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Randomized controlled trial to prevent postpartum depression in adolescent mothers

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Abstract

Objective—To estimate the effect of an interpersonally-oriented intervention on reducing the risk of postpartum depression in primiparous adolescents.

Study design—Randomized controlled trial of 106 pregnant primiparous adolescents who were 17 years old or younger at their first prenatal visit. Participants were randomized to the intervention (n=54) or the attention and dose-matched control program (n=52). Each program included 5 sessions delivered during the prenatal period. To assess for the primary outcome, depression at 6-weeks, 3-months and 6-months after delivery, a structured diagnostic interview was administered.

Results—Participants included Hispanic (53%), non-Hispanic black (17%) and non-Hispanic white (16%) adolescents. The overall rate of depression in the intervention group (12.5%) was lower than the control group (25%) with a HR 0.44 (95% CI 0.17–1.15) at 6 months postpartum.

Conclusion—An intervention delivered during the prenatal period has the potential to reduce the risk for postpartum depression in primiparous adolescent mothers.

Keywords

adolescent pregnancy; clinical trial; interpersonal therapy; postpartum depression; prevention; teen pregnancy

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Introduction

Approximately 400,000 births in the United States each year are to mothers less than 20 years old¹ and approximately 25–36% of postpartum teens experience postpartum depression (PPD)^{2–4}. These rates are significantly higher than adult postpartum women⁵ and higher than non-perinatal adolescents².

PPD puts adolescent mothers and their children at risk during an already challenging time in their lives and this hardship may be a major determinant of poor outcomes for these young mothers and their children. Untreated, depression is associated with school dropout, suicide, and substance use^{6, 7}. Among adolescent mothers, evidence suggests that depression may prevent them from engaging in health-promoting behaviors for their infants and themselves^{8,9}. Overall, children born to mothers with untreated depression show developmental delays, lower levels of social engagement, increased stress reactivity and negative interactions relative to infants of non-depressed mothers^{10–12}.

Although validated treatments for adolescent depression exist, including interpersonal therapy, cognitive behavioral therapy as well as antidepressant medication, teens with mental health problems are mostly under treated^{13, 14}. To date, only one published report of two small open-trial pilot studies (N=14 and N=11) addressed treatment for depression in pregnant adolescents¹⁵. Despite the potentially high burden of depression to young women and their families, studies on the *prevention* of postpartum depression in pregnant adolescents are virtually nonexistent.

A substantial body of research demonstrates that some prevention programs for adults and adolescents with mental health conditions are capable of strengthening protective factors (e.g. social support, stress-management skills), that these interventions can lessen the consequences of risk factors (e.g. other psychiatric symptoms), and that they may have positive economic effects¹⁶. Several experts in the field of PPD have advocated for preventive interventions for PPD to commence in pregnancy^{17, 18}. Pregnancy provides a “window of opportunity”¹⁹ for prevention because pregnancy is a time when women have frequent contact with health care providers and a time when pregnant women may be more open to making changes to improve their health, including mental health, prior to the birth of their baby^{17, 20}.

The objective of the present study was to perform a pilot study of 100 pregnant adolescents to evaluate a novel intervention to prevent PPD in primiparous adolescent mothers. The intervention, the REACH (Relaxation, Encouragement, Appreciation, Communication, Helpfulness) Program, is based on Interpersonal therapy (IPT), which targets those factors that may play a significant role in the development of PPD^{21, 22}. Our primary hypothesis was that the REACH program would be more efficacious than the attention and dose-matched control program focused on prenatal education in reducing risk for depression up to six months postpartum in adolescent mothers.

Materials and Methods

Trial design

A blinded randomized controlled trial was used to evaluate the REACH program as an intervention to prevent PPD. Because the focus of REACH is on prevention of PPD, the intervention and control programs were conducted during the prenatal period. Depression was assessed from intake (during pregnancy) to 6 months postpartum. A pre-intervention survey was conducted to collect data on socio-demographic characteristics, reproductive history, and substance use. Medical charts were reviewed for pregnancy and infant outcomes.

The study protocol was approved the Institutional Review Board of Women & Infants Hospital (WIH), Providence, Rhode Island. Local laws regarding minor participants in research were followed. All participants were consented by obtaining consent from her guardian and assent from the minor participant. The protocol was registered at clinicaltrials.gov (NCT00436150) on February 14, 2007.

Participants (eligibility and setting)

Participants were recruited between February 2007 and August 2008 through an urban prenatal clinic caring for women of all ages and diverse backgrounds. Participants were eligible if they were 17 years old and younger when they conceived their pregnancy and were less than 25 weeks gestational age at their first prenatal visit. The following exclusion criteria were determined prior to randomization: 1) were receiving mental health services from a health care provider or 2) met criteria for a current affective 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 Childhood Diagnoses (KID-SCID)²³. Adolescents who met criteria for any of these disorders were excluded because Project REACH is a prevention program and is not designed to treat any of these disorders. Furthermore, the control condition is relatively inert. Hence, it would have been unethical for us to withhold treatment from an adolescent diagnosed with one of these disorders.

Intervention

The Project REACH intervention was an adaptation of an IPT-based prevention intervention, which was found to reduce PPD in pregnant adults on public assistance^{21, 22}. The Project REACH intervention is the product of an extensive, iterative treatment development process. To maximize acceptability of the intervention, Project REACH was extensively tailored and refined to be culturally appropriate and appealing to adolescents from diverse racial and ethnic backgrounds. Modifications were guided by input and feedback from postpartum adolescent focus groups, expert consultants (in adolescent medicine and depression and perinatal care among low-income minority adolescent females and an expert in interventions for minority teens), pilot participants and pilot facilitators.

Project REACH is a highly-structured, adolescent-oriented intervention delivered over the course of five one-hour prenatal sessions with a postpartum booster session that includes

multimedia (video snippets), interactive (role-playing) components and homework with feedback. The content of Project REACH focused on developing effective communication skills to manage relationship conflicts before and after the birth of their baby, expectations about motherhood, stress management, “baby blues” vs. depression, development of a support system, healthy relationships, goal setting, and psychosocial resources for new mothers. The structured format and detailed facilitator manual ensured that specific defining elements of IPT such as enhancing social support and therapeutic strategies (e.g., role-playing, communication analysis) remain the central features of the intervention. The highly structured nature of the Project REACH intervention and the control program allowed for efficient facilitator training and monitoring for adherence and competency.

Each participant was given the book *Baby Basics: Your Month by Month Guide to a Healthy Pregnancy*²⁴, a comprehensive pregnancy guide developed by the What to Expect Foundation. The attention and dose matched control condition involved using the *Baby Basics* book as a guide for the didactic control program. This program included information about maternal health throughout pregnancy and the early postpartum period, fetal development, nutrition, preparing for labor, and getting the house ready for taking home a baby. The control condition had no overlapping content with the Project REACH curriculum.

The initial plan was for the Project REACH and Control Program sessions to be delivered as group sessions once a week for five consecutive weeks and an individual booster session delivered in the hospital postpartum, with accommodations for make-up sessions. As the study progressed, it became clear through rescheduling and qualitative assessment that the participants preferred individual sessions. Thus accommodations were made to deliver the sessions individually. The intervention and control sessions were administered in similar fashions to balance contact time with the facilitator. Each session lasted approximately 30 to 60 minutes depending on the discussion.

Outcome Assessment

PPD was classified as an episode of major depressive disorder (MDD) that occurred within the first 6 months after delivery. Although the DSM-IV defines PPD as MDD with an onset within 4 weeks after delivery, research has shown that at least a third of women report onset of PPD between 2–6 months²⁵ and among teens 32% have scores that indicate depression at 4 months postpartum³. Moreover, most investigators classify a depression that occurs within the first 6 months after delivery as PPD^{26, 27}. Onset of a depressive episode during pregnancy, even if the episode extends to the postpartum period, was not included as a case of PPD, because the onset was not strictly postpartum. To account for variability in gestational age at birth among the participants, we used delivery as a clear and consistent marker for measuring the onset of the condition (PPD).

The KID-SCID was used to assess for a major depressive disorder. Antepartum assessments were performed pre-randomization and post-intervention, and postpartum assessments were performed within 48 hours of delivery and at the 6-week, 3-month, and 6-month follow-up visits. All assessments were administered by trained research assistants who were blinded to study group assignment from the initial contact through follow-up.

Sample size calculation (DSMB and interim analysis)

The purpose of the project REACH pilot study was to develop a PPD prevention intervention that was tailored to the specific needs of a racially and ethnically diverse group of pregnant adolescents and to pilot test the intervention compared with the control program under clinical trial conditions to determine an effect size for a larger clinical trial. The study target was designed to evaluate 100 randomized participants and to assess feasibility of study recruitment and retention procedures for pregnant adolescents.

Randomization method

The randomization scheme was developed prior to starting the study. Stratified block randomization was used to keep the groups balanced in terms of prior history of depression. The block lengths varied to keep the randomizations scheme blinded. The groups were labeled A and B. Opaque envelopes were labeled by number and stratum. The study coordinator held the key to the randomization scheme. After a participant was fully screened for eligibility, the study group was unveiled and reported to the interventionist so that appointments could be scheduled in order to administer the intervention or control group program. The group allocation was not revealed to the research team members doing the initial and follow up assessments.

Statistical methods

Descriptive statistics were used to compare the distribution of baseline characteristics between the intervention and control groups. Categorical variables were compared by Fisher's exact test and continuous variables were compared by the Wilcoxon rank-sum test. All participants with at least one postpartum assessment were included in the primary analysis and were classified according to their randomly assigned study group (intention-to-treat). PPD incidence in each group was calculated as a positive major depressive disorder diagnosis by the KID-SCID at one or more postpartum visits. The hazard rate ratio (HR) and 95% confidence interval (CI) for PPD in the REACH program versus the control group were estimated by Cox proportional hazards regression. Tied events resulting from the discreteness of the time scale were handled by the exact method. History of depression, the stratification factor for randomization, was included as a covariate in all models. Baseline variables distributed differently between study arms were also included as covariates where appropriate. The proportional hazards assumption was assessed by a global Wald test of product interaction terms between covariates and follow-up time point.

The primary analysis was repeated among participants who attended all follow-up visits. In order to formally perform an intention-to-treat analysis, assumptions were made about missing outcome data due to discontinued participation or missed visits. In the first scenario, a diagnosis of PPD was imputed for all missing assessment visits. In the second scenario, it was assumed that no PPD was diagnosed at missing visits. Data analysis was performed with SAS version 9.1 (SAS Institute, Cary, NC). Two-tailed p-values less than 0.05 were considered statistically significant.

Results

Participant recruitment

Between February 2007 and August 2008, 177 patients presenting for their first prenatal visit were screened for study eligibility (Figure 1). Of these patients, 140 were consented and scheduled for an initial visit. Current depression was diagnosed at the first visit in 10 enrollees and four had spontaneous abortions. Twenty additional patients were excluded from the study due to ineligibility, withdrawal from the study prior to initiating the intervention or failure to attend the initial visit.

A total of 106 participants were randomized to the REACH program (n=54) or the control program (n=52). All participants who remained in the study through delivery completed the five sessions in their assigned programs; however, three patients assigned to the Project REACH program discontinued participation during the intervention. Following delivery, 100 participants (94%) attended at least one postpartum follow-up visit and were assessed for PPD.

Baseline data

The median age for participants was 16 years, and the majority of participants were from Hispanic backgrounds. (Table 1) Overall, a history of depression was identified in 16% of participants. There were no significant differences between REACH program and control group participants in terms of age, gestational age, race/ethnicity, history of depression and pregnancy history, and current educational level. A few participants (n=12) were 18 years of age or beyond 25 weeks gestation at the time of randomization due to the time that elapsed between eligibility screening and the randomization visit.

Outcomes

None of the participants were diagnosed with depression at the study assessment visit immediately following delivery. A total of 19 participants (19%) were diagnosed with PPD at a subsequent study visit through 6 months postpartum. The incidence of PPD was 12.5% (95% CI: 3.1–21.9%) for the Project REACH program compared with 25.0% (95% CI: 13.2–36.8%) for control program (Table 2), for an absolute difference of –12.5% (95% CI: –27.5 – 2.5%) by 6 months postpartum. After adjusting for history of depression by Cox proportional hazards regression, the incidence of PPD was 56% lower for Project REACH compared with the control program (HR=0.44, p=0.1). Further adjustment for baseline patient age and gestational age did not change the estimates (HR=0.44; 95% CI: 0.17–1.17). PPD incidence in each group was similar when the analysis was limited to 91 participants with complete follow-up assessments (risk difference = –10.0%, 95% CI: –25.6–5.7%; adjusted HR=0.50, p=0.2).

Three participants discontinued participation prior to delivery, three participants discontinued following delivery and eight participants missed one or more postpartum visits. A sensitivity analysis was done to evaluate the impact of missing data on the results; the analysis was repeated assuming PPD diagnoses for all missing assessments and then assuming no diagnosis of PPD for the missing assessments. A 33% reduction in PPD risk for

the REACH program compared to the control persisted when a PPD diagnosis was imputed for participants with missing data.

Harms

No harmful effects were noted from participants in this trial.

Comment

To our knowledge, this is the first clinical trial of prevention for postpartum depression in adolescent mothers. This pilot study of primiparous adolescent mothers found initial efficacy for a prenatal intervention to prevent PPD compared with an attention and dose matched control condition. In part, this was a pilot study to test the feasibility of the program and the results show an overwhelmingly positive trend in support of the IPT-based intervention program. In addition to the positive outcome, the present study demonstrated strong feasibility in that there were high rates of recruitment, intervention participation and retention; notable rates for a vulnerable group of adolescents.

The rate of PPD in the control group (25%) is consistent with national rates of PPD in adolescent mothers, suggesting that we had a representative sample for our study. Since our sample of study participants were ethnically diverse, the results are likely generalizable to the community of pregnant adolescents. The structured nature of the program with a thorough training manual and guide for both the Project REACH intervention and the control program, suggests that Project REACH can be implemented in other clinical settings. Of note, a recent study published by Howell et al. implemented a structured behaviorally-based educational intervention that included a focus on bolstering social support in black and Latina adult mothers during their postpartum hospitalization demonstrated a reduction in screening positive for depression at 3 weeks and 3 months postpartum.²⁸

The limitations of the current study include the nature of a pilot study with a small sample size that was underpowered to detect a statistically significant difference between the study groups. The study was designed to deliver the intervention and control programs as group sessions; however, during the course of the study, it became clear that the participants preferred individual sessions and therefore the sessions were modified and delivered as individual sessions. Because we did not have complete follow up on all of the study participants, we performed a sensitivity analysis. A protective effect for the REACH intervention was observed under each scenario, suggesting that substantial bias due to missing data is unlikely.

Interpretation

Findings from our study, suggest that Project REACH, specifically tailored for pregnant adolescents, has promise as an intervention to prevent PPD. Moreover, Project REACH appears to be an accessible and feasible intervention for pregnant adolescents. With further evaluation, Project REACH has the potential to decrease disease burden for adolescent mothers and their offspring and to be a cost effective alternative to the treatment of PPD.

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Figure 1.
Participant selection and follow-up.

Table 1

Baseline characteristics by study arm.

	REACH Program	Control Condition	P- value
Total randomized	54	52	
Age (years) at randomization, median (range)	16 (13–18)	16 (14–18)	0.4 ¹
Gestational age (weeks) at randomization, median (range)	19.7 (12.6–28.9)	21.3 (9.1–30.9)	0.2 ¹
Race/ethnicity, n (%)			
Hispanic	29 (53.7)	27 (51.9)	0.6 ²
Black, non-Hispanic	9 (16.7)	9 (17.3)	
White, non-Hispanic	7 (13.0)	10 (19.2)	
Asian	2 (3.7)	0	
American Indian/Alaskan Native	0	1 (1.9)	
Multiracial	5 (9.3)	2 (3.9)	
No answer	2 (3.7)	3 (5.8)	
History of depression, n (%)	9 (16.7)	8 (15.4)	1.0 ²
Previous pregnancy, n (%)	4 (7.4)	4 (7.7)	1.0 ²
Currently in school, n (%)			
Yes	44 (81.5)	38 (73.1)	0.5 ²
No, completed 12 grade	2 (3.7)	2 (3.9)	
No	8 (14.8)	12 (23.1)	

¹Wilcoxon rank-sum test.²Fisher's exact test.

Table 2REACH program and incidence of PPD¹ by 6 months postpartum

	PPD/Total (%)		HR (95% CI) for REACH vs. Control	
	REACH	Control	Unadjusted	Adjusted ²
Any postpartum follow-up (n=100)	6/48 (12.5)	13/52 (25.0)	0.46 (0.18–1.22)	0.44 (0.17–1.15)
Complete postpartum follow-up (n=91)	6/47 (12.8)	10/44 (22.7)	0.54 (0.20–1.48)	0.50 (0.18–1.37)
<i>Sensitivity analysis³</i>				
Missing outcome = PPD (n=106)	13/54 (24.1)	18/52 (34.6)	0.68 (0.33–1.39)	0.67 (0.33–1.36)
Missing outcome = no PPD (n=106)	6/54 (11.1)	13/52 (25.0)	0.41 (0.16–1.09)	0.40 (0.15–1.04)

¹ PPD diagnosed by KID-SCID.² Proportional hazards model included stratification factor, history of depression.³ Assumed missing postpartum assessments were all PPD diagnoses or no PPD diagnoses.