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Trauma-Focused Smoking Cessation for Smokers Exposed to the World Trade Center Disaster: A Randomized Clinical Trial

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Abstract

Introduction: The main objective was to evaluate the efficacy of an 8-session, group-based comprehensive smoking cessation and trauma management (CSC-T) treatment among daily smokers (≥5 cigarettes/day) exposed to the World Trade Center (WTC) disaster with elevated WTC-related post-traumatic stress disorder (PTSD) symptoms.

Methods: Participants (N = 90) were randomly assigned to CSC-T (N = 44; 63.6% white; 27.3% female; mean age = 51.32 ± 7.87) or comprehensive smoking cessation (CSC) alone (N = 46; 71.7% white; 28.3% female; mean age = 48.74 ± 10.66), which was comparable in length and time. Assessments included a diagnostic clinical interview and self-report measures of PTSD and respiratory symptoms, and smoking behavior, and biologically confirmed smoking abstinence. Evaluations occurred at a baseline visit, each treatment session, and at 1-, 2-, 4-, 12-, and 26-weeks post-treatment.

Results: The two treatments did not differ in regard to PTSD symptom improvement. After quit day (week 6), the two groups had similar 7-day (~15%) and 6-month (~20%) abstinence rates as well as average number of cigarettes smoked, and PTSD and respiratory symptoms.

Conclusions: It is possible that the Cognitive Behavioral Therapy skills specific to quitting smoking, group-based support, and degree of therapist contact, that were available in both treatments may have played a role in equalizing the abstinence rates between the two conditions. Although the current study found no evidence that the CSC-T was superior to the CSC alone treatment, the abstinence rates observed were high relative to previous trials of smokers with diagnosed PTSD. Further development of smoking cessation programs tailored to the needs of smokers with PTSD symptoms continues to be needed.

Implications: This study suggests that a CSC program aids in smoking abstinence for smokers with PTSD symptoms and that incorporating trauma management skills, may not add additional benefits for abstinence and PTSD and respiratory symptom relief. Further work is needed to improve smoking cessation efforts for smokers with PTSD symptoms.

Introduction

Following the September 11, 2001 (9/11) attacks on the World Trade Center (WTC), thousands of individuals were directly exposed to toxic physical hazards, horrific psychological trauma, or both. Respiratory illness and post-traumatic stress disorder (PTSD) are primary health sequelae of 9/11 and are often comorbid.[1–4] Nearly half (46.5%) of the responders to the WTC disaster participating in health monitoring had lower respiratory symptoms (LRS) at their first clinic visit that began or worsened after 9/11[5] regardless of their history of tobacco use, and 11.1% had symptoms consistent with the diagnosis of PTSD.[6] In addition, prospective studies of individuals exposed to the disaster indicate that WTC-related PTSD symptoms and LRS are associated overtime and that the severity of PTSD symptoms is linked to new onset and persistence of LRS.[1,7]

One modifiable health behavior associated with both LRS and PTSD is cigarette smoking. It is well documented that smoking is the leading contributor to respiratory illness.[8] Smoking cessation programs are a front-line intervention for smokers with pulmonary problems.[9] Indeed, research supports that LRS and lung functioning improve following smoking cessation.[10] In addition, studies have demonstrated a significant association between smoking and PTSD symptoms.[11] Among those with PTSD, rates of smoking, which range from 40% to 86%, are 2–5 times higher than rates in the general population.[12–14] Smokers with PTSD also smoke more cigarettes per day and have higher rates of nicotine dependence[15,16] than smokers without PTSD. Moreover, PTSD is associated with an increased odds of cessation failure.[17–19] Similarly, recent analyses of prospective data among general population samples directly exposed to the WTC disaster found that WTC-related PTSD symptoms were significantly associated with persistent smoking over time.[20,21]

Smokers with PTSD symptomatology have greater difficulty quitting on their own, are likely to fail standard cessation interventions, and are more likely to relapse than smokers with other anxiety psychopathology and those without mental illness.[22–24] Potential mechanisms driving the PTSD-smoking association and cessation difficulties include shared underlying affective experiences. For example, negative affect and anxious arousal symptoms are common to both PTSD and smoking, especially in terms of nicotine withdrawal.[25] Indeed, smokers with PTSD symptoms are motivated to smoke for negative affect regulation.[26,27] Similarly, anxious arousal symptoms predict decreased abstinence[21] and greater negative affect is associated with more intense nicotine withdrawal symptoms.[25] As such, addressing anxious arousal symptoms concomitantly with smoking cessation may aid in the reduction of symptoms and improve cessation success.

There are several possible approaches to treatment.[28] Independent, concurrent treatments, wherein PTSD symptoms and smoking are treated individually but within the same sessions, have shown initial promise. Hertzberg and colleagues[29] evaluated the effect of bupropion sustained-release compared to placebo on smoking cessation among veterans with PTSD (n = 15) undergoing outpatient PTSD treatment. Patients in the bupropion sustained-release group were more likely to remain in treatment and achieve abstinence than the placebo condition. However, there were no significant changes in PTSD symptoms in either group. McFall and colleagues[22,30] evaluated a combined care approach, wherein brief smoking cessation counseling (~20 minutes) occurred in the context of usual PTSD treatment. Here, veterans enrolled in PTSD treatment were randomized to receive (1) brief cessation counseling from their PTSD treatment provider at the end of each PTSD treatment session (combined treatment) or (2) the same brief cessation counseling delivered separately by smoking cessation specialists (standard care). Compared to standard care, combined treatment delayed smoking relapse and approximately doubled smoking abstinence rates (9%–15% abstinence).[22] A 10% reduction in PTSD symptoms was observed across groups, but groups did not differ, suggesting no advantageous effect of combined care on PTSD symptoms relative to PTSD treatment as usual.

Integrated treatment has the potential to increase efficacy by targeting mechanisms thought to maintain the comorbidity.[21,31] For example, Zvolensky and colleagues[24,32] developed integrated treatments that target smoking cessation and reduction of cognitive vulnerability processes underlying smoking and anxiety (ie, anxiety sensitivity and distress intolerance).[31] In an initial test of heavy smokers (>20 cigarettes/day) with elevated anxiety sensitivity, 67% remained abstinent at 3-month follow-up.[24] In a recent randomized clinical trial, sedentary, daily smokers with elevated anxiety sensitivity (N = 136) received 15 weeks of standard smoking cessation treatment (Cognitive Behavioral Therapy [CBT] plus nicotine replacement therapy [NRT]) and were simultaneously randomized to 15 weeks of an anxiety sensitivity reduction exercise program or wellness education intervention.[33] Point prevalence abstinence and prolonged abstinence rates were significantly higher for the exercise program at 4 and 6 months post-cessation. These clinical trial results, in conjunction with earlier work,[32] suggest that smoking programs that can reduce emotional vulnerability factors, may increase the odds of cessation for emotionally at-risk smokers. However, past work, has neither been oriented to trauma-exposed smokers, nor has it explored the impact on respiratory health.

To address management of PTSD symptoms and LRS simultaneously, we developed and tested an integrated smoking cessation treatment that targets shared underlying affective and behavioral processes of PTSD and smoking (ie, anxious arousal and behavioral avoidance). Specifically, we combined state-of-the-art comprehensive smoking cessation (CSC) strategies that included CBT skills and NRT with trauma management techniques[34,35] and transdiagnostic CBT-based anxiety reduction skills[36,37] to form the Comprehensive Smoking Cessation and Trauma Management (CSC-T) treatment (see description below). The CSC-T intervention combined NRT with (1) psychoeducation regarding anxiety, smoking and nicotine withdrawal, and the anxiety-smoking maintenance cycle; (2) exposure and problem solving techniques to address physiologic arousal symptoms common to PTSD and nicotine withdrawal (ie, racing heart) and avoidance to cues triggering PTSD symptoms and smoking; and (3) cognitive restructuring skills to challenge misinterpretations regarding feared somatic sensations, smoking, and avoided smoking and trauma-related triggers.

The purpose of the current study was to conduct a randomized clinical trial to test whether smokers with elevated WTC-related PTSD symptoms, who received CSC-T, showed greater improvement in quit rates and reductions in PTSD and LRS than similarly affected smokers who received the CSC treatment alone. It was hypothesized that smokers receiving CSC-T would have more favorable outcomes over a 6-month follow-up period than those receiving CSC alone.

Methods

Sample and Procedures

Participants were recruited from the WTC Health Program, a federally-funded program designed to monitor health and treat WTC-related

conditions for responders to the disaster; the WTC Health Registry, a New York City Department of Health surveillance program for community members living near the WTC disaster, responders, and others affected by the disaster; and newspaper and online advertisements. Interested persons were given a description of the study and screened over the phone to determine potential eligibility using the following criteria: (1) smoking ≥ 5 cigarettes per day; (2) reporting interest in quitting smoking; (3) direct exposure to the WTC disaster (eg, responding to the event or witnessing the event in person); and (4) scoring at least in the intermediate range (≥30)[38] on the PTSD Checklist (PCL).[39] Exclusion criteria were: (1) current participation in another smoking cessation treatment; (2) alcohol dependence within the last 6 months; and (3) psychosis or current mania.

Participants meeting screening criteria were scheduled for an in-person baseline assessment to confirm eligibility. Upon arrival, written informed consent was obtained. The baseline assessment procedures included the Structured Clinical Interview for DSM-IV (SCID)[40] verification of smoking status via expired carbon monoxide (CO; >5 ppm), and completion of a battery of self-report measures.

Eligible participants were then randomized to the CSC or CSC-T treatments (descriptions below) and completed five follow-up assessments at 1-, 2-, 4-, 12-, and 26-weeks after the treatment ended. Outcomes were also tracked during treatment visits. Participants were compensated as follows: $50 for baseline assessment; $50 bonus for attending all sessions; $30 for each follow-up; and $50 bonus for completing all follow-up assessments (ie, up to $300). At the end of the study, participants who did not return the last self-report follow-up assessment were incentivized to complete the questionnaire packet by entry into a raffle for an iPad mini. The study was approved by the Institutional Review Board of Stony Brook University and registered at clinicaltrials.gov (#NCT02538601).

Treatment

Experienced mental health professionals (ie, clinical psychologists and social workers) were trained in and administered both treatments. For both treatments, written therapist and patient manuals were created to standardize delivery (available from AG). Participants in both conditions were offered and instructed how to use NRT in the form of Nicoderm CQ (ie, 24-hour transdermal nicotine patches) at the session immediately prior to quit date. Up to 6 weeks of patches were provided, and participants were encouraged to continue using the patch if needed. Participants who lapsed during treatment (ie, any smoking, even a puff) were encouraged to set a new quit date and continue their cessation attempt.

Comprehensive Smoking Cessation (CSC). The CSC condition (A. Gonzalez et al., unpublished data, 2011) was an adapted group-based smoking cessation treatment delivered in 8 sessions (1.5 h/session; Supplementary Table 1) based on the most recent clinical practice guidelines from the USDHHS.[41] Standard cessation elements included psychoeducation on reasons for smoking and barriers to quitting, enlisting social support, monitoring, and tapering cigarette use, counseling regarding high-risk smoking situations and unhelpful ways of thinking about smoking and abstinence, and relapse prevention combined with NRT. The treatment was similar to protocols used in other smoking cessation research.[42,43]

Comprehensive Smoking Cessation and Trauma Management (CSC-T). The CSC-T (A. Gonzalez et al., unpublished data, 2011) treatment was an 8-session (1.5 hours each; Supplementary Table 1) group treatment for quitting smoking comprised of an optimized protocol that incorporated all elements of the CSC treatment as well as trauma management techniques[34,35] and transdiagnostic CBT-based anxiety reduction skills.[36,37] Specifically, to address the management of PTSD and anxious arousal symptoms and withdrawal symptoms, the CSC-T intervention included the following techniques: (1) repeated interoceptive exposures to feared bodily sensations (eg, participants engage in exercises such as breathing through small straws to produce physical sensations associated with anxiety and nicotine withdrawal symptoms [dizziness and racing heart]); (2) corrective information about anxiety and cognitive interventions to teach patients alternatives to catastrophic misinterpretations of somatic sensations (eg, "I will lose control"); and (3) use of graduated in vivo exposure to feared and avoided situational experiences related to anxiety, WTC-related PTSD triggers, and smoking (eg, going to lower Manhattan; driving without smoking).

Patients in the CSC-T treatment were also asked to remain cigarette-free for increasing amounts of time prior to certain sessions before the quit date to allow for direct extinction training during sessions when interoceptive exercises were conducted. These smoke-free hours before the session also encouraged participants to practice resisting the urge to smoke, thus weakening the link between discomfort and cigarette use.

Measures

"The non-patient version of the Structured Clinical Interview for DSM-IV (SCID-NP)"[44] was administered at baseline by master's and doctoral level clinical psychologists (with diagnostic assessment experience to assess Axis I psychopathology. Over 10% of interviews (n = 19) were reviewed by an independent rater for inter-rater reliability. Overall there was 94.7%–100% agreement across diagnoses (Kappa = 0.64–1.0).

PTSD Checklist-Specific Version (PCL)

This 17-item measure, administered at baseline, each treatment session, and all follow-up assessments, assessed the severity of DSM-IV PTSD symptoms.[39] Participants were asked to rate how bothered they were by problems in the past week "in relation to 9/11" on a scale of 1 (not at all) to 5 (extremely). The scale possesses good temporal stability, internal consistency, test –retest reliability, and convergent validity.[45] In the current sample, the PCL demonstrated excellent internal consistency (Cronbach's α = 0.93).

Smoking History Questionnaire

This 26-item measure, administered at baseline, assessed smoking rate and history and past quit attempts.[46] The Smoking history questionnaire has been successfully used in previous studies.[47,48]

Fagerstrom Test for Nicotine Dependence (FTND)

This 6-item measure, administered at baseline, assessed level of tobacco dependence. Scores range from 0 to 10, with higher scores reflecting greater physiological dependence on nicotine.[49] The FTND is positively correlated with physiological measures of tobacco use (eg, saliva cotinine) and has high test–retest reliability. Internal consistency was relatively low in this sample (α = 0.43), which is not atypical for this measure.[50]

Time Line Follow-Back (TLFB) for Daily Cigarette Use

This retrospective measure assessed daily number of cigarettes smoked starting from 2 weeks prior to baseline assessment and

continuing throughout treatment and the follow-up assessment period.[51] At each assessment point, the average number of cigarettes smoked in the past week was calculated. After quit day, 7-day abstinence status was calculated at each time point. Abstinence was confirmed with the biochemical verification methods outlined below. The TLFB was also used to assess number of cigarettes smoked per day throughout the study, which was used to calculate time to first lapse and relapse. Consistent with previous work, a lapse was defined as any smoking, even a single puff [52,53] and relapse was defined as smoking at ≥5 cigarettes a day on 3 consecutive days.[53,54] The TLFB procedure has demonstrated good reliability and validity.[51] For the current study, the TLFB showed good agreement with biochemical measures of smoking, with kappa of 0.62 when comparing 7-day self-reported abstinence with a negative reading on CO monitor (<5 ppm) across all data points gathered after quit day.

Biochemical Verification

Self-reported abstinence was verified using two assays. Saliva cotinine was assessed at 2-weeks post-quit day (session 8) and at each follow-up. Samples were frozen and analyzed by an outside laboratory for cotinine level using radioimmune assay. CO analysis of breath samples with a Vitalograph Breathco CO monitor[55] was used to assess abstinence at quit day, sessions 7 and 8, and all follow-up assessments. Detected CO values > 5 ppm or cotinine levels >10 ng/mL indicated current smoking.[56,57]

Lower Respiratory Symptoms

This measure (developed for the study) assessed the severity of six LRS (shortness of breath, chest tightness, wheezing, dry cough, productive cough, and overall difficulty breathing). Participants rated the degree to which each symptom was a problem in the past week on a 5-point Likert-type scale ranging from 0 (none) to 4 (almost a constant problem). Internal consistency was high ($\alpha = 0.82$). The average inter-item correlation was $r = 0.43$, the corrected item-total correlations were >0.46, and test–retest reliability was high ($r = 0.79$ for 1-week retest).

Participant Adherence

Adherence was based on attendance at each treatment session. Incentives to facilitate attendance included convenient scheduling, reminder calls/emails, and bonus payment ($50) for completing all treatment sessions (regardless of smoking status).

Therapist Adherence

All sessions were audiotaped. Adherence to manualized treatment protocols was monitored in weekly face-to-face clinical supervision with an experienced licensed psychologist (FF) and assessed with fidelity ratings by two psychologists (FF and BM) for a randomly selected 15% of sessions.

Data Analyses

The primary question was whether the four outcomes (7-day point abstinence, average number of cigarettes smoked per day in the past 7 days, PCL score, and LRS score) differed between treatments. Treatments were compared in cross-sections using χ^2 tests and t tests. Longitudinal comparisons were performed with multi-level modeling.[58] First, each person's trajectory was modeled over 13 time points (session 1 to follow-up 5) by specifying a random intercept and random slopes of time. Treatment was entirely finished by follow-up 3 (end date for NRT), and outcomes were expected to begin deteriorating after that date; therefore, trajectories were modeled as two segments with the knot (ie, bend in the curve) at follow-up 3. Next, treatment condition entered the model as a between-subjects predictor of intercept and slopes. Hence, abstinence and LRS models included intercept, linear slope of time, and the knot. The trend in PCL scores did not conform to a straight linear change, and thus a quadratic effect of time was added to that model. Cigarette use showed a sharp discontinuity at quit day, and thus it was split into three segments (sessions 1–6, session 7 to follow-up 3, and follow-ups 3–5). There was a sharp boundary between first and second segments, resulting in separate intercepts for these segments and a smooth transition between second and third segments as in the other models. Linear slopes of time were fit in each segment. Grand mean standardization was used to compute standardized coefficients. Models were fit using PROC MIXED and PROC GLIMMIX procedure in SAS version 9.2.

Randomized participants were included in longitudinal analyses following intention-to-treat design. For abstinence, missing observations were conservatively counted as non-abstinent. For the other outcomes, full information maximum likelihood approach to missing data allowed for the use of all available observations.

Effects of treatment on the risk of lapse and relapse were tested using proportional hazards regression with treatment condition as the predictor in each model. Kaplan–Meier plots were constructed to illustrate the pattern. Estimation was done in R version 3.0.2 using coxph and survfit packages.

Results

Sample

Ninety daily smokers were randomly assigned to CSC-T ($N = 44$; 27.3% female; mean age = 51.32 ± 7.87) and CSC ($N = 46$; 28.3% female; mean age = 48.74 ± 10.66) groups. There were no significant differences between treatment conditions in demographic and smoking characteristics and current Axis I SCID diagnoses (Table 1). The flow of participants through the course of the study is shown in Supplementary Figure 1. There were no group differences in the average number of sessions (CSC-T: $M = 5.0 \pm 2.9$ and CSC: $M = 5.4 \pm 2.7$), follow-up visits (CSC-T: $M = 3.1 \pm 2.1$ and CSC: $M = 3.2 \pm 1.9$), study completion defined as attending at least 6 sessions (CSC-T: 57% and CSC: 59%) and receipt of NRT (ie, nicotine patches; CSC-T: 66.8% and CSC: 67.7%).

Treatment Fidelity

A sample of approximately 15% ($N = 19$; CSC = 8; CSC-T = 11) of audio-recorded treatment sessions were reviewed for treatment fidelity by two independent psychologists. Each reviewer examined a different random sample of sessions from the CSC and CSC-T conditions. There were no significant differences between the raters on overall ratings of adequacy of skill delivery (CSC-T [$t(8) = 0.87$, $p = .41$]; CSC [$t(7) = 2.26$, $p = .06$]) or non-specific treatment factors (eg, therapist interpersonal skills, basic group facilitation skills; $t[17] = 1.32$, $p = .21$). There were no significant differences between the CSC ($M = 4.00$, $SD = 0.37$) and CSC-T (M = CSC-T = 3.77 $SD = 0.78$) groups with regards to fidelity to prescribed session content ($t[17] = 0.83$, $p = .42$). There were also no significant differences between CSC ($M = 3.64$, $SD = 0.61$) and CSC-T ($M = 3.79$ $SD = 0.51$) on non-specific treatment factors ($t[17] = 0.58$, $p = .57$). On average, 80% of prescribed session content was covered in the

Table 1. Demographics, Smoking Characteristics, and Diagnoses at Baseline

	CSC-T group (N = 44)		CSC group (N = 46)	
Characteristic	Mean/*N*	*SD*/%	Mean/*N*	*SD*/%
Age	51.32	7.87	48.74	10.66
Gender (male)	32	72.70%	33	71.70%
Partner status (Partnered)	18	40.91%	25	54.35%
Race				
White	28	63.60%	33	71.70%
Black	12	27.30%	13	28.30%
Asian	1	2.30%	0	0.00%
Other/multiracial	3	6.80%	0	0.00%
Ethnicity (Hispanic)	7	15.90%	5	10.90%
Employment				
Full-time	8	18.50%	20	43.50%
Part-time	11	25.00%	9	19.50%
Unemployed	10	22.70%	6	13.00%
Retired/disabled	15	24.08%	11	23.92%
Smoking characteristics				
Cigarettes/day	16.99	8.85	19.67	11.22
CO ppm	16.67	10.49	18.96	10.39
Age at first cigarette	15.08	3.74	14.98	5.96
Years of daily smoking	30.89	10.22	29.09	12.65
Past quit attempts	4.56	2.95	3.90	2.70
FTND	5.80	1.80	5.36	1.78
Current axis I SCID diagnoses				
WTC-PTSD	18	40.9%	19	41.3%
Major depressive disorder	16	36.4%	13	28.3%
Specific phobia	16	36.4%	11	23.9%
Dysthymic disorder	9	20.5%	7	15.2%
Panic disorder or Agoraphobia	7	15.9%	7	15.2%
Generalized anxiety disorder	7	15.9%	8	17.4%
Obsessive-compulsive disorder	5	11.4%	4	8.7%
Social phobia	1	2.3%	5	10.9%
Alcohol abuse (past 6 mon)	0	0	2	4.3%
Bipolar disorder	0	0	1	2.2%

CSC = comprehensive smoking cessation; CSC-T = comprehensive smoking cessation and trauma management; CO = carbon monoxide; FTND = Fagerstrom Test for Nicotine Dependence; PTSD = post-traumatic stress disorder; SCID = Structured Clinical Interview for DSM-IV; *SD* = standard deviation; WTC = World Trade Center. Group differences were non-significant ($p > .05$) on all characteristics.

CSC-T condition and 75.2% in the CSC condition. In most cases when session material was not covered it was because the content was thoroughly covered previously or not relevant to the group (eg, all participants reporting strong social support).

Treatment Effects

Outcome levels at all assessment points are shown in Supplementary Table 2. In particular, at session 7 (week after quit day), abstinence rates were 15.9% (7/44) in the CSC-T group and 15.2 % (7/46) in the CSC group. At follow-up 5, abstinence rates were 20.5% (9/44) in the CSC-T group and 19.6 % (9/46) in the CSC group. There were no cross-sectional differences between treatment conditions, except for higher LRS in CSC-T group at session 2 ($p = .03$), follow-up 2 ($p = .05$), and follow-up 5 ($p = .02$).

Longitudinal analyses of abstinence revealed gradually increasing rates that peaked at follow-up 3 (6-weeks post-quit day), with 26% in CSC-T and 20% abstinent in CSC, but then declined somewhat (Supplementary Figure 2A). This pattern did not significantly differ between treatment conditions (Supplementary Table 3). There was a significant decrease in cigarette use over the six sessions leading to quit day with a further drop of 5 cigarettes/day during quit week; after that, cigarette use remained effectively constant through follow-up 5 (Supplementary Figure 2B). Treatment conditions differed with regard to the initial slope ($p = .02$), so that from session 1–6, the CSC-T group reduced smoking by 4 cigarettes/day, and the CSC group reduced smoking by 7 cigarettes/day (Supplementary Table 3). The trajectories did not significantly differ after quit day. PTSD symptoms improved through follow-up 3 with the pace of improvement gradually decelerating (Supplementary Figure 2C). Symptoms increased somewhat during the long-term follow-up, but this increase did not reach significance ($p = .07$). The pattern did not differ between treatment conditions (Supplementary Table 3). LRS also improved through follow-up 3 but increased after that (Supplementary Figure 2D). This trajectory also did not differ by treatment (Supplementary Table 3).

Regardless of treatment condition, there was a main effect for number of attended sessions. Specifically, number of attended sessions was significantly associated with a reduced number of cigarettes in the past week at session 8 ($r = –0.52$, $p < .001$), follow-ups 1, 2, 3, and 5 ($r = –0.47$, $–0.48$, $–0.42$, and $–0.30$, $p < .001$; respectively), but not follow-up 4 ($r = –0.22$, $p = .10$). Additionally, number of attended sessions was significantly associated with abstinence at follow-up 3 ($r = 0.31$, $p = .003$), follow-up 4 ($r = 0.24$, $p = .03$), and 5 ($r = 0.25$, $p = .02$). There was no association between number of attended sessions and PCL scores and LRS at any time-point.

Analyses of smoking lapse and relapse were conducted in 72 participants who stayed in treatment to quit day. Among participants who lapsed, the median number of days to lapse was one (IQR = 1 to 5.5 days) in CSC-T and 1.5 in CSC (IQR = 1 to 8.75 days). Among participants who relapsed, the median number of days to relapse was one (IQR = 1 to 25 days) in CSC-T and 5 (IQR = 1 to 69 days) in CSC (Supplementary Figure 3). Treatments did not differ with regard to time to lapse (CSC-T vs. CSC hazard ratio = 0.78; p = .34), but relapse occurred faster in CSC-T than in CSC (hazard ratio = 0.52; p = .03). We also evaluated a treatment condition by PCL score interaction, which was not related to lapse, relapse, cigarettes smoked in the past week, and abstinence.

Safety Monitoring and Concerns

No significant adverse reactions or side effects were reported throughout the course of the study. Less than 5% of participants reported minor skin irritation at the administration site of the nicotine patch.

Discussion

The current study evaluated the efficacy of an integrated group-based CSC-T treatment versus a CSC treatment alone for smokers with elevated PTSD symptoms resulting from exposure to the 9/11 WTC disaster. Contrary to expectation, the CSC-T group was not superior to the CSC group with respect to improvements in PTSD symptoms. Given the lack of a treatment effect for PTSD symptoms, it is not surprising that the treatment conditions did not differ on smoking abstinence, average number of cigarettes smoked per day after quit day, and LRS. Seven-day abstinence rates following quit day were 15.9% in the CSC-T group and 15.2 % in the CSC group. At the final (26 weeks) follow-up, 7-day abstinence rates were 20.5% (9/44) in the CSC-T group and 19.6 % (9/46) in the CSC group. It is possible that the CBT skills specific to quitting smoking (eg, coping strategies and enlisting social support), group-based support and degree of therapist contact, which were available in both treatments, may have played a role in equalizing the abstinence rates between the two conditions. Indeed, Brown and colleagues[42] also did not find group-based treatment differences when comparing integrated CSC and depression management skills versus CSC alone in smokers with a history of depression. Of note, the CSC comparison intervention utilized in the current study was similar to the treatment used in the Brown et al. trial. Nevertheless, both treatments in the current study led to relatively high quit rates when compared to previous trials of smokers with PTSD.[22,30] In addition, our abstinence rates are on par with rates observed in the US Public Health Service meta-analysis of 6000 studies involving follow-up assessments of at least 5 months (15–25% abstinence).[41]

There was a significant difference in the number of days to relapse by treatment group. Specifically, the CSC-T group reported fewer days to relapse than the CSC group. It is possible that the degree of attention and focus on abstinence and planning for high-risk situations post-quit in the CSC group may have aided in the process of delaying relapse. The CSC-T group also covered these skills, however, post-quit sessions also focused on the trauma management skills. Future work is needed to determine the specific aspects of CSC that are most useful for delaying and preventing relapse.

Although both treatment groups experienced clinically significant reductions in PTSD symptoms overtime, there were no differences by treatment condition. It is possible that the group-based support, coping skills, and smoking reduction may have facilitated these symptom improvements. Of note, other research has also found that non-specific group treatments resulted in reductions in PTSD symptoms.[59] In addition, the anxiety management skills provided in the CSC-T intervention were designed to target fear and anxiety-based processes that underlie both PTSD and smoking maintenance (ie, fear and intolerance of arousal symptoms). Although patients were instructed to monitor and restructure trauma-related cognitions and focus on avoided trauma reminders (ie, visiting lower Manhattan and riding the subway), more attention to WTC-specific triggers may have been needed for greater PTSD symptom reduction in the CSC-T treatment. Moreover, the complexity of the CSC-T treatment may have blunted the acquisition of anxiety management skills.

Limitations

First, the sample included eight light smokers (5–9 cigarettes per day) and effect of treatment may be smaller in this subgroup, due to a restriction of range. Nevertheless, the overall sample showed moderate levels of smoking (18 cigarettes/day) and the treatment produced clinically significant effects (reduction of 13 cigarettes). Second, participants reported PTSD symptoms of moderate severity from a trauma that occurred over a decade ago (ie, 9/11 disaster). In addition, the current study did not account for exposure to other traumatic events. As such, results may not generalize to smokers with PTSD symptoms from an acute trauma, those with an extensive trauma history, and smokers diagnosed with PTSD. Third, there were moderate retention rates (52%–78%) at the follow-up assessments across both treatments groups. As such, the study may have been underpowered to detect significant treatment group differences in the outcomes. Future work is needed to evaluate the efficacy of the CSC-T treatment with a larger sample of heavy smokers diagnosed with PTSD. Moreover, it is necessary to explore methods for improving completion of follow-up assessments including greater financial incentives. Fourth, the participants attending the treatments were recruited specifically for smoking cessation and not for PTSD treatment. Future work should explore whether patients interested in smoking cessation and PTSD treatment would differentially benefit from the current treatments; that is, patients specifically motivated to work on reducing PTSD symptoms and quit smoking might have different levels of engagement with treatment skills related to the management of PTSD symptoms. In addition, the trauma management skills employed in the current study did not include exposure to or direct processing of the 9/11 WTC disaster. Future work might investigate the impact of incorporating these therapeutic techniques, as they are key ingredients of empirically supported PTSD treatments.[34,35] Last, we did not systematically collect data on homework practice and NTR use/discontinuation for either group. Future trials ought to assess engagement in treatment skills outside of session to account for level of skill acquisition and use, and detailed data regarding NTR dosing, use and discontinuation.

Conclusion

The CSC-T treatment for smokers with elevated WTC-related PTSD symptoms was not more efficacious than CSC treatment alone. Both interventions showed comparable levels of smoking abstinence at 6-month follow-up and rates were higher than those observed in previous trials with patients experiencing PTSD symptoms. Although there is a demonstrated need for tailored treatments to address smoking cessation in psychiatric populations,[60] results from the current study indicate that more work is needed to further adapt and

refine treatment protocols to improve cessation outcomes for individuals with elevated PTSD symptoms.

Supplementary Material

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

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Declaration of Interests

None declared.

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