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Randomized Controlled Trial of Behavioral Activation Smoking Cessation Treatment for Smokers With Elevated Depressive Symptoms

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Objective: Depressive symptoms are associated with poor smoking cessation outcomes, and there remains continued interest in behavioral interventions that simultaneously target smoking and depressive symptomatology. In this pilot study, we examined whether a behavioral activation treatment for smoking (BATS) can enhance cessation outcomes. ***Method:*** A sample of 68 adult smokers with mildly elevated depressive symptoms ($M = 43.8$ years of age; 48.5% were women; 72.7% were African American) seeking smoking cessation treatment were randomized to receive either BATS paired with standard treatment (ST) smoking cessation strategies including nicotine replacement therapy ($n = 35$) or ST alone including nicotine replacement therapy ($n = 33$). BATS and ST were matched for contact time and included 8 sessions of group-based treatment. Quit date was assigned to occur at Session 4 for each treatment condition. Participants completed a baseline assessment; furthermore, measures of smoking cessation outcomes (7-day verified point-prevalence abstinence), depressive symptoms (Beck Depression Inventory–II; Beck, Steer, & Brown, 1996), and enjoyment from daily activities (Environmental Reward Observation Scale; Armento & Hopko, 2007) were obtained at 1, 4, 16, and 26 weeks post assigned quit date. ***Results:*** Across the follow-ups over 26 weeks, participants in BATS reported greater smoking abstinence (*adjusted odds ratio* = 3.59, 95% CI [1.22, 10.53], $p = .02$) than did those in ST. Participants in BATS also reported a greater reduction in depressive symptoms ($B = -1.99$, $SE = 0.86$, $p = .02$) than did those in ST. ***Conclusions:*** Results suggest BATS is a promising intervention that may promote smoking cessation and improve depressive symptoms among underserved smokers of diverse backgrounds.

Keywords: smoking cessation, behavioral activation, depressive symptoms, low-income and minority smokers

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Moderately elevated levels of pretreatment, current depressive symptoms are associated with poor smoking cessation outcomes (e.g., Cinciripini et al., 2003; Niaura et al., 2001). Antidepressant medications and/or mood-specific cognitive–behavioral treatments largely have not impacted depressive symptoms during quit attempts (e.g., Kahler et al., 2002), and treatment effects appear unrelated to depressive symptom change (e.g., Piper et al., 2008). Beyond the putative role of depressive symptoms in cessation failure, emerging research indicates a critical role of low positive affect in poor cessation outcomes (e.g., Leventhal, Ramsey, Brown, LaChance, & Kahler, 2008; McCarthy et al., 2008) and in deprivation-induced withdrawal and craving (e.g., Cook, Spring, McChargue, & Hedeker, 2004). Although extant research typically has focused on the role of negative affectivity/mood on cessation failure (cf. Spring et al., 2008), it remains crucial to consider low positive affect/anhedonia (i.e., reduced positive emotions and a diminished capacity to experience pleasure; Pizzagalli, Jahn, & O'Shea, 2005), as these dimensions have also predicted smoking cessation-related changes in withdrawal symptoms and relapse beyond depression history (Leventhal et al., 2008).

Behavioral activation (BA; Jacobson, Dobson, Truax, & Addis, 1996; Lejuez, Hopko, & Hopko, 2001) strategies may be a promising adjunct to standard cessation strategies for smokers with elevated depressive symptoms, as this is a brief approach that targets greater contact with more valued environments through systematic efforts to increase rewarding experiences/enjoyment of daily activities, which may simultaneously reduce negative affect and improve positive affect through overt behavior change (Lejuez et al., 2001). We conducted a small scale randomized clinical trial of BA strategies with standard cognitive–behavioral smoking cessation strategies including transdermal nicotine patch (behavioral activation treatment for smoking; BATS). The comparison condition received standard smoking cessation treatment including transdermal nicotine patch (standard treatment; ST), matched for overall contact time. We hypothesized participants in BATS would evidence higher point-prevalence abstinence rates at 1, 4, 16, and 26 weeks post assigned quit date, as well as decreased depressive symptoms and enjoyment from daily activities at those time periods.

Method

Participants and Procedures

The initial phone screen required participants to be 18–65 years of age, to be a current regular smoker (≥1 year), to be currently smoking ≥10 cigarettes per day, to have a Beck Depression Inventory–II (BDI-II; Beck, Steer, & Brown, 1996) score ≥10, to have no evidence of a current *Diagnostic and Statistical Manual of Mental Disorders* (4th ed.; *DSM–IV*; American Psychiatric Association, 1994) disorder (including major depressive disorder) as assessed by the screening items from the Structured Clinical Interview for *DSM–IV*, Non-Patient Version (SCID-NP; First, Spitzer, Gibbon, & Williams, 1995), and to not meet any of the exclusion criteria (Items b–e) listed below. At the baseline assessment (scheduled within 2 weeks of the phone screen), participants were excluded if their BDI-II scores dropped to less than 7—to allow some inevitable drift while still providing a meaningful level of depressive symptoms (e.g., Thorndike et al., 2008)—or if they evidenced (a) a current Axis I disorder (including major depressive disorder) as assessed by the SCID-NP, (b) current use of psychotropic medication, (c) current participation in psychotherapy, (d) physical concerns contraindicating use of the nicotine patch, (e) current use of smoking cessation pharmacotherapy, or (f) current use of smokeless tobacco products. We recruited participants from April 2006 to January 2008 using radio, web-based, and newspaper advertisements for a smoking cessation intervention consisting of group therapy plus nicotine patch. Advertisements did not mention depressive symptoms, and participants were blinded to study goals and hypotheses. Of the 1,123 potential participants initially screened by phone for eligibility, 68 participants were randomized by cohort (ranging in size between three and eight participants) to one of the two treatment conditions (see Figure 1 for participant flow). Of these 68 participants, 26 dropped out prior to attending any treatment sessions. Specifically, 17 participants dropped out prior to receiving any treatment in the ST group, and nine participants dropped out prior to receiving any treatment in the BATS group. Dropout cannot be attributed to treatment assignment because it was not indicated to participants prior to Session 1. These 26 participants who dropped out did not differ from the 42 who attended one session on demographics or on any other baseline characteristics (e.g., smoking history).

Primary analyses include the 68 randomized individuals: 33 participants in ST and 35 in BATS. Groups did not differ on any demographic variable or on any baseline characteristics (see Table 1). Quit date was assigned to occur at Session 4 of both treatment conditions. Assessments were conducted at each treatment session, and follow-ups were conducted at 16 and 26 weeks post assigned quit date (i.e., 12 and 22 weeks post end of the 8-week treatment protocol). Assessments were conducted by research assistants blinded to treatment condition.

ST. ST included eight, 1-hr weekly group sessions. Participants began using the transdermal nicotine patch on the scheduled quit date with an initial dose of 21 mg for 4 weeks, followed by 2 weeks of 14 mg, and 2 weeks of 7 mg. Participants who smoked on average 10–12 cigarettes per day started with the 14-mg patch for the first 6 weeks, per manufacturer's recommendations. Content was based on the most recent clinical practice guidelines of the U.S. Department of Health and Human Services (Fiore et al., 2000) and included self-monitoring, identifying effective and ineffective cessation strategies from prior quit attempts, relaxation, coping with triggers, identifying social support for cessation, making lifestyle changes (such as increasing physical activity and reducing stress), relapse prevention, and homework.

BATS. BATS also included the transdermal nicotine patch and was composed of 30 min of BA (adapted from Lejuez et al., 2001) and 30 min of core ST components and content described in the previous paragraph, excluding relaxation strategies. Relaxation strategies were not included in BATS because relaxation has been documented to be neither effective nor iatrogenic for smoking cessation (Fiore et al., 2000). Thus, removal from BATS but retention in ST was useful for equating contact time without unduly harming either condition. Specific to the BA content, Session 1 began with the therapist providing the treatment rationale focused on structuring a variety of reinforcing activities to promote a more rewarding nonsmoking lifestyle. The therapist also introduced activity monitoring that involved recording of all daily activities as well as associated mood and smoking at these times. Completion of daily activity monitoring was assigned to occur

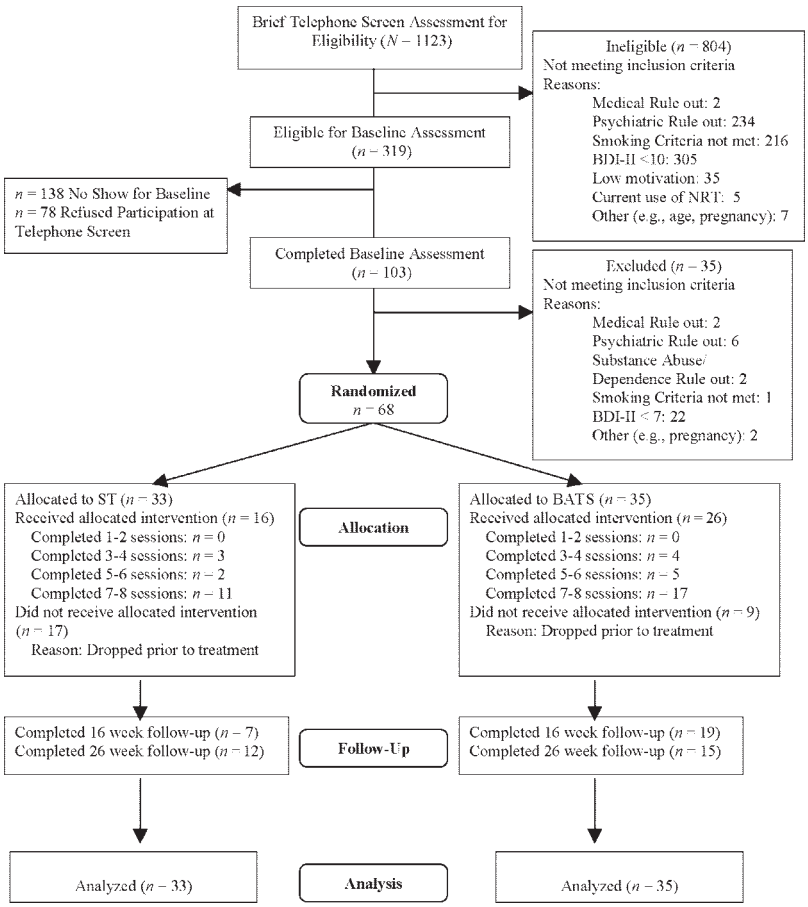

Figure 1. Consolidated Standards of Reporting Trials (CONSORT) flowchart of study participants, randomization, treatment, follow-ups, and inclusion analyses. ST = standard treatment (i.e., standard smoking cessation treatment including nicotine replacement therapy [NRT]); BATS = behavioral activation treatment for smoking (i.e., ST and NRT integrating behavioral activation strategies); BDI-II = Beck Depression Inventory–II.

each day of the following week. At the start of Session 2, the therapist led the group in a review of daily activity monitoring completed for each day of the previous week. Next, participants identified their values and life goals, which were used to identify important and/or enjoyable activities. Several activities were then planned for the coming week with the behavioral checkout form, which allowed participants to track their activities and progress toward achieving weekly goals. For homework, participants were instructed to record engagement in each planned activity (Lejuez et al., 2001). We encouraged using BA strategies for engagement in activities as part of a nonsmoking lifestyle. In Sessions 3–8, we focused on the behavioral checkout form starting with monitoring of planned activities from the previous week and then planning of activities for the coming week. In Session 3, we included a focus on activities related to quit preparation. In Session 4, we focused on quit-related activities. In Sessions 5–8, we focused on activities consistent with remaining abstinent and addressing lapses in the larger context of their specific values and life goals. Participants were encouraged to use the monitoring and planning in BA to incorporate activities consistent with the standard smoking cessation strategies, including nonsmoking lifestyle and coping with triggers.

Therapists. Therapists were four women and one man; two had clinical psychology doctoral degrees, and three were clinical psychology doctoral students. Training for both conditions included a 4-hr workshop, followed by scheduled practice and observation of a full group. Weekly supervision was conducted for all therapists, which included review of therapy audiotapes. Each therapist provided treatment in both conditions. All therapists conducted at least one group in both conditions, and no therapist conducted more than three groups in any condition. Sessions were audiotaped, and independent raters rated a random 20% to assess therapist adherence to the protocol using separate rating checklists and scales developed for the BATS and ST protocols. Adherence rates were over 95% for both treatment conditions.

Measures

At the baseline interview, participants provided demographic and other background information, including age, gender, ethnicity, marital status, income level, employment status, and education level. Duration of previous quit attempts, age of onset of regular smoking, and recent smoking behavior were assessed. *Motivation to quit* was assessed via a single item on a 10-point scale ranging

Table 1
Comparisons on Baseline Demographic, Smoking History, and Affective Variables Across Treatment Conditions

Characteristic	BATS (n = 35)			ST (n = 33)			p
	M	*SD*	%	*M*	*SD*	%	
Demographic variables							
Age	45.0	12.2		42.6	11.5		.40
Gender (% female)			48.6			48.5	.99
Ethnicity (% African American)			69.7			75.8	.34
Employment status (% employed)			54.8			58.6	.96
Education							
High school graduate/GED credential or lower			21.2			24.4	.24
Some college/technical school/college			78.8			65.6	
Household income							
$0–$49,9999			63.3			61.5	.99
$50,000–$99,999			30.0			30.8	
$100,000+			6.7			7.7	
Smoking history variables							
Smoking history in years	24.1	12.7		23.2	14.0		.79
Nicotine dependence (FTND)	5.8	1.8		6.1	2.1		.49
Average cigarettes per day	18.8	7.1		17.3	8.1		.44
No. of prior quit attempts	3.6	2.4		4.3	4.1		.39
Motivation to quit	8.4	1.7		8.8	1.3		.28
Affective variables							
BDI-II score	10.8	5.2		10.4	7.5		.80
EROS score	26.6	3.6		26.5	4.8		.89

Note. BATS = behavioral activation treatment for smoking; ST = standard treatment; GED = General Educational Development; FTND = Fagerström Test for Nicotine Dependence; BDI-II = Beck Depression Inventory–II; EROS = Environmental Reward Observation Scale.

from 1 (*not motivated at all*) to 10 (*extremely motivated*). Nicotine dependence was assessed with the six-item Fagerström Test for Nicotine Dependence (Heatherton, Kozlowski, Frecker, & Fagerström, 1991), with higher scores indicating greater nicotine dependence. The BDI-II (Beck et al., 1996) was used to assess current elevations in depressed mood. BDI-II scores ranging from 0 to 13 are indicative of minimal depression, and BDI-II scores ranging from 14 to 19 are indicative of mild depression (Beck et al., 1996). Finally, the Environmental Reward Observation Scale (EROS; Armento & Hopko, 2007) was used to measure the extent to which individuals experienced pleasure from daily activities, and it was used as the primary measure of BA. It includes 10 items rated on a 4-point Likert scale, with higher scores indicating greater environmental reward. Internal consistency of the EROS (α = .86) was established among adults (M = 29.6, SD = 4.9; Armento & Hopko, 2007) as well as its sensitivity to BA-based interventions among individuals with depression who use substances (Daughters et al., 2008).

Smoking outcome was point-prevalence abstinence defined as self-reported abstinence of ≥7 days prior to an assessment point. Smoking was assessed at 1 week, 4 weeks (end of behavioral treatment), 16 weeks, and 26 weeks post assigned quit date. Self-reported abstinence was verified via expired carbon monoxide. In addition, saliva samples for cotinine analysis were collected at the 16- and 26-week follow-up points in which verification of abstinence required a combination of carbon monoxide ≤10 ppm and cotinine ≤15 ng/ml (SRNT Subcommittee on Biochemical Verification, 2002). *Continuous abstinence* was defined as the length of time from quit day until the end of follow-up period in which the participant reported no smoking. Of those who attended at least one session of treatment (n = 42), biochemically verified smoking data were obtained for 78.6%, 83.3%, 61.9%, and 64.3% of participants at 1, 4, 16, and 26 weeks post assigned quit date, respectively. Although rates are lower than typically reported in smoking cessation trials, they are consistent with rates in largely low-income and minority samples (cf. El-Khorazaty et al., 2007). The proportion of participants who completed each assessment point was unrelated to treatment condition (ps >.25). Only those individuals whose smoking status was biochemically verified were considered abstinent at each time point, whereas those with missing data were considered as having smoked (Hughes et al., 2003). No subsequent follow-up data were obtained for the 26 participants who dropped prior to treatment; therefore, all data were coded as having smoked. One participant in BATS died between 16 and 26 weeks; this death was unrelated to study participation. Unlike other missing data, this 26-week follow-up was retained as missing.

Data Analysis

Repeated measures analyses were conducted with generalized estimating equations (GEEs) to test group differences in the odds of being abstinent at 1, 4, 16, and 26 weeks post assigned quit date for both the full randomized sample (n = 68) and the subsample attending at least one treatment session (n = 42). Included covariates were gender, nicotine dependence, BDI-II symptoms, and current income—all of which are commonly linked to poor cessation outcomes (cf. Cinciripini et al., 2003). We also included a linear effect of time. Hierarchical linear modeling analyses were conducted for the subsample (n = 42) to examine treatment group differences in depressive symptoms and EROS scores, from baseline across the same time periods as the abstinence outcomes. In

Table 2
Abstinence Rates Across Treatment Conditions for the Randomized Sample and for the Subsample Who Completed One Treatment Session

	Randomized sample (n = 68)			Subsample (n = 42)		
Point prevalence abstinence (%)	ST (n = 33)	BATS (n = 35)	*OR* (95% CI)	ST (n = 16)	BATS (n = 26)	*OR* (95% CI)
1-week post quit	9.1	28.6	4.00	18.8	38.5	2.71
4-week post quit	9.1	17.1	2.06	18.8	23.1	1.30
16-week post quit	3.0	11.4	2.71	6.3	15.4	2.71
26-week post quit	0.0	14.3	—	0.0	19.2	—

Note. An em dash indicates that odds ratios (ORs) were not computed for the 26-week post quit date because of the 0% abstinence in standard treatment (ST). BATS = behavioral activation treatment for smoking.

these analyses, we covaried gender, treatment condition, smoking status at each time point as a time-varying covariate, and the linear effect of time.

Results

The 68 randomized participants and the subsample who completed at least one session (n = 42) did not differ by gender, age, ethnicity, employment, income, or education (all ps >.15). Additionally, there were no differences on baseline and smoking characteristics between treatment conditions for either sample. See Table 1 for descriptives of the 68 participants, and see Table 2 for abstinence rates for the randomized sample and the subsample.

In GEE analyses for 7-day point-prevalence abstinence for the randomized sample (n = 68), BATS had significantly greater odds of abstinence across the follow-up period compared with ST (see Table 3). A significant linear effect of time indicated abstinence rates generally decreased from 1 week through 26 weeks post assigned quit date. Female gender and higher baseline BDI-II score were associated with lower odds of abstinence. The interaction between treatment condition and the linear effect of time was nonsignificant, indicating no differential effects of treatment across time. Continuous abstinence rates did not differ across treatment conditions (5.7% in BATS vs. 0% in ST; p = .11). There were no group differences in use of the transdermal nicotine patch or in bio-verified smoking data during treatment or the follow-up period (ps > .20). Results of the GEE model examining the main treatment effect on 7-day point-prevalence for the subsample (n = 42) were similar, although gender and mood did not significantly predict smoking status.

In the hierarchical linear model predicting depressive symptoms, the linear effect of time on depressive symptoms was significant (B = −1.53, SE = 0.68, p = .03), indicating a reduction in depressive symptoms from baseline through the 26 weeks post assigned quit date (see Table 4). However, an interaction between treatment condition and the linear effect of time (B = −1.99, SE = 0.86, p = .02) revealed that the reduction in depressive symptoms over time was greater for BATS than for ST participants (see Figure 2). All EROS analyses were nonsignificant.

Table 3
Generalized Estimation Equations Analyses Predicting 7-Day Point Prevalence Smoking Abstinence at 1, 4, 16, and 26 Weeks Post Quit Date for the Randomized Sample (n = 68)

Variable	*OR*	95% CI	*p*
Main effects			
Time	0.42	[0.21, 0.87]	.02
Female gender	0.27	[0.08, 0.95]	.04
FTND	0.79	[0.54, 1.14]	.21
BDI-II score	1.11	[1.02, 1.21]	.01
Household income	1.23	[0.65, 2.33]	.53
BATS compared with ST	3.59	[1.22, 10.53]	.02
BATS × Time	1.64	[0.72, 3.73]	.24

Note. Odds ratios (ORs) < 1 indicate reduced odds of abstinence; ORs > 1 indicate increased odds of abstinence. All continuous variables were centered. FTND = Fagerström Test for Nicotine Dependence; BDI-II = Beck Depression Inventory–II; BATS = behavioral activation treatment for smoking; ST = standard treatment.

Discussion

BATS added to standard smoking cessation resulted in greater odds of point-prevalence abstinence than ST across the 6-month follow-up period among smokers with elevated depressive symptoms. Additionally, depressive symptoms were lower throughout the follow-up period for BATS participants, whereas they slightly increased over time for ST participants. Sample size prevented testing depressive symptoms as a mediator of the time by treatment effect, but results suggest potential viability of such analyses in future work. The lack of a treatment effect on EROS score was

Table 4
Hierarchical Linear Modeling Analyses Predicting Depressive Symptoms (BDI-II Scores) at Baseline and 1, 4, 16, and 26 Weeks Post Quit Date for the Subsample (n = 42)

Variable	*B*	*SE*	*t*	*p*
Main effects				
Time	−1.53	0.68	−2.23	.03
Female gender	0.87	1.53	0.57	.58
Smoking status	1.89	1.01	1.88	.07
BATS compared with ST	−2.54	1.83	−1.44	.17
BATS × Time	−1.99	0.86	−2.31	.02

Note. All continuous variables were centered. BDI-II = Beck Depression Inventory–II; BATS = behavioral activation treatment for smoking; ST = standard treatment.

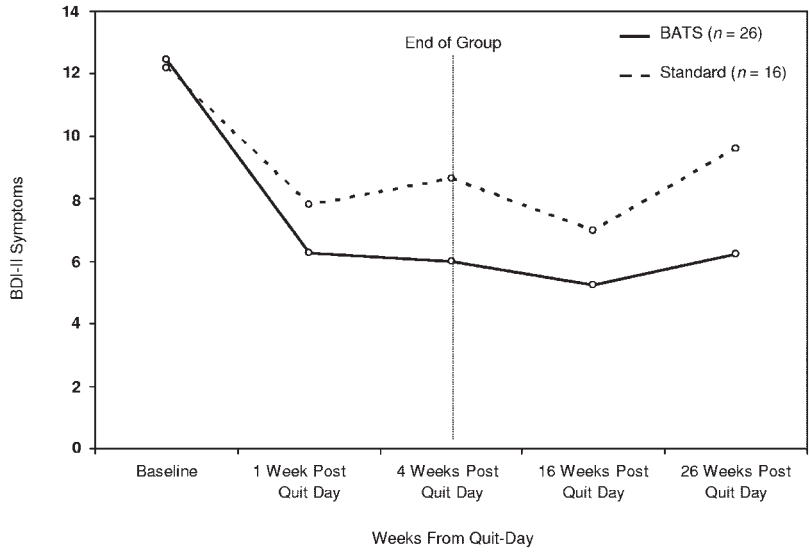

Figure 2. Changes in Beck Depression Inventory–II (BDI-II) symptoms for behavioral activation treatment for smoking (BATS) and standard treatment (Standard) conditions in the subsample ($n = 42$). Note that 1 week post quit day = Week 4 of behavioral treatment; 4 weeks post quit day = Week 8 and end of behavioral treatment; 16 weeks post quit day = 12 weeks from end of behavioral treatment; and 26 weeks post quit day = 22 weeks from end of behavior treatment.

unexpected. Future efforts should aim to determine whether the short assessment time frame here is sufficient to capture changes in pleasure that may be slower to occur than overt behavior change as well as to include the additional assessment of actual activity engagement, which is likely to change more quickly than pleasure derived from activities.

There are several study limitations. First, our control condition did not include another psychosocial depression treatment or an antidepressant medication. Second, recruitment issues raise some concerns regarding internal validity. Specifically, the refusal rate was high, although consistent with those seen in other randomized controlled trials of combined behavioral therapy plus pharmacotherapy for smoking cessation in samples with either history or current depressive syndromes (Evins et al., 2008; Spring et al., 2007). Additionally, there was differential pretreatment attrition across the two treatment conditions. Participants were unaware of treatment assignment prior to the first session, and project staff were blinded to treatment condition during both the telephone screening and the baseline assessments. Thus, this differential attrition likely reflects random chance. The effects of treatment were significant and of similar magnitude even when examining only those participants who attended at least one session. Balancing these limitations, a strength of this work is the ethnic and socioeconomic diversity of the sample (75% ethnic minority and 37% of low income), given the historic underrepresentation of low-income and ethnic minority participants in clinical trials for smoking cessation. However, it is notable that generalizability to the larger population of smokers remains unclear.

Results indicate that BATS is a promising intervention for smoking cessation and the reduction of depression among smokers with elevated depressive symptoms. Given its brief nature, it may be a viable option for smoking cessation efforts across multiple settings and populations. This sets the stage for future work to replicate and extend these findings to quantify change in BA. It also can serve as a foundation for more comprehensive efforts to control for key variables, such as psychotropic medication utilization, as well as BA treatment acceptability, homework completion, and group cohesion. Future work would benefit from efforts to identify moderators of treatment effects, including biological variables such as stress response and reward sensitivity.

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