2 weeks after delivery, they receive a check-in call for 10 to 15 minutes during which they receive a refresher in the psychoeducation they received about PPD, and at 6 weeks after delivery, they receive another 30-minute in-person meeting during which they again are given information about PPD and referred to treatment when appropriate. Of the 30 women in ETAU, 3 were referred for mental health treatment. None of these 3 took up treatment, although 1 of the 3 engaged in 3 treatment sessions with a psychologist she had seen previously.

Outcome measures

Women's depression levels were evaluated at enrollment in the study and at 6 weeks, 10 weeks, and 16 weeks after delivery using the interviewer-administered Hamilton Rating Scale for Depression (HRSD),[31] self-report Edinburgh Postnatal Depression Scale (EPDS),[32] and Patient Health Questionnaire (PHQ-9).[33] Anxiety symptoms were evaluated at the same time points using the Hamilton Rating Scale for Anxiety (HRSA)[34] given that some data, although not all,[35] suggest that PPD is characterized by considerable anxiety.[36,37] Each depression scale has strengths and weaknesses relevant to the study aims and is reliable for prenatal and postpartum research,[38] and the 4 scales have been used together in previous research.[6,39,40] The HRSD provides observer ratings; in some studies, the self-report EPDS has demonstrated greater reliability than the PHQ-9 for postpartum women,[41–43] whereas the PHQ-9 has robust evidence for use in primary care settings.[42] The following cutoffs were used to test PPD outcomes, which have been used in a previous research as cutoffs for depression diagnosis[38]: EPDS, 9 (a cutoff value found to be optimal among low-income, urban women)[44]; HRSD, 7[38]; HRSA, 14[45,46]; and PHQ-9, 10.[41,43]

Analyses

Data were analyzed on an intention to treat basis. Generalized estimating equations with Poisson distribution were used for continuous outcomes. For dichotomous outcomes, GLIMMIX logistic models were used. For all models, multiple imputation was used to account for missing data. SAS version 9.4 (SAS Institute Inc., Cary, NC) was used for all analyses.

Results

Screening and eligibility

Of the 754 women who were screened for the study between July 2016 and February 2018, 60 were enrolled, which is approximately 8% (Figure 2). Nearly 75% of women (n=563) who were screened over the phone for the intervention were not eligible for the study. Most of these did not meet the study's income criteria (n=147; 19%), did not complete the phone screen (n=137; 18%), or had delivered their child before being screened for the study (n=123; 16%). In addition, 7% of women (n=51) were ineligible because they did not meet the age criterion, 6% (n=42) were excluded owing to medical complications, and 3% (n=21) were either outside of the study area or did not speak English. Of the 191 women who were eligible after the phone screen and came in for an in-person screening, 131 (69%) were not ultimately enrolled. Of the 191 eligible women, 48 (26%) were referred for more intensive psychological or psychiatric services—8 women because of meeting the MINI criteria for major depressive disorder and 40 women because of self-reporting psychiatric diagnoses or considerable stress in pregnancy; 40 were lost to follow-up (21%), 33 were not interested in participating in the intervention (17%), and 10 additional women delivered their babies before the first study visit (5%). The 60 enrolled participants were randomized to either the PREPP intervention or the ETAU groups.

Intervention adherence

Notably, 83% of participants (25 of 30) who were randomized to PREPP completed the entire treatment protocol. All participants (100%) underwent the first 2 sessions—the prenatal session and the session immediately after delivery. Of those 5 who did not complete the intervention protocol, 2 women could not be reached for the 2-week postnatal phone check-in, and 3 additional participants did not return to the clinic for the final PREPP session 6 weeks after birth.

Research session attrition

All participants in the intervention and control groups completed the prenatal and newborn postnatal research assessments. Of the 60 women who were randomized to PREPP or ETAU, 16 women (26.6%) did not complete the 6-week postnatal assessment (PREPP, n=6; ETAU, n=10). At 10 weeks after delivery, 32 participants (53.3%) did not complete the assessments (PREPP, n=16; ETAU, n=16). At 16 weeks after delivery, 39 participants (65%) did not complete the assessments (PREPP, n=19; ETAU, n=20). Women who were lost to follow-up did not differ significantly on key demographic variables or symptom severity at screening (Supplemental Table). The Consolidated Standards of Reporting Trials (CONSORT) diagram of screening, enrollment, and research attrition is presented in Figure 2.

Demographics and baseline mood measures

Notably, 84% of the participants were Hispanic or Latina, with a mean age of 28 years, and 40% were primiparous. Those who were randomized to PREPP or ETAU did not differ on any baseline demographic factors or mood measures (Table 2). Overall depressive symptom levels at baseline were relatively low (eg, average of 4.8 on the EPDS).

Treatment effects: prevalence of clinically important postpartum depressive and anxiety symptoms

Across the whole sample, 16.7% of women were depressed at baseline, 6.8% of women were depressed at 6 weeks after delivery, and 10.5% were depressed at 16 weeks after delivery based on the EPDS cutoff of 9.[44] The percentage of women classified as having an evidence of depressive symptoms at 6 weeks after delivery was lower in the group that was randomized to PREPP vs ETAU at 6 weeks after delivery (4.2% vs 10.0%), 10 weeks (0% vs 13.3%), and 16 weeks (9.1% vs 12.5%), although these differences were not statistically significant. For the HRSD, the pattern showed some similarity at 6 weeks although not at later time points: 8.3% vs 20.0% at 6 weeks, 28.6% vs 21% at 10 weeks, and 18.2% vs 10.0% at 16 weeks based on a score of 7.[38] Again, these results were not statistically significant. On the PHQ-9 (cutoff 10),[41,43] the results were as follows, with no statistically significant differences: 0% in both groups at 6 weeks, 0% in PREPP vs 6.7% in ETAU at 10 weeks, and 10.0% in PREPP vs 0% in ETAU at 16 weeks. The percentage of women who met the cutoff for anxiety on the HRSA (based on a cutoff score of 14)[45,46] did not differ significantly between PREPP and ETAU: 2.3% vs 4.8% at 6 weeks, 3.4% vs 3.2% at 10 weeks, and 4.4% vs 4.0% at 16 weeks, respectively.

Treatment effects: change in maternal mood

Depressive and anxiety symptoms were relatively low across the whole sample at baseline (average EPDS score, 4.8; HRSA score, 5.3; PHQ-9 score, 4.8; and HRSD score, 5.6), 6 weeks (average EPDS score, 2.8; HRSA score, 3.4; PHQ-9 score, 2.9; and HRSD score, 4.0), 10 weeks after delivery (average EPDS score, 3.0; HRSA score, 3.3; PHQ-9 score, 2.6; and HRSD score, 3.9), and 16 weeks after delivery (average EPDS score, 3.3; HRSA score, 4.2; PHQ-9 score, 2.9; and HRSD score, 3.9).

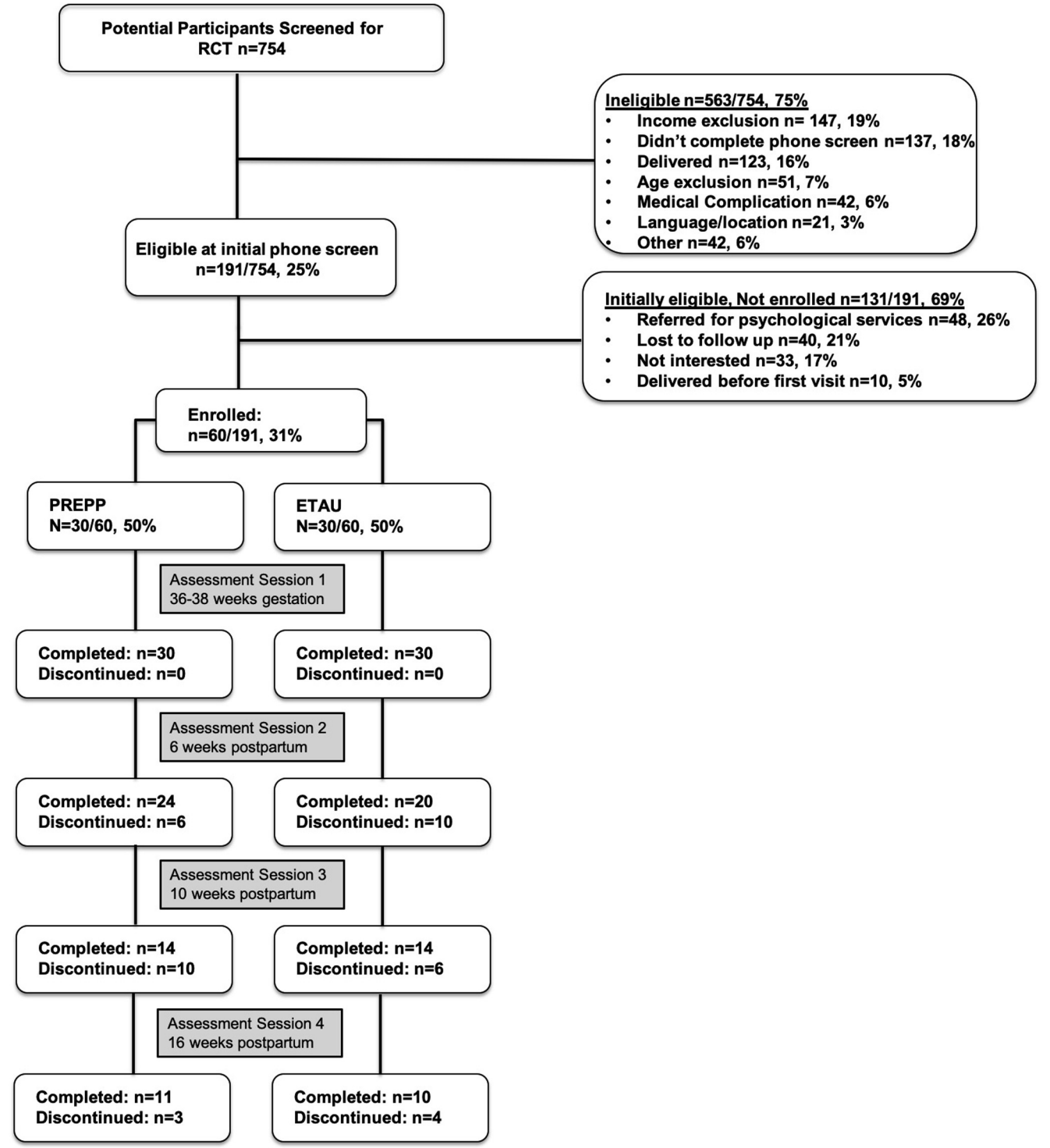
At 6 weeks after delivery, women who were randomized to PREPP compared with those randomized to ETAU had lower mean EPDS scores (1.9 vs 3.9; P=.018), lower mean HRSD scores (3.0 vs 5.0; P<.001), and lower mean HRSA scores (2.3 vs 4.8; P=.041). These differences did not remain statistically significant at later time points (Figure 3). Differences between treatment groups on the PHQ-9 and HRSD were not statistically significant. Results are presented without adjusting for relevant covariates—maternal age, infant sex, and baseline EPDS score—because these factors did not differ between groups (Table 2).

Comment

Principal findings

Consistent with previous results of PREPP[6]—a novel, dyadic approach to preventing MMHDs delivered within OB clinical care—this study found that PREPP reduced postnatal depressive and anxiety symptoms at 6 weeks after delivery in a sample of women at risk of PPD based on poverty status. Similar to

FIGURE 2
CONSORT diagram for research study



CONSORT, Consolidated Standards of Reporting Trials; *ETAU*, enhanced treatment as usual; *PREPP*, Practical Resources for Effective Postpartum Parenting.

Scorza et al. Pilot efficacy of a dyadic intervention to prevent MMHDs. AJOG MFM 2020.

the previous trial of PREPP, we did not see symptom reductions at later postpartum time points. Because this was a small pilot study with participant attrition for research sessions greater once the intervention ended, our analyses may have been underpowered to detect effects over time. Alternatively, a central component of PREPP, that is, parenting

TABLE 2
Demographic information by treatment condition: PREPP intervention or ETAU (N = 60)

			Treatment				
	Total sample (N=60)		PREPP (n=30)		ETAU (n=30)		Difference between groups
Variables	n	Mean (SD) or %	n	Mean (SD) or %	n	Mean (SD) or %	*P* value[a]
Demographics							
Number of children							.55
0	23	40.40	12	44.40	11	36.70	
>0	34	59.60	15	55.60	19	63.30	
Age	57	28.2 (5.9)	27	27.4 (5.7)	30	28.9 (6.1)	.374
Race or ethnicity							.358
Hispanic or Latina	48	84.20	24	88.90	24	80.00	
Non-Hispanic or non-Latina	9	15.80	3	11.10	6	20.00	
Baby sex							.781
Male	25	48.10	13	50.00	12	46.20	
Female	27	51.90	13	50.00	14	53.80	
Baseline symptoms scores							
EPDS	54	4.8 (3.6)	27	4.5 (3.7)	27	5.2 (3.6)	.418
HRSD	59	5.6 (4.5)	30	5.0 (3.9)	29	6.2 (5)	.28
HRSA	59	5.3 (3.8)	30	4.6 (3.7)	29	6.1 (3.9)	.134
PHQ-9	53	4.8 (3.7)	27	4.6 (3.8)	26	5.0 (3.6)	.664
Baseline disorders							
EPDS							1
≥9	9	16.70	5	18.50	4	14.80	
HRSD							.792
≥7	23	39.00	11	36.70	12	41.40	
HRSA							.612
≥14	3	5.10	1	3.30	2	6.90	
PHQ-9							.669
≥10	6	11.30	4	14.80	2	7.70	

EPDS, Edinburgh Postnatal Depression Scale; *ETAU*, enhanced treatment as usual; *HRSA*, Hamilton Rating Scale for Anxiety; *HRSD*, Hamilton Rating Scale for Depression; *PHQ-9*, Patient Health Questionnaire; *PREPP*, Practical Resources for Effective Postpartum Parenting.

[a] Baseline differences were assessed using Wilcoxon test for continuous measures and Fisher exact test for categorical measures.

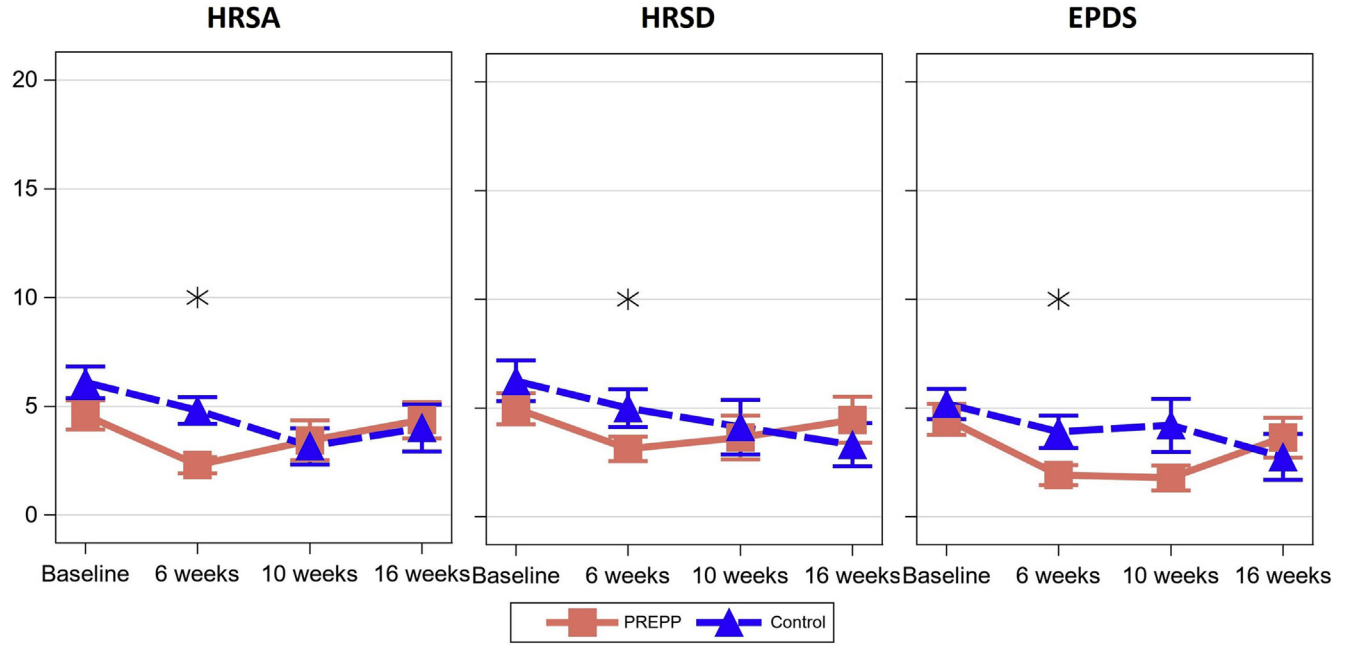
Scorza et al. Pilot efficacy of a dyadic intervention to prevent MMHDs. AJOG MFM 2020.

tools that enhance maternal confidence and potentially facilitate infant regulation and thereby maternal well-being, may need to be augmented to include tools geared toward parenting older infants.

Results in the context of what is known

The USPSTF recommends providing or referring pregnant women who are at an increased risk of perinatal depression to counseling interventions. However, few evidence-based interventions for preventing, rather than treating, perinatal MMHD exist. In addition, the criteria for which women should be considered at an increased risk of perinatal mental disorders and which interventions are effective for preventing MMHDs in at-risk groups have not been demonstrated. This is the second small pilot study showing that PREPP is associated with modest reductions in subclinical anxiety and depressive symptoms in women at risk of postpartum mental health disorders. Neither study found effects at time points later than 6 weeks after delivery, although larger sample sizes could provide more power to detect such effects.

FIGURE 3
Mean symptom scale scores by PREPP intervention and control



HRSA, HRSD, and EPDS scores in the third trimester of pregnancy (baseline) and at 6, 10, and 16 weeks after delivery.

EPDS, Edinburgh Postnatal Depression Scale; *HRSA*, Hamilton Rating Scale for Anxiety; *HRSD*, Hamilton Rating Scale for Depression; *PREPP*, Practical Resources for Effective Postpartum Parenting.

Scorza et al. Pilot efficacy of a dyadic intervention to prevent MMHDs. AJOG MFM 2020.

Clinical implications

The Diagnostic and Statistical Manual of Mental Disorders[47] specifies that the symptoms of PPD must first occur within the first 4 weeks after delivery; our findings indicate that PREPP is a useful tool to reduce depressive symptoms consistent with the clinical focus on this early postpartum time period for the mothers and their infants.

The 17% attrition rate for the PREPP clinical intervention falls at the lower end of the 6% to 70% range of attrition rates reported in a meta-analysis of interventions for treating PPD in primary care.[48] (Attrition for the research assessment sessions in both the PREPP and ETAU groups was greater, as displayed in the CONSORT diagram in Figure 2.) The context of PREPP within OB care and the brief format and its focus on the mother-baby unit—so salient in this life phase—likely account for its success in engaging and maintaining pregnant and postpartum women in treatment. Although this study used a psychologist to deliver PREPP, clinical work in Women's Mental Health @ Ob/Gyn—an embedded service within the Department of Obstetrics and Gynecology at Columbia University—suggests that the intervention can be easily incorporated into an OB practice without a psychologist present. E.W. and C.M. have successfully trained social workers and psychiatric nurse practitioners to deliver PREPP and are currently in the process of training community mental health workers to provide PREPP in OB community clinics.

Research implications

The varying results related to which mood measure was used are consistent with other reports in the literature showing that significance of identified symptoms can range based on measures used, the timing of the measurement, and the population in which the measure is used.[44,49–51] More research is needed to identify which tool has the greatest specificity and sensitivity in identifying clinically relevant mood systems in disadvantaged pregnant women.

Overall, participants had very low levels of depression and anxiety in contrast to other studies with low-income women indicating that they have up to 11 times the risk of having clinically elevated depressive symptoms after delivery.[52] The inclusion and exclusion criteria for this randomized control trial aimed at women living in poverty may have resulted in a very specific sample of women being included, as evidenced in the nearly three-quarters of women who were screened as being deemed ineligible to participate. In particular, women with medical complications, women younger than 18 years of age, women who did not speak English, and women who required more intensive psychological care were excluded. In addition, those eligible but choosing not to participate may have been those with the most logistical or psychological challenges. Therefore, potentially only the most resilient and with fewest problems may have met the inclusion criteria and successfully enrolled in the study. Excluding from

clinical trials those with additional conditions beyond the study focus is a common problem, one that contributed to the establishment of the United States National Institutes of Health's Collaboratory on Pragmatic Clinical Trials. There is a growing concern that the results obtained from clinical research may not apply to "real world" clinical situations and are inadequate to inform clinical service decisions.[53] In contrast, pragmatic clinical trials aim to enroll a sample representative of the patient population in a clinical setting relevant to the patients in need of care.[54]

Strengths and limitations

This study's findings should be considered in light of its limitations. The small sample size increases the possibility of both type I and II errors. The low baseline levels of MMHD symptoms and the large percentage of women ineligible for the study also may challenge the generalizability of the findings, as does the predominance of Latina women, although the previous trial of PREPP yielded similar results with a different sample.[6] In light of the null findings in terms of depression incidence, the brief format of PREPP could be considered a limitation, particularly for depression onset beyond the early postpartum period. However, we consider the accessibility of PREPP as a major strength; its brief format and colocation in OB care increase its potential to be widely implemented. We believe that the most considerable limitation to the study was the stringent inclusion and exclusion criteria, implemented in part to make it a more uniform sample and in part because of ethical considerations (eg, age). These restrictions and the loss to follow-up for the research assessments limited the sample size and power to detect effects at later time points. It is plausible to think that PREPP could contribute to reducing the incidence of PPD at later time points if early sources of stress were removed and positive patterns of dyadic interaction were established in the early postpartum period. A more pragmatic trial approach with limited exclusion criteria might help us answer that question. In addition, providing better incentives for participation or allowing participants to complete assessments remotely could have increased the sample size at later time points. Still, this study is unique in testing the efficacy of a prevention intervention for perinatal MMHD in at-risk women, here based on poverty status.

Conclusions

There is increasingly strong evidence supporting a public health initiative to prevent perinatal mood disorders.[4] We report a pilot efficacy trial of PREPP, which is a PPD prevention intervention for at-risk pregnant women that is (1) integrated into OB care to increase accessibility, (2) brief, and (3) designed with the mother-infant dyad in mind. PREPP shows high levels of patient engagement and relatively low attrition in a sample of women living in poverty and provides modest reductions in subclinical depressive and anxiety symptoms in the early fourth trimester.[55] ■

References

1. Yeaton-Massey A, Herrero T. Recognizing maternal mental health disorders: beyond postpartum depression. Curr Opin Obstet Gynecol 2019;31:116–9.
2. Weissman MM, Berry OO, Warner V, et al. A 30-year study of 3 generations at high risk and low risk for depression. JAMA Psychiatry 2016;73:970–7.
3. Luca DL, Garlow N, Staatz C, Margiotta C, Zivin K. Societal costs of untreated perinatal mood and anxiety disorders in the United States. Mathematica Policy Research. 2019. Available at: https://www.mathematica.org/our-publications-and-findings/publications/societal-costs-of-untreated-perinatal-mood-and-anxiety-disorders-in-the-united-states. Accessed Jan. 10, 2020.
4. O'Connor E, Senger CA, Henninger ML, Coppola E, Gaynes BN. Interventions to prevent perinatal depression: evidence report and systematic review for the US Preventive Services Task Force. JAMA 2019;321:588–601.
5. US Preventive Services Task Force, Curry SJ, Krist AH, et al. Interventions to prevent perinatal depression: US Preventive Services Task Force Recommendation Statement. JAMA 2019;321:580–7.
6. Werner EA, Gustafsson HC, Lee S, et al. PREPP: postpartum depression prevention through the mother-infant dyad. Arch Womens Ment Health 2016;19:229–42.
7. Knitzer J, Theberge S, Johnson K. Reducing maternal depression and its impact on young children: toward a responsive early childhood policy framework. New York, NY: National Center for Children in Poverty; 2008.
8. Cyr C, Euser EM, Bakermans-Kranenburg MJ, Van Ijzendoorn MH. Attachment security and disorganization in maltreating and high-risk families: a series of meta-analyses. Dev Psychopathol 2010;22:87–108.
9. Petterson SM, Albers AB. Effects of poverty and maternal depression on early child development. Child Dev 2001;72:1794–813.
10. Grote NK, Katon WJ, Lohr MJ, et al. Culturally relevant treatment services for perinatal depression in socio-economically disadvantaged women: the design of the MOMCare study. Contemp Clin Trials 2014;39:34–49.
11. Grote NK, Katon WJ, Russo JE, et al. Collaborative care for perinatal depression in socioeconomically disadvantaged women: a randomized trial. Depress Anxiety 2015;32:821–34.
12. Kochanska G, Murray KT. Mother-child mutually responsive orientation and conscience development: from toddler to early school age. Child Dev 2000;71:417–31.
13. Aksan N, Kochanska G, Ortmann MR. Mutually responsive orientation between parents and their young children: toward methodological advances in the science of relationships. Dev Psychol 2006;42:833–48.
14. Feldman R. From biological rhythms to social rhythms: physiological precursors of mother-infant synchrony. Dev Psychol 2006;42:175–88.
15. Feldman R. Parent-infant synchrony and the construction of shared timing; physiological precursors, developmental outcomes, and risk conditions. J Child Psychol Psychiatry 2007;48:329–54.
16. Olds DL, Kitzman H, Hanks C, et al. Effects of nurse home visiting on maternal and child functioning: age-9 follow-up of a randomized trial. Pediatrics 2007;120:e832–45.
17. Cassidy J, Ziv Y, Stupica B, et al. Enhancing attachment security in the infants of women in a jail-diversion program. Attach Hum Dev 2010;12:333–53.
18. Huber A, McMahon C, Sweller N. Improved parental emotional functioning after Circle Of Security 20-week parent-child relationship intervention. J Child Fam Stud 2016;25:2526–40.
19. Sadler LS, Slade A, Close N, et al. Minding the baby: enhancing reflectiveness to improve early health and relationship outcomes in an interdisciplinary home visiting program. Infant Ment Health J 2013;34:391–405.
20. Slade A, Holland ML, Ordway MR, et al. Minding the Baby®: enhancing parental reflective functioning and infant attachment in an attachment-based, interdisciplinary home visiting program. Dev Psychopathol 2020;32:123–37.
21. Sheehan DV, Lecrubier Y, Sheehan KH, et al. The Mini-International Neuropsychiatric Interview (M.I.N.I.): the development and validation of a structured diagnostic psychiatric

interview for DSM-IV and ICD-10. J Clin Psychiatry 1998;59(Suppl20):22–33. quiz 34–57.
22. Dimidjian S, Goodman SH, Felder JN, Gallop R, Brown AP, Beck A. An open trial of mindfulness-based cognitive therapy for the prevention of perinatal depressive relapse/recurrence. Arch Womens Ment Health 2015;18:85–94.
23. Dimidjian S, Goodman SH, Felder JN, Gallop R, Brown AP, Beck A. Staying well during pregnancy and the postpartum: a pilot randomized trial of mindfulness-based cognitive therapy for the prevention of depressive relapse/recurrence. J Consult Clin Psychol 2016;84:134–45.
24. Tragea C, Chrousos GP, Alexopoulos EC, Darviri C. A randomized controlled trial of the effects of a stress management programme during pregnancy. Complement Ther Med 2014;22:203–11.
25. Meins E, Fernyhough C, Wainwright R, Das Gupta M, Fradley E, Tuckey M. Maternal mind-mindedness and attachment security as predictors of theory of mind understanding. Child Dev 2002;73:1715–26.
26. Pinilla T, Birch LL. Help me make it through the night: behavioral entrainment of breast-fed infants' sleep patterns. Pediatrics 1993;91:436–44.
27. Barr RG, Rivara FP, Barr M, et al. Effectiveness of educational materials designed to change knowledge and behaviors regarding crying and shaken-baby syndrome in mothers of newborns: a randomized, controlled trial. Pediatrics 2009;123:972–80.
28. van Sleuwen BE, Engelberts AC, Boere-Boonekamp MM, Kuis W, Schulpen TW, L'Hoir MP. Swaddling: a systematic review. Pediatrics 2007;120:e1097–106.
29. Hunziker UA, Barr RG. Increased carrying reduces infant crying: a randomized controlled trial. Pediatrics 1986;77:641–8.
30. St James-Roberts IS, Hurry J, Bowyer J, Barr RG. Supplementary carrying compared with advice to increase responsive parenting as interventions to prevent persistent infant crying. Pediatrics 1995;95:381–8.
31. Hamilton M. A rating scale for depression. J Neurol Neurosurg Psychiatry 1960;23:56–62.
32. Cox JL, Holden JM, Sagovsky R. Detection of postnatal depression. Development of the 10-item Edinburgh Postnatal Depression Scale. Br J Psychiatry 1987;150:782–6.
33. Kroenke K, Spitzer RL, Williams JB. The PHQ-9: validity of a brief depression severity measure. J Gen Intern Med 2001;16:606–13.
34. Hamilton M. The assessment of anxiety states by rating. Br J Med Psychol 1959;32:50–5.
35. Hoertel N, López S, Peyre H, et al. Are symptom features of depression during pregnancy, the postpartum period and outside the peripartum period distinct? Results from a nationally representative sample using item response theory (IRT). Depress Anxiety 2015;32:129–40.
36. Miller ES, Hoxha D, Wisner KL, Gossett DR. Obsessions and compulsions in postpartum women without obsessive compulsive disorder. J Womens Health (Larchmt) 2015;24:825–30.
37. Battle CL, Zlotnick C, Miller IW, Pearlstein T, Howard M. Clinical characteristics of perinatal psychiatric patients: a chart review study. J Nerv Ment Dis 2006;194:369–77.
38. Ji S, Long Q, Newport DJ, et al. Validity of depression rating scales during pregnancy and the postpartum period: impact of trimester and parity. J Psychiatr Res 2011;45:213–9.
39. Chabrol H, Teissedre F, Saint-Jean M, Teisseyre N, Rogé B, Mullet E. Prevention and treatment of post-partum depression: a controlled randomized study on women at risk. Psychol Med 2002;32:1039–47.
40. Evans LM, Myers MM, Monk C. Pregnant women's cortisol is elevated with anxiety and depression - but only when comorbid. Arch Womens Ment Health 2008;11:239–48.
41. Hanusa BH, Scholle SH, Haskett RF, Spadaro K, Wisner KL. Screening for depression in the postpartum period: a comparison of three instruments. J Womens Health (Larchmt) 2008;17:585–96.
42. Buysse DJ, Reynolds III CF, Monk TH, Berman SR, Kupfer DJ. The Pittsburgh Sleep Quality Index: a new instrument for psychiatric practice and research. Psychiatry Res 1989;28:193–213.
43. Pettersson A, Boström KB, Gustavsson P, Ekselius L. Which instruments to support diagnosis of depression have sufficient accuracy? A systematic review. Nord J Psychiatry 2015;69:497–508.
44. Chaudron LH, Szilagyi PG, Tang W, et al. Accuracy of depression screening tools for identifying postpartum depression among urban mothers. Pediatrics 2010;125:e609–17.
45. Suri R, Burt VK, Altshuler LL. Nefazodone for the treatment of postpartum depression. Arch Womens Ment Health 2005;8:55–6.
46. Matza LS, Morlock R, Sexton C, Malley K, Feltner D. Identifying HAM-A cutoffs for mild, moderate, and severe generalized anxiety disorder. Int J Methods Psychiatr Res 2010;19:223–32.
47. First MB, Frances A, Pincus HA. DSM-IV-TR guidebook. Washington, DC: American Psychiatric Publishing, Inc; 2004.
48. Stephens S, Ford E, Paudyal P, Smith H. Effectiveness of psychological interventions for postnatal depression in primary care: a meta-analysis. Ann Fam Med 2016;14:463–72.
49. Ukatu N, Clare CA, Brulja M. Postpartum depression screening tools: a review. Psychosomatics 2018;59:211–9.
50. O'Connor E, Rossom RC, Henninger M, Groom HC, Burda BU. Primary care screening for and treatment of depression in pregnant and postpartum women: evidence report and systematic review for the US Preventive Services Task Force. JAMA 2016;315:388–406.
51. Tandon SD, Cluxton-Keller F, Leis J, Le HN, Perry DF. A comparison of three screening tools to identify perinatal depression among low-income African American women. J Affect Disord 2012;136:155–62.
52. Goyal D, Gay C, Lee KA. How much does low socioeconomic status increase the risk of prenatal and postpartum depressive symptoms in first-time mothers? Womens Health Issues 2010;20:96–104.
53. Ioannidis JP. Why most clinical research is not useful. PLoS Med 2016;13:e1002049.
54. Weinfurt KP, Hernandez AF, Coronado GD, et al. Pragmatic clinical trials embedded in healthcare systems: generalizable lessons from the NIH Collaboratory. BMC Med Res Methodol 2017;17:144.
55. Tully KP, Stuebe AM, Verbiest SB. The fourth trimester: a critical transition period with unmet maternal health needs. Am J Obstet Gynecol 2017;217:37–41.

Author and article information

From the Departments of Obstetrics and Gynecology (Drs Scorza, Monk, and Werner) and Psychiatry (Drs Monk, Berry, and Werner), Columbia University, New York, NY; and New York State Psychiatric Institute, New York, NY (Drs Monk, Lee, and Feng).

Received June 1, 2020; revised Aug. 27, 2020; accepted Sept. 16, 2020.

The authors report no conflict of interest.

This study was supported by the Robin Hood Foundation.

Corresponding author: Pamela Scorza, ScD. pls2122@cumc.columbia.edu

SUPPLEMENTAL TABLE

Differences in symptom severity at baseline and demographic characteristics of participants who were lost to follow-up vs those who were not lost to follow-up (entire sample)

Variables	Non-dropoff (n=21) Mean	Dropoff (n=38) Mean	Differences between groups *P* value
HRSA	5.6666667	5.1578947	.426774
HRSD	6.7619048	4.9473684	.103325
EPDS	3.952381	5.3939394	.249468
PHQ-9	4.6190476	4.875	.992713
Maternal age	29.7025663	27.2606809	.228001
Parity	0.95	0.8611111	.970839

EPDS, Edinburgh Postnatal Depression Scale; *HRSA*, Hamilton Rating Scale for Anxiety; *HRSD*, Hamilton Rating Scale for Depression; *PHQ-9*, Patient Health Questionnaire.

Scorza et al. Pilot efficacy of a dyadic intervention to prevent MMHDs. AJOG MFM 2020.