Journal of Affective Disorders 189 (2016) 263–268

Contents lists available at ScienceDirect

Journal of Affective Disorders

journal homepage: www.elsevier.com/locate/jad

Research report

Randomized controlled trial to prevent postpartum depression in mothers on public assistance

Caron Zlotnick [a,b,*], Golfo Tzilos [c], Ivan Miller [c], Ronald Seifer [d], Robert Stout [e]

[a] Women and Infants Hospital, Providence, RI 02905, United States
[b] Department of Psychiatry and Mental Health, University of Cape Town, Observatory, Cape Town, South Africa
[c] Butler Hospital, Brown University, 345 Blackstone Blvd, Providence, RI 02912, United States
[d] Bradley Hospital, Brown University, 1011 Veterans Memorial Parkway, East Providence, RI 02915, United States
[e] Decision Sciences Institute, Pacific Institute for Research and Evaluation, Pawtucket, RI 02860, United States

ARTICLE INFO

Article history:
Received 10 July 2015
Received in revised form
18 September 2015
Accepted 25 September 2015
Available online 30 September 2015

Keywords:
Postpartum
Pregnancy
Depression
Intervention
Interpersonal therapy

ABSTRACT

Introduction: Postpartum depression (PPD) is a significant and common public health problem for women. Aims: To examine the efficacy of an intervention based on the principles of interpersonal therapy (IPT) in reducing the risk of PPD in pregnant women. Methods: Randomized controlled trial of 205 pregnant women who were 18 years old or older, on public assistance, and at risk for PPD. Participants (mean age=23; 38% Hispanic and 23% Black) were randomized to either the IPT group intervention ($n=104$) or the treatment as usual control (TAU) program ($n=101$). Results: At 6 months, the overall depression rate in the intervention group (16%) was lower than the control group (31%) and the effect of the intervention was statistically significant at $p<0.05$. Limitations: It is unknown if findings will generalize to a more heterogeneous sample of women than the current study, such as women from a range of socio-economic and cultural backgrounds, or marital status. There was a differential amount of contact between TAU and intervention conditions. Conclusions: An IPT based intervention during the prenatal period has the potential to reduce cases of PPD within 6 months postpartum in at risk mothers on public assistance.

1. Introduction

Postpartum depression (PPD) is a significant public health problem for women occurring in 10–15% of recently delivered mothers, (Horowitz et al., 2011; O'Hara and Swain, 1996) and among financially disadvantaged women the prevalence rates of PPD are even higher (Hobfoll et al., 1995; Scholle et al., 2003). Timely and effective interventions to reduce the risk of PPD are critical because the postpartum period can be a period of increased risk for depression (Dave et al., 2010; Vesga-Lopez et al., 2008) and for negative infant and later child outcomes (Grace et al., 2003; Murray and Cooper, 1997).

A proportion of women who suffer from PPD do not receive treatment, especially low-income women (Campbell et al., 1995; Abrams et al., 2009), which is due in part to the stigma associated with the disorder as well as limited access to effective treatments (Abrams et al., 2009; Callister et al., 2011; Sword et al., 2008). Further, when there is routine screening and regular follow-up of women with PPD, overall rates of treatment use are low (O'Mahen and Flynn, 2008; Yonkers et al., 2009). Moreover, certain treatments (e.g., pharmacological) are often met with hesitancy or resistance from breastfeeding mothers (Ferreira et al., 2007; Djulus et al., 2006). The burden of PPD is especially high in low-income women and their offspring (Murray et al., 1996). Although the literature remains equivocal regarding the causes of PPD, a number of risk factors have been shown to independently predict it, such as prenatal depression, child-care and life stress, and social support (see meta-analyses by Beck, 2001; Robertson et al., 2004). Risk factors for PPD, including inadequate social support and interpersonal conflict (Muzik et al., 2010), are modifiable and can be the focus of a preventative intervention.

A recent Cochrane review of 28 preventative interventions for PPD (Dennis and Doswell, 2013a) suggest, overall, women who received a psychosocial or psychological intervention were significantly less likely to experience PPD or depressive symptoms compared to those who received standard care. The authors concluded that the most promising interventions in the prevention of PPD were professionally-based home visits, (e.g., intensive home-nurse visits) postpartum lay (peer)-based telephone support, and those based in interpersonal psychotherapy. Others in their review

* Correspondence to: Women & Infants Hospital, 101 Dudley Street, Providence, RI 02905, United States. Fax: +401 276 7871.
E-mail address: czlotnick@butler.org (C. Zlotnick).

http://dx.doi.org/10.1016/j.jad.2015.09.059
0165-0327/

(O'Hara and McCabe, 2013) have noted that more current preventive intervention trials for PPD provide only observed effects that have been small with modest evidence for these intervention studies and they have relied entirely on self-report of depressive symptoms. Additionally, another recent review reported that no definite conclusions can be made regarding which interventions are most likely to prevent PPD because few preventive interventions have demonstrated efficacy, replicated findings, used validated diagnostic measures for PPD, or included heterogeneous samples of women (Tzilos et al., 2015).

Interpersonal therapy (IPT) is an empirically-based treatment for a major depressive episode (MDE) (Elkin et al., 1989) and IPT-based trials and trials that target an at-risk population appear to hold the most promise for further study (Werner et al., 2015). IPT-based interventions target those factors that appear to play a role in PPD (e.g., social support, role transitions, life stressors). Previously, we conducted two randomized control pilot studies which used a selective IPT-based intervention to reduce the likelihood of PPD in pregnant women on public assistance and at risk for PPD. The first study (Zlotnick et al., 2001) was a pilot study ($n=37$) that randomized women on public assistance who were between 20 and 35 weeks' gestation and at high risk for developing PPD to the IPT-based intervention and usual care condition or to only the usual care condition. The intervention significantly decreased depressive symptoms and decreased rates of PPD within the 3-month postpartum period, such that none of the women in the intervention condition developed PPD as compared to 33% of the women in the usual care condition. In a larger trial, a selective intervention (Zlotnick et al., 2006), 99 pregnant women who were at risk for PPD were randomized to the IPT-based intervention or to usual care. Compared to usual care, participation in the IPT-based preventive intervention significantly decreased PPD cases within 3 months postpartum.

Since it is unknown if the findings from these prior pilot studies will generalize to a larger sample of adult women whose onset of PPD was strictly after delivery and to a time period beyond three months postpartum, the objective of the present study was to examine the efficacy of this IPT-based intervention on reducing the risk of PPD in a sample of 205 pregnant women at risk for PPD and on public assistance who were followed up to 12 months after delivery.

2. Materials and methods

2.1. Trial design

Recruitment was conducted at three prenatal clinics in the Northeast, including a University-affiliated hospital, and two primary care sites. We conducted a blinded, randomized controlled trial to evaluate the efficacy of the intervention to reduce the risk of PPD in our sample. The intervention took place during pregnancy, and the booster took place within two weeks after delivery. Episodes that began during pregnancy were not considered a PPD case, and any new episodes of major depression after delivery were assessed up to 12-months postpartum.

2.2. Participants

Inclusion criteria for the study were: 1) pregnant status, 2) 18 years or older, 3) between 20 and 35 weeks gestation, 4) received public assistance, 5) English-speaking, 6) attended an urban, prenatal medical clinic in the Northeast, and 7) a score of 27 or more on the Cooper Survey Questionnaire (First et al., 2002) (CSQ; see *Procedures*), which is the empirically derived threshold for high-risk status. Exclusion criteria prior to randomization included: 1) currently receiving mental health services, 2) did not understand English (Spanish-speaking only), or 3) met criteria for a current mood disorder, substance use disorder, anxiety disorder (excluding simple phobia) or psychosis as determined by the relevant modules of the Structured Clinical Interview for DSM-IV Axis I Disorders-Non-Patient Edition (Cooper et al., 1996).

The study protocol was approved by the Institutional Review Board of Women & Infants Hospital (WIH), Providence, Rhode Island, and was registered at clinicaltrials.gov (NCT00601757) on January 22, 2008.

2.3. Procedures

A research assistant approached women privately in the clinic exam room while waiting for their medical appointment and described the study. Participants completed an assessment that included demographic and obstetric information and the self-report Cooper Survey Questionnaire (CSQ), a 17-item risk validated predictive index for PPD (First et al., 2002), which assesses factors that have been shown to be related to PPD such as current and previous postpartum mood disturbances and relationship discord (e.g., “How have you and your partner been getting along in recent months?”). Possible scores on the index range from 0 to 63, with higher scores indicating higher risk. Assessments were conducted at 3-, 6- and 12-months after delivery. The Treatment Services Review (TSR) was used to assess if mental health treatment was received within a 90 day period at the 3, 6, and 12-months postpartum assessment points (McLellan et al., 1992).

2.4. Intervention

The IPT–based intervention, ROSE (Reach Out, Stand strong, Essentials for new mothers) Program, is designed to be administered antenatally to women in small groups (2–5 women), is highly structured, contains psychoeducational components, and IPT-based skills for improving relationships and building social support, that includes role plays and homework with feedback. The intervention consists of four, 90-minute group sessions over a 4-week period and a 50-minute individual booster session within 2 weeks after delivery. The content of the intervention focuses on managing role transitions with an emphasis on transition to motherhood, developing a support system, developing effective communication skills to manage relationship conflicts before and after the birth of their baby, goal setting, and psychosocial resources for new mothers. Due to the highly structured nature, training of interventionists consisted of a “mock” trial of the intervention with supervision by the first author (Zlotnick). Interventionists were monitored for adherence and competency. Trained interventionists consisted of a health educator (a registered nurse), and two individuals with bachelor's degrees. Independent raters found that all three interventionists had average ratings of 3 or higher (adequate adherence and competence) for all adherence and competence scales ($n=101$).

2.5. Statistical methods

Urn randomization, a procedure to help produce better-balanced treatment groups (Stout et al., 1994), was used to assign participants to treatment, taking into account whether the participant had a previous major depressive episode. After a participant had completed the baseline assessment, and met eligibility criteria for the study, a computer-based urn randomization program was used and the study group was unveiled. The group allocation was not revealed to the research team members who conducted the follow up assessments. Women were randomly assigned to receive either the ROSE Program in addition to standard antenatal care, or