ORIGINAL ARTICLE

PREPP: postpartum depression prevention through the mother–infant dyad

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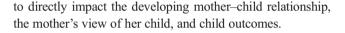
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Abstract Most interventions to prevent postpartum depression (PPD) focus on the mother rather than the mother-infant dyad. As strong relationships between infant sleep and cry behavior and maternal postpartum mood have been demonstrated by previous research, interventions targeted at the dyad may reduce symptoms of PPD. The goal of the current study was to examine the effectiveness of Practical Resources for Effective Postpartum Parenting (PREPP). PREPP is a new PPD prevention protocol that aims to treat women at risk for PPD by promoting maternally mediated behavioral changes in their infants, while also including mother-focused skills. Results of this randomized control trial (RCT) (n=54) indicate that this novel, brief intervention was well tolerated and effective in reducing maternal symptoms of anxiety and depression, particularly at 6 weeks postpartum. Additionally, this study found that infants of mothers enrolled in PREPP had fewer bouts of fussing and crying at 6 weeks postpartum than those infants whose mothers were in the Enhanced TAU group. These preliminary results indicate that PREPP has the potential to reduce the incidence of PPD in women at risk and

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Of the over 4 million live births each year in the USA, nearly 800,000-or 20 %-of these mothers will develop major or minor depression within the first 3 months postpartum. These numbers dwarf prevalence rates for gestational diabetes (2-5%)and preterm birth (12.7 %) (Dabelea et al. 2005; Saigal and Doyle 2008). Postpartum Depression (PPD) affects the mother and her infant. It is associated with marital discord and impaired occupational and social functioning, particularly with respect to maternal-infant interactions that are characterized by disengagement, hostility, and intrusion (Burke 2003; Lovejoy et al. 2000; Martins and Gaffan 2000; Murray et al. 1995). Child outcomes include poor cognitive functioning, as well as emotional and behavioral problems such as increased risk for externalizing disorders and future psychopathology (Cicchetti et al. 1998; Grace et al. 2003; Kurstjens and Wolke 2001). These deleterious effects on child developmental trajectories have been shown even when controlling for family SES and subsequent maternal mental illness, indicating the importance of preventing PPD during this critical period in development (Hay et al. 2001).

Existing clinical treatments for the prevention of PPD use standard approaches that focus solely on the mother, e.g., pharmacologic and psychological interventions to reduce women's symptoms. Given the complex genetic, biological, and environmental etiology of depression, there is a need for an array of intervention and treatment options; given the specific context in which PPD occurs, it is logical to exploit the unique dyadic orientation of this period when designing new treatment strategies. It also is important to consider the reasons



that PPD is significantly undertreated when developing a new prevention protocol (Werner et al. 2014), e.g., time constraints during the postpartum period and reluctance to take psychotropic medications when breastfeeding (Ballestrem et al. 2005; Boath et al. 2004; Whitton et al. 1996).

This report describes a small, randomized control trial (RCT) of a novel, brief, preventive intervention for PPD called PREPP, Practical Resources for Effective Postpartum Parenting, which aims to determine if a behavioral intervention primarily targeting maternal caregiving of young infants can increase infant sleep and reduce fuss/cry behavior, and thereby reduce the incidence and/or severity of postpartum maternal depression. PREPP integrates emerging, evidence-based caregiving techniques, traditional psychotherapy approaches, psycho-education, as well as mindfulness meditation training to treat at-risk women by promoting maternally mediated behavioral changes in their infants.

Risks for PPD, including infant behaviors

Established risk factors for PPD include prenatal depression and anxiety, low social support, and a history of psychopathology (O'Hara and Swain 1996; Beck 1996; Seguin et al. 1999). Emerging data shows strong associations between infant behavior and maternal mood dysregulation. In several papers, greater infant fuss/cry and poor sleep behavior were associated with maternal depression (Armstrong et al. 1998; Bayer et al. 2007; Dennis and Ross 2005; Hiscock and Wake 2001; Maxted et al. 2005; Radesky et al. 2013; Vik et al. 2009). More specifically, in a study of 55 dyads, infant crying at 3 months (based on maternal report and laboratory observation) accounted for 30 % of the variance in PPD symptoms; the effect was direct, and indirect, through the mediation of reducing levels of parenting self-efficacy (Cutrona and Troutman 1986). In a prospective study of 180 women at risk for PPD, objectively assessed neonatal irritability and poor motor function predicted PPD at 2 months (estimated contribution to log odds were 1.37 and 1.18, respectively, p < 0.0005); as these infant behaviors improved, so did maternal depression scores (Murray et al. 1996). Barr et al. found that at 6 weeks postpartum, mother-reported infant cry/fuss duration and frequency were positively associated with postpartum distress (r(88)=0.45 and 0.28, p<0.01, respectively) (Miller et al. 1993). Distress levels increased pre- to postpartum in women whose infants met clinical criteria for "colic" (Miller et al. 1993). There also is an association between infant sleeping problems and PPD, which may be mediated via disruption in women's sleep (Armstrong et al. 1998; Bayer et al. 2007; Dennis and Ross 2005; Hiscock and Wake 2001). To date, including the treatment of infant behaviors in PPD interventions is only beginning (Hiscock and Wake 2002; Hiscock et al. 2014).

Prevention of PPD

There have been many RCTs of psychological preventive interventions for PPD. In a recent systematic review, Werner and colleagues (2014) identified 37 psychological and psychosocial intervention RCTs of which 17 were found to be effective. Of these 17 effective RCTs, 13 were conducted with at-risk populations, suggesting the importance of utilizing known PPD risk factors as inclusion criteria when targeting women for PDD preventive treatment. These authors (Werner et al. 2014) and others (Boath et al. 2004; Whitton et al. 1996; Ballestrem et al. 2005) highlight several reasons that treatments to prevent PPD may not be effective, including (1) non-validated approaches to measure risk for PPD (Werner et al. 2014), (2) emphasis on pharmacology when women are breast feeding (Boath et al. 2004; Whitton et al. 1996), and (3) high rates of attrition (Werner et al. 2014), which may result from (a) stigma associated with receiving mental health care (McIntosh 1993), (b) lack of accessibility, including difficulty attending appointments with a new baby (Ballestrem et al. 2005), and (c) a sole focus on the mother-which overlooks the child-centered orientation of the perinatal period and the salience of maternal-infant interactions to maternal well-being (Kochanska et al. 2000, 2001, 2009; Kochanska and Aksan 2006; Feldman and Eidelman 2006; Feldman 2007). Addressing these limitations is crucial to developing successful PPD preventive interventions (Werner et al. 2014).

Infant sleep and cry interventions

Largely independent of PPD interventions, several caregiving techniques have been shown to positively affect infant sleep and fuss/cry behavior (Meyer and Erler 2011; Pinilla and Birch 1993; St. James-Roberts and Gillham 2001; Van Sleuwen et al. 2007). For example, Pinilla and Birch (1993) found that their intervention program was highly effective in changing parent behavior and improving infant sleep duration when delivered to parents in the home over multiple sessions up to 8 weeks post-delivery, though parents were less compliant with the same protocol when given instructions for it during a $1 \times$ home visit within 8–14 days post-birth, and there was little effect on infant sleep (St. James-Roberts and Gillham 2001). In Pinilla and Birch's study of 26 first-time parents, 13 were assigned to a behavioral intervention, which, by 4 weeks postpartum, resulted in 38 % of infants sleeping through the night (defined as sleeping without signaling for attention between 12 and 5 A.M. for several consecutive nights) compared to 7 % for the control group; by 8 weeks postpartum, 100 % of the intervention group slept through the night compared to 23 % (Pinilla and Birch 1993). This intervention protocol encompassed several infant behavioral techniques to increase nighttime sleeping in infants, including providing a

focal feeding to the infant between 10 P.M. and midnight, accentuating differences between day and night by providing higher levels of stimulation during the day, and lengthening the latency to feeding time in the middle of the night by engaging in other attentive activities such as walking with the baby and diapering, thereby extinguishing the association between night time waking and feeding (Pinilla and Birch 1993; St. James-Roberts and Gillham 2001). In other research, swaddling has been identified as a tool that can promote sleep continuity, fewer awakenings, and more quiet sleep as evidenced in both laboratory and descriptive studies (Van Sleuwen et al. 2007). In an RCT conducted in Germany (Meyer and Erler 2011) of 85 healthy infants studied in a sleep laboratory, swaddling was found to reduce the rate of spontaneous awakening, the number of sleep stage changes, and the amount of time spent awake. It also was found to promote quiet sleep and sleep efficiency (Meyer and Erler 2011).

There are other behavioral techniques to reduce infant fussing and crying behavior. Barr et al. conducted a randomized controlled trial on the effects of increased carrying on infant fuss/cry behavior (Hunziker and Barr 1986). At 3 weeks postpartum, 99 dyads were randomly assigned to increased carrying or no intervention; by 6 weeks post-delivery, the peak age for crying, infants in the intervention group cried and fussed 43 % less overall and 51 % less during 4 P.M. to midnight; similar but smaller differences were found at 4, 8, and 12 weeks (Hunziker and Barr 1986). However, these results have not been consistently replicated. For example, when the carrying intervention was taught to women in the hospital in Britain immediately following birth, there were no effects of increased carrying on infant cry/fuss behavior (St. James-Roberts et al. 1995).

As indicated, few studies have examined whether these caregiving techniques have an impact on maternal depressive symptoms. In the first of its kind, Hiscock et al. (2014) provided 781 mother-infant dyads with written materials and an educational DVD that presented information about infant sleep cycles and crying patterns, strategies to promote independent settling (e.g., swaddling), and information about selfcare for parents. Mothers in the intervention group were significantly less likely to meet criteria for possible depression (>9 on the Edinburgh Postnatal Depression Scale) when their infant was 6 months old, though there were no differences between the intervention and control groups at 4 months postpartum. These caregiving techniques also were effective in reducing daytime sleep and crying problems, but only for a subset of their participants who they characterized as "frequent feeders" by caregiver report. These findings provide promising evidence that behavioral techniques targeting maternal care can be a useful component of PPD intervention programs, though they require replication, and several questions remain. For example, maternal depressive symptoms were studied at 4 and 6 months postpartum, yet the Diagnostic and Statistical Manual of Mental Disorders (5th ed.; American Psychiatric Association, 2013) specifies that PPD has an onset within the first 4 weeks after birth. Given the significance of this early developmental period for children's long-term functioning (e.g., Hay et al. 2001), examining maternal depressive symptoms earlier in development is critical. Second, Hiscock et al.'s intervention program recruited women 7-10 days postpartum, potentially after mothers already had started to become symptomatic. It remains unclear if intervening earlier (i.e., during pregnancy) would help to prevent these symptoms from developing, resulting in differences in maternal well-being that are observable earlier in the child's life. Third, these authors-and most other PPD prevention studies (Werner et al. 2014)-only focused on maternal depressive symptoms when assessing postpartum mood. However, there is evidence that women with PDD often have severe anxiety and even panic attacks (Miller et al. 2006). The extent to which these caregiving techniques also may improve maternal anxiety in the postnatal period has been not been studied.

Other tools for maternal mood intervention postpartum

The use of psychoeducation about the hormonal and psychosocial changes that occur during the postpartum period has been shown to be effective in the reduction of postpartum depressive symptoms (Elliott et al. 2000; Matthey et al. 2004). In addition, programs like the Period of PURPLE crying (Barr et al. 2009) have been effective in improving maternal knowledge about infant crying and developing coping mechanisms to deal with the maternal upset caused by inconsolable crying. Mindfulness meditation is another strategy that can help women to cope better when their babies are distressed and/or unsoothable. The success of a recent trial of a mindfulness-based therapy for the prevention of perinatal depressive relapse/recurrence suggests that the use of these types of techniques may contribute to the prevention of PPD (Dimidjian et al. 2014). To date, these therapeutic tools that are aimed directly at helping the mother (e.g., mindfulness meditation, psychoeducation about perinatal biological and emotional changes) have not been added to an intervention protocol focused on caregiving techniques.

The current study

The goal of the current study was to examine the effectiveness of PREPP, a new PPD prevention protocol that aims to treat atrisk women by promoting maternally mediated behavioral changes in their infants, while also including mother-focused skills. In a sample of 54 dyads, we sought to test if PREPP compared to an enhanced treatment as usual (ETAU) group (1) reduces depression and anxiety symptoms during the early postnatal period, (2) decreases infant fuss and cry behavior, and (3) has high rates of treatment compliance given the brief number of sessions that are timed to perinatal medical sessions and the description of the intervention as coaching.

Methods

Overview

Figure 1 provides a schedule of participants' assessment and PREPP sessions. Women were recruited and screened for study eligibility by telephone (including PPD risk using the Predictive Index of Postnatal Depression, Cooper et al. 1996) in their third trimester of pregnancy. Between 34 and 38 weeks' gestation, potential participants came to the laboratory to provide informed consent and complete mood questionnaires by self-report and interviewer administration (Assessment 1). They 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, while those in the ETAU group were provided with an information session about PPD, a brief clinical mood assessment, and a referral for treatment if warranted or requested by the participant. Between 18 and 36 h 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 postpartum, participants in the PREPP group received a check-in telephone call from the psychologist with whom they had been working. Those in the ETAU group received a brief check-in call from the research assistant. At 6 weeks postpartum, all participants returned to the laboratory to complete

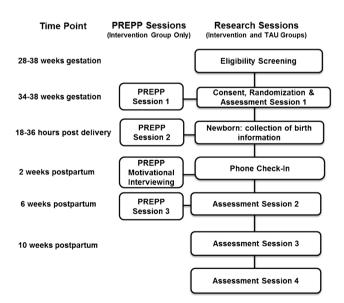


Fig. 1 Assessment and treatment session schedule

mood assessments and meet with the psychologist (Assessment 2). Women in the PREPP group received their final PREPP session, while those in the ETAU group were again given information about PPD and were clinically assessed and referred to treatment when appropriate. At 10 weeks postpartum, participants were contacted by telephone and completed the mood questionnaires via telephone (Assessment 3). At 16 weeks postpartum, these questionnaires were administered in person in the laboratory (Assessment 4).

Participants

Pregnant women ages 18–45 in their second or third trimester of pregnancy were recruited through the Department of Obstetrics and Gynecology at Columbia University Medical Center (CUMC) and via flyers posted at CUMC. Women who reported smoking tobacco or using recreational drugs, lacking fluency in English, currently receiving psychological/ psychiatric treatment, taking medication, having a medically complicated pregnancy, or carrying a non-singleton pregnancy were not eligible for enrollment in this study. This trial was registered with clinicaltrials.gov: NCT01379781. All study procedures were approved by the Institutional Review Board of the New York State Psychiatric Institute/CUMC. Participants were compensated for their assessment sessions, and the travel to and from the meetings, but not for intervention sessions.

Assessment measures

Predictive index of PPD

When women were 28–38 weeks pregnant, potential participants were screened via telephone for their risk for PPD. PPD risk was defined as scoring above 24 on the Predictive Index of Postnatal Depression (Cooper et al. 1996). This 17-item questionnaire asks women about factors that may predispose them to PPD (e.g., "Have you felt particularly depressed or miserable over the last few weeks?" "After any previous delivery were you particularly miserable or depressed at any time during the following year?" "Has this pregnancy been a positive experience for you?"). This widely used measure has been shown to have adequate sensitivity and specificity (Cooper et al. 1996).

Hamilton rating scales of depression and anxiety

Maternal depressive symptoms were measured by a trained interviewer blind to the participants' group assignment using the Hamilton Rating Scale for Depression (HRSD), a 15–20-min rater-administered measure that indexes depressive symptoms over the previous 2 weeks (Williams 1988). The HRSD values of 8–13 indicate mild depression,

14–18 indicate moderate depression, and 19–22 indicate severe depression (Hamilton 1960). Maternal symptoms of anxiety were measured using the 10–15-min Hamilton Anxiety Rating Scale (HAM-A, Hamilton 1959), which also indexes symptomatology over the previous 2 weeks. Values less than 17 on this scale indicate mild severity, 18– 24 indicates mild to moderate anxiety, and 25–30 indicates moderate to severe anxiety (Hamilton 1959). The validity and reliability of the HRSD and HAM-A is well established (Maier et al. 1988; Ramos-Brieva and Cordero-Villafafila 1988; Trajković et al. 2011).

Patient health questionnaire

Maternal depressive symptoms also were assessed using the depression module of the patient health questionnaire (PHQ-9; Kroenke and Spitzer 2002), a nine-item self-report measure that assesses the DSM-IV diagnostic criteria for depression (α ranged from 0.72 to 0.77 at the various assessment time points). Respondents are asked to rate on a 3-point Likert-type scale (where 0=*not at all* and 3= *nearly every day*) how frequently they were bothered by specific symptoms over the past 2 weeks. An example item reads "feeling down, depressed, or hopeless." Scores of 0–4 on this scale indicate minimal depression, 5–9 indicates mild depression, 10–14 indicates moderate depression, 15–19 indicates moderately severe depression, and 20–27 indicates severe depression (Kroenke et al. 2001).

Infant fuss/cry episodes

Data about infant fussing and crying were obtained using the Baby's Day Diary (Barr 1985). Over four 24-h periods, mothers recorded the duration and frequency of seven infant behavioral states: awake, alert, fussing, crying, inconsolable crying, feeding, and sleeping. Mothers also recorded the duration and frequency of body contact with their infants. A number of variables are produced from these diaries, including the total number of episodes during which the infant was fussing or crying. Following previously published reports using this measure (e.g., Wolke et al. 1994), the total number of episodes during which the infant was fussing or crying was averaged over the 4 days to arrive at an average daily frequency of fuss/ cry episodes. This measure has been well validated, as evidenced by high correlations between its metrics and audio recordings of fussing and crying (e.g., agreements around 0.9) (Barr et al. 1988; St. James-Roberts et al. 1993). Importantly, previous research has found that the quality of reporting using this measure is not biased by caregiver depressive symptoms (Miller et al. 1993).

Intervention: PREPP and ETAU

PREPP

PREPP comprised a number of infant behavioral interventions and targeted psychotherapy techniques. The participants in the PREPP arm of the study received three consecutive in-person sessions with a Ph.D.-level psychologist. These sessions were described to the participants as "coaching" sessions to minimize stigma that many women associate with receiving mental healthcare during the perinatal period (Dennis and Chung-Lee 2006). The psychologist also contacted participants by telephone at 2 weeks postpartum and, using motivational interviewing techniques, encouraged the use of PREPP skills and answered specific participant questions. To increase accessibility for patients, the three in-person sessions were scheduled to coincide with standard medical visits: (1) 34-38 weeks (third trimester ultrasound), (2) in the hospital postdelivery (delivery), and (3) 6 weeks postpartum (6-week well baby visit). Although this was a standardized protocol, the instructional visits were personalized and varied in response to women's needs and concerns.

The intervention protocol encompassed the following five specific infant behavioral techniques, supported by emerging research and aimed at reducing infant fuss/cry behavior and promoting sleep (Barr et al. 2009; Meyer and Erler 2011; Pinilla and Birch 1993; St. James-Roberts and Gillham 2001; Van Sleuwen et al. 2007): (1) feeding the infant between 10 P.M. and midnight, even if s/he must be awakened ("a focal feed") (Pinilla and Birch 1993; St. James-Roberts and Gillham 2001); (2) accentuating differences between day and night by providing higher levels of stimulation during the day (Pinilla and Birch 1993; St. James-Roberts and Gillham 2001); (3) lengthening the latency to feeding time in the middle of the night by engaging in other attentive activities such as walking with the baby and diapering, thereby extinguishing the association between night time waking and feeding (Pinilla and Birch 1993; St. James-Roberts and Gillham 2001); (4) carrying infants for a minimum of 3 h a day, throughout the day, in addition to the carrying that occurs in response to crying and feeding (Barr et al. 2009); and (5) learning to swaddle the baby (Van Sleuwen et al. 2007). As part of the intervention, women also were provided with (1) supportive psychological interviewing that encourages reflection on their own childhood and how it will inform the development of their parental identity, (2) psychoeducation about the postpartum period (e.g., hormone levels, Baby Blues, infant cry behavior/patterns based on materials from the Period of Purple Crying campaign; Barr et al. 2009), and (3) various mindfulness techniques aimed at (a) helping them to cope better when their babies are distressed and/or unsoothable and (b) aiding them to return to sleep after tending to their babies during the nighttime. In the first visit, participants are given a carrier and a swaddling blanket to use with their babies.

Enhanced TAU

Participants in the ETAU condition met with a Ph.D.-level clinical psychologist on two occasions: (1) 34–38 weeks' gestation and (2) 6 weeks postpartum. During these visits, the psychologist discussed PPD symptoms with participants and offered referrals for mental health care. The psychologist provided suitable referrals and clinical follow-up for all participants who reported symptoms of depression or anxiety or if the participant expressed interest in such a referral. Participants also were provided with printed educational materials about the symptoms of PPD and supportive services in the community.

Analytic strategy

A series of linear mixed effects models (McCulloch and Neuhaus 2001) were used to assess the effect of the PREPP intervention on participants' psychiatric symptomatology. Specifically, three linear mixed effects models were conducted, one for each of the maternal mood measures (i.e., HRSD, HAM-A, and PHQ-9). In each of these models, the participant's intervention status (0=ETAU, 1=PREPP) was entered as a predictor of change in maternal mood over time. Linear mixed effects models can accommodate missing data, and therefore no participants were excluded from analyses due to missing data. A univariate analysis of variance (ANOVA) was used to test whether women in the PREPP and ETAU groups differed in their report of infant fuss/cry behaviors. All analyses were conducted using SPSS version 22.0 (IBM Corporation, Armonk, NY) and adhered to intention-to-treat principles with one exception: one participant who was randomized to the PREPP condition was immediately referred to intensive psychiatric treatment during the first intervention session and subsequently attended twice-weekly treatment throughout the duration of the study. As current mental health treatment was an exclusion criterion for the study (and in an effort not to overestimate the effectiveness of the study treatments), we made an a priori decision to exclude her from analyses.

Results

Recruitment and enrollment

Of the 619 individuals who were screened for this study between July 2011 and December 2013, 95 (15 %) were eligible to enroll. The majority of individuals who were deemed ineligible did not score high enough on the Predictive Index of Postnatal Depression to be considered at risk for PPD (n=261); other common reasons for ineligibility were if they were having a medically complicated pregnancy (n=54), if they delivered their child prior to being screened for the study (n=52), and if they were not interested in participating in research (n=50). Of the 95 women who were eligible for the current study, 54 (57 %) were enrolled and randomized to either the PREPP (n=27) or ETAU (n=27) condition. The majority of women who were eligible but did not enroll were lost to follow-up (n=22) or did not show to their consent appointment (n=13). More detailed information about screening, eligibility, and enrollment can be found in Fig. 2.

Demographics and baseline mood measures

Demographic information about the sample appears in Table 1. The groups did not differ significantly from one another on any of these variables.

Treatment adherence and assessment attrition

All participants who were randomized to the PREPP intervention condition received the entire treatment. That is, they all attended and completed the prenatal, newborn, and 6-week postpartum treatment sessions and had a phone session with the psychologist at 2 weeks postpartum. With respect to assessment sessions, there are missing data.

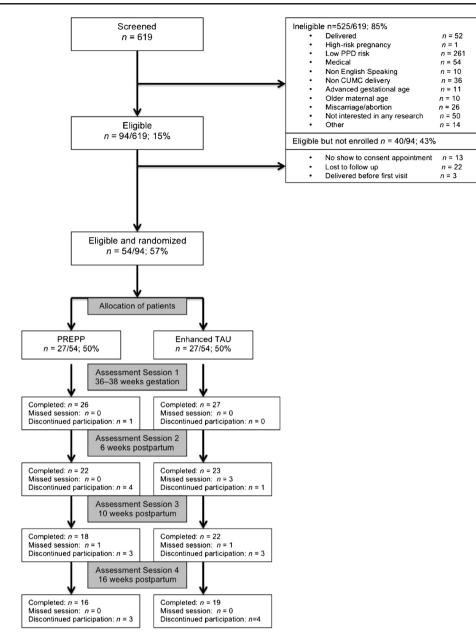
Of the 54 participants who were randomized to either the PREPP or the ETAU conditions, all completed the first assessment. The participant (described above) who was randomized to the PREPP condition but who was immediately referred to intensive psychiatric treatment discontinued participation at this session. Eight individuals did not complete the 6-week postpartum session, 13 did not complete the 10-week postpartum session, and 18 did not complete the 4-month postpartum session. Individuals who did or did not participate in these assessments did not differ from one another on any of the demographic or pre-randomization mood variables, with one exception: participants who did not complete the 6-week assessment (n=8), on average, had lower Predictive Index of Postnatal Depression scores at screening (m=27, SD=2.5) than those who did participate (m=30.7, SD=2.5), p<0.05. Figure 2 presents more detailed information about participant attrition for assessment sessions.

Treatment effects

Clinical relevance of average maternal mood by group at each session

Participant scores on the Predictive Index of Postnatal Depression at screening and descriptive information (i.e.,

Fig. 2 Consort diagram



Note. 1. All participants randomized to the PREPP intervention completed all PREPP sessions, except one participant who was randomized, but dropped out prior to attending any PREPP intervention sessions or completing any mood assessments (completed demographics only). 2. One participant who was randomized to PREPP was immediately referred to intensive psychiatric treatment during the first PREPP intervention session and attended twice weekly treatment throughout the duration of the study. As no current mental health treatment was an inclusion criteria for the study and to not overestimate the effectiveness of the study treatment, we excluded her from analyses.

means, standard deviations, range) about women's HRSD, HAM-A, and PHQ-9 scores prior to randomization (at 36–38 gestational weeks) and at the various assessment time points appear in Table 2. At the pre-randomization assessment, participants (n=53), on average, scored in the "moderate depression" range on the HRSD (m=16.11, SD=11.86), in the "mild anxiety" range on the HAM-A (m=16.45, SD=12.26), and in the "mild depression" range on the PHQ-9 (m=7.12, SD=3.97). The PREPP and ETAU groups did not differ statistically from one another on any of these variables at study entry, although the mean of the PREPP group fell in

the "moderate depression" range and the ETAU group's mean was in the "mild depression" range.

At the 6-week postpartum session, participants in the PREPP group, on average, scored in the "mild depression" range on the HRSD (m=12.09, SD=7.31), whereas those in the ETAU group scored in the "moderate depression" range (m=17.17, SD=9.81). As can be seen in Table 2, both groups, on average, scored in the "mild depression" range at the 10and 16-week postpartum sessions. At 10 weeks postpartum, the average PHQ-9 score for the PREPP group indicated "mild depression"; the average score was at the "moderate

Table 1 Participant demographicinformation and mood variablesprior to randomization

	PREPP		Enhanced TAU		
	Mean (SD) or %	n	Mean (SD) or %	n	
Maternal age (years)	30.87 (6.51)	26	29.60 (5.67)	27	
Relationship status					
Living together	34.60 %	9	33.33 %	9	
Married	38.50 %	10	29.63 %	8	
Not living together	7.69 %	2	11.11 %	3	
Single	15.40 %	4	18.52 %	5	
Divorced	0.00 %	0	7.41 %	2	
Race					
Asian	7.70 %	2	7.41 %	2	
Black/African American	15.40 %	4	22.22 %	6	
White/Caucasian	15.40 %	4	7.41 %	2	
Biracial	3.80 %	1	0.00 %	0	
Other	53.80 %	14	62.96 %	17	
Ethnicity					
Hispanic	57.70 %	15	59.26 %	16	
Not Hispanic	38.50 %	10	37.04 %	10	
Maternal education (years)	15.94 (4.19)	25	14.82 (2.53)	27	
Number of other children	0.44 (0.65)	25	0.67 (.83)	27	
Employment status					
Not working outside of home	38.50 %	10	48.15 %	13	
Full time	38.50 %	10	25.93 %	7	
Part time	19.20 %	5	25.93 %	7	
Paternal age (years)	35.25 (8.41)	24	31.15 (6.71)	27	

Table 2 Means and standard deviations of maternal mood variables

	PREPP intervention			Enhanced TAU		
	Mean (SD)	Range	Severity	Mean (SD)	Range	Severity
Predictive index of postnatal depression						
28–38 weeks GA	31.19 (6.09)	25-47		29.07 (2.81)	25-35	
HRSD						
36–38 weeks GA	18.48 (12.82)	0–48	Moderate	13.83 (10.64)	1–44	Mild
6 weeks postpartum	12.09 (7.31)	1–24	Mild	17.17 (9.81)	2-35	Moderate
10 weeks postpartum	11.48 (8.45)	0-27	Mild	13.44 (10.48)	0–40	Mild
16 weeks postpartum	10.48 (10.31)	0-33	Mild	11.12 (9.43)	0–30	Mild
HAM-A						
36–38 weeks GA	19.35 (13.79)	1–44	Mild/moderate	13.67 (10.11)	1-36	Mild
6 weeks postpartum	11.73 (8.20)	1–26	Mild	14.17 (8.49)	3-31	Mild
10 weeks postpartum	11.07 (8.22)	0–28	Mild	12.00 (8.96)	1–33	Mild
16 weeks postpartum	9.33 (9.77)	0-33	Mild	11.53 (9.10)	0-33	Mild
PHQ-9						
36–38 weeks GA	6.45 (3.57)	0-15	Mild	7.79 (4.31)	1-18	Mild
6 weeks postpartum	7.16 (4.39)	0-14	Mild	10.08 (5.03)	1-16	Moderate
10 weeks postpartum	7.06 (5.04)	1-21	Mild	8.29 (4.06)	1-17	Mild
16 weeks postpartum	4.00 (3.30)	0-11	Minimal	7.22 (4.13)	0-17	Mild

depression" level for the ETAU group; at 16 weeks, PHQ results showed the PREPP participants at the "minimal level" of depression, while those in the ETAU sample had an average score that remained in the "mild" range.

Change in maternal mood by treatment group

Results from the mixed effects models that were used to test whether the PREPP intervention had an effect on maternal symptoms of depression or anxiety are presented in Table 3. Consistent with expectation, these results indicate that women who underwent PREPP compared to those who received the ETAU differed significantly from one another in their change in symptomatology over time.

Specifically, HRSD and HAM-A results show women who received the PREPP intervention decreased significantly in their HRSD-rated depressive symptoms (B=-6.54, p=0.01) between the pre-randomization assessment (i.e., at 36-38 weeks' gestation) and the 6-week postpartum session. In contrast, women in the ETAU group had no significant change between the prenatal and 6-week postpartum assessment (B=3.02, p=0.22). The results for anxiety are consistent with those for depression, such that women in PREPP decreased significantly in their HAM-Arated symptoms of anxiety between the pre-randomization assessment and 6 weeks postpartum (B=-7.84, p<0.01), whereas those in the ETAU group did not change significantly over this period of time (B=0.24, p=0.94). These PREPP effects remained marginally significant (p < 0.10) at the 10-week assessment for both HRSD and HAM-A findings and were statistically significant for HAM-A scores at 16 weeks postpartum (p < 0.05). As a complement to the results from these mixed effects models, Figs. 3 and 4 present the average change scores (presented separately by treatment condition) for HRSD and HAM-A scores, respectively.

For the PHQ-9, results from the mixed effects model were as follows. The PREPP group did not change significantly between the prenatal and 6-week postpartum session (B=0.61, p=0.58). The ETAU group, however, reported significantly more depressive symptoms at the 6-week postpartum session, relative to the pre-randomization assessment (B=2.44, p=0.02). Figure 5 presents the average change scores for the PHQ-9 scores, presented separately by treatment condition.

Effects on infant fuss/cry behavior

Data from the *Baby's Day Diary* was available on a subset of participants enrolled in the current study (n=30); this subsample did not differ significantly from the complete sample on any of the demographic variables, but did differ significantly on their score on the PHQ-9 prior to randomization, with the respondents scoring higher than the non-respondents. Results from the ANOVA used to test whether infants in the PREPP versus ETAU conditions differed from one another in the frequency of their fuss/cry behavior are visually depicted in Fig. 6. Consistent with expectation, mothers who received the PREPP intervention reported fewer bouts of fuss/cry behavior (m=4.07, SD=2.50) than those in the ETAU condition (m=6.30, SD=2.63), F(1, 28)=5.68, p=0.02.

Discussion

The current study provides preliminary evidence in support of the effectiveness of PREPP in preventing the development of

HRSD HAM-A PHQ-9 Variable В SE B В SE B В SE B 14.21** 14.01** 7.78** 0.84 Intercept 2.00 1.95 Main effects Intervention group^a 4.27 2.87 5.34† 2.79 -1.261.18 Time^b 6 weeks postpartum 3.02 2.460.24 2.41 2.44* 1.05 -1.06 -2.102.47 0.41 1.07 10 weeks postpartum 2.53 16 weeks postpartum -3.422.43 -2.432.67 -0.821.18 Interaction effects -9.56** Intervention group×time 6 weeks postpartum 3.51 -8.07*3.44 -1.83*1.52 10 weeks postpartum -6.17† 3.47 -6.67† 3.60 -0.111.55 3.60 -2.2016 weeks postpartum -4.113.94 -7.69*1.75

 Table 3
 Results of linear mixed effects models

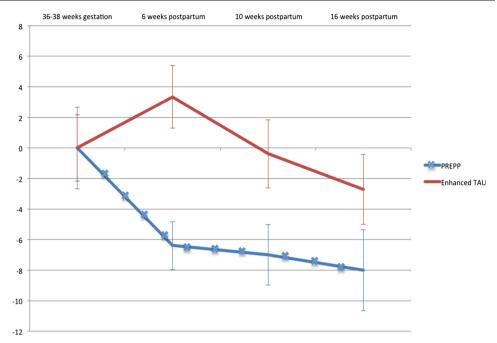
HRSD Hamilton Rating Scales for Depression, HAM-A Hamilton Rating Scales for Anxiety, PHQ-9 Patient Health Questionnaire

*p<0.05, **p<0.01, †p<0.10

^a0=Enhanced Treatment as Usual, 1=PREPP

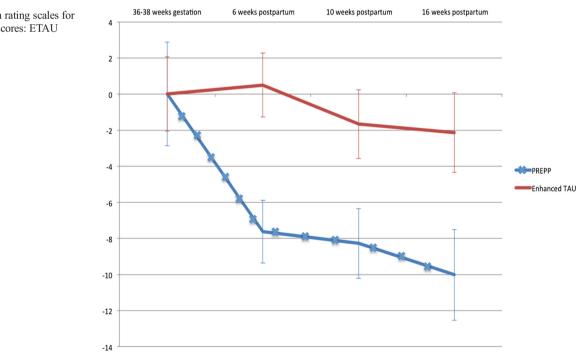
^b The reference group for all time effects is 36-38 weeks' gestation (prior to randomization)

Fig. 3 Hamilton rating scales for depression change scores: ETAU versus PREPP

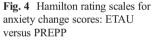


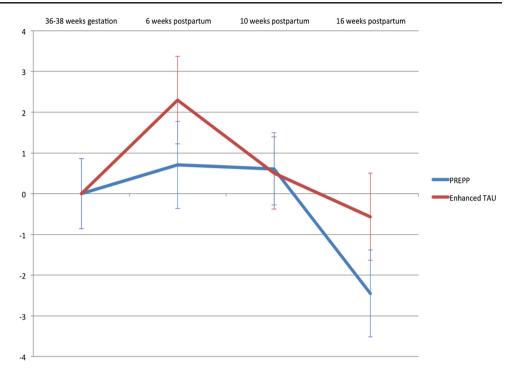
Note: Change scores are calculated with respect to the previous assessment timepoint. The mood assessment at 36-38 weeks gestation occurred prior to randomization.

PPD symptoms. These effects were most consistently observed at 6 weeks postpartum; given that the DSM-V specifies that symptoms of PPD must first occur within the first 4 weeks postpartum, these findings indicate that PREPP is a useful tool consistent with the clinical focus on this time period for mothers, as well as their infants. In addition, the study also found that mothers who received PREPP reported having infants who fussed and cried fewer times per day at 6 weeks postpartum than



Note: Change scores are calculated with respect to the previous assessment timepoint. The mood assessment at 36-38 weeks gestation occurred prior to randomization.





Note: Change scores are calculated with respect to the previous assessment timepoint. The mood assessment at 36-38 weeks gestation occurred prior to randomization.

infants of the ETAU mothers. These data, along with the 0 % attrition rate for PREPP treatment sessions, suggest that PREPP is a well-tolerated intervention, and one with promising results for preventing PPD in those at risk for it.

Specifically, we found that women at risk for PPD who received the dyadically oriented preventive intervention, on average, reduced symptoms of depression and anxiety judged by blinded, clinician report (HRSD, HRSA) at 6 weeks postpartum, while those at-risk women who were assigned to the ETAU group did not. Additionally, there was a significant increase in self-reported depression in the ETAU group and no change in the PREPP intervention group on this index. PREPP's effects on

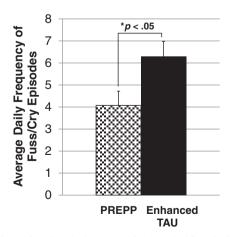


Fig. 6 Infants of mothers in the PREPP fuss/cry significantly fewer times per day than those in the ETAU condition

blind-clinician ratings of maternal depression approached significance at the 10-week assessment. Blind-clinician ratings of anxiety approached significance at the 10-week assessment and were significantly lower than baseline at 16 weeks postpartum.

Despite having robust findings at the 6-week assessment, the current study did not consistently observe statistically significant long-term effects on the clinician-rated and self-report measures administered at 10 and 16 weeks postpartum. These less consistent results may be due to several factors. First, this is a small pilot study, so our analyses may have been underpowered. Additionally, as indicated, not all participants completed all assessment sessions, which may have contributed further to issues of power. Second, post hoc analyses revealed that there was differential attrition for the ETAU group only, such that participants in this group who did not complete the 16-week assessment had significantly higher HRSD scores pre-randomization. This may have created an artificial appearance of improvement in the symptomatology of the ETAU group, thereby reducing our ability to detect an effect at this later time point. Third, previous research by Hiscock et al. (2014) found that their treatment to prevent infant sleep and cry problems had effects on maternal report of depression symptoms at 6 months but not on these symptoms at 4 months postpartum. Perhaps, if we had followed our sample for an additional 2 months, we, too, may have seen PREPP having a sustained effect on maternal mood 6 months postpartum even though we saw no 16-week effect. If, in future studies, we confirm a lack of effect at these later postpartum assessments,

it may suggest that PREPP would be enhanced by providing infant behavioral interventions that are focused on the caregiving of older babies.

This study also found that the PREPP intervention was effective in reducing the number of episodes of infant fuss/ cry behavior by maternal report. On average, women who received PREPP reported over two fewer bouts of fuss/cry per day. These results add support to previous findings that demonstrated that the use of specific infant care techniques is effective at reducing infant fuss/cry behavior (Hunziker and Barr 1986; Hiscock et al. 2014). Unlike Hiscock et al. (2014), who found that their intervention reduced crying problems only in babies classified as "frequent feeders," the current study found that the effects on maternal report of cry behavior were not limited to a subset of infants. However, it is important to note that our infants actually may represent a subset because we only recruited women at risk for PPD for this study. Although this study did not have the power to test whether reductions in infant crying is the mechanism through which maternal mood was improved, the fact that reductions in distressed mood and in infant fuss/cry behaviors both occurred at 6 weeks supports our theoretical prediction of the dyadic influence of mother and infant behavior.

In addition to finding that this treatment can affect maternal mood and infant fuss/cry behavior, we also found that PREPP is a well-tolerated and accessible treatment for PPD. All participants who were randomized to the PREPP condition completed all treatment sessions, yielding a 0 % attrition rate. This rate is much lower than those reported by many other PPD prevention programs (Stamp et al. 1995; Brugha et al. 2000; Le Strat et al. 2011), some of which describe attrition rates over 50 % (e.g., Lara et al. 2010). We attribute our 0 % attrition rate to our careful attention to the barriers to PPD treatment, including calling our intervention "coaching sessions" to address the stigma associated with receiving mental health care (McIntosh 1993) and improving the accessibility of this treatment by offering it at the same time women are receiving routine medical care. In addition, we hypothesize that targeting the dyad and teaching infant care techniques in addition to the use of traditional psychotherapeutic techniques may have increased engagement in the treatment.

Strengths

There were several methodological strengths of this study. For example, we utilized both blind, clinician-rated assessments and self-report measures of maternal mood. In addition, this study also benefits from assessing both symptoms of depression and anxiety as outcome measures. As PPD often encompasses symptoms of anxiety as well as depression (Miller et al. 2006), the inclusion of anxiety assessment is essential when determining the effectivity of a preventive PPD intervention.

Limitations

This study also had a number of limitations. Most notably, this pilot study had a small sample size, which may have reduced our ability to detect certain findings. Despite its small sample size, the current study reports several statistically significant findings, a fact that may reflect the robust nature of these effects. We also had a differential attrition rate for the assessment sessions in the ETAU group, such that the most depressed (those with highest HRSD scores pre-randomization) dropped out of the study, which artificially reduced the severity of the mood scores in the ETAU group over time. As described above, this may have provided an overly conservative assessment of the effectiveness of PREPP over time. However, there still were trends at 10 weeks postpartum for the HRSD and HAM-A, and a significant result for the HAM-A at 16 weeks postpartum. Future research with a larger sample may provide further support for the effectiveness of PREPP in reducing symptoms over time. Another weakness of this study is that crying and fussing bouts were assessed by maternal report. However, they were assessed using the Baby's Day Diary (Barr 1985), a widely used tool that has been shown to be highly reliable and valid (St. James-Roberts and Gillham 2001). Further, as Radesky et al. recently suggested (2013), because we are aiming to reduce maternal depression/anxiety symptoms by reducing fussing/ crying behavior in infants, an alteration in maternal perception of these infant behaviors, a "dyadic measure," may be effective on its own in improving maternal mood via improvement in self-efficacy. Last, the current study did not include a self-report measure of anxiety and only relied on a clinician rating, despite the fact that anxiety symptoms are a major feature of PPD. However, clinician assessments are often considered a more valid assessment of symptomatology than self-report measures.

Summary and conclusions

Building on developmental data showing the profound bidirectionality of emotional and behavioral influences between mother and infant (Kochanska et al. 2000, 2001, 2009; Kochanska and Aksan 2006; Feldman and Eidelman 2006; Feldman 2007), PREPP takes a dyadic behavioral approach to the prevention of PPD. The current pilot study indicates that this novel, brief intervention, which also includes psychoeducation and mindfulness skills, was well tolerated and effective in reducing maternal symptoms of anxiety and depression, particularly at 6 weeks postpartum. Additionally, this study found that infants of mothers enrolled in PREPP had fewer bouts of fussing and crying at 6 weeks postpartum than those infants whose mothers were in the Enhanced TAU group. Significantly, reports show that remission from PPD using standard treatment does not improve women's ratings of their children's behavior, nor child outcomes (Forman et al.

2007). These preliminary results indicate that PREPP has the potential to reduce the incidence of PPD in women at risk and to directly impact the developing mother–child relationship, the mother's view of her child, and child outcomes.

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