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Effects of an Intensive Depression-Focused Intervention for Smoking Cessation in Pregnancy

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Abstract

Objective—The objective of this study was to evaluate a depression-focused treatment for smoking cessation in pregnant women, versus a time and contact health education control. We hypothesized that the depression-focused treatment would lead to improved abstinence and reduced depressive symptoms among women with high levels of depressive symptomatology. No significant main effects of treatment were hypothesized.

Method—Pregnant smokers ($N=257$) were randomly assigned to a 10-week intensive depression-focused intervention (Cognitive Behavioral Analysis System of Psychotherapy-CBASP) or to a time and contact control focused on health and wellness (HW); both included equivalent amounts of behavioral and motivational smoking cessation counseling. Fifty-four percent of the sample was African American; 37% met DSM-IV criteria for major depression; mean age (SD) was 25 (5.9) and women averaged 19.5 (8.5) weeks gestation at study entry. Ongoing symptoms of depression were measured using the Center for Epidemiological Studies Depression scale (CES-D).

Results—The results showed that at 6-months posttreatment, women with higher levels of baseline depressive symptoms treated with CBASP had a higher probability of prolonged abstinence ($F(1,253)=5.61, p=.02$) and more improved depression ($F(1,2620)=10.49, p=.001$) than those treated with HW, whereas those with low baseline depression fared better in HW. The differences in abstinence were not retained at 6-months postpartum.

Conclusions—The results suggest that pregnant women with high levels of depressive symptoms may benefit from a depression-focused treatment in terms of improved abstinence and depressive symptoms, both of which could have a combined positive effect on maternal and child health.

Keywords

smoking cessation; depression; cognitive behavioral therapy; women; pregnancy

Recent data (CDC, 2006) reports an overall smoking rate of 11%–12% among women during pregnancy. Low socioeconomic status (SES) and depression have been found to be independent risk factors for continued smoking during pregnancy (Solomon & Quinn, 2004) (Ludman et al., 2000; Pritchard, 1994; Solomon et al., 2006; Zhu & Valbo, 2002) as well as post-partum relapse (Solomon et al., 2007). There is evidence that depression clusters with SES and other risk factors for persistent smoking during pregnancy, and that the clustering of such factors predicts smoking in a gradient fashion (Kahn, Certain, & Whitaker, 2002). That depression co-occurs with low SES is not surprising. Children who grow up with low SES parents are at two to three times greater risk for developing major depressive disorder (MDD) than those who grow up with parents of higher SES, even when parental MDD status is controlled (Ritscher, Warner, Johnson, & Dohrenwend, 2001; Gilman, Kawachi, Fitzmaurice, & Buka, 2002). Because persistent smoking during pregnancy is increasingly concentrated among low SES women, it might be assumed that the prevalence of MDD and depressive symptoms would be high in pregnant smokers. Evidence for this prediction comes from studies utilizing both epidemiological and clinical samples. In nationally representative samples of pregnant women, rates of depressive disorders have been estimated to be 11.4% in current tobacco users without nicotine dependence and 41% in women with DSM-IV nicotine dependence (Goodwin, Keyes, & Simuro, 2007); and the percentage of women above the Centers for Epidemiological Studies Depression Scale (CES-D) cutoff for depression has been found to be 37.5% (Zhu & Valbo, 2002). In a population based sample of low-income women, 9% met criteria for MDD within the past year (Flick et al., 2006). In a sample of women being screened for participation in a low intensity smoking cessation intervention trial, 46.1% of women met criteria for MDD, dysthymia or minor depression (Blalock, Fouladi, Wetter, & Cinciripini, 2005).

Very few studies have examined the impact of depression on smoking cessation in pregnant women. One study found that baseline depressive symptoms failed to predict smoking cessation during late pregnancy among pregnant women participating in a telephone counseling smoking cessation intervention trial. (Ludman et al., 2000) However, the overall severity of depressive symptoms was low in the study sample, and this may have reduced the likelihood of detecting a significant relationship. Higher levels of depressive symptoms at end of pregnancy were found to predict relapse at 6 months postpartum in one study (Solomon et al., 2007). In a sample of pregnant smokers who were participating in a low intensity (videos) smoking cessation intervention (Blalock, Robinson, Wetter, & Cinciripini, 2006), we found that women with dysthymia or minor depression at baseline were less likely to be abstinent than women without current depressive disorders, although the effect for depressive disorder was marginal (OR = 6.3, 95% CI = [.757, 52.17], $p = .076$).

Despite the lack of data on the impact of depression on smoking outcome in pregnant smokers, it seems likely that high levels of depression may pose barriers to cessation in this population and that the relative ineffectiveness of smoking cessation interventions for pregnant smokers may be due in part to lack of attention to such symptoms. While meta-analytic reviews indicate that psychosocial interventions are more effective for smoking cessation than usual care in pregnant smokers (Fiore et al., 2008; Lumley, Oliver, & Waters, 2000), the overall prenatal abstinence rates remain low with an average of 7.6% in control conditions and 13.3% in experimental conditions. More intensive interventions (e.g., greater than 90 minutes of therapist contact::Dornelas et al., 2006) or more frequent visits (e.g., up to 8::Albrecht et al., 2006), have been associated with higher abstinence rates during pregnancy; 28% at end of pregnancy and 39% at 8-weeks post—randomization, respectively. However, abstinence rates

decline during the postpartum period and in most studies, perinatal differences between experimental and control conditions are no longer significant at postpartum follow-ups (Fiore et al., 2008; Melvin & Gaffney, 2004).

The current study was designed to evaluate whether adding an intensive depression-focused treatment component to standard smoking cessation counseling would improve abstinence and depression outcomes in pregnant smokers. We evaluated Cognitive Behavioral Analysis System of Psychotherapy (CBASP), which is a learning-theory based approach that specifically targets interpersonal skills and coping deficits of the chronically depressed individual (McCullough, 2000). Given its interpersonal focus, CBASP appeared especially relevant for addressing a spectrum of psychosocial concerns among pregnant smokers, particularly those with high levels of depressive symptoms. In the current study, a combined smoking cessation and CBASP intervention was compared to a time and intensity matched smoking cessation and Health and Wellness (HW) educational control. Based on previous studies indicating that depression treatment components improve abstinence outcomes among those with more severe forms of depressive disorders and/or symptoms, but not among those with less severe forms of depression and/or symptoms (Brown et al., 2001; Haas, Munoz, Humfleet, Reus, & Hall, 2004; Patten, Drews, Myers, Martin, & Wolter, 2002), we hypothesized that only those with higher levels of baseline depressive symptoms would derive more benefit from the CBASP treatment, in terms of abstinence and symptom reduction, in comparison to HW. Those without such symptoms were expected to fare equally well with CBASP or HW treatments. Treatment effectiveness irrespective of symptoms of depression was not expected to vary.

Method

Study Design

Participants were randomly assigned to receive either the experimental treatment, CBASP, or a time and intensity matched control, Health and Wellness Education (HW). Both conditions included standard behavioral and motivational smoking cessation counseling in addition to the varied treatment component. Adaptive randomization (Pocock, 1983) was used to stratify the groups on age, race, history of depression, baseline smoking rate, baseline depressive symptom severity (CES-D $\geq$ or <16), and longest duration of last depressive episode.

Participants

Participants were recruited through newspaper, television ads, and physician referral between January 2005 and January 2008. To be included in the trial women were required to be ≥ 16 years of age, ≤ 32 weeks pregnant, have smoked at least a puff or more during the past 7 days, have a telephone, and express a willingness to quit smoking during the study (i.e., women with a goal of reducing cigarette consumption only were not eligible). Women who had not yet been to a doctor were given a urine test to confirm their pregnancies. Women were excluded if they were currently participating in psychotherapy or other smoking cessation treatment, had unstable medical conditions that would adversely affect attendance, or demonstrated psychological instability during the screening (e.g., high suicide risk, symptoms of cognitive disorder or severe intellectual impairment). A total of 266 women were randomized into the trial. The study was approved by the institutional review board at the University of Texas M. D. Anderson Cancer Center.

Demographic characteristics of the sample are presented in **Error! Reference source not found.**Table 1. No significant differences were noted between groups in any baseline characteristic. Fifty four percent of women were African American. On average, the women were 25 years old and smoked 10 cigarettes per day at baseline. The majority were not living with a partner. The average CES-D score was 19. Nearly half of the women were unemployed.

Based on the Structured Clinical Interview for Axis I DSM-IV Disorders (SCID::First, Spitzer, Gibbon, & Williams, 1994), 37% of women met DSM-IV criteria (American Psychiatric Association, 2000) for a current major depressive episode at threshold or in partial remission, of which the majority were rated moderate in severity (see **Error! Reference source not found.**Table 1). Seventy-six percent of women had a lifetime history of major depressive disorder (MDD), 67% of whom had recurrent MDD (not shown in Table 1); and 4% had a lifetime history of bipolar disorder, 3% of whom evidenced current hypomania or depression. Only 16% of the sample reported no mood disorder history.

Procedure

As shown in Figure 1, 730 women were assessed for basic eligibility using a brief telephone screen. Women eligible after this step were invited to attend an in-person screening. Four hundred and sixty four women were excluded, including 317 who failed to attend the in-person screening and 119 who did attend but failed to meet criteria. The remaining 294 were asked to return within 3–7 days for the combined randomization and first treatment visit, 28 of whom failed to do so. No significant differences in any of the demographic characteristics described in **Error! Reference source not found.**Table 1 were noted between women who did not return for randomization and the 266 (133 per group) that were randomized and exposed to treatment.

After randomization, all participants were scheduled for 10 prenatal individual counseling visits. While the majority of participants completed one individual counseling visit per week, those who had less than ten weeks until projected delivery were scheduled for counseling visits for as many as two times a week in order to complete the visits prior to delivery. The final counseling visit (Visit 10) was considered the end of treatment (EOT) point. The amount of time between EOT and delivery varied across participants, depending on how far along they were in their pregnancy at the beginning of the study.

Smoking status and depression assessments were conducted in-person at each of the 10 counseling sessions. In addition, assessments were conducted by telephone at 2, 4 and 6 weeks post-end of treatment (some before and some after delivery; this varied by participant depending on how soon they delivered following EOT) and at 2 weeks postpartum. The final in-person follow-up assessments were scheduled for 3- and 6-months postpartum. Participants unwilling or unable to attend the postpartum visits could complete the assessments by telephone. Women were compensated \$40 for each of the 10 in-person assessments they completed at the treatment sessions and for completing each of the 3- and 6-month postpartum follow-ups. Women who completed assessments by phone and, when requested, provided a mail-in postpartum saliva sample, received a \$15 gift card.

Treatment Conditions

Each of the 10 individual counseling sessions were scheduled for 60 minutes. Each session consisted of 15 minutes of standard behavioral and motivational smoking cessation counseling (common to both groups) plus 45 minutes of either CBASP or the HW control.

Smoking Cessation Counseling Component—The 15-minute behavioral and motivational smoking cessation counseling component was based on the Clinical Practice Guidelines (Fiore et al., 2008). At Visit 1, participants were asked to set a quit date of their own, sometime prior their 8th treatment session (to allow for a two-week grace period before the end of treatment). Counseling typically involved active efforts to prepare for quitting and maintaining abstinence using self monitoring of their smoking prior to the quit date, identification of high risk situations for smoking, and development of coping skills and support before and after the quit date. However, if participants expressed resistance to keeping or resetting a quit date or to maintaining abstinence following the quit date, therapists employed

motivation enhancement strategies based on techniques of motivational interviewing (Miller & Rollnick, 1991). The core features included exploration of participant ambivalence, use of open ended questions, reflective listening, expressed empathy, rolling with resistance, and use of strategies to develop perceived discrepancy between smoking behavior and important personal goals and values.

Approximately 28%, 31%, and 41% of the women in CBASP set their quit date between Sessions 2 and 4, 5 and 6, and 7 and 8, respectively. Similarly, 25%, 35%, and 40% of the women in HW set their quit date between Sessions 2 and 4, 5 and 6, and 7 and 8, respectively.

Cognitive Behavioral Analysis System of Psychotherapy (CBASP)—CBASP was originally developed for the treatment of chronic depression (McCullough, 2000). It is an integrative model of psychotherapy that focuses on reducing interpersonal stress and on increasing the quality of one's relationships with significant others. At Visit 1, women were told that the primary goal of the CBASP treatment was to help them develop effective ways to deal with negative feelings and interpersonal stress so they could avoid turning to smoking when they experienced these stressors. The primary CBASP treatment strategy is a social problem-solving exercise called Situational Analysis (SA), which is a technique used to create awareness of the contingent relationship between participants' behavior and outcomes in stressful interpersonal situations. To complete an SA, participants were first asked to identify a recent, distressing interpersonal or smoking-related situation. SA consists of three phases. During elicitation, participants were asked to describe the event, their interpretations of what occurred, their behaviors during the event, the actual outcome of the event, their desired outcome, and whether the desired outcome was achieved. In the remediation phase, the therapist worked with participants to modify their interpretation of the event, their behavior and/or desired outcome, such that the likelihood of achieving the desired outcome would be increased. In the generalization phase, participants learned to apply these new skills or understandings to other situations. Another CBASP treatment strategy involved increasing participants' awareness of the contingent relationship between their behavior and interpersonal outcomes within the therapeutic relationship, and to apply this learning to relationships within the participants' daily living arenas. The CBASP model assumes that repeated practice of SA within and outside of treatment and increased understanding of participants' interpersonal impact on the therapist leads to acquisition of new perceptual and behavioral skills that improve interpersonal problem resolution. In turn, this is assumed to decrease interpersonal stress and depressive symptoms.

Health and Wellness (HW)—Women assigned to this condition were told the primary goal of the HW treatment was to educate them on ways to decrease stress, respond to stressful events, and to take care of themselves physically during their pregnancies. The purpose of this condition was to provide a time and attention matched control for CBASP that was pregnancy relevant but *instructional* in nature, typical of health-education interventions. Participants were allowed to choose from a list of discussion topics including stress, pregnancy symptoms, sleep, exercise, yoga, relaxation training, time management, parenting tips, dealing with anger, negative thoughts and feelings, and postpartum depression. All participants received the stress management, pregnancy symptoms, postpartum depression, and relaxation modules. During the HW sessions, therapists reviewed (read and paraphrased) the content contained in the standardized handouts that addressed the chosen topic, noting the connection between the HW topics and smoking, where appropriate. Therapists were allowed to provide reflective and supportive listening regarding participants' comments on the HW topics and regarding general events raised by participants during the session (for up to 25 minutes). To avoid contamination by more directive therapeutic strategies, therapists were *prohibited* from conducting solution-focused exercises related to HW topics or other problems that participants raised, assigning

homework, or initiating discussions of progress that had been made between treatment sessions concerning any of the HW topics that were discussed.

Treatment Fidelity

The CBASP intervention was delivered by 5 Ph.D. level postdoctoral fellows in clinical psychology with zero to two years of post-degree experience. The HW intervention was delivered by the same Ph.D. level therapists, who delivered 49% of all HW sessions, and an additional 2 masters-level counselors with one to four years of post-degree experience, who delivered 51% of all HW sessions. Before seeing study patients, CBASP and HW therapists were expected to achieve an overall competence rating of 3 (sufficient delivery) or 4 (good delivery) on the last 3 sessions of two pilot cases, as rated by CBASP and HW clinical supervisors (see on-line supplement).

Therapists followed written treatment manuals in both conditions and all sessions were video recorded. Supervisors rated 9% to 10% of all sessions for compliance, consistent with the recommendations of Waltz and colleagues (Waltz, Addis, Koerner, & Jacobson, 1993). Eight to nine percent of those sessions were also rated by a trained secondary outside rater. Adherence rating scales were constructed for therapist behaviors performed as outlined in the HW and CBASP treatment manuals, as well as those prohibited within the treatment conditions. Global competence ratings for CBASP, HW, and the smoking cessation counseling interventions were measured on a scale of 1 (does not attempt intervention) to 4 (good use of intervention). No differences in competence between the groups were noted, averaging 3.8 ($SD = 0.5$) to 3.9 ($SD = 0.4$) across conditions. Statistical agreement of competence ratings between primary and secondary raters was high, with a Cohen's kappa (Landis & Koch, 1977) of 0.93 (95% CI = [0.86, 1.0]; see on-line supplement for more information regarding treatment fidelity).

Participants attended an average of 8 ($SD = 2.8$) total therapy sessions of approximately 58 minutes ($SD = 10.1$) in length, with no significant differences in length of session between treatment groups. Seventy-eight percent of the sample completed at least 7 therapy sessions, 74% completed at least 8 therapy sessions, and 70% completed at least 9 therapy sessions. There were no between-group differences in treatment session attendance.

Measures

Mood disorders were assessed at screening using the Mood Module of the Patient Edition of the SCID (First et al., 1994), supplemented with the Clinical Course Timeline method (McCullough, 2001), which provides information on the course and duration of mood disorder episodes.

Level of depressive symptom severity was assessed using the Center for Epidemiologic Studies Depression Scale (CES-D). The CES-D is a 20-item self-report measure developed to assess depressive symptoms in community populations (Radloff, 1977). The CES-D was administered at all contacts and served as the primary measure of change in depressive symptoms used in the data analysis. We also administered the Edinburgh Postnatal Depression Scale (Cox, Holden, & Sagovsky, 1987), a 10-item self-report measure designed to screen for postnatal depression in the community. Because all results are identical for the CES-D and Edinburgh, only the CES-D results are reported.

The Fagerström Test for Nicotine Dependence (FTND) is a 6-item questionnaire that was obtained at baseline that measures nicotine dependence by assessing various components of smoking behavior such as daily intake, difficulty in refraining from smoking, and time to first cigarette (Fagerström, 1982; Heatherton, Kozlowski, Frecker, & Fagerström, 1991).

Motivation to quit smoking was measured at each contact using the average score from a 10 item scale that was developed by the authors and which is currently being used and evaluated within several of our smoking cessation trials. The scale includes such items as: 'My desire to be a nonsmoker is very strong,' 'I am extremely motivated to be smoke-free,' and 'This time I'm going to stay off cigarettes for good.' Items were rated using a 5-point Likert scale ranging from 'strongly disagree' to 'strongly agree'.

Abstinence

Abstinence data was collected using a timeline follow-back (TLFB) interview (Brown et al., 1998; Law et al., 2003) conducted at every in-clinic (Visits 1–10; 3- and 6-months postpartum) and telephone contact (2-weeks postpartum; 2-, 4- and 6-weeks post-EOT). A computerized program was used to provide the interviewer with a calendar on which to record the amount of cigarettes smoked on each day since the last contact, highlighting the days between contacts for easy reference. Personal events (holidays, birthdays, etc.) were incorporated into the calendar serving as prompts for the interview and to aid in accurate reporting.

Abstinence outcomes conformed to the recently developed guidelines from the Society of Research on Nicotine and Tobacco (SRNT::Hughes et al., 2003) which recommends reporting 7-day point prevalence, continuous and prolonged abstinence rates. Seven-day point prevalence abstinence was defined as a self-report of no smoking, not even a puff, in the 7 days prior to the selected time point of interest (e.g., EOT, 3- and 6-months postpartum). Continuous abstinence was defined as no smoking, not even a puff, from EOT to a future time point. Prolonged abstinence served as our primary smoking outcome measure. Because this study allowed for a variable quit date up to the 8th week of treatment, the common starting point for assessing prolonged abstinence was Visit 10 (i.e., EOT), thereby allowing the recommended 2-week grace period. Beginning at EOT, relapse was defined by either 7 consecutive days of smoking, or smoking at least 1 cigarette over two consecutive weeks within the period of interest (e.g., EOT to 3- and 6- months postpartum::Hughes et al., 2003). Hence prolonged abstinence allows a more liberal definition of relapse than continuous.

Given that the TLFB interview was conducted at each physical contact, whether in-person or by phone, over a time span encompassing the 10 treatment visits through 6 months postpartum, two "virtual" assessment points were constructed at 3- and 6-months following EOT. These points occurred within this time span but were not associated with an actual in-clinic contact. Because women entered treatment at various stages of their pregnancy, the post-treatment assessments occurred at different distances from the delivery. Mean weeks postpartum averaged 9.5 ($SD = 4.6$) and 17.5 ($SD=7.3$) respectively, for 3- and 6-months post-treatment assessments. Similarly, the postpartum assessments occurred at varying distances from EOT. Mean weeks post-treatment averaged 21.5 ($SD = 8.6$) and 34.4 ($SD = 8.6$) for the 3- and 6-months postpartum assessment points. Thus we could examine prolonged abstinence in reference to two milestones: EOT and delivery, providing a comparison to previous smoking cessation studies in the general population as well as those with pregnant smokers, respectively.

Biochemical Verification of Smoking Status

Subjects' expired CO was assessed at each in-person contact throughout treatment and the postpartum follow-ups, using a Bedfont EC50 Micro III Smokerlizer (Bedfont Scientific, Medford, NJ). In addition, saliva cotinine samples were obtained at all follow-up contacts; and for those women completing any scheduled assessments by telephone, a mail-in saliva sample was obtained. Samples were analyzed by Salimetrics LLC in State College, PA.

Given the varying definitions of abstinence used in this study and the half-lives of CO (~6 hrs) and cotinine (~20 hrs::Benowitz et al., 2002), the only abstinence definition that could be

reasonably verified was 7-day point prevalence. Moreover, because the TLFB procedure provided abstinence assessments for which there were no physical visits (i.e., 3 and 6 months from EOT), and because the definition of prolonged abstinence allows for limited smoking, no direct biochemical verification could be obtained for these points. However, biochemical verification of 7-day point prevalence abstinence that is tied to a physical visit can provide a reasonable estimate of the veridicality of the abstinence self-reports, which might be a concern in this population. Smokers who reported no smoking for the previous 7 days and who produced a CO <4 ppm or a cotinine less than 15 ng/ml were considered abstinent at the selected time point. Both the expired CO and cotinine cut-offs are below the levels normally used in smoking cessation studies (e.g. 10 ppm for CO and <25 ng/ml for cotinine), but the lower values are more appropriate for the low smoking rates observed in this population (Higgins et al., 2007). Using these lower cut-offs, we noted that only 4.48% of all self-reported 7-day point prevalence abstinence was associated with discrepant or lack of biochemical verification. No differences were noted between treatment groups and the majority of cases occurred at the last treatment visit. These discrepancies were limited to 19 individuals. Using the higher cut-off values, only 1.65% of the abstinence observations was considered discrepant and was limited to 7 individuals. All abstinence analyses were conducted with and without coding women identified by either method as smokers, and no differences in the results were noted. Therefore, these women were included and treated as smokers in the results presented below.

Statistical Analysis

Data collected from the TLFB yielded over 100,000 observations (days of data). Where there were gaps between assessments in the TLFB data, a statistical algorithm was used to impute smoking status. In the event of missing data (unable to be contacted), all individuals were treated as having smoked during that period (30% of the total observations—predominately at post-treatment), except where data was missing between two acquired data points that were either both coded as abstinent (0.5% of the total observations), or where the first data point was coded as non-abstinent but the second acquired data point was coded as abstinent (0.6% of the total observations). No difference in missing data frequency was noted between the groups. In the CBASP and HW groups we were unable to contact 22 and 54 women for the 3-month, and 9 and 42 women for the 6-month postpartum assessments, respectively. There were no between or within group differences in the demographic characteristics shown in Table 1, between women who did or did not attend either of the follow-ups, nor did the groups differ in loss to follow-up frequency. In every case, the last known status of these women was a smoker. All analyses were carried out on the intent-to-treat (ITT) sample which included 128 participants in the CBASP group and 129 participants in the HW group; excluding only those who experienced a miscarriage during the study (5 in CBASP and 4 in HW).

Student t-tests (continuous variables) and χ^2 tests (discrete variables) were used to examine group differences on baseline demographics. For smoking abstinence, we used SAS PROC GLIMMIX (Version 9.1.3, SAS Institute Inc, Cary, NC), an adaptation of SAS PROC MIXED suitable for a mixed model evaluation of a dichotomous outcome variable. For our primary outcome, prolonged abstinence, the effect of treatment was evaluated separately for the 3- and 6-months postpartum, and 3- and 6-months post EOT endpoints, using models that included treatment Group (CBASP versus HW) and baseline CES-D as between-subject fixed effects, and subject as a random effect. Similar analyses were conducted for continuous and 7-day point prevalence abstinence. Using SAS PROC MIXED, the secondary outcome variable, depression (CES-D), was evaluated as a continuous variable in mixed models that included treatment Group and Time (Visits 1–10; 2-, 4- and 6-week post-treatment and 2-week postpartum phone calls; and 3- and 6-months postpartum visits) as a between-subject fixed effect, subject as a random effect, the baseline CES-D value as a covariate, and 7-day point prevalence abstinence as a time varying covariate. For interactions in all models involving treatment Group, Time

(for modeling CES-D outcome only) and baseline CES-D, we calculated slopes for change in abstinence or CES-D and report the associated point estimates and standard errors (Brown & Prescott, 1999). All models were also tested including baseline cigarettes smoked per day, days of gestation, number of completed treatment visits, FTND score, motivation to quit, education, therapist, and therapist level of education as covariates. No differences were found by including these covariates and the results are reported for the unadjusted models.

Results

Abstinence

As Table 2 indicates, no main effects of treatment group were noted at any of the time points for any of the abstinence definitions. Given our hypothesis that those with the highest level of depressive symptoms would benefit proportionally more from the CBASP treatment, we also tested the interaction between baseline CES-D and treatment Group. Significant interactions between baseline level of depression on the CES-D and treatment Group were noted at the 6-month post EOT time point for prolonged, $F(1,253)=5.61$, $p=.02$, 7-day point prevalence, $F(1,253)=6.73$, $p=.01$, and continuous, $F(1,253)=3.8$; $p=.05$ abstinence definitions. The interaction was not significant for any definition of abstinence at 3-month post EOT or at 3- or 6-months postpartum.

The 6-month post treatment time point corresponds to an average of nearly 18 weeks or 4.5 months postpartum. This suggests that the beneficial effects of the CBASP treatment became apparent for women with high levels of depressive symptoms 6-months after treatment, and within a range of months postpartum, although such effects were not noted at times prior. To visualize this interaction, we plotted the regression lines (see Figure 2) for the probability of prolonged abstinence (our primary outcome variable) at 6-months posttreatment, using the mean and ± 1 SD of the baseline CES-D as discrete points. As shown in Figure 2, higher CES-D scores at baseline are associated with a higher probability of prolonged abstinence with CBASP treatment, whereas lower baseline CES-D values are predictive of higher prolonged abstinence in the HW condition. On average, a 1 unit increase in the CES-D score is associated with a 0.4% increase in prolonged abstinence in the CBASP group and a 0.4% decrease in HW. Each unit increase from the mean in the baseline CES-D score results in an increase of 0.08 in the odds ratio favoring CBASP, whereas a similar decrease reduces the odds by .08. Thus, as can be seen in Figure 2, differences between the groups in abstinence can be expected to be greater at the extreme ends of the distribution. To provide a context for understanding this relationship, we also computed prolonged abstinence rates within each quartile of the baseline CES-D distribution, which averaged 5.53 ($SD=2.87$), 13.11 (2.06), 21.16 (3.44) and 35.08 (5.07) across quartiles I-IV respectively. Predicted abstinence rates for CBASP and HW were 6% and 28% ($OR=.17$, 95% $CI= [0.03, 0.90]$); 13% and 6% ($OR=2.07$, 95% $CI= [0.34, 12.5]$); 13% and 16% ($OR=.74$, 95% $CI= [0.18, 2.96]$); and 26% and 9% ($OR=3.36$, 95% $CI= [0.80, 14.5]$) for quartiles I-IV, respectively. HW was associated with a significant increase in abstinence in the lowest CES-D quartile while CBASP substantially increased abstinence at the upper quartile, although the OR confidence intervals in the latter case do cross one. This is not surprising given the substantially reduced sample size associated with computing the odds ratio in this manner (~32 per quartile/group). Similar results for this interaction were obtained when we divided the groups on the basis of the baseline CES-D score ≥ 16 , $F(1,253)=4.45$, $p=.04$, a commonly employed clinical cut-point suggestive of probable depression (Radloff, 1977).

Depression

Depression scores using the CES-D were also evaluated as a secondary outcome measure. Significant effects were noted for treatment Group, $F(1,254)=4.31$, $p=.04$, Time, $F(1,2619)$

=52.22, $p<.0001$), the treatment Group by Time interaction, $F(1,2618)=9.1423$, $p=.003$, and the Group by Time by baseline CES-D interaction, $F(1,2620)=10.49$, $p=.001$. To characterize the 3-way interaction we compared the slopes of the regression lines predicting CES-D scores over time for both CBASP and HW treatments, within quartiles of the baseline CES-D distribution, as described for the abstinence analyses. It appears that both treatments are associated with roughly equivalent reduction in depressive symptoms over time in quartiles I–III. For HW and CBASP, respectively, slopes (SE) were .02 (.079) and $-.15$ (.077) for quartile I; $-.10$ (.080) and $-.12$ (.084) for quartile II; and $-.28$ (.072) and $-.19$ (.075) for quartile 3. However, a progressively steeper decline was noted in quartile IV for CBASP, $-.80$ (.081), versus HW, $-.14$ (.082); and this difference was significant, $F(1, 2616)=26.16$, $p=.0001$. In quartile IV, HW and CBASP depression scores initially diverged between visits 7 and 8. $t(616) = 2.07$, $p=.04$, and remained significantly separated at 3- and 6-months postpartum, $p<.05$. (Also see on-line supplement for more information).

Discussion

We hypothesized that women with the highest levels of baseline depressive symptoms would benefit more from CBASP treatment than those who received HW, and that those with lower symptom levels would show no treatment related differences. Our predictions were partially supported. At 6-months following the end of treatment, level of baseline depression severity moderated the effect of treatment such that increasing levels of depression were associated with a higher probability of prolonged abstinence in individuals treated with CBASP. Contrary to our prediction that women with lower symptom levels would benefit equally from the two treatments, decreasing levels of depression were associated with a higher probability of abstinence in individuals treated with HW. Examination of abstinence rates within quartiles of the baseline CES-D distribution revealed that those with average scores in the lowest quartile ($M=5.53$) were more likely to be abstinent at 6-months posttreatment following HW treatment, while those in the highest quartile ($M=35.08$) responded more favorably to CBASP treatment. Between those ranges little differences in treatment outcome were noted. Given our sample size and study design, we cannot specify an absolute threshold for which a mood focused treatment such as CBASP would either be indicated or contraindicated. However, it seems safe to say that progressive differences in abstinence favoring CBASP are most apparent at severe levels of depressive symptoms as measured on the CES-D, while HW is favored when symptoms are extremely low. Consistent with our abstinence results, we also noted similar findings for change in depression. Women with the highest baseline level of depressive symptoms experienced a significant decline in depression when they received CBASP versus HW treatment.

The two main findings of this study suggest that women who present with high levels of depressive symptoms may benefit in terms of abstinence and depression, from a depression-focused smoking cessation treatment that emphasizes problem resolution in the interpersonal domain. These findings suggest that for certain individuals, interventions that reduce depressive symptoms may facilitate cessation. Although future studies are required to determine if a reduction in depression mediates the abstinence treatment effect, reducing high levels of depressive symptoms with CBASP has important implications in its own right. The adverse effects of depressive symptoms during pregnancy include pre-term birth, low birthweight, obstetric complications, other physical symptoms, and newborn irritability (Alder, Fink, Bitzer, Hosli, & Holzgreve, 2007; Orr & Miller, 1995; Pritchard & Teo, 1994; Rondo et al., 2003; Zuckerman, Bauchner, Parker, & Cabral, 1990), many of which are also associated with maternal smoking. Our findings highlight the potential for achieving additive benefits on maternal and child health from smoking cessation treatments that also ameliorate depressive symptoms, and suggest this may be an important area of future research.

Although depression severity moderated the impact of treatment on prolonged abstinence at 6-months posttreatment, such differences were not noted at end of treatment. This is in contrast to other (Brown et al., 2001; Hall, Muñoz, & Reus, 1994; Hall et al., 1998; Patten et al., 2002; Zelman, Brandon, Jorenby, & Baker, 1992), but not all (Hall et al., 1996) trials evaluating psychological treatments for smoking cessation where differences between active and control conditions have emerged at the end of treatment or shortly thereafter in depression vulnerable smokers. The absence of treatment differences prior to 6 months from EOT (~4.5 months postpartum) suggests that the smoking cessation counseling and intensity of therapist contact that were common to both treatments, may have had beneficial effects for a period of time following treatment, regardless of the severity of baseline depressive symptoms. However, it is possible that CBASP treated women with the highest levels of depressive symptoms may have been less likely to relapse as time went on, given their potential to resolve interpersonal stressors more effectively than HW treated women. Although treatment differences in abstinence dissipated by 6-months postpartum, the continued benefit of CBASP on depression during this time highlights the added value of the treatment. Replication of these effects, exploration of treatment mediators related to interpersonal skills and the potential effect on birth outcomes are issues to be addressed in future studies.

The 7-day point prevalence abstinence rates at EOT (~43%) in this study are substantially higher than overall prenatal rates in the most recent Clinical Practice Guidelines meta-analysis of psychosocial interventions for pregnant smokers (~13.3%::Fiore et al., 2008). Our EOT results may be due, in part, to the intensity of both treatments (60-minute sessions); the high rate of attendance (women averaged 8.2/10 sessions); and delivery of treatments by Ph.D. and masters level psychologists. In contrast, the majority of the studies on which the Clinical Practice Guidelines meta-analysis (Fiore et al., 2008) was based tested physician advice and/or 10- to 15-minute counseling interventions that were delivered by nurses, midwives, and health education counselors. However, two of the studies included in this meta-analysis examined high intensity interventions in samples that were similar to the current study—low-income and racially diverse—both of which produced higher abstinence rates relative to the minimal intensity interventions. One study evaluated an 8-session group CBT intervention provided by masters or doctoral level nurses with and without peer support and noted EOT abstinence rates around 40% and 25%, respectively, compared to 12% in usual care (Albrecht et al., 2006). A second study evaluated a 90-minute telephone-delivered “brief psychotherapy” intervention focusing on psychological distress and difficulties quitting during pregnancy that was delivered by masters level mental health counselors. At end of pregnancy, abstinence rates were 28.3% compared to 9.4% for usual care (Dornelas et al., 2006). Results from these studies and the current study suggest that pregnant smokers, many of whom have high levels of depression and face multiple stressors (i.e., financial and employment difficulties, partner and family issues, domestic abuse, drug and alcohol use; Adams, Melvin, & Raskind-Hood, 2008; Bullock, Mears, Woodcock, & Record, 2001; Wakschlag et al., 2003), may require repeated and lengthier smoking cessation counseling sessions that are delivered by mental health practitioners in order to achieve cessation during the prenatal period.

Despite the intensity of both treatments and the effectiveness of CBASP in reducing depressive symptoms among the most depressed women during the postpartum period, abstinence rates at 6-months postpartum were about 8% in the total sample, with no differences across treatment groups and no moderating influence of baseline depression. Thus, despite the relatively high abstinence rates at EOT, 80% of abstinent women had relapsed by 6-months postpartum, a rate of relapse that is on the high side of the range of postpartum relapse (i.e., 29% to 85%; Fang et al., 2004). Factors that have been identified as predictive of postpartum relapse include low levels of intrinsic motivation for quitting during pregnancy, having other smokers in the home, and the experience of stressful life events and negative mood following delivery (Mullen, 2004; Park et al., 2009). It seems likely that all of these factors were highly prevalent in this

group of low-income, underemployed women, the majority of whom were single parents. As has been noted by other researchers (Mullen, 2004), interventions may have to extend into the postpartum period in order to effectively address the challenges that arise following birth.

Our findings add to a growing body of evidence that mood-focused or supportive psychosocial treatments may benefit smokers with more severe depressive symptoms but may be of little benefit to those with less severe depressive symptoms (Brown et al., 2001; Haas et al., 2004; Patten et al., 2002; Zelman et al., 1992). In fact, it appears that CBASP had a detrimental effect on 6-month posttreatment abstinence, relative to HW, among those with very low levels of baseline depressive symptoms. Researchers have hypothesized that for such smokers, depression treatment components may add unnecessary complexity and subjective burden, may have low credibility, or be experienced as aversive (Hall et al., 1994; Patten et al., 2002). Anecdotal reports by participants with low baseline depressive symptoms suggest they had difficulty making sense of why they were being asked to identify interpersonal situations targeted by the CBASP intervention. In contrast, such women in HW could focus on pregnancy symptoms and wellness exercises, and engage in supportive discussions with their therapists, all of which may have had held greater value for them.

There are a number of strengths of this study, including an assessment of treatment outcome in relation to level of depressive symptoms and a design which allowed us to disentangle the effects of the depression-focused treatment from that of time and contact. There are also a number of important limitations. The demand characteristics of the intervention (i.e., attending 10, 60-minute sessions) may have resulted in recruitment of highly motivated participants and/or biased the sample towards inclusion of unemployed, lower income women with higher levels of depressive symptoms, which in either case may not be representative of pregnant smokers. However, we did not note any significant differences in any of the demographics of the randomized and excluded samples. Participants in this study were also compensated \$40 per visit for completion of study procedures. While it is likely that this level of compensation increased retention and attendance to study sessions, it may limit the generalizability of our findings. In addition, competent delivery of our depression focused intervention (CBASP) requires a high level of therapeutic skill and training which limits the ability to disseminate this treatment.

Despite these limitations, results of this study may have important implications for the treatment of pregnant smokers with high levels of depressive symptoms. These women may be the least likely to benefit and be served by traditional interventions, yet they may be at greater risk for the adverse maternal and child health consequences that result from the combination of smoking and depression. Our population consisted of mostly minority women, with a high school education or less, and limited social and financial resources. These women are among the most vulnerable in our society. While posttreatment related differences in abstinence for those with high levels of baseline depressive symptoms had dissipated by the 6-month postpartum follow-up, the beneficial effect of the CBASP intervention on their depressive symptoms was observed throughout the postpartum period. This may be an important consideration for incorporating such therapies into smoking cessation treatments directed at this population.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Figure 1.
CONSORT Flow Diagram for patient entry and processing through the trial.

Figure 2.

Illustration of the interaction between Treatment Group (CBASP and HW) and level of baseline depression as measured by the CES-D. The mean and plus or minus one standard deviation of the mean baseline CES-D scores are plotted on the X-axis. The Y-axis represents the predicted rate of prolonged abstinence at 6-months posttreatment for each of these points, based on the regression model described in the text. Baseline CES-D included as a covariate in the model.

Table 1**Baseline Demographic and Smoking Characteristics**

Variable	CBASP (n=128)	HW (n=129)	Total (N=257)
Race/Ethnicity	% (N)	% (N)	% (N)
African-American, Non-Hispanic	55.5 (71)	52.7 (68)	54.1 (139)
White, Non-Hispanic	32.0 (41)	34.9 (45)	33.5 (86)
Hispanic	10.2 (13)	8.5 (11)	9.3 (24)
Other	2.3 (3)	3.9 (5)	3.1 (8)
Education Level			
Less than high school	29.7 (38)	34.1 (44)	31.9 (82)
High school/GED	35.2 (45)	34.9 (45)	35.0 (90)
Vocational school, some college, or greater	35.2 (45)	31.1 (40)	33.1 (85)
Marital Status			
Married & living with partner	18.8 (24)	19.4 (25)	19.1 (49)
Not married & living with partner	21.1 (27)	24.0 (31)	22.6 (58)
Never married, not living w/ partner	50.0 (64)	47.3 (61)	48.6 (125)
Widowed, divorced, or separated	10.2 (13)	9.3 (12)	9.7 (25)
Employment Status			
Employed/Student	31.3(40)	33.3 (43)	32.3 (83)
Homemaker	17.2 (22)	21.7 (28)	19.5 (50)
Unemployed	51.6 (66)	45.0 (58)	48.2 (124)
Receiving Medicaid or County Health Care	61.7 (79)	64.3 (83)	63.0 (162)
Annual Family Income			
Less than \$10,000	37.5 (48)	31.0 (40)	34.2 (88)
\$10,000 – \$19,999	14.8 (19)	13.2 (17)	14.0 (36)
\$20,000 – \$29,999	3.9 (5)	4.7 (6)	4.3 (11)
More than \$30,000	19.5 (25)	21.7 (28)	20.6 (53)
Prefer not to say	24.2 (31)	29.7 (38)	26.8 (69)
Diagnosis and Mood Disorder Specifiers	% (N)	% (N)	% (N)
Major Depressive Disorder, Lifetime	74.2 (95)	76.7 (99)	75.5 (194)
Major Depressive Disorder, Current	25.8 (33)	20.9 (27)	23.3 (60)
Major Depressive Disorder, in Partial Remission	13.3 (17)	14.0 (18)	13.6 (35)
Major Depressive Disorder, in Full Remission	35.2 (45)	42.6 (55)	38.9 (100)
Dysthymic Disorder, Lifetime	7.0 (9)	3.9 (5)	5.4 (14)
Bipolar Disorder, Lifetime	3.9 (5)	3.1 (4)	3.5 (9)
Bipolar Disorder, Current	2.3 (3)	3.1 (4)	2.7 (7)
Bipolar Disorder, in Full Remission	1.6 (2)	0.0 (0)	0.8 (2)
Negative History of Mood Disorder	14.8 (19)	16.3 (21)	15.6 (40)
Current Major Depressive Episode by Severity			
Mild	5.5 (7)	0.8 (1)	3.1 (8)
Moderate	15.6 (20)	16.3 (21)	16.0 (41)

Diagnosis and Mood Disorder Specifiers	% (N)	% (N)	% (N)
Severe	4.7 (6)	3.9 (5)	4.3 (11)

Smoking & Other	Mean (SD)	Mean (SD)	Mean (SD)
CES-D (Total Score)	18.6 (12.0)	19.0 (11.0)	18.8 (11.4)
Age (years)	24.4 (6.5)	25.5 (5.3)	25.0 (5.9)
Weeks Pregnant	19.5 (8.5)	19.6 (8.5)	19.5 (8.5)
Known breast feeding at 3 mo. post-partum (N=164)	11.6 (10)	14.1 (11)	12.8 (21)
Age started smoking (years)	15.4 (3.2)	15.9 (3.9)	15.7 (3.6)
Smoking rate before finding out pregnant (cigs/day)	16.8 (8.7)	15.8 (9.1)	16.3 (9.0)
Current smoking rate (cigs/day)	9.8 (7.1)	9.7 (6.7)	9.8 (6.9)
Motivation to quit smoking (0–50)	40.8 (7.6)	41.3 (6.1)	41.1 (6.9)
FTND score	3.2 (2.1)	3.5 (2.0)	3.4 (2.0)

Note. All frequencies are calculated within group (column). There were no significant differences between the CBASP and HW groups for any of the comparisons. CBASP = Cognitive Behavioral Analysis System of Psychotherapy; HW = Health and Wellness.

Table 2

Abstinence Rates by Treatment Group

	<i>Continuous Abstinence¹ % Abstinent (n)</i>	<i>7-Day Point Prevalence² % Abstinent (n)</i>	<i>Prolonged Abstinence³ % Abstinent (n)</i>
End of Treatment			
CBASP Group (n= 128)	-----	45.3 (58)	-----
HW Group (n= 129)	-----	39.2 (51)	-----
		OR 1.2., 95% CI [0.7–2.0]	
3 Months after End of Treatment			
CBASP Group	23.4 (30)	36.7 (47)	31.3 (40)
HW Group	21.0 (27)	31.0 (40)	27.1 (35)
	OR 1.2, 95% CI [0.6–2.1]	OR 1.3, 95% CI [0.8–2.2]	OR 1.2, 95% CI [0.7–2.1]
6 Months after End of Treatment			
CBASP Group	11.1 (14)	18.0 (23)	14.1 (18)
HW Group	8.5 (11)	16.3 (21)	14.7 (19)
	OR 1.3, 95% CI [0.6–3.0]	OR 1.1, 95% CI [0.6–2.2]	OR 1.0, 95% CI [0.5–2.0]
3 Months Postpartum			
CBASP Group	11.7 (15)	18.8 (24)	16.4 (21)
HW Group	10.9 (14)	17.8 (23)	18.6 (24)
	OR 1.1, 95% CI [0.6–2.0]	OR 1.1, 95% CI [0.5–2.4]	OR 0.9, 95% CI [0.5–1.7]
6 Months Postpartum			
CBASP Group	3.1 (4)	7.0 (9)	7.8 (10)
HW Group	1.2 (3)	9.3 (12)	6.2 (8)
	OR 1.7, 95% CI [0.4–7.3]	OR 0.8, 95% CI [0.3–1.8]	OR 1.3, 95% CI [0.5–3.4]

Note. No significant treatment group differences in abstinence were noted. CBASP = Cognitive Behavioral Analysis System of Psychotherapy; HW = Health and Wellness.

¹ Continuous abstinence is defined as no smoking on any day.

² 7-day point prevalence is defined as no smoking in the last seven days of the given time period.

³ Prolonged abstinence; relapse is defined by smoking for 7 or more consecutive days or by smoking at least 1 cigarette over two consecutive weeks.