

OBSTETRICS

Randomized controlled trial to prevent postpartum depression in adolescent mothers

Maureen G. Phipps, MD, MPH; Christina A. Raker, ScD; Crystal F. Ware, BA; Caron Zlotnick, PhD

OBJECTIVE: The purpose of this study was to estimate the effect of an interpersonally oriented intervention on the reduction of the risk of postpartum depression in primiparous adolescents.

STUDY DESIGN: We conducted a randomized controlled trial of 106 pregnant primiparous adolescents who were ≤ 17 years old at their first prenatal visit. Participants were assigned randomly to the intervention program ($n = 54$) or the attention and dose-matched control program ($n = 52$). Each program included 5 sessions that were delivered during the prenatal period. A structured diagnostic interview was administered to assess for the primary outcome and depression at 6 weeks, 3 months, and 6 months after delivery.

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 hazard rate ratio of 0.44 (95% confidence interval, 0.17–1.15) at 6 months after delivery.

CONCLUSION: An intervention that is delivered during the prenatal period has the potential to reduce the risk for postpartum depression in primiparous adolescent mothers.

Key words: adolescent, clinical trial, interpersonal therapy, postpartum depression, prevention, teen pregnancy

Cite this article as: Phipps MG, Raker CA, Ware CF, et al. Randomized controlled trial to prevent postpartum depression in adolescent mothers. *Am J Obstet Gynecol* 2013;208:192.e1-6.

Approximately 400,000 births in the United States each year are to mothers who are <20 years old¹; approximately 25–36% of these teens experience postpartum depression (PPD) after delivery.^{2–4} These rates are significantly higher than adult postpartum women⁵ and higher than nonperinatal adolescents.²

★ EDITORS' CHOICE ★

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 who are born to mothers with untreated depression show developmental delays, lower levels of social engagement, increased stress reactivity, and negative interactions relative to infants of nondepressed mothers.^{10–12}

Although validated treatments for adolescent depression exist and include interpersonal therapy, cognitive behavioral therapy, and antidepressant medication, teen mothers with mental health problems are mostly under treated.^{13,14} To date, only one published report of 2 small open-trial pilot studies ($n = 14$ and $n = 11$) addressed treatment for depression in pregnant adolescents.¹⁵ Despite the potentially high burden of depression to young women and their families, studies on the

prevention of PPD 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 (eg, social support, stress-management skills), that these interventions can lessen the consequences of risk factors (eg, other psychiatric symptoms), and that the interventions may have positive economic effects.¹⁶ 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 healthcare providers and is a time when pregnant women may be more open to making changes to improve their health, which would include mental health, before 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, which targets those fac-

From the Departments of Obstetrics and Gynecology (Drs Phipps and Raker), Epidemiology (Dr Phipps), Psychiatry and Human Behavior (Dr Zlotnick), Warren Alpert Medical School of Brown University (Drs Phipps, Raker, and Zlotnick) and Women & Infants Hospital of Rhode Island (all authors), Providence, RI.

Received Aug. 31, 2012; revised Dec. 10, 2012; accepted Dec. 27, 2012.

Supported by a grant from the National Institute of Mental Health (R34MH77588).

The authors report no conflict of interest.

Presented orally in abstract form at the 58th annual meeting of the Society for Gynecologic Investigation, Miami Beach, FL, March 16–19, 2011.

Reprints not available from the authors.

0002-9378/free

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http://dx.doi.org/10.1016/j.ajog.2012.12.036



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tors 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 that is focused on prenatal education in the reduction of risk for depression up to 6 months after delivery 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 the REACH program is on the prevention of PPD, the intervention and control programs were conducted during the prenatal period. Depression was assessed from intake (during pregnancy) to 6 months after delivery. A preintervention survey was conducted to collect data on sociodemographic 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, Providence, Rhode Island. Local laws regarding minor participants in research were followed. All participants were consented by written consent from her guardian and assent from the minor participant. The protocol was registered at clinicaltrials.gov (NCT00436150) on Feb. 14, 2007.

Participants (eligibility and setting)

Participants were recruited between February 2007 and August 2008 through an urban prenatal clinic that cared for women of all ages and diverse backgrounds. Participants were eligible if they were ≤ 17 years old when they conceived their pregnancy and were < 25 weeks gestational age at their first prenatal visit. The following exclusion criteria were determined before randomization: (1) received mental health services from a healthcare 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 the Diagnostic and Statistical Manual for Mental

Disorders, 4th edition, (DSM-IV) Childhood Diagnoses (KID-SCID).²³ Adolescents who met the criteria for any of these disorders were excluded because the REACH program 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 who had been diagnosed with one of these disorders.

Intervention

The REACH program intervention was an adaptation of an interpersonal therapy-based prevention intervention, which was found to reduce PPD in pregnant adults on public assistance.^{21,22} The REACH program intervention is the product of an extensive, iterative treatment development process. To maximize acceptability of the intervention, the REACH program was tailored extensively 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 female patients and an expert in interventions for minority teens), pilot participants, and pilot facilitators.

The REACH program is a highly structured, adolescent-oriented intervention that is delivered over the course of 5 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 the REACH program focused on the development of effective communication skills to manage relationship conflicts before and after the birth of the baby, expectations about motherhood, stress management, "baby blues" vs depression, development of a support system, development of healthy relationships, goal setting, and psychosocial resources for new mothers. The structured format and detailed facilitator manual ensured that specific defining elements of interpersonal therapy such as enhancing social support and therapeutic strategies (eg, role-playing, communication analy-

sis) remain the central features of the intervention. The highly structured nature of the 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 which is a comprehensive pregnancy guide that was 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, preparation for labor, and preparation of the home for taking a baby home. The control condition had no overlapping content with the REACH program curriculum.

The initial plan was for the REACH program and control program sessions to be delivered as group sessions once each week for 5 consecutive weeks and an individual booster session that is delivered in the hospital after the delivery, 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 30-60 minutes, depending on the discussion.

Outcome assessment

PPD was classified as an episode of major depressive disorder that occurred within the first 6 months after delivery. Although the DSM-IV defines PPD as major depressive disorder with an onset within 4 weeks after delivery, research has shown that at least one-third of women report the onset of PPD at 2-6 months²⁵; among teens, 32% have scores that indicate depression at 4 months after delivery.³ Moreover, most investigators classify a depression that occurs within the first 6 months after delivery as

PPD.^{26,27} The 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 after delivery. 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 before randomization and after intervention; 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 evaluation.

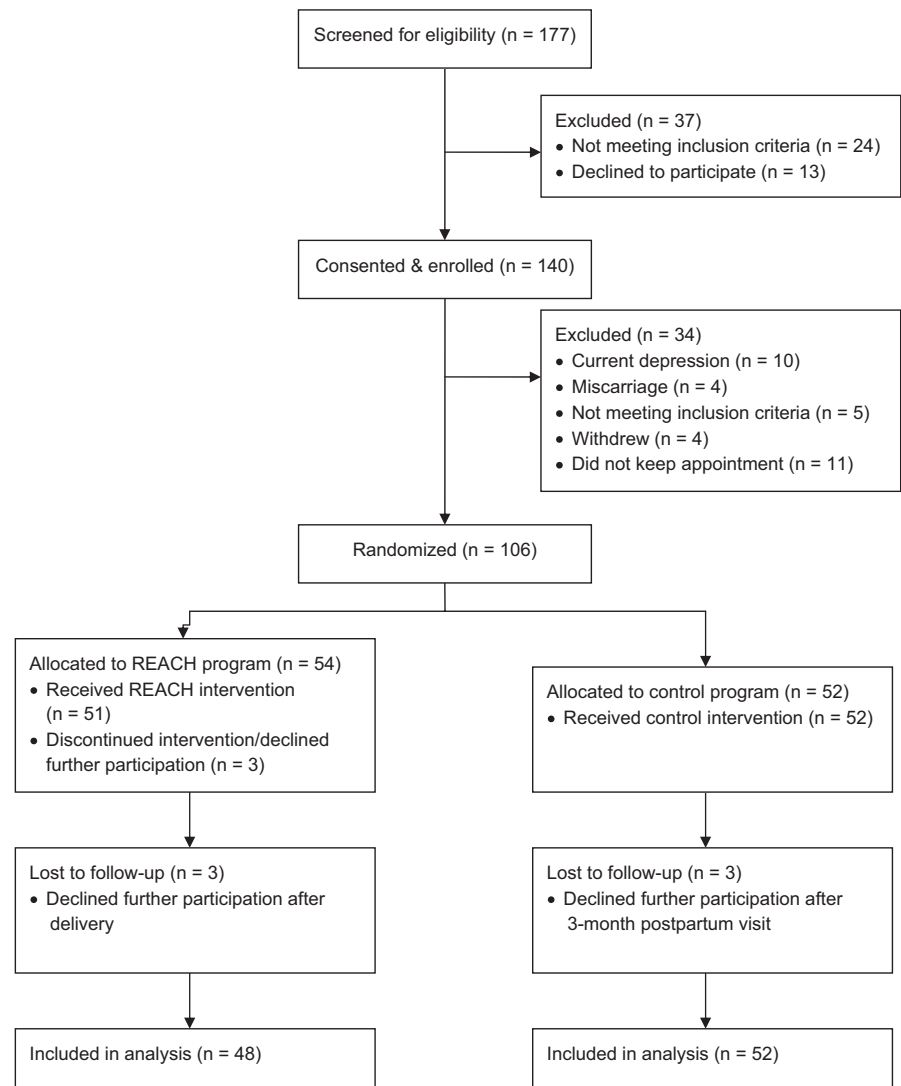
Sample size calculation

The purpose of the REACH program 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 effective size for a larger clinical trial. The study target was designed to evaluate 100 randomly assigned participants and to assess feasibility of study recruitment and retention procedures for pregnant adolescents.

Randomization method

The randomization scheme was developed before the study was begun. Stratified block randomization was used to keep the groups balanced in terms of 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 screened fully for eligibility, the study group was unveiled and reported to the interventionist so that appointments could be scheduled to begin the intervention or control group program. The group allocation was not revealed to the research

FIGURE
Participant selection and follow-up evaluation



REACH, the Relaxation, Encouragement, Appreciation, Communication, Helpfulness program.

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team members who performed 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. The Fisher exact test was used to compare categorical variables, and the Wilcoxon rank-sum test was used for the comparison of continuous variables. All participants with at least 1 postpartum assessment were included in the primary analysis and were classified according to their randomly assigned study group (intention-to-treat). PPD inci-

dence in each group was calculated as a positive major depressive disorder diagnosis by the KID-SCID at ≥ 1 postpartum visits. The hazard rate ratio (HR) and 95% confidence interval (CI) for PPD in the REACH program vs the control group were estimated by Cox proportional hazards regression. Tied events that resulted from the discreteness of the time scale were handled by the exact method. History of depression, which was the stratification factor for randomization, was included as a covariate in all models. Baseline variables that were distributed differently between study arms were also included as covariates

TABLE 1
Baseline characteristics by study arm

Variable	REACH program	Control program	P value
Total randomized patients, n	54	52	
Age at randomization, y ^a	16 (13-18)	16 (14-18)	.4 ^b
Gestational age, wk ^a	19.7 (12.6-28.9)	21.3 (9.1-30.9)	.2 ^b
Race/ethnicity, n (%)			.6 ^c
Hispanic	29 (53.7)	27 (51.9)	
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 ^c
Previous pregnancy, n (%)	4 (7.4)	4 (7.7)	1.0 ^c
Currently in school, n (%)			.5 ^c
Yes	44 (81.5)	38 (73.1)	
No, completed 12 grade	2 (3.7)	2 (3.9)	
No	8 (14.8)	12 (23.1)	

REACH, Relaxation, Encouragement, Appreciation, Communication, Helpfulness.

^a Data are given as median (range); ^b Wilcoxon rank-sum test; ^c Fisher exact test.

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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. To formally perform an intention-to-treat analysis, assumptions were made about missing outcome data because of 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 software (version 9.1; SAS Institute, Cary, NC). Two-tailed probability values of $< .05$ were considered statistically significant.

RESULTS

Participant recruitment

Between February 2007 and August 2008, 177 patients were screened for study eligibility during their first prenatal visit (Figure). Of these patients, 140

were consented and scheduled for an initial visit. Current depression was diagnosed at the first visit in 10 enrollees; 4 participants had spontaneous abortions. Twenty additional patients were excluded from the study because of ineligibility, withdrawal from the study before the intervention was initiated, or failure to attend the initial visit.

A total of 106 participants were assigned randomly to the REACH program ($n = 54$) or the control program ($n = 52$). All participants who remained in the study through delivery completed the 5 sessions in their assigned programs; however, 3 patients who were assigned to the REACH program discontinued participation during the intervention. After delivery, 100 participants (94%) attended at least 1 postpartum follow-up visit and were assessed for PPD.

Baseline data

The median age for participants was 16 years, and most participants were from Hispanic backgrounds (Table 1). Over-

all, a history of depression was identified in 16% of participants. There were no significant differences between the REACH program and control group participants in terms of age, gestational age, race/ethnicity, history of depression, pregnancy history, and current educational level. A few participants ($n = 12$) were 18 years old or >25 weeks' gestation at the time of randomization because of 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 after delivery. A total of 19 participants (19%) were diagnosed with PPD at a subsequent study visit through 6 postpartum months. The incidence of PPD was 12.5% (95% CI, 3.1–21.9%) for the REACH program compared with 25.0% (95% CI, 13.2–36.8%) for the control program (Table 2), which results in an absolute difference of -12.5% (95% CI, -27.5 to 2.5%) at 6 months after delivery. After adjustment for history of depression by Cox proportional hazards regression, the incidence of PPD was 56% lower for the REACH program compared with the control program (HR, 0.44; $P = .1$). 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 to 5.7% ; adjusted HR, 0.50; $P = .2$).

Three participants discontinued participation before delivery; 3 participants discontinued participation after delivery, and 8 participants missed ≥ 1 postpartum visits. A sensitivity analysis was performed to evaluate the impact of missing data on the results; the analysis was repeated with the assumption of PPD diagnoses for all missing assessments and then the assumption of no diagnosis of PPD for the missing assessments. A 33% reduction in PPD risk for the REACH program, compared with the control program, persisted when a PPD diagnosis was imputed for participants with missing data.

TABLE 2
The REACH program and incidence of postpartum depression^a by 6 months after delivery

Variable	Postpartum depression, n/N (%)		Hazard rate ratio (95% CI) ^b	
	REACH program	Control program	Unadjusted	Adjusted ^c
Any postpartum follow-up evaluation (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 evaluation (n = 91)	6/47 (12.8%)	10/44 (22.7%)	0.54 (0.20–1.48)	0.50 (0.18–1.37)
Sensitivity analysis ^d				
Missing outcome: postpartum depression (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 postpartum depression (n = 106)	6/54 (11.1%)	13/52 (25.0%)	0.41 (0.16–1.09)	0.40 (0.15–1.04)

CI, confidence interval; REACH, Relaxation, Encouragement, Appreciation, Communication, Helpfulness.

^a Diagnosed by Structured Clinical Interview for the Diagnostic and Statistical Manual for Mental Disorders, 4th edition, Childhood Diagnoses; ^b For the REACH program vs control; ^c Proportional hazards model included stratification factor, history of depression; ^d Assumed missing postpartum assessments were all postpartum depression or no postpartum depression diagnoses.

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No harmful effects were noted from participants in this trial.

COMMENT

To our knowledge, this is the first clinical trial of prevention for PPD 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 interpersonal therapy–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 and 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, which suggests that we had a representative sample for our study. Because 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 REACH program intervention and the control program suggests that the REACH program can be implemented in other clinical settings. Of note, a recent study published by Howell et al,²⁸ who implemented a structured behavioral-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 positive screening for depression at 3 weeks and 3 months after delivery.

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; therefore, the sessions were modified and delivered as individual sessions. Because we did not have complete follow-up data on all of the study participants, we performed a sensitivity analysis. A protective effect for the REACH intervention was observed under each scenario, which suggests that substantial bias because of missing data is unlikely.

Findings from our study suggest that the REACH program, which is tailored specifically for pregnant adolescents, has promise as an intervention to prevent PPD. Moreover, the REACH program appears to be an accessible and feasible intervention for pregnant adolescents. With further evaluation, the REACH program 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.

ACKNOWLEDGMENTS

We thank Nicole Girard and Larissa Chiulli, who previously worked for the Department of Obstetrics & Gynecology Division of Research at Women & Infants Hospital (N.G. 2006-2008; L.C. 2006-2007), for their contribution to the implementation of this study.

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