Original investigation

Smoking Cessation for Pregnant Smokers: Development and Pilot Test of an Emotion Regulation Treatment Supplement to Standard Smoking Cessation for Negative Affect Smokers

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Abstract

Introduction: Negative affect has been identified as a factor influencing continued smoking during pregnancy. In this study, a multi-component emotion regulation intervention was developed to address negative emotional smoking triggers and pilot-tested among low-income pregnant smokers. Treatment feasibility and acceptability, cotinine-verified rates of smoking cessation, and self-report of mean cigarettes smoked were assessed.

Methods: Pregnant smokers who self-reported smoking in response to negative affect ($N = 70$) were randomly assigned to receive one of two 8-session interventions: (1) emotion regulation treatment combined with standard cognitive-behavioral smoking cessation (ERT + CBT) or (2) a health and lifestyle plus standard smoking cessation active control (HLS + CBT). Outcomes for the 4-month period following the quit date are reported.

Results: Treatment attendance and subjective ratings provide evidence for the feasibility and acceptability of the ERT + CBT intervention. Compared with the HLS + CBT control condition, the ERT + CBT condition demonstrated higher abstinence rates at 2 months (ERT + CBT = 23% vs. HLS + CBT = 0%, OR = 13.51; 95% CI = 0.70–261.59) and 4 months (ERT = 18% vs. HLS = 5%; OR = 2.98; 95% CI = 0.39–22.72) post-quit. Mean number of cigarettes per day was significantly lower in ERT + CBT at 2 months (ERT + CBT = 2.73 (3.35) vs. HLS + CBT = 5.84 (6.24); $p = .05$) but not at 4 months (ERT + CBT = 2.15 (3.17) vs. HLS + CBT = 5.18 (2.88); $p = .06$) post-quit.

Conclusions: The development and initial test of the ERT + CBT intervention supports its feasibility and acceptability in this difficult-to-treat population. Further development and testing in a Stage II randomized clinical trial are warranted.

Implications: Negative affect has been identified as a motivator for continued smoking during pregnancy. To date, smoking cessation interventions for pregnant smokers have not specifically addressed the role of negative affect as a smoking trigger. This treatment development pilot study provides support for the feasibility and acceptability of a multi-component ERT + CBT for

low-income pregnant smokers who self-report smoking in response to negative affect. Study findings support further testing in a fully-powered Stage II efficacy trial powered to assess mediators and moderators of treatment effects.

Introduction

Despite the known negative health effects of smoking to the developing fetus,^{1,2} 14% of US women continue to smoke throughout their pregnancy. Factors associated with continued smoking in pregnancy include socio-demographics such as younger age, less education, lower socioeconomic status,³⁻⁵ and negative emotional factors including greater anxiety, dysthymia, anger, and stress.⁶⁻¹⁰ A recent study following young, urban pregnant smokers found that those who continued to smoke persistently throughout pregnancy reported significantly higher levels of negative affect including stress, anger, and hostility at a second trimester interview compared to lighter, intermittent smokers.¹¹ However, empirical evidence linking smoking and negative affect is derived primarily from cross-sectional studies, thus making it difficult to determine the causal direction of influence between continued smoking in pregnancy and negative affect. A recent longitudinal study examined the relationship between DSM-IV depressive disorders and smoking cessation and reduction in a sample of pregnant women receiving low intensity smoking cessation treatment. Women diagnosed with current dysthymia significantly increased their mean cigarette consumption during the 30-day post-target quit date period while those without a depressive disorder evidenced no significant change in smoking.⁶ In addition, women in the dysthymic group were smoking significantly more cigarettes at 30 days post-quit date as compared with women without DSM-IV depressive disorders. This negative affect and smoking relationship is supported by evidence found among more general samples of smokers seeking smoking cessation treatment.¹² In a longitudinal study utilizing a latent variable modeling approach, a negative affect/stress variable consisting of depressive symptoms, perceived stress and negative affect assessed on the quit date was indirectly associated with smoking status at the 4-week post-quit date follow-up. The tested model indicated that higher levels of negative affect/stress were related to lower levels of negative affect regulation expectancies and self-efficacy to manage high-risk situations without smoking, which in turn, were related to status as a smoker at follow-up. These studies provide evidence of the influence of negative affect on smoking status, and support for addressing negative affect as part of smoking cessation treatment for pregnant women.

To date, smoking cessation interventions have not specifically addressed the role of negative affect as a factor in the maintenance of prenatal smoking. However, interventions targeting negative affect in general samples of smokers have shown some success.^{13,14} Most interventions targeting smoking cessation among pregnant smokers have been brief providing either advice to quit^{15,16} or strategies to enhance motivation to quit.¹⁷⁻¹⁹ Despite the appeal of these low intensity interventions, they have had limited impact on rates of smoking cessation. For example, no significant between-group differences in rates of smoking cessation emerged in a recent study of low-income pregnant smokers comparing the effect of a brief motivational enhancement intervention with treatment as usual involving advice to quit delivered as part of prenatal care.¹⁹ Therefore, despite the appeal and ease of dissemination of brief interventions, their limited efficacy among pregnant smokers indicates a need for additional treatment options, including more intensive interventions for this specific population of

smokers.²⁰ Given evidence of a role for negative affect in maintaining pregnancy smoking, an emotion regulation intervention that can be added to existing empirically-supported smoking cessation treatment has the potential to enhance cessation rates during pregnancy.

The current study is part of a larger research program designed to develop and assess the impact of multi-component emotion regulation interventions for addictive disorders.²¹ In this study, we developed an emotion regulation treatment (ERT) supplement to standard cognitive-behavioral smoking cessation (CBT) skills training. The ERT intervention is individually-administered and was initially developed and integrated with the standard smoking cessation intervention utilizing a sample of 10 pregnant smokers meeting the identical study inclusion/exclusion criteria described below. Feedback was obtained from these participants at the end of treatment (or following their final treatment session) employing individual exit interviews. Changes to the treatment were made in several iterations and the treatment was finalized at the end of this treatment development period. The finalized treatment was pilot-tested and we examined the feasibility and acceptability of the ERT + CBT intervention, and the effects of this intervention on rates of smoking cessation and mean number of cigarettes smoked in a sample of ethnically diverse, low SES, urban pregnant women who self-reported smoking in response to negative affect. This intervention was specifically designed to address smoking cessation during the prenatal period as different factors have been found to influence smoking abstinence during the prenatal as compared with the postnatal period.^{22,23}

Methods

Study Design

Participants were randomly assigned to receive ERT + CBT or an active control condition, Health and Lifestyle + Cognitive-Behavioral Therapy (HLS + CBT). Urn randomization further equated the two groups on variables known to influence smoking cessation outcomes among pregnant women including age (<22 vs. ≥22), years of education (9 vs. ≥10), number cigarettes smoked per day (<6 vs. ≥6), and presence/absence of an anxiety or mood disorder. The intention-to-treat principle was adopted.²⁴ The two treatment conditions were matched for contact time and intensity, and patient expectation of treatment effects. As described above, development of ERT was conducted in an iterative process guided by the stage model of behavioral therapies research.^{25,26} Both conditions received eight, individually-administered, 1-hour sessions comprised of: (1) 20 minutes of empirically-supported, individually-delivered CBT for smoking cessation adapted from "The Tobacco Dependence Handbook: Guide to Best Practices"²⁷ and (2) 40 minutes of an individually-administered ERT or HLS intervention. Given that both conditions consisted of the same smoking cessation treatment and were equated for contact time, the study design involved a "strong" test of the ERT + CBT intervention.²⁸

Participants and Procedure

Participants were women (N = 70) seeking care from a publicly-funded women's prenatal health center who were screened for eligibility between July 2009 and June 2011. Study inclusion criteria

included: (1) age 18 years or older, (2) singleton pregnancies, (3) smoked, on average, at least 1 cigarette per day over the prior week, (4) less than 24 weeks gestation, (5) negative affect smoker as defined by a mean of 5.6 or greater on the negative affect reduction (NA) scale of the Brief Smoking Consequences Questionnaire-Adult (BSCQ-A, NA²⁹; —see Measures section), (6) able to provide a collateral contact, defined as a person who is familiar with their smoking, (7) no more than 0.50 ounces of ethanol (1 drink per day) and no incidence of binge drinking during pregnancy (≥ 4 drinks per occasion). Exclusion criteria included: (1) no telephone, (2) acute psychosis or severe cognitive impairment, (3) diagnosed drug use disorder other than marijuana as assessed by the Mini International Neuropsychiatric Interview MINI,³⁰ and (4) lack of fluency in the English language.

This study was approved by the University at Buffalo's Institutional Review Board. All treatment and research sessions took place at the Research Institute on Addictions at the University at Buffalo. Of the 2134 women screened, 286 met initial inclusion/exclusion criteria which included participant age, gestational age, smoking status, ethanol consumption, access to telephone and English language fluency criteria and thus qualified for further eligibility assessment. A total of 147 completed the in-person eligibility assessment with 43 “excluded for the following reasons”: diagnosis of alcohol or drug use disorder other than marijuana ($n = 5$), BSCQ-A, NA scale score of less than 5.6 ($n = 32$; ie, did not meet inclusion criteria as a negative affect smoker), no longer smoking ($n = 2$), no longer pregnant ($n = 1$), evidence of psychosis ($n = 1$); two declined study participation. Of the 102 who were eligible and agreed to participate, 78 completed a pretreatment assessment; 24 participants did not attend this assessment. Following the pretreatment assessment, eight participants were excluded because they were no longer pregnant. Of the remaining 70 participants, 36 were randomized to ERT + CBT and 34 to HLS + CBT.

Participants completed research interviews at pretreatment just prior to the start of treatment, and at 2-, 4-, and 6-months post-quit date, which occurred at Session 2. They received retail gift cards totaling up to \$200 as compensation. Participants were not paid to attend treatment sessions.

Treatment Conditions

Cognitive-Behavioral Smoking Cessation Treatment

The skills-based smoking cessation program was identical for both the ERT + CBT and HLS + CBT. During the first session, participants were strongly encouraged to set a Session 2 quit date. Those who were unable or unwilling to set a Session 2 quit date were encouraged by the counselors in subsequent sessions to set a quit date. Session-specific topics were as follows: Session 1: Reasons for Quitting, Smoking Triggers, Preparation for Session 2 Quit Day; Session 2: Benefits of Quitting Smoking, Urge Management, Quit Day Experiences; Session 3: Coping Strategies for Avoiding Smoking, Coping with Slips; Session 4: Identifying High-risk Situations; Session 5: Obtaining Social Support for Quitting; Session 6: Managing High-Risk Situations; Session 7: Thoughts That Lead to Smoking, Managing High-Risk Situations; Session 8: Smoke-free Action Plan or Tips for Future Progress Towards Cessation Goal.

Emotion Regulation Treatment

The ERT intervention consisted of three major components: (1) coping skills for managing negative emotions with the goal of developing emotional awareness and providing skills to modulate negative

affect and tolerate distress, (2) guided imagery (imaginal exposure) to elicit negative emotions consistently associated with smoking and promote emotional processing of these triggers, and (3) mindfulness meditation skills including mindful breathing, mindfulness in daily activities and “urge surfing”.³¹ Session-specific topics were as follows: Session 1: ERT Program Rationale, Introduction to Emotions, and Emotions and Smoking; Session 2: Dedicated Mindfulness Practice and Mindfulness in Daily Activities; Session 3: Preparing for Guided Imagery/Exposure to Negative Affect Smoking Situations, Mindfulness; Session 4: Emotions and Urges, Physiologically-Focused Guided Imagery/Exposure to Negative Affect Smoking Situations; Sessions 5, 6, and 7: Mindfulness Review, Guided Imagery/Exposure to Negative Affect Smoking Situations; Session 8: Review of Progress. Participants were provided with handouts, worksheets, and a 10-minute mindful breathing CD and asked to practice with it twice daily.

Health and Lifestyle Intervention

The HLS intervention consisted of educational information with accompanying handouts and worksheets on health-related topics relevant to pregnant women. Each session covered a health topic as follows: Session 1: Benefits of a Healthy Lifestyle; Session 2: Personal Values and Priorities; Session 3: Nutrition 1; Session 4: Nutrition 2; Session 5: Avoiding Carbon Monoxide Poisoning; Session 6: Reducing HIV Risk; Session 7: Balancing Life Roles, and Session 8: Review of Health and Lifestyle Changes. Topics were chosen based on (1) their relevance and interest to pregnant women, (2) success as an active control intervention in prior studies, for example,²¹ (3) limiting discussion of negative affect, and (4) providing health information while minimizing provision of skills. Participants in HLS were given daily health-related assignments equal in time commitment and effort to maintain consistency between the treatment conditions.

Measures

All measures demonstrated good to excellent internal consistency in the present sample. At the pretreatment assessment, the MINI was administered to assess mental health and substance use disorders. The BSCQ-A,²⁹ NA scale was used to select for negative affect smokers. This scale consists of four items rated on a scale from 0 = very unlikely to 9 = very likely that assess the degree to which an individual expects to reduce their negative affect by smoking cigarettes. In a prior study, the mean score on the NA scale for a sample ($N = 407$) of adult smokers was 5.6 on this 0–9 scale.³² Thus women scoring a mean of 5.6 or greater on this subscale were classified as “negative affect smokers.” The Fagerstrom Test for Nicotine Dependence (FTND)³³ was used to characterize smokers at pretreatment. The measure consists of six items that classify smokers into one of five dependence levels: very low (0–2), low (3–4), medium (5), high (6–7) and very high (8–10).

Cigarette use was assessed by self-report at all assessments utilizing the Timeline Follow-Back³⁴; with the main outcome variables of: (1) 7-day point prevalence smoking abstinence (PPA; abstinent/smoking) and (2) mean number of cigarettes per day (CPD) during the 7 days prior to each assessment. Participants submitted urine samples that were tested for Cotinine (NYMOX Nicalert Test Strips; positive cutoff = 100 ng/ml) and Drug Use (ie, cocaine, amphetamines, opiates, marijuana; OnTrak TeTcup System, Varian, Inc) at all assessments. Following the first treatment session, participants completed a questionnaire that contained three questions assessing Treatment Credibility. Each question was rated on a 10-point scale

from 0 (not at all logical/confident) to 10 (very logical/confident): (1) How logical does this type of treatment seem to you for helping people quit smoking?, (2) How confident are you that this treatment will help you quit smoking? and (3) How confident would you be recommending this treatment to a friend who wants to quit smoking? Following the final treatment session, participants completed the Client Satisfaction Questionnaire (CSQ-8)³⁵, an 8-item scale assessing overall satisfaction with treatment using a 4-point scale (1–4) with a total possible score of 32 indicating the highest level of satisfaction. The Smoking Self-efficacy Questionnaire (SSEQ)³⁶ assesses confidence to remain abstinent and consists of 20 items rated on a scale from 1 (not all confident) to 5 (extremely confident) which are summed and divided by the number of items in the scale to obtain a total score ranging from 1 to 5. Given its relevance to the ERT + CBT treatment, the NA subscale was examined in analyses.

Statistical Analyses

The purpose of this treatment development study is primarily to assess the feasibility and acceptability^{37,38} of the ERT + CBT intervention with a secondary aim of examining differences in smoking outcomes between the ERT + CBT and the HLS + CBT active control condition. Statistical analyses were performed using SAS version 9.4. Proportion of participants lost to follow-up were compared between treatment groups using Chi-squared tests. Descriptive statistics were employed to characterize participant demographics, mean number of cigarettes smoked, 7-day PPA, FTND score and gestational age at pretreatment separately for each group. Comparisons of treatment completers versus noncompleters were conducted using Student's *t* test for continuous variables and Chi-squared tests for categorical variables. Treatment attendance, answers to credibility and satisfaction questions were assessed using the Student's *t* test. Odds ratios and 95% confidence intervals were used to compare rates of 7-day PPA between the ERT + CBT and HLS + CBT groups at pretreatment, 2- and 4-months post-quit date. Mean number of cigarettes smoked per day and SSEQ negative affect scores were compared between ERT + CBT and HLS + CBT treatment groups, using the Student's *t* test. Given the study focus on prenatal smoking, the data of participants who were postpartum at 4 months (*t*₂) were removed from analyses. For these analyses, data from participants that were lost to follow-up were assumed to be missing at random. Because this assumption may not be realistic with smoking cessation data, sensitivity analyses³⁹ were conducted comparing observed 7-day PPAs with 85% of participants assumed to have returned to smoking.

Results

Twenty-seven of the total sample of 70 women were lost to follow-up at 2-months (*t*₁; ERT + CBT = 14; HLS + CBT = 13). One additional participant assigned to ERT + CBT was lost to follow-up at 4-months, and in addition, data from 6 women who were postnatal by 4 months (*t*₂; ERT + CBT = 2; HLS + CBT = 4) were excluded from analyses given the study focus on addressing prenatal smoking cessation. At the 6-month follow-up, no additional participants were lost to follow-up, however, an additional *n* = 28 women (ERT + CBT = 15; HLS + CBT = 13) were postnatal, resulting in a total prenatal sample of *n* = 14 (ERT + CBT = 6; HLS + CBT = 8). Given the small remaining sample, the 6-month (*t*₃) timepoint was dropped from analyses. Within the ERT + CBT and HLS + CBT groups, the follow-up rates were similar for the 2-month (ERT + CBT = 61.1%

vs. HLS + CBT = 61.8%) and 4-month (ERT + CBT = 58.3% vs. HLS + CBT = 61.8%) follow-ups. The results of Chi-squared tests indicated no significant group differences in follow-up rates at the 2-month ($X^2 = 0.09$, $p = .77$) and 4-month ($X^2 = 0.0032$, $p = .96$) assessments.

Participant characteristics are shown in Table 1. Overall, participants were young, single, ethnically diverse, unemployed, low-income women who smoked about 7 CPD with low nicotine dependence.³³ Comparisons between the ERT + CBT and HLS + CBT groups on socio-demographic characteristics evidenced no significant differences.

Treatment Completers Versus Noncompleters

Individuals completing four or more treatment sessions ("completers", *N* = 32) were compared with individuals who completed three or fewer treatment sessions ("noncompleters", *N* = 38) on demographic, and pretreatment measures of smoking including 7-day PPA, CPD, nicotine dependence, and self-efficacy to quit smoking. No significant differences emerged on any of the variables.

Table 1. Pretreatment Demographic and Smoking Characteristics, *N* = 70

	ERT + CBT (<i>n</i> = 36)	HLS + CBT (<i>n</i> = 34)
Age (y), <i>M</i> (<i>SD</i>)	24.8 (4.5)	24.9 (4.7)
Education (y), <i>M</i> (<i>SD</i>)	11.8 (1.9)	12.1 (2.0)
Race/ethnicity, <i>n</i> (%)		
African American	15 (41.7)	15 (44.1)
Caucasian	13 (36.1)	8 (23.5)
Hispanic	4 (11.1)	7 (20.6)
Native American	2 (5.6)	2 (5.9)
Other	2 (5.6)	2 (5.9)
Marital status, <i>n</i> (%)		
Single, never married	17 (47.2)	17 (50.0)
Divorced/separated	3 (8.3)	3 (8.8)
Married/Co-habiting	11 (30.6)	10 (29.4)
Relationship, not living together	5 (13.9)	4 (11.8)
Employment status, <i>n</i> (%)		
Not employed, looking for work	15 (41.7)	16 (47.1)
Not employed, not looking for work/disability	7 (19.4)	5 (14.7)
Employed, part-time	9 (25.0)	9 (26.5)
Employed, fulltime/student	5 (13.9)	4 (11.8)
Total income last year, <i>n</i> (%)		
0 to less than \$10 000	24 (66.7)	24 (70.6)
\$10 000 to \$20 000	9 (25.0)	6 (17.6)
\$20 000 or more	3 (8.3)	4 (11.8)
Smoking history		
Age began smoking, <i>M</i> (<i>SD</i>)	14.3 (2.9)	15.4 (2.6)
Cigarettes/day, <i>M</i> (<i>SD</i>) ^a	7.5 (7.2)	7.5 (11.7)
Ever tried quitting, <i>n</i> (%)	32 (88.9)	28 (82.4)
FTND score, <i>M</i> (<i>SD</i>)	3.3 (2.2)	3.4 (2.5)
Gestational age at pretreatment (wk), <i>M</i> (<i>SD</i>)	15.6 (5.5)	14.9 (4.6)

CBT = standard smoking cessation; ERT = Emotion regulation treatment; HLS = Health and lifestyle; *SD* = standard deviation; FTND = Fagerstrom Test for Nicotine Dependence (range 0–10).

^aSeven-day period prior to pretreatment assessment.

Treatment Attendance, Credibility, and Satisfaction

Participants in the ERT + CBT condition attended a mean of 4.42 ($SD = 3.12$) while the HLS + CBT condition attended a mean of 4.19 ($SD = 3.09$) treatment sessions. There were no significant differences between groups in number of sessions attended ($t(62) = -0.30$, $p = .77$). When the ERT + CBT and HLS + CBT conditions were compared on the three questions assessing treatment credibility, no significant differences were found on questions assessing confidence in quitting smoking with the treatment ($t(68) = -0.39$, $p = .69$) or recommending this treatment to a friend who wants to quit smoking ($t(61) = -1.32$, $p = .17$); however, participants in ERT + CBT ($M = 8.70$, $SD = 0.77$) scored significantly higher than those in HLS + CBT ($M = 8.03$, $SD = 1.56$) on the question assessing how logical the treatment seemed for helping people quit smoking ($t(62) = -2.18$, $p = .04$). A comparison of the mean total scores on the CSQ-8 assessed among those who completed treatment indicated high treatment satisfaction for both groups (ERT + CBT and HLS + CBT) and no significant differences between the ERT + CBT ($N = 11$, $M = 30.18$, $SD = 2.09$) and HLS + CBT ($N = 9$, $M = 29.56$, $SD = 3.09$) conditions on end-of-treatment satisfaction ($t(18) = -0.54$, $p = .60$).

Seven-Day Point Prevalence Abstinence

Table 2 presents the 7-day PPA rates for the ERT + CBT and HLS + CBT conditions at each assessment point. Self-reports of smoking and/or abstinence were cotinine verified for 98.6% of participants at the pretreatment time point, 92.9% at the 2-month post-quit date time point and 94.4% of participants at 4 months post-quit date time point. The ERT + CBT condition demonstrated higher abstinence rates compared to HLS + CBT condition at 2 months post-quit (ERT + CBT = 23%; $SD = 0.42$ vs. HLS + CBT = 0%) and at 4 months post-quit (ERT + CBT = 18%; $SD = 0.38$ vs. HLS + CBT = 5%; $SD = 0.22$). Odds ratios were large but not statistically significant.

Sensitivity Analyses

The previous analyses assumed the missing data were missing-at-random (MAR), that the reason the participant dropped out had nothing to do with her current or future smoking status.^{40,41} In the case of nicotine addiction, assuming MAR is arguably unrealistic, as the most likely reason for dropping out is that the participant resumed smoking or less likely, that the participant quit smoking

and required no further treatment. A simple model for data missing-not-at-random (MNAR), similar to that proposed by Hedeker et al.,³⁹ was used to assess how much the assumption of MAR when MNAR was true distorted the previous results. The sensitivity analysis indicates that the observed results are slightly exaggerated but not invalidated. A more detailed description of these analyses and their interpretation with an accompanying figure have been included under Supplementary Materials.

Number of CPD

The mean number of CPD by condition for each assessment point are presented in Table 2. Although participants in each condition smoked the same number of cigarettes at pretreatment, participants in the ERT + CBT group reduced smoking by more than 3 CPD as compared with the HLS + CBT group at 2-months (ERT + CBT = 2.73; $SD = 3.35$ and HLS + CBT = 5.84; $SD = 6.24$) and 4-months post-quit (ERT + CBT = 2.15; $SD = 3.17$ and HLS + CBT = 5.18; $SD = 6.27$). Differences in CPD between the groups were statistically significant at 2 months ($t(41) = 2.02$, $p = .05$) but not at 4 months ($t(34) = 1.86$, $p = .07$).

Smoking Self-Efficacy

To explore differences between treatment conditions on self-efficacy to remain abstinent in negative affect situations, a treatment target and potential mediator of treatment effects, SSEQ-NA scores at pretreatment, 2- and 4-months post-quit were compared for the ERT + CBT and HLS + CBT conditions (Table 2). No significant group differences were observed at pretreatment (ERT + CBT = 1.58; $SD = 0.78$ vs. HLS = 1.42; $SD = 0.51$, $t(68) = 1.00$, $p = .32$). Mean scores were higher for the ERT + CBT condition as compared with the HLS + CBT condition at both 2- and 4-months. However, differences were significant only at 2 months (ERT + CBT = 3.02; $SD = 1.34$ vs. HLS + CBT = 1.80; $SD = 0.81$, $t(36) = 3.29$, $p = .002$), but not at 4 months (ERT + CBT = 2.77; $SD = 1.17$ vs. HLS + CBT = 2.07; $SD = 1.16$, $t(37) = 1.87$, $p = .07$).

Discussion

The current study reports findings from the development and pilot-testing of a multi-component emotion regulation supplement to standard

Table 2. Results from Pretreatment (t_0), 2 Months (t_1), and 4 Months (t_2) Post-Quit by ERT + CBT and HLS + CBT Treatment Groups ($N = 70$)

		ERT + CBT ($n = 36$)	Percent abstinent (SD)	HLS + CBT ($n = 34$)	Percent abstinent (SD)	OR (95% CI)				
7-day PPA ^a										
	t_0	36	0 (0)	34	3 (17)	0.31 (0.01 to 7.77)				
	t_1	22	23 (42)	21	0 (0)	13.51 (0.70 to 261.59)				
	t_2	17	18 (38)	19	5 (22)	2.98 (0.39 to 22.72)				
							Difference between treatment groups at			
			Means (SD)		Means (SD)		t_0 , t_1 , and t_2	df	T	p
CPD	t_0	36	7.48 (7.19)	34	7.48 (11.69)	0.003 (-4.68 to 4.69)		68	0	1.00
	t_1	22	2.73 (3.35)	21	5.84 (6.24)	3.11 (0.03 to 6.25)		41	2.02	0.05
	t_2	17	2.15 (3.17)	19	5.18 (6.27)	3.03 (-0.31 to 6.37)		34	1.86	0.07
SSEQ, NA	t_0	36	1.58 (0.78)	34	1.42 (0.51)	0.16 (-0.16 to 0.47)		68	1	0.32
	t_1	21	3.02 (1.34)	17	1.80 (0.81)	1.22 (0.50 to 1.94)		36	3.29	0.002
	t_2	18	2.77 (1.17)	21	2.07 (1.16)	0.70 (-0.06 to 1.45)		37	1.87	0.07

CBT = standard smoking cessation; CPD = cigarettes per day; CI = confidence interval; df = degrees of freedom; ERT = Emotion regulation treatment; HLS = Health and lifestyle; OR = odds ratio; p = p -value; PPA = point prevalence smoking abstinence; SD = standard deviation; SSEQ-NA = Smoking Self-efficacy Questionnaire-negative affect subscale; T = from the Student's t test. Data from participants who were postnatal at t_2 were not included.

^aCotinine-verified.

cognitive-behavioral smoking cessation treatment (ERT + CBT) for pregnant smokers. Study results indicate that the ERT + CBT intervention is both feasible and acceptable to pregnant low income, negative affect smokers; a primary purpose of conducting this pilot study.³⁷ The ERT intervention met several of the aims of a Stage Ia/b pilot study including: (1) good patient acceptance among those who completed the treatment, (2) good feasibility of recruitment into the trial, and (3) ease of delivery by study therapists.²⁶ A secondary aim was to examine differences in smoking outcomes. The ERT + CBT condition demonstrated higher rates of abstinence and smoked fewer CPD as compared with the control condition (HLS + CBT) at both 2- and 4-months post-quit with larger differences at 2 months than at 4 months. However, given the small sample sizes, these results reflect the inherent imprecision resulting from estimates involving small sample sizes. Treatment development pilot studies are not intended to examine the efficacy of a new treatment and thus a lack of power to detect significant differences is expected.³⁷ Thus, the determination of efficacy of the ERT + CBT intervention awaits testing utilizing a fully-powered study. At 2-months post-quit, the ERT + CBT condition had greater self-efficacy to maintain abstinence compared with controls; however, this group difference was reduced at 4-months post-quit. These findings suggest that one of the ways the ERT intervention may improve smoking outcomes is by enhancing self-efficacy to remain abstinent in negative affect situations, however, a randomized clinical trial adequately-powered to assess potential mediators and moderators of treatment effects is needed to confirm these findings. A consistent observation is that treatment effects on smoking and self-efficacy outcomes were strongest immediately post-treatment (2-month assessment) and eroded over time. Thus, additional strategies that have empirical support for prolonging the durability of smoking cessation effects, such as extending contact over time⁴² or providing voucher incentives should be considered.^{43,44} This study provides additional evidence for negative affect as an intervention target in addiction treatment. A recent study provided evidence for the feasibility and acceptability, and better alcohol outcomes for an intervention supplement targeting negative affect drinking among alcohol-dependent individuals participating in standard cognitive-behavioral outpatient treatment.^{21,45}

Study strengths include cotinine verification of self-reported smoking abstinence, a control condition that included standard smoking cessation treatment, controlled for contact time and participant expectation of treatment effects, thus setting a high bar for observing significant differences between the groups.

Despite these study strengths, it is not without limitations. These include subject attrition for the research follow-ups that reflect difficulties in conducting studies with very low income participants (nearly 70% had family incomes below US\$10 000 per year and 90% were below US\$20 000 per year), many of whom had only pay-as-you-go cell phone plans and unstable living situations that it made it difficult to maintain contact. However, these attrition rates are consistent with prior smoking cessation studies with low-income pregnant smokers.^{46,47} In addition, substantial attrition occurred later in the study due to postnatal status. Women diagnosed with a substance use disorder were excluded which may also impact generalization of study findings. Although a large proportion (78%) of pregnant smokers met the negative affect smoking criteria, this intervention may not be appropriate for all pregnant smokers. On average, participants attended between 4 and 5 sessions demonstrating good acceptability and feasibility; however, this falls short of the intended 8 sessions and thus reflects difficulties and challenges in providing more intensive, face-to-face smoking cessation counseling. Future studies should

consider a reduction in the number of treatment sessions and the integration of the ERT + CBT intervention into prenatal primary care, which may result in greater treatment completion rates. This integration reflects the goals of the Affordable Care Act regarding the addition of behavioral health into primary care.⁴⁸

Given the promising initial findings of this treatment development study, a Stage II randomized clinical trial with sufficient power to assess potential mediators and moderators of treatment effects (ie, self-efficacy to manage negative affect smoking situations, changes in emotion regulation skills) that includes a determination of its cost-effectiveness is warranted.

Supplementary Material

Supplementary data are available at *Nicotine & Tobacco Research* online.

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Declaration of Interests

THB receives research support from Pfizer, Inc. No other authors have competing interests to declare.

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