HHS Public Access

Author manuscript

*J Midwifery Womens Health*. Author manuscript; available in PMC 2016 September 01.

Published in final edited form as:

*J Midwifery Womens Health*. 2015 ; 60(5): 578–592. doi:10.1111/jmwh.12308.

# Performance of a Culturally Tailored Cognitive Behavioral Intervention (CBI) Integrated in a Public Health Setting to Reduce Risk of Antepartum Depression: A Randomized Clinical Trial

**D. Elizabeth Jesse, PhD, CNM [Professor]**,
Graduate Nursing Science, East Carolina University College of Nursing Postal address: ECU College of Nursing 3160 Health Sciences Building Greenville, NC, 27858 Telephone: 252-744-6384 Fax: 252-744-6393 jessed@ecu.edu

**Bradley N. Gaynes, MD, MPH [Professor of Psychiatry]**,
Associate Chair for Research Training and Education CB #7160, Department of Psychiatry Suite 304, Room J, MacNider Building University of North Carolina School of Medicine Chapel Hill, NC 27599-7160 TEL: (919) 445-0214 FAX: (919) 445-0234 bradley_gaynes@med.unc.edu

**Elizabeth Feldhousen, PhD, LMFT [Clinical Assistant Professor]**,
East Carolina University Family Medicine Clinic 101 Heart Drive Mailstop: 654 Greenville, NC 27834 Office Phone: 252-744-3080 feldhousene@ecu.edu

**Edward R. Newton, MD [Professor of Obstetrics & Gynecology]**,
Brody School of Medicine Room 162 Medical Annex - Vidant Medical Center Greenville, NC 27834 Phone 252-744-4662 Fax 252-744-1920 newtoned@ecu.edu

**Shelia Bunch, PhD, LCSW [Professor and Director]**, and
School of Social Work 224 Rivers Bldg. Greenville, NC, 27858 Phone: 252-328-2281 Fax 252-328-1920 bunchs@ecu.edu

**Steven D. Hollon, PhD [Gertrude Conaway Professor of Psychology]**
Department of Psychology 306 Wilson Hall Vanderbilt University Nashville, TN, 37240-7817 **Phone**: (615) 322-3369 steven.d.hollon@vanderbilt.edu

## Abstract

**Introduction—**Cognitive behavioral group interventions have been shown to improve depressive symptoms in adult populations. This article details the feasibility and efficacy of a 6-week culturally tailored cognitive behavioral intervention offered to rural, minority, low-income women at risk for antepartum depression.

**Methods—**146 pregnant women were stratified by high-risk for antepartum depression (Edinburgh Postnatal Depression Scale (EPDS) score of 10 or higher) or low-moderate risk (EPDS score of 4-9) and randomized to a cognitive behavioral intervention or treatment-as-usual. Differences in mean change of EPDS and BDI-II scores for low-moderate and high-risk women in the cognitive behavioral intervention and treatment-as-usual for the full sample were assessed from baseline (T1), post-treatment (T2) and 1-month follow-up (T3) and for African-American women in the subsample.

**Results—**Both the cognitive behavioral intervention and treatment-as-usual groups had significant reductions in the EPDS scores from T1 to T2 and T1 to T3. In women at high-risk for depression (n=62), there was no significant treatment effect from T1 to T2 or T3 for the Edinburgh Postnatal Depression Scale. However, in low-moderate risk women, there was a significant decrease in the BDI-II scores from T1 to T2 (4.92 vs. 0.59, *P*=.018) and T1 to T3 (5.67 vs. 1.51, *P*=.04). Also, the cognitive behavioral intervention significantly reduced EPDS scores for African-American women at high-risk (n=43) from T1 to T2 (5.59 vs. 2.18, *P*=.02) and from T1 to T3 (6.32 vs. 3.14, *P*= .04).

**Discussion—**A cognitive behavioral intervention integrated within prenatal clinics is feasible in this sample, although attrition rates were high. Compared to treatment-as-usual, the cognitive behavioral intervention reduced depressive symptoms for African-American women at high-risk for antepartum depression and for the full sample of women at low-moderate risk for antepartum depression. These promising findings need to be replicated in a larger clinical trial that incorporates methods to maintain greater participant engagement.

### Keywords

antepartum depression; antepartum depressive symptoms; pregnancy; randomized clinical trial; health disparities; cognitive behavioral intervention (CBI)

## INTRODUCTION

Depending on the diversity of populations studied and screening instrument used, a third of pregnant women experience elevated depressive symptoms during pregnancy,[1] also known as antepartum depressive symptoms.[1] As many as 11 -12%[2-5] of pregnant women also suffer from antepartum depression, a major unipolar depressive disorder occurring during pregnancy that includes at least 5 of 9 symptoms (including at least one of depressed mood and loss of interest or pleasure), present every day for more than 2 weeks.[6] Although antepartum depressive symptoms and antepartum depression are less well known than postpartum depression, symptoms are just as real and have considerable negative effects. In a meta-analysis,[7] untreated antepartum depression or clinically significant depressive symptoms were shown to "increase the relative risk of preterm birth by 39%, low birth weight by 49% and intrauterine growth restriction by 45%."[7 pg. 7] Furthermore, antepartum depressive symptoms and depression are the single greatest risk factors for postpartum depression[8-9] and can lead to impairments in mother-infant relationships, compromised child cognitive and emotional development,[10, 11] and death by suicide.[12] In the largest study[9] to date (N=10,000), 33% of women who were screened for postpartum depression identified onset of their depressive symptoms during pregnancy, whereas 40% reported onset of depressive symptoms in the postpartum.

Single, young, rural, African-American and other minority low-income women who receive public insurance or are enrolled in public health clinics are more likely to experience antepartum depressive symptoms and antepartum depression.[1, 13-15] However, they are less likely to seek treatment for depression, or to follow through on referrals to mental health services due to lack of financial resources, understanding of mental illness, stigma, and language barriers.[13, 15, 16] If they do seek treatment, their symptoms typically are severe,[16]

yet many are reluctant to use pharmacological interventions because of fears of negative effects on their unborn baby.[17] Furthermore, many obstetric providers fail to screen, manage, treat or refer these vulnerable women.[18-21] Thus, many women at risk for or experiencing antepartum depression remain undiagnosed and untreated.[18-20]

Despite the clear evidence about the need to address antepartum depressive symptoms, [21] evidence about the best therapeutic approach to use is limited.[5, 22]

Studies[23-25] suggest that cognitive-behavioral interventions are effective in reducing depressive symptoms, preventing depression, and treating major depression among adults in primary care settings. Yet, to-date, only one randomized clinical trial (RCT)[26] of a cognitive behavioral intervention has been conducted that focused on pregnant women at risk for antepartum and postpartum depression but the intervention did not have a significant effect. The authors attributed this to challenges in implementation, issues related to retention of subjects, a poor relationship with the study site, and facilitators who changed often. Several other studies[27-30] used a cognitive behavioral intervention delivered when the woman was pregnant, but the focus was on the outcome to prevent postpartum depression in urban women and none of these study interventions significantly reduced antepartum depressive symptom severity or the effects were not maintained.[30] One RCT[31] of a cognitive behavioral intervention showed promising results with urban minority women with depressive symptoms but the delivery of the intervention was not clearly described and both non-pregnant and pregnant women were included in the study's intervention and control group.[31] Two small RCTs[32-33] of Interpersonal Therapy showed promising results in reducing depressive symptom severity in pregnancy and/or the postpartum in urban adults[32] and adolescents.[33-34] However, a manualized cognitive behavioral intervention that can be delivered by a social worker and a paraprofessional health care provider for low-income and minority women may be more easily replicated in a public health setting than Interpersonal Therapy. There is an urgent need to integrate evidence-based culturally sensitive interventions for diverse groups of women at risk for antepartum depression living in rural and underserved communities. It is especially important since rural low-income women at risk for antepartum depression are often less likely than other women to seek care for depression and fail to complete their referral to community mental health resources.

## SPECIFIC AIMS

The aims of this RCT were to evaluate the feasibility and efficacy of Insight-Plus, a manualized, culturally tailored, and technology-enhanced cognitive behavioral intervention for African-American, Caucasian, and Hispanic rural low-income women at risk for antepartum depression. The women were enrolled at a local health department prenatal clinic, an affiliated regional perinatal center (RPC) in the Southeastern United States. Specifically, the study: 1) determined the extent of treatment feasibility as measured by refusal to participate, participant attendance, and acceptability of the cognitive behavioral intervention, and 2) determined whether the cognitive behavioral intervention significantly reduced depressive symptoms for the full sample of women at low-moderate and high-risk for antepartum depression and for a subsample of African-American women. The aims of this study met the recent recommendations of the American College of Nurse-Midwives

(ACNM) position statement on Depression in Women,[35] the American Psychiatric Association and the American College of Obstetricians and Gynecologists collaborative report for management of depression during pregnancy,[36] and the National Institute of Mental Health (NIMH) mission to devise new approaches for prevention and treatment of mental illness and to eliminate health disparities.[37] Finally, it addressed the National Association of County and City Health Officials (NACCHO)[38] recommendation that women's mental health needs should be a priority for local health departments.

## METHODS

### Study Design

We employed a two-group pre-test/post-test control group design with repeated measures to determine the feasibility and efficacy of Insight-Plus integrated in a local health department and affiliated regional perinatal center prenatal care setting. After institutional review board approval, 146 African-American, Caucasian, or Hispanic rural low-income pregnant women who scored 4 or higher on the EPDS[39] were stratified as high-risk for antepartum depression (EPDS 10 or higher) or low-moderate risk (EPDS 4-9) and randomly assigned to the cognitive behavioral intervention or treatment-as-usual. Block randomization based on a computer generated random number table was used to ensure a balance in sample size in the cognitive behavioral intervention and treatment-as-usual groups. Based on 75 participants per group, the study had 85% power for detecting a medium sized effect at the .05 level of significance, two-tailed.[40]

### Screening, Recruitment, and Retention

The staffs at the local health department and regional perinatal center use the EPDS[39] to routinely screen all pregnant women for depressive symptoms. Women were eligible for the study if they were 18 years or older; between 6-30 weeks pregnant; enrolled at the local health department (LHD) or an affiliated regional perinatal center; self-identified as African American, Caucasian, or Hispanic; able to read at a 4$^{th}$ grade level; scored 4 or higher on the EPDS;[39] and enrolled in Medicaid or were low-income based on Special Supplemental Nutrition Program for Women, Infants, and Children eligibility criteria. Women were excluded if they had experienced a spontaneous abortion before 20 weeks of pregnancy or a fetal demise; had been diagnosed with schizophrenia or bipolar disorder or were currently receiving treatment for depression; had been diagnosed with a high-risk pregnancy requiring bed rest or hospitalization; demonstrated an active suicidal plan; or had a concurrent medical condition, such as hypothyroidism, that could explain depression. This study distinguished between antepartum depressive symptoms, which can be identified through screening, and antepartum depression, diagnosed through a structured interview. We also developed a decision tree for women who were at risk for suicide. If a respondent endorsed the suicide item on the EPDS[39] or the BDI-II[41] during an interview or made statements that suggested suicidality, a research team member validated the participant's feelings, explained the need to break confidentiality, and escorted the woman to her Pregnancy Care Manager or to her physician (or resident on call) to evaluate her further.

Between June, 2010 and January, 2013, registered nurses at both sites universally screened women for depressive symptoms using the EPDS. All pregnant women who scored 4 or higher on the EPDS were given a study brochure with colorful pictures and bullet points that described signs and symptoms of antepartum depression and the study procedures. All women were also given a handout of community resources for antepartum depression, postpartum depression, substance use, and interpersonal violence. Subsequently, each woman was asked if she was interested in learning more about the study. If she was interested, the project coordinator or a research assistant privately approached her with a 5-10 minute motivational interview defined as "a collaborative, person-centered form of guiding to elicit and strengthen motivation for change."[42, pg. 137] The interviewer listened to understand her symptoms, how they interfered with her life, and barriers to receiving treatment, such as lack of transportation, need for childcare, or work and school schedules.[43] An interpreter was available for all interviews and sessions with Spanish speaking women. If the woman was interested and eligible, the project coordinator or research assistant provided her an informed consent form and assured the woman that her care would not be affected if she decided not to participate. The consent form described what would be involved in taking part in the program and that they could be randomly assigned to "participate in Insight-plus, a group that meets in a private room at your prenatal clinic for 2 hours a week for 6 weeks" or to usual care. We explained that some would be in a treatment-as-usual group. After the woman signed the informed consent, she completed the baseline (T1) interview, and then opened the envelope that assigned her to the cognitive behavioral intervention or treatment-as-usual. All women received a $20 gift card after the baseline (T1) screening interview and a $50 gift card for the post-intervention interview (T2) and the 1-month follow-up interview (T3), for a total of $120.00.

## Content and Conduct of Insight-Plus Culturally Tailored Cognitive Behavioral Intervention

The Insight-Plus culturally tailored cognitive behavioral manualized intervention for rural and minority pregnant low-income women is summarized in Table 1 and described in more detail in a previous study.[44] The intervention was adapted from "Insight," a manualized program for non-pregnant women who read at a college reading level.[45-46] Beck's cognitive behavioral model[47-50] and Jesse's bio-psychosocial-spiritual theory[1, 51] provided the theoretical framework for the intervention. Psycho-educational and pregnancy specific information included in the manual was based on the first author's clinical experiences as a nurse-midwife providing care for rural, minority and low-income women. All chapters were written at a fourth grade reading level and were piloted in the earlier study.[44] The manual was translated and back translated into Spanish for Spanish speaking participants.

The intervention was also enhanced with technology. Each woman in the treatment group was given an MP3 player with a pre-programmed play list of a weekly review of homework assignments, a stress-reducing guided visualization, a review of thoughts, feelings, and behaviors, positive affirmations, and motivational and inspiring music. The women were instructed to record their positive affirmations on the MP3 player to listen to later. The recordings on the MP3 player were also recorded in Spanish.

## Cultural Adaptation

The multi-cultural adaptation of cognitive behavioral interventions addressed the unique needs of this diverse racial/ethnic group of pregnant women. No other cognitive behavioral intervention was found that addressed the unique cultural needs of African-American, Caucasian, and Hispanic rural low-income pregnant women. The participant manual and intervention were also culturally-tailored using themes from the first author's focus group study with rural and minority low-income women.[52] For example, African-American women within the focus groups emphasized the need for a positive, non-judgmental facilitator with whom they can develop a trusting relationship. They also suggested including motivational non-denominational spiritual related resources. Caucasian women asked for more support and help to overcome barriers and psycho-educational information. Hispanic women wanted advice on ways to avoid feeling sad and distract themselves from their problems. Women from all racial/ethnic groups wanted professionals to inquire how they are doing, develop rapport, encourage them to open-up, normalize their feelings, and to let them know confidentiality is maintained.

Based on the focus group themes[52] and pilot findings,[44] we reduced barriers to women attending the cognitive behavioral intervention by providing transportation, child care, brief ice breaker games, prizes, humorous and fun activities, and snacks. We also encouraged the women to develop hobbies, to journal, and to listen to relaxing, motivational, and positive music. There was a section that addressed depression and women of color in the first chapter of the manual. Based on the focus group findings, the group facilitators used a combined approach to address the women's diverse cultural needs.

## Conduct and Content of the Intervention

The women in the 6-session intervention met for 2 hours once a week. The groups met at a time convenient for the women, during normal clinic hours, and in a private room at the clinical site where they were enrolled in prenatal care. The groups were composed of 2 to 6 women for a total of 21 groups. The women in the groups were of mixed race and ethnicity, however non-English speaking Hispanic women met separately. Several women met individually, (n=2) if one or more women dropped out before completing the group sessions.

A facilitator's manual included the organization, format, and flow of activities for each group session, including: 1) introduction of the agenda and announcements; 2) an ice breaker activity; 3) a review of group rules (discussed in the first session); 4) a review of material covered in the previous sessions; 5) a presentation of the topic, 6) exercises related to the topic, and 7) a review of homework assignments to be completed between-sessions.

To enhance the likelihood that Insight-Plus cognitive behavioral intervention could be sustained in a real-world setting, the study emphasized cost-effective care similar to that delivered by the staff at the local health department. The social workers at the local health department, called Pregnancy Care Managers, provide a model of care that includes case management and support services to pregnant patients at high psychosocial risk. They work closely with a "resource mom," a paraprofessional staff member from the community who holds an Associate Degree in Human Service Technology. The resource mom offers

additional case management services to pregnant women with the highest psychosocial risks. Similarly, in our study the group facilitators were a master's prepared licensed clinical social worker and other licensed mental health professionals, including a marriage and family therapist and a licensed professional counselor associate. The resource mom co-facilitated the group, offered weekly booster session telephone calls to review the weekly homework and provided case-management services to help women problem solve or resolve issues that hampered participation until the final follow-up interviews were completed. In addition, the resource mom maintained a log to record problems, unexpected life events, home-work adherence, and/or positive life changes identified by participants, such as looking for a job or an apartment, or moving to a safer location.

We maintained a culturally and racially diverse study team and offered culturally sensitive training. All facilitators were of African-American (n=2) or Caucasian (n=1) race. The resource moms were African-American (n=2) and the bilingual interpreter was non-Hispanic Caucasian. The graduate research assistants were from programs in marriage and family therapy, social work, rehabilitation studies, health education, or public health. Another author (SB) who was a PhD prepared social worker, the project coordinator who was a licensed marriage and family therapist, and a licensed clinical social worker who facilitated the groups received cognitive behavioral training on fundamentals of cognitive therapy for depression at the Beck Institute's workshop for Cognitive Behavioral Therapy and Research[53] conducted by Drs. Aaron T. Beck and Judith S. Beck. Finally, the interviewers received training on cultural competent and sensitive interviewing techniques and the instruments used to interview the women, including the M.I.N.I. International Neuropsychiatric Interview (M.I.N.I. 6.0) online version, renamed the Dolphin EDC, (Electronic Data Capture system).[54-55]

### Integrity of Insight-Plus Cognitive Behavioral Intervention

Throughout the study, facilitators and resource moms met monthly with the co-investigator social worker expert and the first author to ensure competency and any inconsistencies or problems were identified and resolved. In addition, the first author and project coordinator had monthly conference calls with the lead psychiatrist on the study team to review the study protocol; any inconsistencies or problems identified were resolved. Finally, the frequencies of the facilitators' adherence to the manualized program were performed. The project coordinator selected one session to be audio-recorded randomly and used the facilitator's comprehensive check list of each session's topics to measure the facilitator's adherence. The findings were used to problem solve difficulties and review training to minimize deviations from the workbook and reach 90% accuracy in the facilitators delivering the cognitive behavioral program.

### Treatment-as-Usual Group

The treatment-as-usual control group was interviewed on a schedule similar to that of the cognitive behavioral intervention group. The Insight-Plus cognitive behavioral program was offered in addition to the routine social services that women in the treatment-as-usual group received. All women at the local health department received prenatal care primarily from certified nurse-midwives (CNMs) or from a women's health nurse practitioner (WHNP);

medical students provided care with CNM or WHNP supervision. Women at the regional perinatal center received prenatal care from women's health nurse practitioners, obstetrical residents, or physicians. At the local health department, a Pregnancy Care Manager and at the regional perinatal center a licensed clinical social worker, screened women for interpersonal violence, depressive symptoms, stress, level of social support, and wantedness of the pregnancy. Women in the study were eligible for social worker services at each of the study sites. Women at both sites were also offered regularly scheduled child birth education classes at the local health department.

## Interviews and Measurements

The baseline data collection interview (T1) lasted 30-40 minutes and included socio-demographic and clinical questions, the Edinburgh Postnatal Depression Scale (EPDS),[42] the Beck Depression Inventory-II,[41] and the Dolphin EDC, Electronic Data Capture system for electronic interviews with patients using the M.I.N.I.-International Neuropsychiatric Interview version 6.0 (M.I.N.I. 6.0).[54, 55] The project coordinator or the research assistant administered the instruments for all women in the study at the baseline interview and at the post-intervention and follow-up interviews. Post-intervention data were collected after the last (sixth) session and the final follow-up interview occurred 1-month after the intervention ended and at a similar time frame for women in treatment-as-usual.

All instruments had been tested previously for reliability and validity with culturally diverse rural low-income women by the first author.[1, 44, 51] Because of the low literacy of the population, all questions on the instruments were read to participants. Socio-demographic data included age, ethnicity/race, type of insurance (Medicaid, Medicare, or uninsured), income, education, partner status, gravida, parity, and history of depression.

The 10-item Edinburgh postnatal depression scale (EPDS)[39, 56] has been used widely to measure depressive symptoms in the last 7 days. Although the EPDS was designed for measuring depressive symptoms in the postpartum, it has been used extensively to screen for antepartum depressive symptoms.[56-61] Each item is on a 4-point scale (0-3); higher scores indicate greater depressive symptom severity. Total scores on the EPDS range from 0–30 with a lower cut-off score of 10 or higher recommended by the developers as a cut-off score for possible risk for depression. The cut-off scores for detecting major depression in research studies varies from 9 or 10 to 12 or 15 depending on the trimester of pregnancy and diversity of the study participants.[56-60] The scale takes less than 5 minutes to administer and is at the 3rd grade readability level. Cronbach's alphas were .84 at baseline and T2 and .87 at T3.

The 21-item Beck Depression Inventory (BD-II)[41] measured depressive symptoms experienced in the past 14 days. While the BDI-II was not designed specifically for pregnancy, it has been widely validated for use in pregnancy.[61] each item is on a 4-point scale ranging from 0-3. Total scores on the BDI-II range from 0-63, with higher scores indicating greater depressive symptom severity. This instrument takes less than 10 minutes to administer and is at the 5th grade reading level. Cronbach's alphas were .88 at baseline and T2 and .91 at T3.

The M.I.N.I.-International Neuropsychiatric Interview (M.I.N.I. 6.0) renamed the Dolphin EDC, (Electronic Data Capture system) for the online version, is a secure online diagnostic evaluation for clinical depression.[54-55] MINI was designed to enable a trained, non-professional interviewer to make a DSM-IV diagnosis. It takes about 15 minutes to complete and contains 2 stem and 10 questions that yield DSM-IV diagnoses for current, recurrent, and past major depressive disorder (MDD) including severity ratings. It has been used widely in psychiatric research, including studies using the EPDS to measure postpartum depressive symptoms.[62]

## Evaluation of the intervention

Participants in the cognitive behavioral intervention also evaluated their satisfaction with the program using an 8-item Client Satisfaction Questionnaire (CSQ-8).[63] Each item is on a 4-point scale (1-4) with higher scores indicating greater satisfaction. Total scores ranged from 8 to 32. In addition, two open-ended questions were asked: “Which aspects of Insight-Plus cognitive behavioral intervention were most helpful to you?” and “Which Insight-Plus activities have you continued to use?” The evaluations were only included in the T2 and T3 interviews administered to the intervention group.

## Analyses

This randomized clinical trial with repeated measures analyzed the feasibility using the consort flow chart. Statistical tests of differences in baseline characteristics and EPDS scores of women at high-risk (EPDS ≥10) and low-moderate risk (EPDS 4-9) were conducted to determine if characteristics were balanced in the outcome measures for the full sample and for the subsample of African-American participants. Next, independent-groups t-tests were conducted to measure change in EPDS and BDI-II scores over time for low-moderate and high-risk women in the cognitive behavioral intervention and the treatment-as-usual for the full sample and for the subsample of African-American participants (sometimes called a test of group differences or mean change scores). Mean change in depressive symptom scores were calculated by subtracting the post-intervention (T2) and the final-follow-up (T3) mean scores from the women’s baseline (T1) mean scores for the intervention and treatment-as-usual groups. African-American participants were analyzed separately because two-thirds of the sample was African-American and in previous studies[1, 51] African-American women were more than twice as likely to be at risk for depression as Caucasian women. Paired t-tests were used to determine mean differences in EPDS and BDI-II scores within each of the cognitive behavioral intervention and the treatment-as-usual groups from baseline to post-intervention and 1-month follow-up.

Because of the attrition in the intervention group, we were not able to perform an intention-to-treat analysis. Instead, we completed a secondary protocol analysis of low-moderate and high-risk groups to address the biasing influences related to different rates of attrition between the intervention and treatment-as-usual participants. Finally, a participation cut off score of 2 or fewer intervention sessions was used to adjust for the exposure of the participants to the intervention. All analysis used SPSS version 20.

# RESULTS

## Consort Flowchart of Recruitment, Attendance, and Retention

The consort flow chart, presented in figure 1, shows the recruitment, attendance, and retention of participants. One hundred ninety-five women scored 4 or higher on the EPDS when they were screened during their initial prenatal visit and agreed to be contacted by the study team; 146 (75 %) of these patients were eligible at the baseline interview, consented to participate, and were randomized. A total of 49 women (25%) were excluded (41 did not meet inclusion criteria and 10 declined to participate); 25 (34%) of the 72 participants who were randomized to the intervention and 2 (3%) of the 74 participants who were randomized to treatment-as-usual dropped out before the intervention began because of the following reasons: work and school schedule conflicts (n=10 and 3 respectfully); or their phones were out of service (n=10); fetal demise (n=1), or lacked access to transportation and lived too far to use a cab or gas card (n=1). Seven (15%) women who began the intervention were excluded from analysis because they became ineligible or dropped out after they received only 1-2 sessions, below a minimum dose of exposure to the cognitive behavioral intervention. The women who became ineligible during the intervention (n=2) were a result of a fetal demise and another after experiencing a spontaneous abortion. Four women dropped out after attending one group session because of work/school schedule conflict, and another dropped out after reading the chapter on domestic violence, stating that it was too painful for her to revisit these issues. Only baseline data were available for these women who dropped out or received 1-2 sessions.

Forty women in the intervention group completed the post-intervention interviews; one woman was killed in a non-study related automobile accident after completing the T2 interview. Thus, 39 intervention participants who received all 6 of the cognitive behavioral intervention sessions and 72 treatment-as-usual participants completed the follow-up interviews (T3). Seven treatment-as-usual participants missed their post-intervention (T2) interviews but completed final follow-up interviews (T3); their T2 scores were imputed using a regression procedure. All of the women who attended all six cognitive behavioral intervention sessions completed the post-intervention (T2) interview and 98% (39) completed the follow-up (T3) interview 1-month later.

## Baseline Characteristics

Table 2 lists baseline socio-demographic, clinical, and psychosocial characteristics of the 146 participants. No significant differences were found in the women's characteristics and mean EPDS scores at baseline (T1) for the full sample and for the subsample of African-American women in the cognitive behavioral intervention and treatment-as-usual groups at baseline (T1). In addition, there were no significant differences in baseline characteristics among the participants who dropped out of the study compared to those who completed the study. Of the eligible study participants, 66 (45%) were at low-moderate risk for antepartum depression (EPDS 4-9) and 80 (55%) were at high-risk (EPDS ≥10). Twenty-three women (16%) were diagnosed with antepartum depression.

## Intervention Outcomes

The mean EPDS and BDI-II scores in the low-moderate and high-risk groups for the full sample, and the African-American subsample, at baseline (T1), post-intervention (T2), and follow-up (T3) are shown in Table 3 and 4 and Figures 2 and 3. The mean change in EPDS and BDI-II scores across these three time periods for the low-moderate and high-risk groups in the full sample are also shown in Table 3 and in Table 4 for the African-American subsample. The mean BDI-II scores decreased significantly for the low-moderate risk women in the cognitive behavioral intervention than for those in treatment-as-usual (4.92 vs. 0.59; *P* = .018; 5.67 vs. 1.51, *P*=.04) (Table 3). While mean change of EPDS and BDI-II scores decreased more for the high-risk women in the intervention than in treatment-as-usual group, the differences were not significant. The mean scores decreased significantly for the high-risk African-American women (n=21) in the intervention than for the high-risk African-American women in the treatment-as-usual group at post-intervention (T2) and follow-up (T3) (5.59 vs. 2.18, *P*=.017; 6.32 vs. 3.14, *P*= .037) (Table 4). In addition, for low-moderate risk African-American women, the mean reduction in BDI-II scores in the intervention group was significantly greater than in the treatment-as-usual group (5.20 vs. . 70; *P* = .02).

Comparing T1, T2, and T3, in the within-group analysis of the high-risk groups demonstrated that depressive symptoms in the cognitive behavioral intervention and treatment-as-usual groups decreased significantly over time but there was not a similar decrease in the low-risk women in treatment-as-usual. There were statistically significant decreases in EPDS scores for high-risk women in the intervention from Time 1 to Time 2 (M=15.19 to10.33 ; *P*= <.0001) and from Time 1 to Time 3 (M= 15.19 to M= 9.37; *P* = <. 001). In the treatment-as-usual group the EPDS scored decreased from Time 1 to Time 2 (M=14.29 to M=11.45; *P* = <.001) and from Time 1 to Time 3 (M=14.29 to M= 10.63; *P* = <.0001). There were also statistically significant decreases in BDI-II scores for high-risk women within the intervention from Time 1 to Time 2 (M=23.48 to M=16.93; *P* = <.001 ) and from Time 1 to Time 3 (M=23.48 to M=16.22; *P* = <.01) and in the treatment-as-usual group from Time 1 to Time 2 (M=23.57 to M=19.69, SD=8.80); *P* = <.0001) and from Time 1 to Time 3 (M=23.57 to M=17.15; *P* = <.0001). Specifically, our results showed significant reductions in EPDS and BDI-II scores for both the intervention and treatment-as-usual groups over time.

## Evaluation of the Cognitive Behavioral Intervention

To evaluate the intervention, participants were asked to complete the 8-item Client Satisfaction Questionnaire (CSQ-8).[63] The mean score on the Client Satisfaction Questionnaire was 24.21 at T2 and 25.52 at Time 3 (range 8-32). At T3, 100% rated the cognitive behavioral intervention as good (7) or excellent (32); 95% felt they got the service they wanted and it met most or almost all of their needs. Also, 100% were mostly satisfied or very satisfied with the amount of help they received and would recommend the program to others in a similar need of help. At the final follow-up interview (T3), participants rated the 6 most helpful aspects as stress management techniques (n=13), sharing with others and having a community of women going through similar things (n=11), group discussions (n=5), education about depression (n=4), the workbook (n=5), and learning about

communication skills (n=4). Additionally, participants noted the top 6 activities they continued to use at the final-follow-up (T3) were stress management techniques (n=12), positive affirmations (n=10), self-care (n=7), the MP-3 player (n=7), music (n=6), and the workbook (n=5).

## DISCUSSION

The purpose of this study was to test the feasibility and efficacy of a 6-week cognitive behavioral intervention for rural, low-income and minority women at risk for antepartum depression. Five key findings emerged from this RCT. First, symptoms of low-moderate risk women in the cognitive behavioral intervention improved significantly more from baseline to post-intervention and follow-up than in the treatment-as-usual group, as measured by the BDI-II. Second, the cognitive behavioral intervention significantly reduced depressive symptoms for African-American women at high-risk for depression. They had significantly greater reductions in EPDS scores from baseline (T1) to post-intervention (T2) and from baseline to follow-up (T3) than the treatment-as-usual group. Furthermore, they were able to sustain their reductions at the 1-month follow-up. African-American women at low-moderate risk for depression also showed significant treatment effect for the cognitive behavioral intervention from baseline to post-intervention (T2). These findings are especially important because of the disproportionate risk for antepartum depressive symptoms among African-American rural low-income women.[12, 51] The findings also highlight the importance of integrating a cognitive behavioral intervention in local health department settings to reach at-risk underserved group for whom this intervention may be especially helpful.

The third new finding showed that women highly rated the cognitive behavioral intervention in quantitative and qualitative interviews. At the 1-month follow-up, they described the most helpful activities were stress management techniques, sharing with other women, group discussions, education about depression, the workbook, and communication skills. Each woman was also asked to describe the top six activities that they continued to use 1-month after the cognitive behavioral intervention was finished. The top activities they continued to use were stress management techniques, positive affirmations, more self-care, the MP-3 player programmed with homework and music, and the workbook activities.

As discussed previously, there is limited evidence of the success of using cognitive behavioral interventions integrated into a prenatal care setting to reduce antepartum depressive symptoms.[26-31] One RCT[26] of a cognitive behavioral intervention focused on pregnant women at risk for depression but it did not significantly reduce depressive symptoms. Several other RCTs[27,28,30] that used a cognitive behavioral intervention were based on the *Mamás y Bebés/mothers and babies* cognitive behavioral intervention course[27] delivered during pregnancy to prevent postpartum depression primarily among urban Latina women, but the cognitive behavioral intervention in those studies did not significantly reduce postpartum depressive symptoms[27-28] or the effects were not maintained.[30] Tandon et al.'s study[31] offered the *Mamás y Bebés/ mothers and babies* course for urban African-American women enrolled in a standard home-visiting program. While the findings were promising, whether the group cognitive behavioral intervention was delivered in the home or

in another facility was not clear. In addition, in that study, non-pregnant women with a child younger than 6 months of age were grouped with pregnant women who either had a lifetime history but not current depressive episode or currently had high-depressive symptoms. With the exception of this study, no other study has demonstrated efficacy of a cognitive behavioral intervention with a diverse sample of rural low-income pregnant women.

The fourth new finding showed that there was a positive within-groups effect in that participants both in the cognitive behavioral intervention and treatment-as-usual improved significantly from baseline (T1) to post-intervention (T2) and 1-month follow-up (T3) on EPDS and BDI-II scores. Similarly, others[28, 29] found that women in a treatment-as-usual or another control condition[64] improved as much as those in the intervention group. The idea of rigor in studies of psychotherapeutic interventions is inherently different than in drug trials. Although randomization to an intervention is possible, blinding to condition is impossible including during data collection/participant assessment. It is therefore difficult to know how to interpret the improvement in measures of depressive symptoms that occurred among the treatment-as-usual control group. It may be due to regression to the mean but it is more likely because depressive symptoms improve over the course of pregnancy. Several researchers[57, 58] reported that pregnant women experience more antepartum depressive symptoms in the first trimester than in the second or third trimesters and even fewer endorse symptoms postpartum. This reduction in the incidence of depressive symptoms over the course of pregnancy may be due to relief from the somatic symptoms as pregnancy progresses and because women have less ambivalence and emotionality which often characterizes early pregnancy.[57, 58, 65]

The improvement in both groups could also be attributed to the “Hawthorne effect.” Because both groups are being studied, the study itself becomes therapeutic. In hindsight, the amount of attention received by the treatment-as-usual group may have been more potent than intended. For example, all women received baseline motivational and follow-up interviews. These interactions and the colorful brochure with pictures and bullet points that described signs and symptoms of antepartum depression and a handout of community resources for antepartum and postpartum depression, substance use, and interpersonal violence may have helped the women better understand, recognize, and normalize their symptoms. In turn this may and may have reduced their fear and shame that resulted in fewer antepartum depressive symptoms.

The final new finding showed that it was feasible to screen, recruit, and enroll rural low-income at risk for antepartum depression in a cognitive behavioral intervention integrated within a local health department and an affiliated regional perinatal center, although attrition rates were high. In the full sample, there was an 18% rate of attrition after randomization and before the intervention began. Thereafter, the intervention group had a higher rate of attrition (35%, n=25) than the treatment-as-usual (TAU) group (3% n=2). However, the higher rate of attrition in the intervention group was not due to depressive symptoms but primarily due to conflicts with work and school schedules that prohibited women from attending the cognitive behavioral intervention sessions, inability to reach women because their phone numbers were out-of-service or were not working, or due to pregnancy loss. Despite offering transportation and child-care, working-women and students were more

likely to drop out because it was difficult to attend two-hour sessions at the clinic offered at a separate time than the woman's prenatal visit during a work-school day. However, women were more likely to stay once they attended at least one session.

The higher than expected rate of attrition in the intervention group suggests the need to improve strategies for maintaining engagement of rural low-income and minority women. To address high attrition in perinatal studies, some researchers have over-recruited,[28] or offered an active treatment-as-usual control activity.[64] But these methods do not address how best to offer/integrate a cognitive behavioral intervention in a real world prenatal care setting.

It may be that women who were busy with work or school agreed to participate in the study even though they knew that the demands of the program required more of them than they could manage; they did not want to disappoint and say "no, I don't have time or interest to meet." Future RCTs with this population should consider a two-step recruitment and engagement process described in Grote et al.'s[32] RCT of an interpersonal psychotherapy for perinatal depression in urban low-income women.

A cognitive behavioral intervention offered in a group format requires a high level of personnel resources to enable women to attend. But if transportation and child-care are not offered, it is unlikely that rural and minority low-income women in public health clinics will be able to attend group sessions. While the women were very positive about the support they received from other women in the group sessions, offering the woman a choice of individual sessions may reduce attrition.

These study findings meet the recommendations of many professional groups[35-37] and the National Association of County and City Health Officials [38] for local health departments (LHDs) to "identify effective methods of early identification, prevention, and intervention that can enhance seamless delivery of services for women and be incorporated into the LHD."[38, pg. 3] It also meets the recommendations of mental health researchers to include more racial-ethnic minority groups in randomized clinical trials of clinical interventions. [66] Despite these recommendations, antepartum depressive symptoms remain unrecognized and largely untreated in the United States and the number of underrepresented minorities in RCTs often remain too small to analyze separately.[66] Sustainable models for treatment, such as the Insight-Plus cognitive behavioral intervention, tailored to the individual's needs, and delivered in rural prenatal clinics, including the local health department (LHD) may help reduce the significant burden of antepartum depressive symptoms and sequelae, consequences, and complications.

## Limitations

Although the cognitive behavioral intervention in this study showed promising results for women at low-risk for antepartum depression and for African-American women at high-risk for antepartum depression, the study had several limitations. Differences in outcome favoring the cognitive behavioral intervention should be attributed to the intervention with caution because of the differential rate of attrition. The study enrolled only rural low-income and minority women at risk for depression; therefore it cannot be generalized to other

groups. The study was underpowered for Spanish speaking Hispanic women; Hispanic women had not been included in the earlier pilot study, therefore we needed to establish feasibility for recruiting Hispanic women. Future studies should consider strategies to engage more non-English speaking pregnant Hispanic women.

## CONCLUSIONS

This randomized clinical trial demonstrated that the cognitive behavioral intervention reduced antepartum depressive symptoms in rural low-income women at low-risk for depression. African-American women at high-risk for depression improved most and were able to sustain these improvements at follow up. The participants rated the cognitive behavioral intervention highly and continued to use many of the activities 1-month after the cognitive behavioral intervention ended. We also found that it is feasible to integrate a cognitive behavioral intervention into routine care in clinical settings to reduce antepartum depressive symptoms and antepartum depression in African-American, Caucasian, and Hispanic rural low-income women, although attrition rates were high. If the cognitive behavioral intervention is efficacious in a larger trial, it can be used as a national model to integrate mental health services into health department settings to reduce antepartum depressive symptoms in a diverse group of low-income women.

## Acknowledgements

Supported by a grant from the National Institute of Mental Health (NIMH) (R34 MH086680-01A1). Clinical Trials ID: NCT 02144844. We thank Melvin Swanson, PhD, Professor at East Carolina University, for his statistical analysis; Ms. Elizabeth Tornquist for her editorial assistance; John Morrow, MD director of the local health department, and the maternal and child nurses and pregnancy care managers (PCM) for their collaboration on this project.

## Author Biographic Sketches

**D. Elizabeth Jesse, PhD, CNM** has been a midwifery and graduate school teacher and researcher at East Carolina University since 2003. She was the principal investigator for this study.

**Bradley N. Gaynes MD, MPH,** is a Professor of Psychiatry and Faculty Research Fellow of the Sheps Center for Health Services Research at the University of North Carolina (UNC) School of Medicine, in Chapel Hill, NC. He was a co-investigator for this study

**Elizabeth Feldhousen, PhD, LMFT** is a Clinical Assistant Professor at the Family Medicine Clinic, East Carolina University. She served as the project coordinator for this study.

**Shelia Bunch, PhD, LCSW** is the director of the School of Social Work at East Carolina University. She was a co-investigator for this study.

**Edward R. Newton, MD** is Professor and former Chairman of the Department of Obstetrics and Gynecology at East Carolina University Brody School of Medicine, Chief of Ob/Gyn Services at Pitt County Memorial Hospital, and Director of Nurse-Midwifery Services at Pitt County Health Department. He was a co-investigator for the study.

**Steven D. Hollon, PhD,** is the Gertrude Conaway Professor of Psychology, Professor of Psychology and Human Development and Professor of Psychiatry at Vanderbilt University. He is an internationally known authority on cognitive behavioral therapy (CBT) and provided ongoing consultation for the study.

## REFERENCES


1. Jesse DE, Kim H, Herndon C. Social support and self-esteem: mediators between perceived stress and depressive symptoms. Res Nurs Health. 2014; 37(3):241–52.10.1002/nurs.21600 [PubMed: 24797585]
2. Gaynes, BN.; Gavin, N.; Meltzer-Brody, S., et al. Perinatal Depression: Prevalence, Screening Accuracy, and Screening Outcomes. Agency for Healthcare Research and Quality; Rockville, MD: 2005. Evidence Report/Technology Assessment No. 119. (Prepared by the RTI-University of North Carolina Evidence-based Practice Center, under Contract No. 290-02-0016.) AHRQ Publication No. 05-E006-2
3. Banti S, Mauri M, Oppo A, Borri C, Rambelli C, Ramacciotti D, et al. From the third month of pregnancy to 1 year postpartum. Prevalence, incidence, recurrence, and new onset of depression. Results from the perinatal depression-research & screening unit study. Compr Psychiatry. 2011; 52(4):343–51. [PubMed: 21683171]
4. Le Strat Y, Dubertret C, Le Foll B. Prevalence and correlates of major depressive episode in pregnant and postpartum women in the United States. J Affect Dis. 2011; 135:128–138. [PubMed: 21802737]
5. Dennis CL, Dowswell T. Interventions (other than pharmacological, psychosocial or psychological) for treating antenatal depression. Cochrane Database Syst Rev. 2013; 31(7):CDOO6795.10.1002/14651858.CD006795.pub3
6. American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders. 5th ed. APA; Washington, DC: 2013.
7. Grote NK, Bridge JA, Gavin AR, Melville JL, Iyengar S, Katon WJ. A meta-analysis of depression during pregnancy and the risk of preterm birth, low birth weight, and intrauterine growth restriction. Arch Gen Psychiatry. 2010; 67(10):1012–1024. [PubMed: 20921117]
8. Beck CT. Postpartum depression: It isn't just the blues. The Am J Nurs. 2006; 106(5):40–51.
9. Wisner KL, Sit DK, McShea MC, Rizzo DM, Zoretich RA, Hughes CL, et al. Onset timing, thoughts of self-harm, and diagnoses in postpartum women with screen-positive depression findings. JAMA Psychiatry. 2013; 70(5):490–8.10.1001/jamapsychiatry.2013.87 [PubMed: 23487258]
10. Kingston D, Tough S, Whitfield H. Prenatal and postpartum maternal psychological distress and infant development: a systematic review. Child Psychiatry Hum Dev. 2012; 43(5):683–714.10.1007/s10578-012-0291-4 [PubMed: 22407278]
11. Grigoriadis S, VonderPorten EH, Mamisashvili L, Tomlinson G, Dennis CL, Koren G, Ross LE. The impact of maternal depression during pregnancy on perinatal outcome: A systemic review and meta-analysis. J Clin Psychiatry. 2013; 74(4):e321–41.10.4088/JCP.12r07968 [PubMed: 23656857]
12. Palladino CL, Singh V, Campbell J, Flynn H, Gold KJ. Homicide and suicide during the perinatal period: Findings from the National Violent Death Reporting System. Obstet Gynecol. 2011; 118:1056–1063.10.1097/AOG.0b013e31823294da [PubMed: 22015873]
13. Bloom T, Bullock LFC, Parsons L. Rural pregnant women's stressors and priorities for stress reduction. Issues Ment Health Nurs. 2012; 33:813–819.10.3109/01612840.2012.71208 [PubMed: 23215982]
14. Gavin AR, Melville JL, Rue T, Guo Y, Dina KT, Katon WJ. Racial differences in the prevalence of antenatal depression. Gen Hosp Psychiatry. 2011; 33(2):87–93. 2011. [PubMed: 21596200]
15. O'Mahen HA, Flynn HA. Preferences and perceived barriers to treatment for depression during the perinatal period. J Women's Health (Larchmt). 2008; 17(8):1301–9.10.1089/jwh.2007.0631 [PubMed: 18816202]

16. Ward EC, Clark LE, Heidrich S. African-American Women's Beliefs, Coping Behaviors, and Barriers to Seeking Mental Health Services. Qual Health Res. 2009; 19(11):1589–1601.10.1177/1049732309350686 [PubMed: 19843967]
17. Tuccori M, Testi A, Antonioli L, Fornai M, Montagnani S, Ghisu N, Colucci R, Corona T, Blandizzi C, Del Tacca M. Safety concerns associated with the use of serotonin reuptake inhibitors and other serotonergic/noradrenergic antidepressants during pregnancy: a review. Clin Ther. 2009; 31(Pt 1):1426–53.10.1016/j.clinthera.2009.07.009 [PubMed: 19698902]
18. Goodman JH, Tyer-Viola L. Detection, Treatment, and Referral of Perinatal Depression and Anxiety by Obstetrical Providers. J Womens Health. 2010; 19(3):477–489.
19. Hackley B, Sharma C, Kedzior A, Sreenivasan S. Managing Mental Health Conditions in Primary Care Settings. J Midwifery Womens Health. 2010; 55(1):9–19. [PubMed: 20129225]
20. Breedlove G, Fryzelka D. CNM, MS Depression Screening During Pregnancy. J Midwifery Womens Health. 2011; 56(1):18–25. [PubMed: 21323846]
21. Rowan PJ, Greisinger A, Brehm B, Smith F, McReynolds E. Outcomes from Implementing Systematic Antepartum Depression Screening in Obstetrics. Archives of Women's Mental Health. 2012; 15:115–120.
22. World Health Organization (WHO) Website. Integrating Mental Health into Primary Care: a global perspective. World Health Organization; Geneva: Available from: http://apps.who.int/iris/bitstream/10665/43935/1/9789241563680_eng.pdf. Published 2008 [Accessed April 16, 2014]
23. Revicki DA, Siddique J, Frank L, et al. Cost-effectiveness of evidence-based pharmacotherapy or cognitive behavior therapy compared with community referral for major depression in predominantly low-income minority women. Arch Gen Psychiat. 2005; 62(8):868–75. [PubMed: 16061764]
24. Luty SE, Carter JD, McKenzie JM, Rae AM, Frampton CMA, Mulder RT, Joyce PR. Randomized controlled trial of interpersonal therapy and cognitive-behavioral therapy for depression. Br J Psychiatry. 2007; 190:496–502. [PubMed: 17541109]
25. Hollon SD, Stewart MO, Strunk D. Cognitive behavior therapy has enduring effects in the treatment of depression and anxiety. Annu Rev Psychol. 2006; 57:285–315. [PubMed: 16318597]
26. Zayas LH, McKee MD, Jankowski KR. Adapting psychosocial intervention research to urban primary care environments: A case example. Ann Fam Med. 2004; 2(5):504–8. [PubMed: 15506589]
27. Muñoz R, Le H, Ippen C, et al. Prevention of postpartum depression in low-income women: Development of the mamás y bebés/mothers and babies course. Cogn Behav Practice. 2007; 14(1): 70–83.
28. Lara MA, Navarro C, Navarrete L. Outcome results of a psychoeducational intervention in pregnancy to prevent PPD: A randomized controlled trial. J Affect Disord. 2009; 122:109–117. [PubMed: 19596446]
29. Austin MP, Frilingos M, Lumley J, Hadzi-Pavlovic D, Roncolato W, Acland S, Saint K, Segal N, Parker G. Brief antenatal cognitive behavior therapy group intervention for the prevention of postnatal depression and anxiety: A randomized controlled trial. J Affect Disord. 2009; 105:35–44. [PubMed: 17490753]
30. Le HN, Perry DF, Stuart EA. Randomized controlled trial of a preventive intervention for perinatal depression in high-risk Latinas. J Consult and Clin Psychol. 2011; 79:135–141. [PubMed: 21319897]
31. Tandon SD, Perry DF, Mendelson T, et al. Preventing perinatal depression in low-income home visiting clients: A randomized controlled trial. J Consult and Clin Psychol. 2011; 79:707–711. [PubMed: 21806298]
32. Grote NK, Swartz H, Geibel S, Zuckoff A, Houck P, Frank E. A randomized controlled trial of culturally relevant, brief interpersonal psychotherapy for perinatal depression. Psychiatric Services. 2009; 60(3):313–321. [PubMed: 19252043]
33. Phipps MG, Raker CA, Ware CF, Zlotnick C. Randomized controlled trial to prevent postpartum depression in adolescent mothers. Am J Obstet Gynecol. 2013; 192:e1–6. [PubMed: 23313720]
34. Bledsoe S, Grote N. Treating depression during pregnancy and the postpartum: a preliminary meta-analysis. Res Soc Work Pract. 2006; 16:103–18.

35. American College of Nurse-Midwives. Position Statement Depression in Women. American College of Nurse-Midwives; Silver Springs, MD: Available from: http://midwife.org/ACNM/files/ACNMLibraryData/UPLOADFILENAME/000000000061/Depression%20in%20Women%20May%202013.pdf. Published May 2013 [Accessed June 16, 2014]
36. Yonkers KA, Wisner KL, Stewart DE, Oberlander TF, Dell DL, Stotland N, et al. The management of depression during pregnancy: A report from the American Psychiatric Association and the American College of Obstetricians and Gynecologists. General Hospital Psychiatry. 2009; 31(5): 403–413. [PubMed: 19703633]
37. National Institutes of Mental Health (NIMH) Mission. [Accessed June 16, 2014] Available from: http://www.nih.gov/about/almanac/archive/2003/organization/NIMH.htm
38. National Association of County and City Health Officials (NACCHO). Issue Brief: Women's Mental Health: Local health department strategies in addressing depression among pregnant and parenting women. 2007. p. 1-4.
39. Cox JL, Holden IM, Sagovsky R. Detection of postnatal depression: Development of the 10-item Edinburgh Postnatal Depression Scale. Brit J Psychiat. 1987; 150:782–786.
40. Cohen J. A power primer. Psychological Bulletin. 1992; 112(1):155–159.10.1037/0033-2909.112.1.155 [PubMed: 19565683]
41. Beck, DI.; Beck, AT.; Brown, G.; Steer, RA. Beck Depression Inventory II Manual. The Psychological Corporation; San Antonia, TX: 1996.
42. Miller WR, Rollnick S. Ten things that Motivational Interviewing is not. Behavioral and Cognitive Psychotherapy. 2009; 37:129–140.
43. Grote NK, Zuckoff A, Swartz HA, Bledsoe SE, Geibel SL. Engaging women who are depressed and economically disadvantaged in mental health treatment. Soc Work. 2007; 52:295–308. [PubMed: 18232240]
44. Jesse DE, Blanchard A, Bunch S, Dolbier C, Hodgson J, Swanson MS. A pilot study to reduce risk for antepartum depression among women in a public health prenatal clinic. Issues Ment Health Nurs. 2010; 31:355–364. [PubMed: 20394482]
45. Gordon, VC. Insight: A cognitive enhancement program for women: Women's workbook. Minneapolis, MN: 2002.
46. Gordon VC, Matwychuk AK, Sachs EG, Canedy BH. A 3-year follow-up of a cognitive-behavioral therapy intervention. Arch Psychiatr Nurs. 1988; 2:218–26. 1988. [PubMed: 3178300]
47. Beck, AT. Depression: Clinical experimental and theoretical aspects. Harper Row; New York: 1967.
48. Beck, AT. Cognitive therapy and the emotional disorders. International Universities Press; New York: 1976.
49. Hollon, SD.; Beck, AT.; Bergin, AE.; Garfield, SL. Handbook of Psychotherapy and Behavior Change: An Empirical Analysis. 4th Ed. Wiley; New York: 1994. Cognitive and cognitive-behavior therapies; p. 428-466.
50. Freeman, A.; Reinecke, M. Cognitive therapy. In: Gurman, A.; Messer, S., editors. Essential Psychotherapies. Guilford; New York: 1995. p. 182-225.
51. Jesse DE, Swanson MS. Risks and resources associated with antepartum risk for depression among rural southern women. Nurs Res. 2007; 56(6):378–386.10.1097/01.NNR.0000299856.98170.19 [PubMed: 18004184]
52. Jesse DE, Dolbier C, Blanchard A. Barriers to seeking help and treatment suggestions for prenatal depressive symptoms: Focus groups with rural low-income women. Issues Ment Health Nurs. 2008; 29:3–19. [PubMed: 18214775]
53. Beck Institute Cognitive Therapy Training Center. [Accessed September 16, 2014] Available from: http://www.beckinstitute.org/cbt-training/
54. Sheehan DV, Lecrubier Y, Amorim P, Janavs J, Weiller E, Hergueta T, Baker R, Dunbar GC. The Mini-International Neuropsychiatric Interview (M.I.N.I.): the development and validation of a structured diagnostic psychiatric interview for DSM-IV and ICD-10. J Clin Psychiatry. 1998; 59(Suppl 20):22–33. quiz 34-57. [PubMed: 9881538]

55. Lecrubier Y, Sheehan DV, Weiller E, et al. The Mini International Neuropsychiatric Interview (MINI): A short diagnostic structured interview: reliability and validity according to the CIDI. Eur Psychiat. 1987; 12:242–231.

56. Murray D, Cox JL. Screening for depression during pregnancy with the Edinburgh Depression Scale (EPDS). J Reprod Infant Psychol. 1990; 8:99–107.

57. Gibson J, McKenzie-McHarg K, Shakespeare J, Price J, Gray R. A systematic review of studies validating the Edinburgh Postnatal Depression Scale in antepartum and postpartum women. Acta Psychiatr Scand. 2009; 119(5):350–64.10.1111/j.1600-0447.2009.01363.x [PubMed: 19298573]

57. Ji S, Long Q, Newport DJ, Hyeji N, Knight B, Zach EB, Morris NJ, Kutner M, Stowe ZN. Validity of depression rating scales during pregnancy and the postpartum period: impact of trimester and parity. J Psychiatr Res. 2011; 45(2):213–9.10.1016/j.jpsychires.2010.05.017 [PubMed: 20542520]

58. Matthey S, Ross-Hamid C. Repeat testing on the Edinburgh Depression Scale and the HADS-A in pregnancy: Differentiating between transient and enduring distress. Journal of Affective Disorders. 2006; 141:213–221. [PubMed: 22695259]

59. Bergink V, Kooistra L, Lambregtse-van den Berg MP, Wijnen H, Bunevicius R, van Baar A, Pop V. Validation of the Edinburgh Depression Scale during pregnancy. J Psychosom Res. 2011; 70(4):385–9. [PubMed: 21414460]

60. Yonkers KA, Smith MV, Gotman N, Belanger K. Typical Somatic symptoms of pregnancy and their impact on a diagnosis of major depressive disorder. Gen Hosp Psychiatry. 2009; 31(4):327–333. [PubMed: 19555792]

61. Holcomb WL, Stone LS, Lustman PJ, Gavard JA, Mostello DJ. Screening for depression in pregnancy: characteristics of the Beck Depression Inventory. Obstet Gynecol. 1996; 88:1021–1025. [PubMed: 8942846]

62. Adewuya AO, Ola BA, Dada AO, Fasoto OO. Validation of the Edinburgh Postnatal Depression Scale as a screening tool for depression in late pregnancy among Nigerian women. J Psychosom Obst Gyn. 2006; 27(4):267–272.

63. Attkisson C, Zwick R. CSQ: The Client Satisfaction Questionnaire: Psychometric properties and correlations with service utilization and psychotherapy outcome. Eval Program Plann. 1982; 5:233–237. [PubMed: 10259963]

64. Spinelli MG, Endicott J, Leon AC, Goetz RR, Kalish R, Brustman LE, Carmona Y, Meyreles Q, Vega M, Schulick JL. A controlled clinical trial of interpersonal therapy for depressed pregnant women at 3 New York City Sites. J Clin Psychiatry. 2013; 74(4):393–399. [PubMed: 23656847]

65. Bowen A, Bowen R, Butt P, Rahman K, Muhajarine N. Patterns of depression and treatment in pregnant and postpartum women. Can J Psychiatry. 2012; 57(3):161–7. [PubMed: 22398002]

66. Santiago CD, Miranda J. Progress in improving mental health services for racial-ethnic minority groups: A ten-year perspective. Psychiatric Services. 2014; 65(2):180–185. [PubMed: 24178249]

## QUICK POINTS

- Low-moderate risk women receiving a cognitive behavioral intervention reported a significantly greater improvement than women in the treatment-as-usual group
- African-American women at high-risk for antepartum depression in the cognitive behavioral intervention reported significantly greater improvement than the women in the treatment-as-usual group
- The higher than expected rate of attrition in the intervention group suggests the need to improve strategies to engage rural low-income and minority women.
- 100% were mostly satisfied to very satisfied with the amount of help they received and continued to use stress management techniques, positive affirmations, self-care, the MP-3 player, music, and the Insight-Plus workbook 1-month after completing the cognitive behavioral intervention.
- Sustainable models for treatment, such as the Insight-Plus cognitive behavioral intervention, tailored to the individual's needs, and delivered in rural prenatal clinics may help reduce the significant burden of antepartum depressive symptoms and sequelae, consequences, and complications.

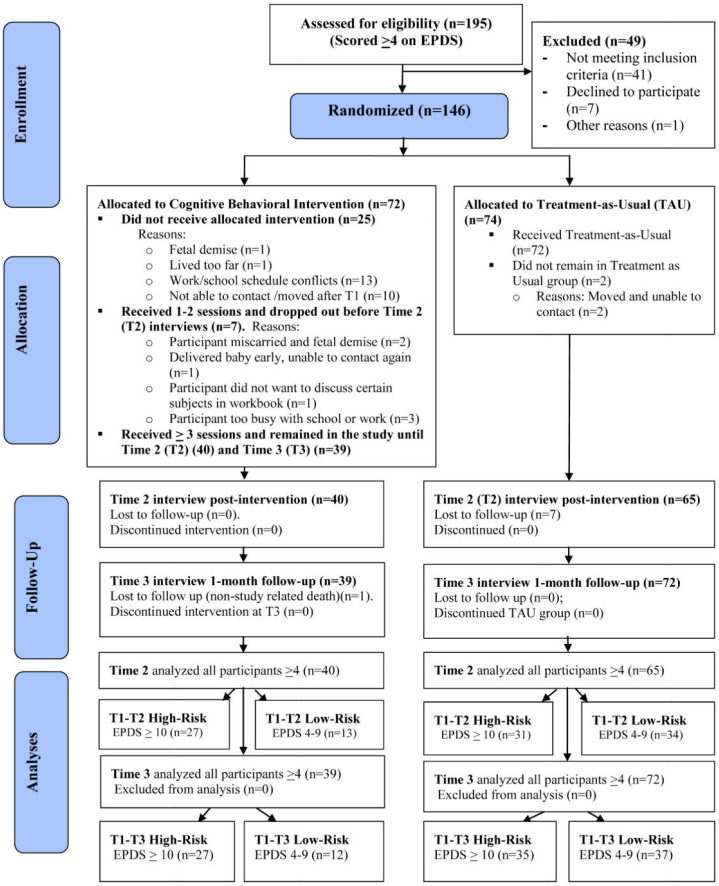


**Figure 1.**
CONSORT flow diagram of participants in the Insight-Plus RCT.

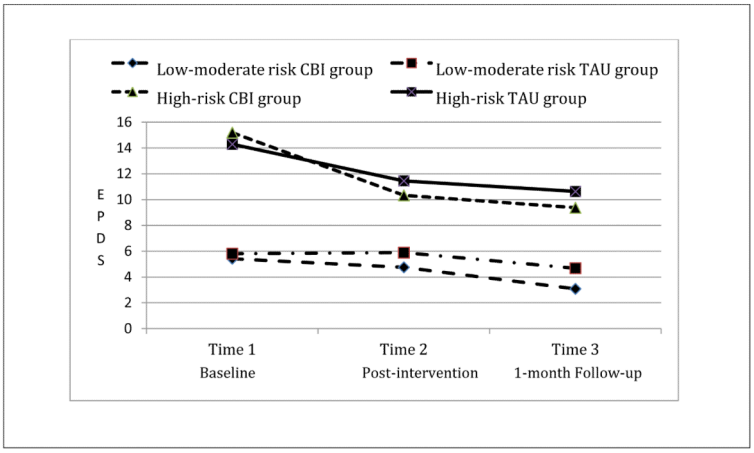


**Figure 2.**

Comparison of Edinburgh Postnatal Depression Scale (EPDS) means over measurement times for women at low-moderate and high-risk for antepartum depression (APD) in the cognitive behavioral intervention (CBI) and treatment-as-usual (TAU) groups (N=146).

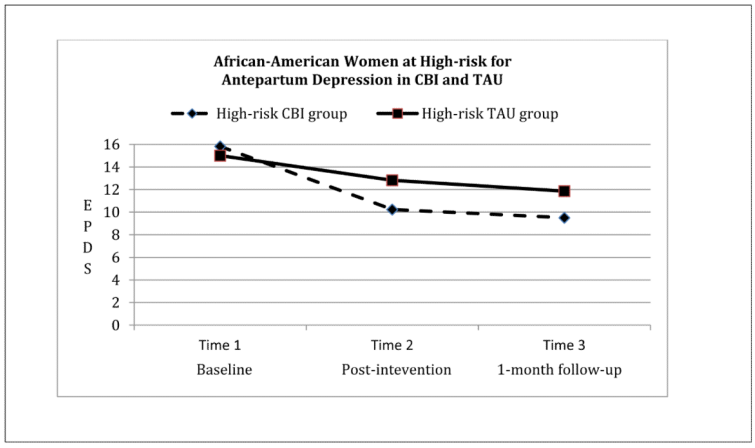


**Figure 3.**

Comparison of Edinburgh Postnatal Depression Scale (EPDS) means over measurement time for African-American Women at high-risk for antepartum depression in the cognitive behavioral intervention (CBI) and treatment-as-usual (TAU) groups (N=43).

**Table 1**

Insight-Plus Culturally Tailored Cognitive Behavioral Intervention

| |
|---|
| Session 1: Introductions, symptoms of depression in pregnancy, goal setting, and distorted thinking |
| Women were given the Insight-Plus Workbook, and the facilitator introduced the program, described group member responsibilities, symptoms of depression in pregnancy, goal setting, distorted thinking, and thoughts, feelings and behaviors. These concepts were reviewed after each session, and homework was assigned. Participants received a brief weekly telephone-based motivational intervention from the resource mom reviewing the homework assignments, for example, writing down goals they wanted to achieve. |
| Session 2: Coping and relaxing |
| Session 2 focused on coping and relaxation, and the women listened to the guided imagery recording. A step by step guide to help with a crisis and crisis resources were included. They were introduced to cognitive distortions and self-monitoring cognitive-behavioral techniques to manage distorted and negative thinking, learning and practicing thought stopping techniques, and increasing positive self-talk and affirmations. Each woman created her own affirmations and wrote these on sticky notes to post around the house and in a spiral bound journal that was provided. Each participant was given an MP-3 player that includes a playlist of homework assignments, to listen at her convenience, such as the guided visualization and relaxation recording and assignment, reviewing distorted thinking, catching automatic negative thoughts (ANTs), and listening to positive affirmations |
| Session 3: Relationships, communication and domestic violence |
| In S3 the facilitator discussed significant other relationships, and domestic violence. They continued to practice relaxation and stress reduction skills and created and used new affirmations to reduce thought distortions and identify significant other relationships. They developed strategies to enhance communication in their support network and all women learned how to create a safety plan. Their homework included relationship evaluation and goals. They were encouraged to invite a significant and safe support person (partner, mother, sibling or other family member, or friend) to participate in a discussion of their progress in Week 4, to have a meal together during part of the session and then review psycho-educational topics and materials on preventing antepartum and postpartum depression, including the signs and symptoms of depression. |
| Session 4: Support person session, signs and symptoms of APD, communication skills, and review |
| In S4, after signing a research/treatment informed consent form, the support persons met to learn more about Insight Plus, signs and symptoms of antepartum depression, communication skills, Cognitive Behavioral Intervention techniques, and problem solving. The group session for the participant's support person, was organized and facilitated by the resource mom and met concurrently with the participants' session facilitated by the social worker. Suggestions were offered on how to elicit open communication in their relationships, what helps women at risk for prenatal depression, and the signs and symptoms for postpartum depression. In the last 40 minutes, the support persons joined the women for shared group activities, including eating a pre-ordered meal together and watching and discussing a DVD on perinatal depression. |
| Session 5: Grief loss, spirituality, and other resources |
| In S5, participants discussed grief and loss, and spirituality. They identified behaviors that reduced depressive symptoms and enhanced relationships, and developed strategies to fight depressive symptoms. They continued the cognitive-behavioral techniques to manage distorted and negative thinking learn and practiced thought stopping techniques, and increased positive self-talk and affirmations. Psycho-educational topics included grieving and the process of healing from a loss and completing a personal loss inventory. Based on suggestions of African-American women in the previous |

| |
|---|
| focus groups, a selection of non-denominational spiritually inspiring literature was included for those who valued spirituality. These resources were also available for women to listen to on their MP3 player and in the workbook to listen to and read at their convenience. |
| Session 6: Signs and symptoms of PPD |
| In S6 participants reviewed the signs and symptoms of postpartum depression and they said goodbye to each other and to the licensed clinical social worker facilitator and resource mom. They reviewed the Insight-Plus techniques and reflected on which have been most helpful for them. They will also reviewed and discussed goals for successfully managing role transitions, with emphasis on motherhood, ways to successfully adapt to their upcoming new role, and signs and symptoms of postpartum depression. |

## Table 2

Baseline Socio-demographic and Clinical Characteristics of Rural Low-Income Pregnant Women Scoring > 4 on the Edinburgh Postnatal Depression Scale (EPDS) in the Insight-Plus Study.

| Characteristics of participants at baseline | Insight-Plus cognitive behavioral intervention N=72 | Treatment-As-Usual N=74 | Total Sample N=146 | *P* Value |
|---|---|---|---|---|
| Maternal age, y, mean (SD) | 24.90 (5.64) | 25.19 (5.37) | 25.05 (5.49) | .74 |
| EPDS score, mean (SD) | 11.17 (4.84) | 9.81 (5.18) | 10.48(5.28) | .12 |
| BDI-II score, mean (SD) | 17.97 (8.53) | 16.46 (9.66) | 17.21 (9.12) | .32 |
| Gravida | | | | .57 |
| Primigravida, n(%) | 24 (33.3) | 25 (33.8) | 49 (33.6) | |
| Multigravida, n(%) | 48 (76.7) | 49 (66.2) | 97 (76.4) | |
| Para | | | | .13 |
| Nulliparous, n(%) | 31 (43.1) | 32 (43.2) | 63 (43.2) | |
| Multiparous, n(%) | 41 (56.9) | 42 (56.8) | 83 (66.8) | |
| Race | | | | |
| African-American, n(%) | 54 (75) | 45 (60.8) | 99 (67.8) | .17 |
| Caucasian, n(%) | 20 (25) | 29 (39.2) | 47 (32.3) | .17 |
| Ethnicity | | | | |
| Hispanic: non-English speaking, n(%) | 1(1.4) | 3 (4.0) | 4 (2.7) | .17 |
| Hispanic: English speaking, n(%) | 5 (6.9) | 8 (10.7) | 13 (8.8) | .42 |
| Highest educational level completed | | | | .13 |
| Less than high school, n(%) | 9 (12.5) | 16 (21.6) | 25 (17.1) | |
| High school or equivalent, n(%) | 25 (34.8) | 16 (21.6) | 41 (28.1) | |
| At least some college, n(%) | 30 (41.7) | 36 (48.6) | 66 (45.2) | |
| College graduate/ advanced degree, n(%) | 8 (11.1) | 6 (8.2%) | 14 (9.6) | |
| Relationship status | | | | .74 |
| Married living with Partner, n(%) | 9 (12.5) | 11 (14.9) | 20 (13.7) | |
| Single living with partner, n(%) | 19 (26.4) | 23 (31.1) | 42 (28.8) | |
| Living alone, n(%) | 44 (61.2) | 40 (54.4) | 84 (57.5) | |
| Employment status | | | | .25 |
| Employed, n(%) | 25 (34.7) | 31 (41.9%) | 56 (38.4) | |
| Unemployed, n(%) | 47 (65.3) | 43 (58.1) | 90 (61.6) | |
| Medical insurance | | | | .32 |
| Medicaid recipient, n(%) | 59 (81.9) | 61 (82.4) | 120 (82.2) | |
| Medicare recipient, n(%) | 4 (5.6) | 3 (4.1) | 7 (4.8) | |

| Characteristics of participants at baseline | Insight-Plus cognitive behavioral intervention N=72 | Treatment-As-Usual N=74 | Total Sample N=146 | *P* Value |
|---|---|---|---|---|
| Veterans insurance, n(%) | 0 (0) | 1 (1.4) | 1 (0.7) | |
| Not insured, n(%)<br>Private, n(%) | 9 (12.5)<br>0 (0.0) | 7 (9.5)<br>2 (2.7) | 16 (11.0)<br>2 (1.4) | |
| WIC[1] recipient, n(%) | 70 (97.2) | 69 (93.2) | 139 (95.2) | .16 |
| Edinburgh Postnatal Depression Scale | | | | .07 |
| EPDS 4-9, n(%) | 27 (37.5) | 39 (52.7) | 66 (45.2) | |
| EPDS ≥ 10, n(%) | 45 (62.5) | 35 (47.3) | 80 (54.8) | |
| Antepartum depression | 13 (18.1) | 10 (13.7) | 23 (15.9) | .32 |
| Depression history, n(%) | | | | |
| History of depression, n(%) | 18 (25.0) | 22 (29.7) | 40 (27.4) | .52 |
| No history of Depression, n(%) | 54 (75.0) | 52 (70.7) | 106 (72.6) | |

[1] *Abbreviation:* WIC = Special Supplemental Nutrition Program for Women, Infants, and Children, 6 were WIC unknown but all had Medicaid

*J Midwifery Womens Health*. Author manuscript; available in PMC 2016 September 01.

**Table 3**

Antepartum Depressive Symptom Means and Change in Means over Time for the Full Sample of Women in the Insight-Plus Cognitive Behavioral Intervention and Treatment-as-Usual (TAU) Groups.

| **Measure and Treatment Condition** | | **Baseline (T1)** | **Post-Intervention (T2)** | **1-month follow-up (T3)** | **Change from T1-T2** | | **Change from T1-T3** | |
|---|---|---|---|---|---|---|---|---|
| | **n** | **M (SEM)** | **M (SEM)** | **M (SEM)** | **M (SEM)** | ***P*** | **M (SEM)** | ***P* Value** |
| **Low-moderate risk for antepartum depression** | | | | | | | | |
| **EPDS** | | | | | | | | |
| Cognitive behavioral Intervention | 12 | 5.42 (0.56) | 4.75 (0.85) | 3.08 (0.73) | 0.67 (1.09) | | 2.33 (1.10) | |
| Treatment-as-Usual | 37 | 5.81 (0.34) | 5.89(0.58) | 4.68 (0.54) | −0.08 (0.56) | .524 | 1.14 (0.58) | .320 |
| **BDI-II** | | | | | | | | |
| Cognitive behavioral Intervention | 12 | 12.25 (1.48) | 7.25 (1.31) | 6.58 (1.20) | 4.92 (1.49) | | 5.67 (1.86) | |
| Treatment- as-Usual | 37 | 10.51 (0.63) | 9.93 (0.72) | 9.00 (0.91) | .59 (.80) | .018 | 1.51 (.95) | .041 |
| **High-risk for antepartum depression** | | | | | | | | |
| **EPDS** | | | | | | | | |
| Cognitive behavioral Intervention | 27 | 15.19 (0.69) | 10.33 (0.82) | 9.37 (1.07) | 4.85 (0.85) | | 5.81 (1.07) | |
| Treatment-as-Usual | 35 | 14.27 (0.62) | 11.45 (0.84) | 10.63 (0.98) | 2.84 (0.77) | .085 | 3.66 (0.83) | .110 |
| **BDI-II** | | | | | | | | |
| Cognitive behavioral Intervention | 27 | 23.48 (1.51) | 16.93 (1.56) | 16.22 (2.02) | 6.56 (1.69) | | 7.26 (2.08) | |
| Treatment-as Usual | 35 | 23.57 (1.53) | 19.69 (1.49) | 17.15 (1.77) | 3.88 (0.93) | .148 | 6.42 (1.03) | .701 |

*Abbreviations:* EPDS, Edinburgh Postnatal Depression Scale; BDI-II, Beck Depression Inventory-II (BDI-II)

*J Midwifery Womens Health*. Author manuscript; available in PMC 2016 September 01.

**Table 4**

Antepartum depressive Symptom Means and Change in Means Over Time for the African-American Subsample of Women in the Insight-Plus Cognitive Behavioral Intervention and Treatment-as-Usual (TAU) Groups.

| | | Time | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **Measure and Treatment condition** | | **Baseline (T1)** | **Post-Intervention (T2)** | **1-month follow-up (T3)** | **Change from T1-T2** | | **Change from T1-T3** | |
| | **n** | **M (SEM)** | **M (SEM)** | **M (SEM)** | **M (SEM)** | ***P*** | **M (SEM)** | ***P* Value** |
| **African-American women at low-moderate risk for antepartum depression** | | | | | | | | |
| **EPDS** | | | | | | | | |
| Cognitive-Behavioral Intervention | 10 | 6.0 (0.47) | 5.2 (0.95) | 3.0 (0.86) | 0.8 (1.31) | | 3.0 (1.18) | |
| Treatment-as-usual | 24 | 6.08 (0.34) | 6.53 (0.73) | 4.58 (0.73) | −.45 (0.68) | .361 | 1.5 (0.68) | .255 |
| **BDI-II** | | | | | | | | |
| Cognitive-Behavioral Intervention | 10 | 12.8 (1.53) | 7.6 (1.47) | 6.7 (1.32) | 5.2 (1.20) | | 6.1 (1.72) | |
| Treatment-as-usual | 24 | 11.25 (0.76) | 10.55 (0.96) | 9.67 (1.27) | .7 (1.11) | .023 | 1.58 (1.32) | .062 |
| **African-American women at high-risk for antepartum depression** | | | | | | | | |
| **EPDS** | | | | | | | | |
| Cognitive-behavioral Intervention | 22 | 15.82 (0.76) | 10.23 (0.96) | 9.5 (1.08) | 5.59 (0.90) | | 6.32 (1.06) | |
| Treatment- as-Usual | 21 | 15 (0.77) | 12.82 (1.06) | 11.86 (1.20) | 2.18 (1.04) | .017 | 3.14 (1.01) | .037 |
| **BDI-II** | | | | | | | | |
| Cognitive-behavioral Intervention | 22 | 24 (1.74) | 17.09 (1.72) | 16 (2.20) | 6.91 (1.76) | | 8 (2.17) | |
| Treatment-as-Usual | 21 | 25.48 (1.65) | 21.83 (1.45) | 19.34 (1.91) | 3.64 (1.27) | .143 | 6.13 (1.13) | .457 |

*Abbreviations:* EPDS, Edinburgh Postnatal Depression Scale; BDI-II, Beck Depression Inventory-II (BDI-II).