Published in final edited form as:

Arch Womens Ment Health. 2015 June ; 18(3): 493–506. doi:10.1007/s00737-014-0483-y.

Perinatal Dyadic Psychotherapy for postpartum depression: A randomized controlled pilot trial

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Keywords

postpartum depression; intervention; psychotherapy; mother-infant relationship; postpartum anxiety

Introduction

Postpartum depression (PPD) affects approximately one in five women in the first year after delivery (Gavin et al. 2005). Its major features include depressed mood, anxiety, compulsive thoughts, loss of control, feelings of inadequacy, inability to cope, irrational fears, fatigue, loss of libido and despair (Miller 2002; Sichel 2000). In some cases the mother may develop suicidal and/or infanticidal thoughts and plans. PPD can lead to a chronic or recurring depressive course throughout a woman's life (Cooper and Murray 1995; Goodman 2004). In addition to depression that meets diagnostic criteria for major depressive disorder (MDD), a high proportion of postpartum women experience sub-threshold yet clinically relevant levels of depressive symptoms that, if left untreated, may progress to more severe depression (Kessler et al. 2003).

Both clinical and subclinical levels of depressive symptoms can impair maternal functioning (Weinberg et al. 2001), depriving mothers of the emotional wellness needed to care for, talk to, play with, comfort, and offer appropriate developmental support to her infant (Beck 1998; Forman et al. 2007; Murray et al. 1996). Research indicates that maternal depression negatively affects infants through the impaired mother-infant interaction that typically

accompanies PPD (Field 1998; Goodman and Gotlib 1999; Murray et al. 1996; van Doesum et al. 2007; NICHD Early Child Care Network 1999; Tronick and Reck 2009). Depressed mothers may be withdrawn and disengaged, or intrusive and over-stimulating (Beck 1995; Cohn et al. 1990; Field 1984). They may look at, talk to, play with, and affectionately touch their infants less often than non-depressed mothers. Compared to non-depressed mothers, they exhibit fewer positive facial expressions and show overall less sensitivity to their infants (Cohn et al. 1990; Field 1984; Herrera et al. 2004; Fleming et al. 1988). In response, infants of depressed mothers alter their own behavior, leading to a broad range of infant deficits including poor emotional and behavioral state regulation, greater fussiness, and fewer positive and more negative facial expressions (Field et al. 1988; Field et al. 1990; Manian and Bornstein 2009).

Children exposed to maternal depression early in life may experience negative effects which can extend well beyond infancy, including impaired cognitive, social and emotional development, long-term behavioral problems, attachment insecurity, persistent disruptions of stress response systems, dysregulated attention and arousal, and development of depressive symptoms in adolescence or later in life (Bagner et al. 2010; Beck. 1998; Essex et al. 2002; Grace et al. 2003; Halligan et al. 2004; Hay et al. 2001; Murray and Cooper 1996; Murray and Cooper 1997; Murray 2009; Murray et al. 1999; Murray et al. 1996; Teti et al. 1995; Weinberg and Tronick. 1998). Other factors associated with PPD may also impair mother-infant relationships and compromise child development. These include maternal anxiety (Heron et al. 2004; Ross and McLean 2006; Wenzel et al. 2005), parenting stress (Abindin 1995; Swendsen and Mazure 2000), poor maternal self-esteem (Weinberg et al. 2001), and lack of confidence in the mothering role (Weinberg et al. 2001).

Effective treatments for depression exist (Claridge 2014; De Crescenzo et al. 2014; Sockol et al. 2011; Stuart and Koleva 2014), however only about 12% to 25% of depressed women receive treatment during the postpartum period (Goodman and Tyer-Viola 2010; Horowitz and Cousins 2006; Marcus et al. 2003). Antidepressants can effectively decrease PPD symptoms (e.g., Cohen et al. 2001; Wisner et al. 2002; Yonkers et al. 2008); nevertheless there is great reluctance among many postpartum women to take medication, even if not breastfeeding (Goodman 2009). Most women instead prefer psychotherapy (Battle et al. 2013; Cooper and al. 2003; Goodman 2009), but the logistics of getting to therapy appointments can be overwhelming for a depressed mother of a newborn. Reducing barriers to depression treatment is essential. PPD interventions that are acceptable, such as psychotherapy, and logistically feasible, such as in-home treatment, are indicated to increase treatment uptake, adherence, and efficacy.

Even if a woman receives effective PPD treatment, however, the negative effects of depression on the mother-infant relationship may persist (Cooper and al. 2003; Forman et al. 2007; Gunlicks and Weissman 2008; Murray et al. 2003; Poobalan et al. 2007). Although a woman's depression may improve, her interaction with her infant may remain compromised, indicating that it is not enough to treat maternal depression alone. Nevertheless, most current PPD treatments treat mothers in isolation, concentrating only on maternal outcomes and neglecting the mother-infant relationship (Nylen et al. 2006; Poobalan et al. 2007). On the other hand, various interventions have been utilized to enhance the mother-infant

relationship in the context of maternal depression (see Nylén et al. 2006 for review). Although these interventions can effectively ameliorate the adverse effects of PPD on infants, they rarely result in decreased depression for the mothers (Kersten-Alvarez et al. 2011; Nylén et al. 2006).

There is a need to develop more comprehensive PPD interventions that address the needs of the mother, the mother-infant relationship, and the infant. Dyadic approaches to the treatment of PPD have the greatest potential to reduce maternal depression as well as to decrease the negative impact of depression on the infant due to the impaired mother-infant relationship. Early identification of mothers with PPD, followed by intervention efforts aimed at reducing maternal depression and the associated disturbances in the mother-infant relationship, hold great promise for minimizing the adverse effects of maternal depression on both mothers and babies (Nylén et al. 2006). Few interventions have been studied that address both maternal depression and mother-infant relationship dysfunction. Because these problems are linked and have reciprocal effects on each other, an integrated approach that addresses both problems simultaneously might lead to synergistic effects.

This study pilot tested a preventive/early intervention that targets maternal depression *and* mother-infant relationship dysfunction in an integrated, potentially synergistic way. Perinatal Dyadic Psychotherapy (PDP) is an investigator-developed intervention aimed at preventing/decreasing PPD and facilitating optimal mother–infant relationships. Prior work has demonstrated the feasibility, acceptability, safety, and preliminary efficacy of the PDP intervention with depressed postpartum women and their infants (Goodman et al. 2013). This study extends that work with a larger sample of dyads which includes postpartum women with subclinical depression as well as diagnosed major depressive disorder (MDD).

Purpose and Aims

The purpose of this study was to pilot test Perinatal Dyadic Psychotherapy, a novel dual-focused mother-infant intervention to prevent/decrease maternal postpartum depression and improve aspects of mother-infant relationships related to child development outcomes in mother-infants dyads in which the mother was experiencing elevated postpartum depression symptoms (sub-threshold or meeting diagnostic criteria for MDD). The specific aims were to: (1) Assess participant acceptability of study intervention and overall feasibility of study procedures, including recruitment, adherence, and retention; (2) Assess the preliminary efficacy of the PDP intervention on the primary outcomes of reducing maternal depression and enhancing the quality of mother-infant interaction at post-intervention and at three-month follow-up in order to provide information to enable sample size calculation for future studies; and (3) Explore the effects of the intervention on secondary outcomes of maternal anxiety, parenting stress, and maternal self-esteem at post-intervention and follow-up.

We hypothesized that, compared to control dyads, mother-infant dyads who received the intervention would evidence significantly (a) fewer maternal depression diagnoses, (b) lower depression severity, (b) more optimal mother-infant interaction, (c) lower maternal anxiety, (d) lower parenting stress, and (e) higher maternal self-esteem, at post-intervention and follow-up.

Method

Study Design

A randomized controlled pilot trial was conducted to compare Perinatal Dyadic Psychotherapy (PDP) to usual care plus depression monitoring for women with elevated postpartum depressive symptoms. Data was collected pre-intervention, post-intervention, and at three months follow-up.

Sample Recruitment

First-time, English-speaking mothers of healthy singleton newborns were recruited from the postpartum units of a large academic teaching hospital and two community hospitals. First-time mothers were targeted to limit potential confounders (i.e., older children), and because new mothers would likely derive the most benefit from the infant developmental aspects of the intervention. Interested potential participants (n = 790) completed a screening process by mail and/or phone at four to six weeks postpartum. Fifty-eight women met initial eligibility for study inclusion by meeting the following criteria: (a) scored > 9 and < 20 on the Edinburgh Postnatal Depression Scale (EPDS; Cox et al. 1987) on two consecutive screens one week apart, (b) were not currently receiving any depression treatment, (c) had no suicidal ideation as determined by EPDS question 10, (d) had no history of psychiatric disorder other than depression or anxiety per self-report, and (e) had no plans to move out of area in subsequent nine months. Screen-positive women received a home visit from a research assistant (RA) at which signed informed consent was obtained, followed by the administration of the mood and anxiety disorders modules of the Structured Clinical Interview for the DSM-IV Axis I Disorders Non-patient Version (SCID-I; First et al. 1996). Women meeting criteria for bipolar disorder and/or lifetime or current psychotic disorder were excluded from the study. A total of 42 mother-infant dyads were included in the study (Figure 1).

Intervention

The Perinatal Dyadic Psychotherapy intervention was developed to promote maternal mental health and to facilitate optimal mother-infant relationships. The conceptual and clinical framework for PDP, as well as a description of the intervention and specific intervention strategies, has been previously presented (Goodman et al. 2013). Briefly, PDP derives from the Mutual Regulation Model of Mother-Infant Interaction (Tronick 2007) in which infant psychological development is seen as a relational process in which infants and mothers are actively engaged in a mutually regulated interaction. Maternal depression is seen as interfering with this mutual regulatory process by compromising maternal affective responsiveness, thereby limiting the degree of “active engagement” infants experience with their mothers and disrupting healthy infant emotional adjustment (Weinberg and Tronick 1998a). PDP integrates the clinical strategies of supportive psychotherapy (Winston et al. 2004), parent-infant psychotherapy (Lieberman et al. 2000), and the Touchpoints™ Model of Child Development (Brazelton and Sparrow 2006). Each of these strategies shares many common features, while each introduces and emphasizes specific components relevant to the mothers’ emotional well-being, mothering an infant, and the mother-infant relationship. The Newborn Behavioral Observation (Nugent et al. 2007) is utilized to help sensitize mothers to

their infant's behavioral and emotional competencies and uniqueness in order to promote positive mother-infant interactions and the early development of positive mother-infant relationships.

PDP consists of eight one-hour long sessions conducted in the participants' homes and delivered over three months by maternal-child nurses trained in the intervention. The two major components of the intervention are: (a) a supportive, relationship-based, mother-infant psychotherapeutic component, and (b) a developmentally-based infant-oriented component designed to enhance maternal sensitive responsiveness and promote positive mother-infant interactions. Three major areas of focus include: (1) maternal emotional well-being, functioning, and adjustment to motherhood, (2) infant behavior and development (getting to know the infant), and (3) the mother-infant relationship. The intervention is individually tailored to each mother and infant at each visit according to a participant's particular situation or concerns.

Procedures

All study procedures were approved by the institutional review boards of the participant hospitals and the academic center prior to the start of the study. Intervention development and interventionist training have been previously described (Goodman et al. 2013). Two bachelor-level registered nurses with experience in maternal-child nursing were successfully trained and carried out the intervention.

Data collection and intervention and control condition implementation—

Research assistants blind to specific screening results collected baseline data at the initial home visit following collection of informed consent and final eligibility determination. Baseline data included depression severity, trait anxiety, state anxiety, maternal self-esteem, and baseline questionnaire which collected information regarding demographics, psychiatric history, social support, past and current psychosocial stressors, and substance use. Baseline psychiatric diagnoses (lifetime and current depressive disorders and anxiety disorders) were assessed by the SCID-I diagnostic interviews administered by RAs. Mother-infant dyads were randomized to intervention or control groups by the study coordinator using consecutively numbered, sealed, opaque envelopes containing randomly generated numbers. Randomization occurred without coordinator's knowledge of or access to baseline data.

Intervention and control conditions were implemented within a week following randomization. Nurse interventionists delivered the PDP intervention to mother-infant dyads in their homes for the series of eight interventions home visits over three months. Visits took place weekly for the first four visits then every other week for the remaining four visits. Each intervention visit lasted approximately one hour and was videotaped. Control group mothers received phone calls from the study coordinator on the same frequency schedule as the intervention visits. Phone calls lasted approximately 10 minutes each and focused on monitoring participant depression status through administration of the EPDS and on maintaining participant engagement in the study. The study coordinator abstained from engaging the mother in conversation about how she was feeling emotionally, how she was coping with her new baby or motherhood, or infant/parenting issues.

Post-intervention and follow-up outcome data were collected at home visits by RAs blind to psychiatric status and group assignment. RAs administered the depression and anxiety portions of the SCID-I and participants completed self-report questionnaires regarding depression severity, trait anxiety, state anxiety, and maternal self-esteem. Mother-infant interaction data was collected by videotaping mothers and infants in a 10-minute free play session. Diagram 1 presents the flow of the study procedures from recruitment through final data collection. All participants received \$200 total compensation for completion of the study.

Quality Control—The PDP manual developed and revised in earlier preliminary work (Goodman et al. 2013) was utilized to train and monitor nurse interventionists. Prior to providing the intervention, the nurse interventionists completed a 10-day training in the PDP intervention and met reliability criteria for providing the intervention based on attainment of at least 90% on interventionist skills checklist during role play evaluation (see Goodman et al. 2013 for details). All intervention sessions were videotaped and intervention fidelity was monitored by randomly selecting three sessions from each participant for fidelity coding: one from sessions 1 to 3, one from sessions 4 or 5, and one from sessions 6 to 8. Selected videotaped sessions were transcribed and graduate nursing students trained and supervised by the principal investigator coded the transcriptions while viewing the videotapes using an intervention fidelity coding manual and form developed by the principal investigator and members of the research team. Selected sessions were transcribed and fidelity-coded for both adherence to intervention protocol and interventionist competence in providing intervention elements. Scores for each session were calculated and an average adherence and competency scores for each participant's sessions were produced based on the participant's three coded sessions. Each coder achieved an inter-rater reliability score of at least 90% in practice coding before independent coding of study videos. Fifteen percent of selected sessions were double-coded on an ongoing basis to ensure maintenance of inter-rater reliability throughout the coding process. All randomly selected videos met intervention fidelity criteria of at least 85% for both adherence and competence, most sessions scoring much higher. No systematic differences in intervention delivery between the two interventionists were found.

During the intervention phase of the study, the principal investigator provided close supervision of the nurse interventionists through weekly review of videotaped sessions and discussion of intervention sessions centered on clinical and intervention issues, case discussion, intervention fidelity, consistency among research nurses, and overall study management. Three RAs conducted baseline and outcome data collection. Two were experienced mental health (social work) clinicians and one a doctoral-level clinical psychology student. All were extensively trained in SCID-I diagnostic interview administration and demonstrated acceptable reliability per SCID guidelines prior to conducting study interviews. All diagnostic interviews with participants were audio recorded and the first 10, and then every fourth interview thereafter, were reviewed by the principal investigator as a quality check, with corrective action taken if needed.

Mother-infant interaction videotapes were coded by two RAs (a clinical psychologist and a graduate psychology student) blind to participant group status. Coders received extensive

training in the coding method and reached inter-rater reliability of 90% prior to independent coding. To prevent drift, raters met regularly with the principal investigator/trainer to rate and discuss videotapes. Twenty percent of all available videos were randomly assigned to be double coded. As with the initial reliability, answers were recorded by each coder independently and then compared and discussed. Inter-rater reliability of at least 90% was maintained throughout the study duration.

Safety considerations—Depression severity was monitored at recruitment and throughout the study using the EPDS at each intervention visit for the intervention group, via telephone on a corresponding schedule for the control group, and at all data collection visits for both groups. Per study protocol, if a participant scored 20 on the EPDS or indicated suicidal ideation, a research nurse or the PI assisted the participant in accessing the appropriate level of care (e.g., perinatal social worker located in the clinic, mental health provider, obstetric provider, or emergency care) and the principal investigator was notified. A resource list of mental health providers and depression hotlines was given to all mothers who scored 20 on the EPDS and to any woman who requested depression help information.

Assessments and Measures

Feasibility and acceptability were assessed by recording recruitment rates and intervention and study, participation, adherence, and completion rates.

Psychiatric diagnoses—The *Structured Clinical Interview for DSM-IV Axis I Disorders, Non-Patient Edition* (SCID-I; First et al. 1996) was administered at baseline, post-intervention and follow-up to determine diagnoses of depressive disorders and/or anxiety disorders. Baseline SCID-I results were also used as part of final eligibility determination, with women with lifetime or current bipolar and/or psychotic disorders excluded from the study.

Depression Severity—The *Edinburgh Postnatal Depression Scale* (EPDS; Cox et al. 1987) is a 10-item self-report measure designed to assess presence and severity of PPD symptoms. It is the most commonly used measure to assess symptoms of PPD in prevention and treatment trials. The EPDS has adequate sensitivity and specificity when compared to the Diagnostic and Statistical Manual of Mental Disorders (4th ed., text rev.; DSM-IV-TR; American Psychiatric Association, 2000) psychiatric diagnoses of major and minor depression and is sensitive to changes in depression over time. The EPDS was used to determine study eligibility, measure level of depressive symptoms, and monitor for clinical deterioration throughout the study. Cronbach alphas for the 42 participants at baseline, post-intervention, and follow-up were .53, .80 and .81 respectively.

Maternal Anxiety—State and trait anxiety were measured by the *State-Trait Anxiety Inventory* (STAI; (Spielberger et al. 1970). The 20-item *State* subscale measures transient/current anxiety and is sensitive to changes over time. The 20-item *Trait* subscale measures more general long-standing anxiety. Internal consistencies were .86 for trait anxiety at

baseline and .92, .92, and .90 for state anxiety at baseline, post-intervention and follow-up respectively.

Maternal Self-Esteem—Maternal self-esteem was measured by the global score of the *Maternal Self-Report Inventory* (MSRI; Shea and Tronick 1988) which includes dimensions of maternal caretaking ability, general preparedness for mothering role, acceptance of baby, expected relationship with baby, complications during labor and delivery, parental influence, and body image and maternal health. The full MRSI was administered at baseline and an abbreviated version, which eliminates questions pertaining to labor and delivery and questions redundant for follow-up, was administered at post-intervention and follow-up. Internal consistencies were .96, .96, and .94 at baseline, post-intervention, and follow-up respectively.

Parenting Stress—The *Parenting Stress Index-Short Form* (PSI-SF; Abidin 1995) is a 36-item self-report measure developed to identify potentially dysfunctional parent-child relationships that place a child at risk for emotional disturbance, and to measure the relative magnitude of stress in the relationship. The PSI-SF yields a Total Stress score derived from the three sub-scales (Parental Distress, Parent-Child Dysfunctional Interaction, and Difficult Child). The Total Stress score was used for this study. Internal consistencies were .93, and .89 post-intervention and follow-up respectively.

Mother-Infant Interaction—Mothers-infant dyads were video-recorded in 10-minute free-play sessions at both post-intervention and follow-up. Recordings were analyzed using the Coding Interactive Behavior manual (CIB; Feldman 1998), a well-validated method for measuring parent-infant interactions that has demonstrated sensitivity to infant age, culture, biological and psychiatric risk, and intervention effects (Feldman 2007; Feldman and Eidelman 2005; Feldman and Masalha 2007). The CIB includes 42 codes rated from 1 (low) to 5 (high) which make up eight composites. Three composites were used in the present study: Maternal Sensitivity, Infant Involvement/Engagement, and Dyadic Reciprocity. The Maternal Sensitivity composite included codes relating to the mother's acknowledgement of the infant's interactive signals, joint attention with infant, appropriate range of affect, positive affect, elaborating and expanding on infant communications, warm vocal quality, affectionate touch, resourcefulness in dealing with the infant's negative states, consistency of style, and supportive presence. The Infant Involvement/Engagement composite included codes relating to the infant's gaze/joint attention, positive affect, vocalization, initiation in interaction with his/her mother, and alertness. The Dyadic Reciprocity composite included codes relating to infant and maternal reciprocity, adaption/regulation, and fluency during interaction. Internal consistencies were .91, .85, and .87 for the maternal, infant, and dyadic constructs respectively at post-intervention, and .93, .66, and .94 at follow-up.

Analyses

All analyses were conducted using Stata, version 13.1. Descriptive statistics were calculated for demographic and study variables. Cronbach's alpha was computed for all study measures. Intervention and control groups were compared using Chi square and t-tests to assess for differences between groups at baseline. Exact logistic regression (Hirji et al. 1987)

was conducted to assess differences in psychiatric diagnoses between the intervention and control groups over the three time points (baseline, post-intervention, and follow-up). The baseline was used as the reference group and dummy coding was used for the others (i.e., if the time was post-baseline, the value was “1”, otherwise “0”, and if the time was follow-up, the value was “1”, otherwise “0”). Traditional (i.e., non-exact) methods could not be used because there were no participants in the control group who had any of these diagnoses at the follow-up period. Mixed effect regression analyses were conducted to assess differences in depression, anxiety, and self-esteem scores between the intervention and control groups at baseline, post-intervention and follow-up time points. Mixed effects regression analyses (Fitzmaurice et al. 2011) were conducted to determine if there were any significant differences between the intervention and control groups at post-intervention and at follow-up time points on the PSI total scores and the CIB subscales Parental Sensitivity, Child Involvement, and Dyadic Reciprocity.

Results

Sample characteristics

Of the 42 women included with their infants in the study, 13 (31%) met criteria for major or minor depression at baseline. The remaining participants were at high risk for development of PPD as indicated by two consecutive elevated EPDS scores. See Table 1 for full description of participants' baseline psychiatric diagnoses.

Baseline descriptive statistics were calculated for demographic and study variables and are presented in Table 2. Means and standard deviations of all outcome measures at each time point are presented in Table 3. A series of Chi square contingency tables between groups (intervention and control) and the following variables were conducted: (a) race, (b), categorized income, (c) marital status, (4) education level, (3) primary language, (4) delivery type, (5) whether pregnancy was planned, and (6) whether pregnancy was desired. Results of the Fisher's Exact Test indicated no statistically significant differences between the groups on these demographics. A series of independent samples t-test indicated no statistically significant differences between groups at baseline on age, EPDS total score, trait anxiety score, and MSRI total score; however, there was a statistically significant difference on state anxiety score, with the intervention group showing significantly higher baseline state anxiety than controls ($p = .02$). Results of the chi-squared tests indicated no statistically significant differences at baseline between the intervention and control groups on (a) past history of MDD, (b) depression diagnosis at baseline; (c) lifetime (past and/or current) anxiety disorder; (d) current anxiety disorder, or (e) depression and/or anxiety disorder diagnosis.

Acceptability and feasibility

Of the 50 women eligible for the study, 42 (84%) consented to participate and were randomized. Intervention acceptability was demonstrated by high intervention adherence and completion rates. At least seven of the eight intervention sessions (Mean = 7.8, SD = 0.39) was completed by all intervention-group dyads. Completion of control group phone calls was also high, with a mean of 7.2 (SD= 0.98) phone calls completed. There was no

attrition from the study for either the intervention or control groups. All participants completed all main study assessments.

Outcomes

Table 1 outlines findings regarding psychiatric diagnoses across the study time frame. Of the 13 women who met diagnostic criteria for depression (7 major and 6 minor) at baseline, three (7.2%) met criteria at the post-intervention time point, and only one (2.4%) at follow-up. Of the seven women with MDD at baseline, only one (4.8%) continued to meet criteria at post-intervention and this participant was no longer depressed at follow-up. Of the six women with minor depression at baseline, two (one intervention and one control) continued to meet criteria for minor depression at post-intervention. One of these participants was no longer depressed at follow-up (control), whereas the other continued to be depressed, meeting criteria for MDD at follow-up. This participant experienced undiagnosed medical problems beginning a couple of months postpartum causing her significant distress for several months. She was one of only two participants (both intervention group women), who received extra-study depression treatment (individual therapy) during the study. The other participant, who had no diagnosis at any time point, started therapy post-intervention. In sum, of the 13 women who met criteria for major or minor depression at baseline, 10 no longer met criteria at post-intervention and 12 were without a depression diagnosis at follow-up. Furthermore, no participants developed onset of postpartum depression during the course of the study.

In addition to depression diagnoses, 17 women (40.5%) met criteria for one or more anxiety disorders at baseline, eight (19%) at post-intervention, and two (4.8%) at follow-up.

Seven women (four intervention, three control) had one or more anxiety disorders comorbid with depression at baseline. Ten additional women (five intervention, five control) had one or more anxiety disorders without diagnosed depression. At post-intervention, the number of women with one or more diagnosed anxiety disorders decreased to eight (19%) and by follow-up only two women (4.8%) had an anxiety disorder. Twenty-three women (54.8%) met criteria for major or minor depression and/or an anxiety disorder at baseline, nine (21.4%) at post-intervention, and three (7.1%) at follow-up. There was a statistically significant decrease in depression diagnoses, anxiety disorder diagnoses, and any diagnoses (depression and/or anxiety) over time for both intervention and control groups. Because we coded time as two indicator (dummy) variables rather than a linear variable, there are two p-values for each of the outcome variables: For depression, $p = 0.01$ at post-intervention and $p = 0.003$ at follow-up; for anxiety, $p = 0.05$ for post-intervention and $p < 0.001$ for follow-up; for any diagnosis, $p = 0.001$ for post-intervention and $p < 0.001$ for follow-up. There were no statistical differences between the intervention and control groups on any of the diagnoses at any time point (see Table 4).

Both intervention and control groups showed significant decreases (improvement) in EPDS scores and STAI-State scores, and increases (improvement) in MSRI scores from baseline to post-intervention, and these effects continued (further improved) from post-intervention to three month follow-up ($p < 0.001$ for all outcomes). There were no significant differences between intervention and control groups on any of these outcomes. Mixed effects regression

models conducted to determine if there were any significant differences between the intervention and control groups at post-intervention and at follow-up time points on the PSI-SF total scores and the CIB subscales showed the following results: For PSI-SF, CIB-sensitivity, and CIB-reciprocity, neither time nor group was statistically significant. For CIB-involvement, time was statistically significant ($p < 0.001$) but group was not ($p > 0.9$). In no case, was there a statistically significant interaction between time and group (see Table 5).

Discussion

In this pilot RCT, we found that Perinatal Dyadic Psychotherapy offers promise as a feasible and effective intervention in a sample of depressed postpartum women. Recruitment of participants was labor intensive, mainly due to the fact that we screened the available general population of first-time postpartum women ($n = 790$) who delivered at the three study hospitals during our recruitment time period. As expected, most women were screen-negative. Of the 50 women eligible for the study, however, 42 (84%) consented to participate and were randomized, demonstrating an excellent recruitment rate. The PDP intervention was highly acceptable to participants. All women offered the intervention accepted, session attendance rates were very high, and all intervention group mothers completed the intervention. Home visits have been shown to be effective means of delivering social and psychological support for postpartum women (Ammerman et al. 2013; Leis et al. 2009) and likely facilitated such high adherence. Not having to leave the house or find childcare, especially in the early months, is a great advantage of home-based therapies. The fact that the intervention sessions were individually tailored to each participant's needs at each session also likely fostered acceptance and adherence.

Using a randomized controlled trial design, we compared the PDP intervention to usual care plus depression monitoring. Intervention group mothers showed significantly decreased depression (severity and diagnoses) at both post-intervention and follow-up; however, control mothers showed similar improvements, and there were no significant differences between the two groups. In addition, there were no significant between group differences on aspects of mother-infant interaction at post-intervention and follow-up. There was a significant decrease in anxiety diagnoses and anxiety severity, and an increase in maternal self-esteem in both intervention and control groups from baseline through follow-up with no significant difference between groups. Lastly, there were no significant changes in parenting stress scores from post-intervention to follow-up in either group.

Our sample was made up of women at high risk for PPD: 31% met depression criteria at baseline and the remaining 69% had two consecutively elevated EPDS scores prior to enrollment. Half of the women in our study had a history of MDD, and almost half met diagnostic criteria for one or more past or current anxiety disorders. Established risk factors for PPD include elevated EPDS scores in the early postpartum, history of depression, and past or current anxiety disorders (Dennis et al., 2004; Milgrom et al 2008; Prenoveau et al. 2013; Robertson et al.2004). Thus, the women in our sample who did not already meet depression criteria at baseline were nonetheless at high risk for developing PPD. The finding that no new cases of PPD developed during the study in this high risk sample is noteworthy,

and suggests possible preventive effects; however much larger samples are needed to further explore this possibility.

Overall, results indicate a significant and continuous improvement on study assessments over time for both the intervention and control groups. One possible explanation for this finding is that women improved over time as a natural course of PPD. Previous research has shown, however, that whereas for some women PPD spontaneously remits, for 30% to 50% of women, PPD can become chronic, extending throughout the first year postpartum and beyond (Vliegen et al. 2014). In this study, all women except one improved over time, a rate unlikely accountable to the effects of time alone.

A second possible explanation for our findings is that our control condition may have provided enough of a beneficial intervention itself to elicit the positive results seen in the control group. Control group mothers received eight phone calls over three months. Although the content of the calls was focused on completing the EPDS, this regular contact from a friendly person inquiring about their emotional health may have provided a helpful level of support and reassurance. Control group mothers also received three home visits from RAs over the course of the study. Self-reflection required to answer frequent questions about emotions, supports, stresses, and mental health may have promoted increased self-awareness and self-monitoring by the mothers in regards to their emotional well-being, possibly leading to improved self-care, thus constituting an effective intervention.

It is interesting to note that several other well-designed randomized controlled trials of psychologically-based PPD prevention and treatment interventions have similarly reported lack of a significant difference between intervention and control groups on depression and related outcomes (Austin et al. 2008; Beeber et al. 2013; Cooper et al. 2003; Dugravier et al. 2013; Horowitz et al. 2013; Murray et al. 2003; Prendergast and Austin 2001; Tsivos et al. 2014; Wiggins et al. 2005). The need for effective non-pharmacological treatments for PPD is great. Therefore, there is much work to be done to determine what might account for these findings – whether issues of study design, the natural progression of PPD, sample characteristics, or the interventions themselves.

Our finding that usual care with depression monitoring may be an effective intervention is supported by a number of studies which have shown that low-intensity interventions, such as guided self-help via written materials, limited professional support, or internet-delivered interventions are effective in non-postpartum patients with MDD, even when depression is severe (Andrews et al. 2010; Bower et al. 2013; Cuijpers et al. 2011). Among postpartum mothers, preparation by providers for the postpartum experience has been associated with decreased PPD (Howell et al. 2010), and peer telephone support provided to mothers at high-risk for PPD, has resulted in significantly fewer EPDS scores in the depressed range (> 12) at 12 weeks postpartum (Dennis et al. 2009). In a randomized controlled trial of a supportive counseling intervention provided by public health nurses to women with PPD (Glavin et al. 2010), the majority of women (66%) had only one counseling session -- constituting a non-intensive intervention. These women showed depression scores comparable to women who received two to seven sessions, and significantly more improved compared to a control group. Together these studies suggest that stepped care PPD

management protocols which provide low-intensity depression interventions as a first-line treatment for PPD could provide an efficient, cost-effective, and ultimately effective strategy for management of women at risk for or experiencing PPD. Our study results add to these findings and support a need for further research and consideration of low-intensity PPD interventions.

There are several strengths of this study. We used strict eligibility criteria for participant enrollment. We required that potential participants have two positive EPDS scores one week apart, thus recruiting a sample of women for whom depressive symptoms were more persistent rather than temporary. We used diagnostic interviews to determine depression diagnoses, as well as the presence of anxiety disorders which are often comorbid and may complicate postpartum health and functioning. We investigated the intervention's impact on mother-infant interaction – an important outcome that is gaining greater consideration in PPD treatment (Nylen et al. 2006). We provided intensive training of nurse interventionists and utilized strict intervention fidelity monitoring. Outcome assessors were blind to group allocation and to prior depression results. All data, including mother-infant interaction data was collected in participants' homes, enabling more naturalistic data collection than what is typically collected in a lab setting. All participants completed the condition to which they were allocated and there was no attrition from the study, enhancing the validity of the results.

There are also a number of study limitations which must be considered in interpreting the results. As a pilot study, these results must be treated as preliminary and interpreted with caution as no formal power calculations were carried out and power to detect significant differences between groups on outcomes was limited, possibly due to insufficient sample size or to lower than expected effect sizes. The CIB was our sole interaction outcome and may not have been sensitive enough to pick up on subtle group differences in maternal sensitivity, infant engagement, and dyadic reciprocity. Although the EPDS Cronbach's alpha for our sample was adequate at post-intervention and follow-up, it was low at baseline. It is possible that if we had a group for which Cronbach's alpha was more reliable at baseline, the confidence interval for the effect might have been larger and results may have been different.

Conclusion

This study partially supports PDP intervention for early treatment of postpartum depressive symptoms. PDP holds potential for treating depression in the context of the mother-infant relationship, but further research with larger sample sizes is needed to more fully examine the intervention. Depression monitoring by phone showed equal benefit and raises the possibility that it may provide an effective, less intensive intervention that could be used as a first step in a stepped care approach to treatment. Further research is needed to explore this possibility and to determine what subset of at-risk or depressed postpartum mothers might benefit most from the PDP intervention.

Acknowledgments

Support for this study was provided by grants to J. Goodman from the Robert Wood Johnson Foundation and from the National Institute of Child Health and Development (1R21HD065156-01). We wish to acknowledge the valuable contributions of our research team: Jennifer Bernard, Laura Betz, Melissa Burnett, Kayse Eichelberger, Mary Ellen Flanagan, Avery Forget, Christine Godbout, Carol Gordon, Deborah Koopman, Francesca Longo, Stephanie Lubin-Levy, Rebecca Petersen, Rachael Phillips, and Gabrielle Santangelo.

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Figure 1.

Table 1

Psychiatric Diagnoses over Study Time Frame (N = 42)

Diagnosis	Baseline N (%)			Post-Intervention N (%)			Follow-Up N (%)		
	Intervention	Control	Total	Intervention	Control	Total	Intervention	Control	Total
History of major depression	13 (61.9%)	8 (38.1%)	21 (50%)						
History of anxiety disorder diagnosis - lifetime (past and/or current)	11 (52.4%)	9 (42.9%)	20 (47.6%)						
Depression diagnosis									
Major depression	5 (23.8%)	2 (9.5%)	7 (16.7%)	0	1 (4.8%)	1 (2.4%)	1 (4.8%)	0	1 (2.4%)
Minor depression	2 (9.5%)	4 (19%)	6 (14.3%)	1 (4.8%)	1 (4.8%)	2 (4.8%)	0	0	0
Major or minor depression	7 (33.3%)	6 (28.6%)	13 (31%)	1 (4.8%)	2 (9.6%)	3 (7.2%)	1 (4.8%)	0	1 (2.4%)
Any anxiety disorder diagnosis *	9 (42.9%)	7 (33.3%)	16 (38.1%)	5 (23.8%)	3 (14.3%)	8 (19%)	2 (9.5%)	0	2 (4.8%)
Any depression and/or anxiety diagnosis	12 (57.1%)	11 (52.4%)	23 (54.8%)	6 (28.6%)	3 (14.3%)	9 (21.4%)	3 (14.3%)	0	3 (7.1%)

* Anxiety disorders included generalized anxiety disorder, panic disorder, agoraphobia, social phobia, obsessive compulsive disorder, specific phobia, and posttraumatic stress disorder.

Table 2

Baseline Descriptive Statistics for Intervention (n = 21) and Control Groups (n = 21)

	<u>Intervention Group</u> Mean (SD) or N (%)	<u>Control Group</u> Mean (SD) or N (%)	P
Maternal age (years)	30.57 (SD = 4.760)	30.81 (SD = 5.316)	0.88
Education			0.69
High school or less	2 (10%)	1 (4.8%)	
Associate or Bachelor's degree	12 (60%)	15 (71.4%)	
Graduate or professional degree	6 (30%)	5 (23.8%)	
Marital Status			0.92
Single	4 (19.0%)	3 (14.3%)	
Married or living with partner	17 (81.0%)	18 (85.7%)	
Income			0.30
< \$40K	4 (21.0%)	1 (4.8%)	
\$40K – \$100K	8 (42.1%)	11 (52.4%)	
\$100K	7 (36.8%)	9 (42.9%)	
Missing	2 (9.5%)		
Race			0.91
Hispanic	5 (23.8%)	5 (23.8%)	
White	12 (57.1%)	13 (61.9%)	
Other	4 (19.0%)	3 (14.3%)	
Primary Language			0.21
English	16 (76.2%)	19 (90.5%)	
Not English	5 (23.8%)	2 (9.5%)	
Type of Delivery			1
Vaginal	15 (71.4%)	15 (71.4%)	
Cesarean	6 (28.6%)	6 (28.6%)	
Pregnancy was Planned			0.50
No	5 (23.8%)	7 (33.3%)	
Yes	16 (76.2%)	14 (66.7%)	
Pregnancy was Desired			0.29
No	3 (14.3%)	1 (4.8%)	
Yes	18 (85.7%)	20 (95.2%)	
EPDS Total Score	12.48 (SD = 3.39)	12.14 (SD = 2.69)	0.73
State Anxiety Score	43.62 (SD = 9.47)	36.00 (SD = 10.39)	0.02
Trait Anxiety Score	44.67 (SD = 8.68)	43.67 (SD = 7.43)	0.69

	<u>Intervention Group</u>	<u>Control Group</u>	p
	Mean (SD) or N (%)	Mean (SD) or N (%)	
MSRI Total Score	3.52 (SD = 0.56)	3.79 (SD = 0.36)	0.08
History of Major Depression	13 (61.9%)	8 (38.1%)	0.12
History of Anxiety Disorder Diagnosis – Lifetime (Past or Current)	11 (52.4%)	9 (42.9%)	0.54
Depression Diagnosis			0.37
- Major Depression	5 (23.8%)	2 (9.5%)	
- Minor Depression	2 (9.5%)	4 (19%)	
- Major Or Minor Depression	7 (33.3%)	6 (28.6%)	
Any Anxiety Disorder Diagnosis	9 (42.9%)	7 (33.3%)	0.52
Any Depression and/or Anxiety Diagnosis	12 (57.1%)	11 (52.4%)	0.76

MDD = major depressive disorder

Table 3

Means and Standard Deviations for Study Measures across 3 Time Points (N = 42)

	Mean (SD)		
	Baseline	Post-Intervention	Follow-Up
EPDS			
Intervention	12.48 (3.39)	6.19 (3.64)	4.86 (3.35)
Control	12.14 (2.67)	6.35 (5.45)	6.05 (4.50)
Total sample	12.31 (3.02)	6.27 (4.55)	5.45 (3.96)
State Anxiety			
Intervention	43.62 (9.47)	35.29 (9.03)	33.43 (7.49)
Control	36.00 (10.39)	31.40 (9.65)	29.76 (8.24)
Total sample	39.81 (10.55)	33.39 (9.43)	31.60 (7.99)
MSRI (total)¹			
Intervention	3.52 (0.56)	4.05 (0.34)	4.17 (0.36)
Control	3.79 (0.36)	4.16 (0.34)	4.26 (0.36)
Total sample	3.66 (0.48)	4.10 (0.34)	4.21 (0.36)
PSI-SF (total)			
Intervention	NA	73.67 (18.61)	69.43 (15.46)
Control		64.30 (15.35)	63.81 (13.44)
Total sample		69.10 (17.53)	66.62 (14.59)
CIB – Maternal Sensitivity¹			
Intervention	NA	3.69 (0.59)	3.73 (0.84)
Control		3.95 (0.55)	3.88 (0.66)
Total sample		3.82 (0.58)	3.80 (0.75)
CIB – Infant Involvement¹			
Intervention	NA	3.20 (0.69)	3.79 (0.52)
Control		3.34 (0.78)	3.66 (0.48)
Total sample		3.27 (0.74)	3.73 (0.50)
CIB – Dyadic Reciprocity¹			
Intervention	NA	3.46 (0.68)	3.72 (0.97)
Control		3.60 (0.83)	3.73 (0.91)
Total sample		3.53 (0.75)	3.72 (0.93)

¹ For comparison purposes, total mean scores presented are total mean score/number of items

Table 4

Exact logistic regression results

Independent variable (or predictor)	OR	P-value	95% CI
Depression diagnosis			
Post-intervention	0.18	0.01	[0.03, 0.72]
Follow-up	0.12	0.00	[0.01, 0.57]
Group	1.33	0.80	[0.41, 4.50]
Anxiety disorder diagnosis			
Post-intervention	0.33	0.05	[0.10, 0.99]
Follow-up	0.83	0.00	[0.01, 0.40]
Group	1.97	0.34	[0.62, 5.13]
Any depression or anxiety diagnosis			
Post-intervention	0.19	0.00	[0.06, 0.56]
Follow-up	0.09	0.00	[0.02, 0.31]
Group	1.97	0.19	[0.76, 5.35]

OR = odds ratio; CI = confidence interval

Table 5

Mixed-effects regression analyses results

Independent variable/predictor	Coefficient	z	P-value	95% CI
EPDS				
Post-intervention	−5.10	−8.68	0.00	[−7.35, −4.64]
Follow-up	−6.86	−9.76	0.00	[−8.23, −5.48]
Group	−0.37	0.97	0.71	[−2.27, 1.54]
STAI-State				
Post-intervention	−6.46	−4.37	0.00	[−9.36, −3.56]
Follow-up	−8.21	−5.90	0.00	[−10.94, −5.49]
Group	5.05	2.18	0.03	[0.50, 9.60]
MSRI				
Post-intervention	0.46	8.24	0.00	[0.35, 0.57]
Follow-up	0.57	8.37	0.00	[0.44, 0.70]
Group	−0.17	−1.62	0.11	[−0.37, 0.35]
Total PSI				
Time	−2.35	−1.54	0.12	[−5.35, 0.65]
Group	7.51	1.64	0.10	[−1.45, 16.47]
CIB Sensitivity				
Time	−0.01	−0.10	0.92	[−0.21, 0.19]
Group	−0.21	−1.16	0.25	[−0.56, 0.15]
CIB Child Involvement				
Time	0.47	3.76	0.00	[0.22, 0.71]
Group	0.01	0.07	0.95	[−0.29, 0.31]
CIB Reciprocity				
Time	0.19	1.21	0.23	[−0.12, 0.50]
Group	−0.09	−0.40	0.70	[−0.51, 0.34]

CI = confidence interval