

## Research Article

# A PILOT RANDOMIZED CONTROLLED TRIAL OF COGNITIVE BEHAVIORAL THERAPY FOR PERINATAL DEPRESSION ADAPTED FOR WOMEN WITH LOW INCOMES

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**Background:** *Perinatal women with identified depression in prenatal care settings have low rates of engagement and adherence with depression-specific psychotherapy. We report the feasibility and symptom outcomes of Cognitive Behavioral Therapy (CBT) modified (mCBT) to address the needs of perinatal, low-income women with Major Depressive Disorder (MDD). Methods:* Pregnant women ( $n = 1421$ ) were screened for depressive symptoms in obstetrics clinics in conjunction with prenatal care visits. A total of 59 women met diagnostic criteria for MDD; 55 women were randomly assigned to mCBT or Treatment as Usual (TAU). The mCBT intervention included an initial engagement session, outreach, specific perinatal content and interpersonal components. Measures were gathered at pre-treatment, 16 week post-randomization, and 3-month follow-up. **Results:** Most participants attended at least one CBT session and met study criteria for treatment adherence. Active research staff outreach promoted engagement and retention in the trial. Treatment satisfaction was rated as very good. In both observed and multiple imputation results, women who received mCBT demonstrated greater improvement in depressed mood than those in TAU at 16-week post-randomization and 3-month follow-up, Cohen's  $d = -0.71$  (95% CI  $-4.93, -5.70$ ). **Conclusions:** Modified CBT offers promise as a feasible and acceptable treatment for perinatal women with low-incomes in prenatal care settings. Targeted delivery and content modifications are needed to engage populations tailored to setting and psychosocial challenges specific to the perinatal period. *Depression and Anxiety* 30:679–687, 2013. © 2013 Wiley Periodicals, Inc.

**Key words:** *CBT/cognitive behavior therapy; depression; pregnancy and postpartum; treatment; maternal-child; primary care, behavioral activation, behavior therapy*

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## INTRODUCTION

Depression during the perinatal period is a significant public health problem. Rates of depression peak during the childbearing years. Approximately, 12.8% of women will suffer from depression prenatally, 9.9% postnatally.<sup>[1,2]</sup> The impact of perinatal depression is substantial, affecting both mother and child.<sup>[3,4]</sup> Despite

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this impact, less than half of women suffering from perinatal depression will receive mental health treatment.<sup>[5]</sup> Low-income women are particularly unlikely to receive treatment<sup>[6]</sup> despite their higher rates of depression.<sup>[7]</sup> Among perinatal women, this disparity is troubling given that a low-income status intensifies the negative effects of maternal depression on child outcomes.<sup>[8,9]</sup> There is consequently a significant need to improve access to effective and acceptable interventions for perinatal depression, especially for low-income women.

Cognitive behavioral therapy (CBT) is an empirically supported treatment for major depressive disorder (MDD). In meta-analyses, it has a moderate between-group effect sizes (CBT: effect size = 0.68<sup>[10]</sup>). However, CBT for perinatal depression has a small effect size (effect size = 0.36;<sup>[10]</sup> effect size = 0.40<sup>[11]</sup>), and its uptake among women with low incomes has been low,<sup>[12]</sup> suggesting further development and research of CBT for low-income women with perinatal depression is needed.

Effect sizes for CBT during the perinatal period may be due to variation in the content and purity of the intervention, study population, and women's access to treatment. To date, 10 trials of individual CBT for perinatal depression have been conducted. Two of these targeted perinatal women with low incomes.<sup>[12,13]</sup> Of these, one study found a reduction in depressive symptoms in women who received a CBT-oriented treatment compared with a nonrandomized comparison group.<sup>[13]</sup> The other, a randomized controlled trial (RCT) of a multicomponent treatment that included CBT, had low rates of adherence, and failed to find statistically significant differences in outcomes between women in the CBT and control groups.<sup>[12]</sup> Other trials were of brief CBT (one to six sessions<sup>[14-16]</sup>), CBT informed strategies provided in combination with other approaches (e.g., psychodynamic;<sup>[17]</sup> pharmacological<sup>[18]</sup>), and trials that did not define depression in terms of clinical diagnostic criteria.<sup>[16,19,20]</sup>

Two recent RCTs have found that group CBT can be effectively delivered to racial minority or low-income women at risk for perinatal depression who do not meet current diagnostic criteria for MDD.<sup>[21,22]</sup> However, there is little research providing a comprehensive test of the feasibility and acceptability of a CBT intervention that is consistent with the essential components of CBT, modified for the perinatal period, and delivered to low-income women who are *currently* clinically depressed.

### TREATMENT MODIFICATIONS: WHAT IS NEEDED?

A growing body of research suggests that delivery modifications are needed to improve treatment utilization among depressed women with low incomes. Psychological interventions for MDD that have failed to address both the practical and psychological barriers that women with low incomes faced had low rates of adherence (7–57%<sup>[12,23]</sup>). In contrast, studies that provided a broader range of support reported adherence rates

between 68 and 77%.<sup>[23,24]</sup> Women with low incomes struggle with practical and psychological factors that may negatively impact on their ability to seek treatment (e.g., multiple jobs, exclusive caregiving of child(ren), and stigma related to depression and income level).<sup>[6,25,26]</sup> During the perinatal period, these factors interact with perinatal specific treatment barriers that span psychological, practical, and logistical arenas (e.g., lack of time, fear of child being taken away).<sup>[3,27,28]</sup> Addressing these factors in treatment delivery may be key to improving the feasibility and acceptability of treatment for perinatal depression.

The current study was a pilot RCT of individual CBT modified for delivery to a racially diverse, primarily low-income sample of clinically depressed perinatal women (mCBT) seeking prenatal care in obstetrics (OBs) clinics. We aimed to examine the preliminary feasibility and effectiveness of mCBT compared with treatment as usual (TAU). Because adherence and acceptability are important factors in low-income populations, we also examined demographic and psychological factors affecting the feasibility of mCBT.

## METHOD

### PROCEDURES

All procedures were approved by the University of Michigan Medical School Institutional Review Board. Participants were 55 pregnant women with MDD recruited in OBs clinic settings who were randomly assigned to mCBT ( $n = 30$ ) or TAU ( $n = 25$ ). Since the perinatal period can be unpredictable and busy, we sought to improve adherence to the treatment by recruiting women in the latter stages of pregnancy when prenatal care visits are more frequent, and continuing treatment delivery during the postpartum period. Postpartum, the treatment schedule followed OB appointments wherever possible in order to better connect mental health to OB care. Inclusion criteria were as follows: age 18 or older, 24 or more weeks pregnant, not currently receiving any treatment for depression, and meeting Diagnostic and Statistical Manual – IV (DSM-IV) criteria for MDD. Once randomized, use of other treatments was allowed to vary per usual practice. Women were excluded if they did not speak English, did not plan to return to the clinic for additional care (e.g., moving out of the area), suffered from a cognitive disability or any psychotic disorder, or met criteria for current alcohol/drug abuse or dependence.

We maximized recruitment of women with low incomes by recruiting from five OBs clinics, four of which primarily serve women of low income. Three of the clinics were part of a nonprofit organization focused on treating underserved populations in urban settings. The other two clinic sites were affiliated with a university hospital system, one provided care primarily for women with Medicaid. Research assistants approached women in clinic waiting rooms, and administered the Edinburgh Postnatal Depression scale (EPDS<sup>[29]</sup>) to pregnant women, who gave written consent. Women meeting inclusion criteria were invited to participate in a clinical interview that included a diagnostic assessment for MDD. Women meeting criteria for MDD were randomly assigned to treatment (mCBT) or TAU (see Fig. 1).

### TREATMENTS

The mCBT intervention consisted of up to twelve 50-min individual sessions of CBT, adapted for the perinatal period. The delivery methods and content of CBT were modified based on the results, a

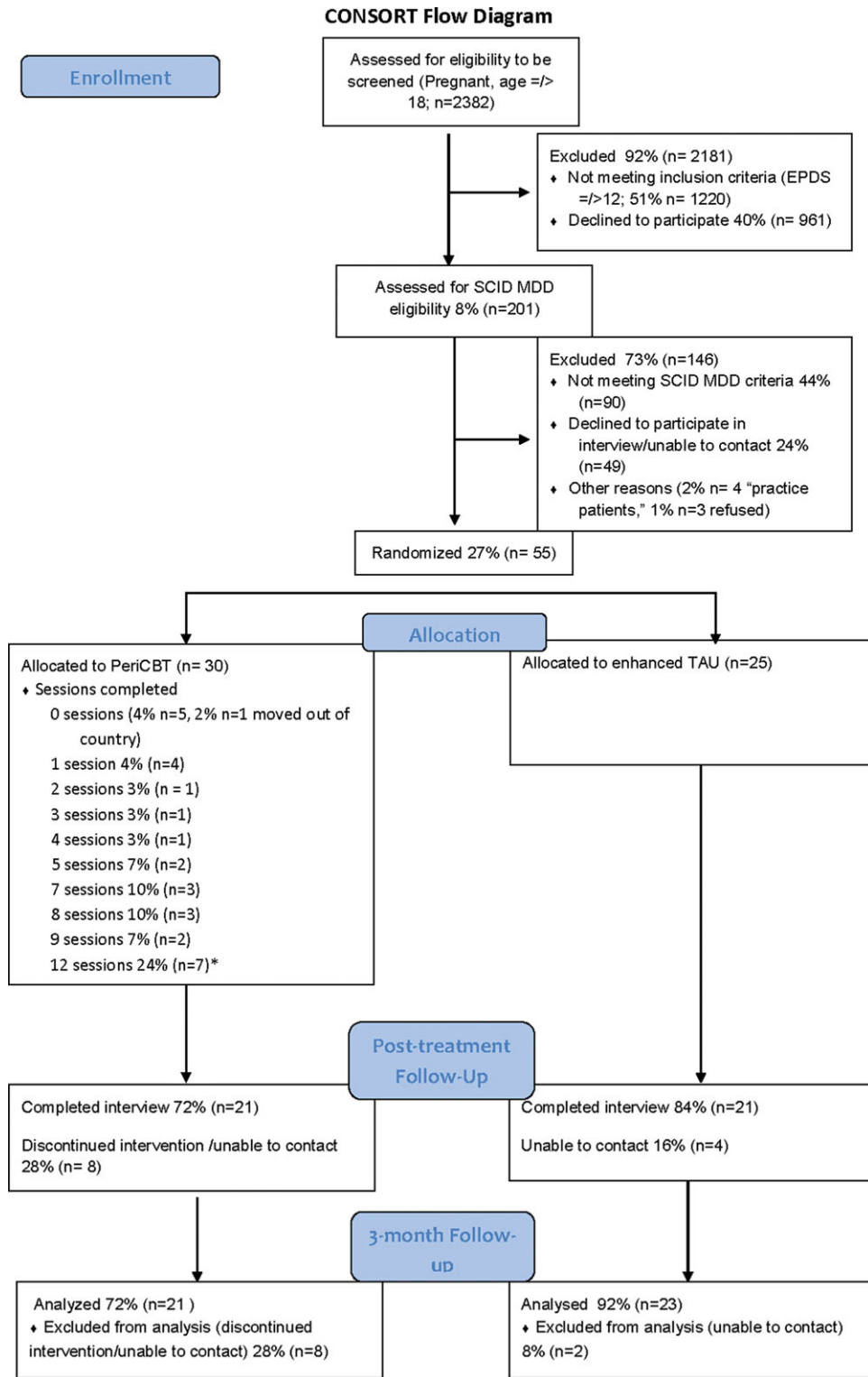


Figure 1. Consort Flow Diagram

Phase I Medical Research Council (MRC)<sup>[30]</sup> qualitative study we conducted with 22 purposively sampled perinatal women.<sup>[31,32]</sup> Women indicated they preferred to have the delivery modality (e.g., home, clinic-based) and treatment content individualized for their particular needs and stage of pregnancy (pregnant or postpartum; O'Mahen<sup>[32]</sup>). The mCBT treatment manual was piloted with 11 perinatal women (not included in the present analyses) and further refined by masters and doctoral level clinical psychologists and social workers with expertise in CBT and perinatal depression.

The final mCBT included an initial engagement session, which integrated Motivational Interviewing (MI),<sup>[33,34]</sup> and three treatment modules: Behavioral Activation<sup>[35]</sup> (BA), Cognitive Restructuring (CR), Interpersonal Support (IS). The first (engagement) session consisted of: (1) an initial perinatal specific assessment; (2) CBT conceptualization tailored to the woman's individual treatment goals; (3) psychoeducation about perinatal depression and psychotherapy; and (4) engagement strategies to identify and alleviate potential psychological and practical barriers. Throughout the engagement session, MI was used at any point in the interaction that pertained to behavior change, including ambivalence or motivation about behavior change. Consistent with previous CBT recommendations,<sup>[36]</sup> women proceeded to the BA module. Specific BA techniques included the use of a functional analytical approach to develop an understanding of behaviors that interfere with meaningful, goal-oriented behaviors and included self-monitoring, identifying "depressed behaviors," developing alternative goal-oriented behaviors, and scheduling. Because mothers in the Phase I research described difficulties with balancing activities, rather than inactivation per se, the treatment focused on helping mothers achieve a balance in valued activities. Based on their perinatal case conceptualization, women struggling with depressive cognitions or interpersonal difficulties as core problem areas also completed the CR module, modified to focus on perinatal specific cognitions (e.g., rigid motherhood beliefs<sup>[32]</sup>) and/or the IS module. The IS module conceptualized interpersonal problems in a functional analytical framework consistent with CBT. The therapist worked with the client to develop alternative interpersonal behaviors. The mCBT manual also included an appendix with perinatal specific materials and skills (e.g., labor and delivery, sleep) that could be used as tools to support the work in the other modules. Each week women were asked to complete either written or verbally agreed treatment exercises in-between sessions.

We employed an active outreach strategy for women who cancelled or missed therapy appointments. Therapists were encouraged to make multiple phone calls, send letters, and visit women to improve adherence. Because many of the women in our trial were in unstable living situations, participants were asked to provide two additional contacts with permission to contact these individuals should the woman be unreachable.

Masters and doctoral level social workers and psychologists ( $n = 4$ ) with experience in CBT and/or treatment for perinatal depression were trained to deliver the mCBT intervention to competence. Training consisted of: reading the mCBT manual, review and training in key concepts with either the Principal Investigator or Clinical Supervisor and coinvestigator, and completion of an initial participant under close supervision. Therapist competence was assessed with the Revised Cognitive Therapy Scale (CTS-R<sup>[37]</sup>). A randomly selected 10% of audiotaped cases were monitored for adherence to the treatment by the clinical supervisor. Issues of nonadherence to mCBT were addressed in weekly clinical supervision (e.g., therapists were advised how to refocus treatment to mCBT).

## TREATMENT AS USUAL

Following the regular care that occurred in all clinics, women allocated to TAU, and those women who did not meet criteria for the

trial, were given feedback about their depression status from an on-site social worker, psychoeducational materials about perinatal depression, and local referral information about psychotherapy and case management. They continued to receive midwife/obstetrical care as normal. Risk was assessed at each interview point. If a woman was identified as being at risk for suicide, University of Michigan risk procedures were followed.

## MEASURES

At enrollment women were screened for symptoms of depression. Eligible women completed additional measures at the baseline clinical interview (when randomization occurred), posttreatment (16 weeks postrandomization), and at 3-month follow-up posttreatment. The baseline and follow-up assessments were carried out by a researcher blind to treatment status (see consort diagram in Fig. 1).

**Depression.** We used the EPDS,<sup>[29]</sup> a 10-item scale, to screen for depression.<sup>[38]</sup> We used a cut-off of 12 or greater for detecting depression.<sup>[39]</sup>

Diagnostic status was assessed with the Structured Clinical Interview for DSM-IV Axis I Disorders—Patient Edition (SCID-I<sup>[40]</sup>).

The Beck Depression Inventory-II (BDI-II<sup>[41]</sup>) is a reliable measure of mood with perinatal populations<sup>[42]</sup> and is frequently used in CBT trials.<sup>[10]</sup> Continuous scores on the BDI-II were used as the primary outcome measure.

**Adherence.** A measure of adherence (telephone calls, completion of homework) was completed at each session.<sup>[24]</sup> Clients completed open-ended questions assessing the applicability of mCBT, barriers to mCBT participation, and satisfaction with mCBT (percent scale 0–100). Women who dropped out from mCBT were asked to complete an open-ended interview asking about their reasons for disengaging. Responses were content coded.

**Barriers.** We assessed practical, logistical, and psychological barriers to help seeking using a 25-item measure<sup>[27]</sup> with a 5-point Likert scale ("not at all" to "completely").

**Activation.** We used the 25-item BA for depression scale (BADS<sup>[43]</sup>) scale ( $\alpha = 0.82$ ) to assess activation and avoidance behaviors which may impact engagement, adherence, and outcome. The BADS has four subscales, Activation ( $\alpha = 0.76$ ), Avoidance/Rumination ( $\alpha = 0.86$ ), Work/School Impairment ( $\alpha = 0.70$ ), and Social Impairment ( $\alpha = 0.79$ )<sup>[43,44]</sup> Higher scores are indicative of greater activation.

**Sample Size.** We calculated the minimum sample size to detect a clinically meaningful difference in depressive symptoms (BDI) as significant at the 0.05 level, with a power of 0.8,  $n = 2(0.84 + 1.96)^2 \times (\sigma/\delta)$ . Based on previous published data (BDI = 23,  $\sigma = 8.09$ <sup>[45]</sup>), a difference ( $\delta$ ) of 6.5 points would take BDI scores below Dozoi et al.<sup>[46]</sup> cut-off of 17 on the BDI. The sample size required per condition therefore was  $n = 15.7(8.09/6.5)^2 = 24.3$ . We therefore aimed to recruit at least 48 women into the trial.

## RANDOMIZATION

A statistician computer generated random assignment block was used. Interviewers were provided with an opaque, sealed envelope that contained information about which condition the participant would be assigned to. At the conclusion of the assessment, if the participant met the inclusion criteria for the study, the interviewer opened the envelope and revealed its information to the participant and interviewer.

## STATISTICAL ANALYSIS

The mCBT and TAU conditions were compared on the baseline measures at preintervention using Chi-square, Pearson correlations, and *t*-test analyses on categorical and continuous measures. Chi-square analyses were conducted to test for bias due to attrition. Intent-to-treat analyses were first conducted with observed data, then using

**TABLE 1. Demographics and clinical characteristics of participants at baseline**

	mCBT <i>n</i> = 30	TAU <i>n</i> = 25
Age		
<i>m</i> ( <i>SD</i> )	27.40 (5.32)	26.62 (6.01)
Range	19–39	18–43
Weeks pregnant	30.9 (4.16)	30.9 (3.62)
Number of pregnancies	3.5 (2.22)	4.04 (1.90)
Relationship status		
Partnered % ( <i>n</i> )	70.0(21)	64.0 (16)
Married	36.7(11)	24.0(6)
Cohabiting	26.7(8)	24.0(6)
Not living together	6.7(2)	8.0(2)
Race		
African American	53.3 (16)	64.0 (16)
White	33.3 (10)	28.0 (7)
Asian	10.0 (3)	4.0 (1)
Other	3.3 (1)	4.0 (1)
Educational level		
Below high school	23.3 (7)	24.0 (6)
High school	23.3 (7)	36.0 (9)
Some college	16.7 (5)	24.0 (6)
College graduate	23.3 (7)	8.0 (2)
Beyond college	13.3 (4)	8.0 (2)
Currently employed for pay	13.3 (4)	16.0 (4)
Health insurance	96.7 (29)	100.0 (25)
Private	43.4 (13)	44.0 (11)
Medicaid	56.6 (17)	56.0 (14)
Comorbid conditions		
Panic disorder %( <i>n</i> )	16.7(5)	0(0)
Social phobia	10(3)	16(4)
Specific phobia	6.7(2)	4(1)
Obsessive compulsive disorder	10(3)	0(0)
Generalized anxiety disorder	10(3)	12(3)
Posttraumatic stress disorder	16(4)	12(3)
Income bracket % ( <i>n</i> ) (US \$) <sup>a</sup>	( <i>n</i> = 29)	( <i>n</i> = 22)
<10,000	13.7 (4)	18.1 (4)
10,000–19,999	44.8 (13)	59.0 (13)
20,000–39,999	17.2 (5)	9.0 (2)
40,000–59,999	10.3 (3)	4.5 (1)
60,000–79,999	6.9 (2)	9.0 (2)
≥80,000	6.9 (2)	n/a

mCBT, cognitive behavioral therapy modified; TAU, treatment as usual.

<sup>a</sup>A subsample of women declined to respond to the family income question.

multiple imputation by chained equations, using 50 imputations.<sup>[47]</sup> The effects of study condition on posttest outcome measures were examined using repeated measures Analysis of Covariance (ANCOVA). Predictors of feasibility and acceptability were analyzed with correlation, *t*-tests, and multiple regression. Alpha level was set to *P* < .05 for all tests. Cohen’s *d* based on pooled standard deviations was used to calculate effect sizes. We used Jacobson and Truax’s<sup>[48]</sup> procedures for calculating reliable and clinically significant change to quantify clinical improvement in depressive symptoms on the BDI-II. Because multiple imputation methods do not supply individual participant-level data, we report last observation carried forward (LOCF) analyses as it is likely to be a conservative analysis.<sup>[49]</sup>

## RESULTS

### BASELINE CHARACTERISTICS

Figure 1 describes the flow of women through the trial. Table 1 shows the baseline characteristics of women in the trial, including racial minority representation (African American 58%, *n* = 32/55) and anxiety comorbidity in the sample (44%, *n* = 24/55). There were no significant demographic or depression score differences between groups in the mCBT versus TAU groups. Because the BADS subscale work/school impairment was positively correlated with posttreatment (16-week post-randomization) BDI-II scores, *r*(45) = .49, *P* = .05, it was controlled for in primary analyses of depression outcomes (SCID and BDI-II).<sup>[50]</sup> There were no other significant relationships between any of the demographic variables and 16-week postrandomization BDI-II scores or SCID MDD outcomes. There were significant between-group differences in attrition,  $\chi^2$  (1) = 13.19, *P* = .001. A lower percent of individuals completed the 16-week postrandomization questionnaires in the mCBT group (70%, *n* = 21/30) than in the control group (84%, *n* = 21/25).

### FEASIBILITY

**Engagement and Adherence.** In the treatment group, 83% (*n* = 25/30) of women attended the first session; 72% engaged with the treatment, defined as attending the second session. Women who were more functionally impaired in work and social domains, *t* (29) = 11.86, *P* = .002, and had higher EPDS scores at screening, *t* (29) = 4.53, *P* = .04, were less likely to attend the first session. There were no demographic or psychological factors (avoidance, barriers) associated with treatment engagement.

Figure 1 shows the number of sessions attended. Women received an average of 2.30 (*SD* = 2.16) sessions during pregnancy, and 5.35 (*SD* = 4.07) postpartum. In TAU five women (17%) received psychotherapy (*m* = 3.66, *SD* = 1.88). Seventy-three percent of sessions were conducted in the participants’ homes, 12% in the therapist’s office, 8% in the OB clinic, 6% over the phone, and 1% at a different location (e.g., homeless shelter). Therapists called women approximately three (*SD* = 2.34, range 0–9) times between each scheduled therapy contact, and sessions were rescheduled on an average of three times (*SD* = 1.11, range = 0–4). Sixty percent of women (*n* = 18/30) were adherent with the treatment, defined as completing four or more (30%) sessions, a number associated with improved symptoms and functioning.<sup>[21,50,51]</sup> 43% (*n* = 13/30) completed seven or more sessions. Women who were adherent had lower 16-week postrandomization BDI-II scores, *F*(29) = –7.14, *P* = .008. There were no demographic or psychological variables (barriers, avoidance) associated with adherence. Barriers to therapy adherence included struggling with the care demands of a new baby, child illnesses,

TABLE 2. Mean depression scores and frequency of cases above depression (BDI-II) threshold

	Baseline		Posttreatment <sup>a</sup> (16 weeks postrandomization)		3 months posttreatment	
	Intervention	TAU	Intervention	TAU	Intervention	TAU
Depression						
Mean BDI-II	29.93 (9.66)	26.56 (6.52)	15.85 (7.84)	22.24 (12.67)	14.54 (9.86)	19.71 (13.81)
Imputed scores	n/a	n/a	15.19 (2.12)	23.39 (2.31)	14.20 (2.20)	21.47 (2.40)
BDI-II $\geq$ 14	29 (96.7%)	25 (100%)	9 (65%)	15 (60%)	8 (44.4%)	14 (68.3%)
Imputed scores	n/a	n/a	15 (50%)	15 (60%)	15 (50%)	14 (56.7%)
BADS	70.65(22.22)	71.81(21.11)	88.63 (23.75)	81.09 (20.02) <sup>a</sup>	n/a	n/a <sup>b</sup>

BDI-II, Beck Depression Inventory-II; BADS, behavioral activation for depression scale; TAU, treatment as usual.

<sup>a</sup>Pre-post between-group differences on the BADS for completers were  $F(1, 38) = 1.54, P = .22$ , multiple imputation,  $F(1, 51) = 9.85, P = .02$ .

<sup>b</sup>Data on the BADS at 3 months was not available.

pregnancy-related pain, and housing concerns, and lacking a private, safe home in which to meet.

**Treatment Applicability and Satisfaction.** Women reported high levels of content applicability in session-by-session assessments of mCBT content ( $m = 2.92, SD = 0.67$ , range 1.67–4.00). They also reported high rates of treatment satisfaction, ( $m = 3.20, SD = 0.70$ , range 0.67–4.00). Satisfaction was correlated with the applicability of the material,  $r(28) = .80, P = .001$ . After controlling for mood at baseline, treatment applicability was not related with mood at posttreatment,  $r(18) = .09, P = .78$ , but greater treatment satisfaction was negatively correlated with EPDS scores,  $r(18) = .54, P = .03$ .

**Treatment Nonadherence.** Of the 12 women who were nonadherent with mCBT, seven (58%) completed a disengagement interview. Women's reasons for nonadherence included the following: not liking the session-by-session questionnaires, wanting more practical advice from the therapist, feeling doubtful that the therapist could "help with my past," not having time, difficulties prioritizing self over family, and childcare difficulties.

## SYMPTOM REDUCTION

Table 2 reports the means and standard deviation mood scores for women in the control and mCBT groups. A repeated-measures ANCOVA observed analysis with BDI-II score at 16-week postrandomization and 3-month follow-up as the repeated measure revealed that, after controlling for baseline depression (BDI-II) and BADS work/school avoidance, women in mCBT had a greater decrease in their depressive symptoms than women in the control group at 16-week postrandomization and 3-month follow-up,  $F(1, 32) = 6.27, P = .02$  (see Fig. 2). Mean differences were greater at 16-week postrandomization,  $-7.7$ , Cohen's  $d = -0.71$  (95% CI  $-4.93, -5.70$ ) than at 3-month follow-up,  $-5.17$ , Cohen's  $d = -0.44$  (95% CI  $-4.65, 5.21$ ). These results were replicated in multiple imputation analyses,  $F(1, 51) = 6.94, P = .01$ . Mean differences favored mCBT over TAU at 16-week postrandomization =  $-4.54$ , Cohen's

$d = -3.79$  (95% CI  $-4.70, 2.80$ ), and at 3-month follow-up =  $-7.27$ , Cohen's  $d = -3.23$  (95% CI  $-4.12, 2.24$ ).<sup>1</sup>

At posttreatment (16 weeks postrandomization), observed analyses indicated there was no difference between the mCBT ( $n = 4/30, 13.3\%$ ) and TAU ( $n = 1/25, 4\%$ ) groups on reliable and clinically significant change (OR = 6.40, 95% CI: 0.65, 62.84). In LOCF analyses, more women in the mCBT ( $n = 8/29, 27.58\%$ ) experienced reliable and clinically significant change than women in TAU ( $n = 1/25, 4\%$ ), (OR = 8.60, 95% CI 0.91, 10.460).

## DISCUSSION

In this pilot RCT, we found that individual CBT adapted for the perinatal period offered promise as a feasible and effective intervention in a sample of mainly low-income women with MDD. Our treatment adherence rates (attending four or more sessions<sup>[50,51]</sup>) were similar to other trials with depressed low-income women defined by Levy and O'Hara as having "better" adherence. Although treatment adherence was related with a greater reduction in depression scores, larger trials are needed to delineate the minimum number of sessions needed to detect treatment effects. This is particularly important when working with difficult-to-engage populations where the expenses of outreach efforts are weighed against number of treatment sessions and their therapeutic effect.

Similar to other studies with low-income women,<sup>[6,24]</sup> we found that intensive outreach efforts and the ability to deliver treatments in flexible times and locations were critical to keeping women involved with mCBT. Our outreach efforts included an initial engagement session, multiple reminder phone calls, flexible appointment rescheduling, and maintaining positive working

<sup>1</sup>We conducted similar analyses after removing the somatic items from the BDI. The completer results were  $F(1,32) = 6.78, P = .01$ ; multiple imputation analyses were  $F(1, 51) = 6.91, P < .01$ . In analyses not adjusting for the BADs work/school avoidance subscale, completer analyses were  $F(1,32) = 2.86, P = .08$ , multiple imputation analyses were  $F(1, 51) = 5.08, P = .03$ .

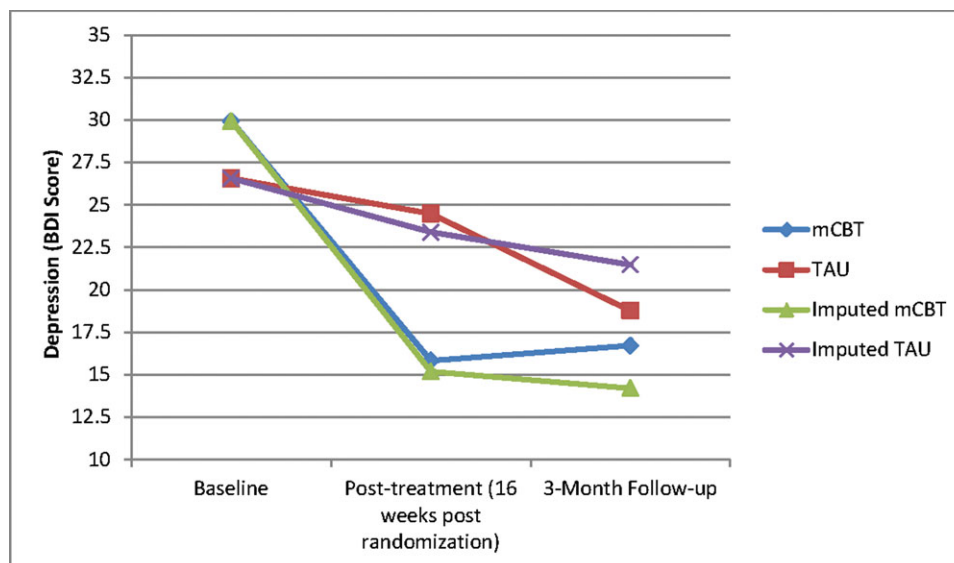


Figure 2. Between-group change in depression score across posttreatment (16-week postrandomization) and 3-month follow-up.

relationships with other care providers and family members who supported women's involvement with the trial. Despite these efforts, five women did not attend the first therapy/engagement session, and these women also did not complete the outcome assessments. We observed that these women had particular concerns around child protection and stigma. The remaining attended an average of 7 of 12 therapy sessions. This finding suggests that once women attend one session, they may be likely to remain engaged with continuing outreach efforts. Thus, although our overall rates of recruitment and attrition to the treatment were comparable to other depression treatment trials with low-income populations, more work is needed on outreach methods to engage women experiencing complex life circumstances, stigma, and overall service disengagement.

The extent to which similar outreach efforts are sustainable within health-care systems should be addressed in future studies. Notably, women in this study reported high rates of session-by-session satisfaction with mCBT. Satisfaction was associated with the perceived applicability of mCBT to their lives and to improvements in depression scores, suggesting mCBT was an acceptable intervention. Embedding mCBT in settings outside of specialty care (such as prenatal care settings) appears promising, but this approach also requires mental health providers available in the setting to provide treatment in a flexible fashion that meets with the changing schedules of women with high levels of social and economic stress. Further, treatment adherence may be improved by offering practical incentives for treatment adherence (e.g., food pantries, diapers, and linking treatment with case management services). The efforts involved in treating mothers with low-income may be offset by the public health costs associated with their untreated depression.<sup>[6]</sup>

Consistent with epidemiological studies of depression across the perinatal period, depression improved in all women. In both observed and multiple imputation analyses, however, depression scores improved more in women who received mCBT compared with those in the TAU group, and these effects were sustained at 3-month follow-up (effect size = 0.61). These results were clinically and reliably significant in LOCF analyses, although not significant in observed analyses. However, this was a small pilot trial, and the variability in the observed results indicates caution in interpreting the results.<sup>[52]</sup>

In sum, the results of this study suggest that mCBT is a feasible, acceptable treatment for low-income, racial minority women suffering from SCID diagnostic MDD identified in prenatal care settings.

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