



Efficacy of smoking cessation therapy alone or integrated with prolonged exposure therapy for smokers with PTSD: Study protocol for a randomized controlled trial

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ABSTRACT

Posttraumatic stress disorder (PTSD) is related to an increased risk of smoking cessation failure. In fact, the quit rate in smokers with PTSD (23.2%) is one of the lowest of all mental disorders. Features of PTSD that contribute to smokers' progression to nicotine dependence and cessation relapse include negative affect, fear, increased arousal, irritability, anger, distress intolerance, and anxiety sensitivity. Anxiety sensitivity is higher in people with PTSD than in any other anxiety disorder except for panic disorder. High anxiety sensitivity is uniquely associated with greater odds of lapse and relapse during quit attempts. Distress intolerance, a perceived or behavioral tendency to not tolerate distress, is related to both the maintenance of PTSD and problems in quitting smoking. Prolonged exposure (PE) and interoceptive exposure (IE) reduce PTSD symptoms, distress intolerance, and anxiety sensitivity. Thus, they emerge as promising candidates to augment standard smoking cessation interventions for individuals with PTSD. The present study tests a 12-session specialized treatment for smokers with PTSD. This Integrated PTSD and Smoking Treatment (IPST) combines cognitive-behavioral therapy and nicotine replacement treatment for smoking cessation (standard care; SC) with PE to target PTSD symptoms and IE to reduce anxiety sensitivity and distress intolerance. Adult smokers ($N = 80$) with PTSD will be randomly assigned to either: (1) IPST or (2) SC. Primary outcomes are assessed at weeks 0, 6, 8, 10, 14, 16, 22, and 30.

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1. Introduction

Cigarette smoking is the leading cause of death and disability in the United States (U.S.), contributing to over 440,000 deaths each year [65]. Rates of tobacco use in the U.S. represent a significant public health concern with approximately 45–48 million adults who currently use tobacco [15]. Though approximately 70% of current adult smokers are motivated to quit [65], approximately 90–95% of smokers who try to quit smoking on their own [29], and 60–80% who attend treatment programs, relapse to smoking [13]. Notably, persons diagnosed with psychiatric and substance abuse disorders are 2–3 times more likely to be dependent on tobacco and die up to 25 years earlier than the general population [66]. One possible explanation is the selection hypothesis of smoking prevalence which posits that smokers who are able to quit

successfully are not “burdened” by specific characteristics that make it more challenging to quit [37], including medical or psychiatric illnesses. One such high-risk group is individuals with anxiety disorders.

Smokers with a history of anxiety disorders experience significant challenges quitting tobacco [68,69] yet little attention has been paid to the maintenance of tobacco use among persons with anxiety disorders, and in particular, smokers with PTSD. PTSD is a common mental disorder, with lifetime prevalence in the USA of 6.8% [40,41]. The prevalence of current smoking in persons with current PTSD is 44.6%, compared to 22.5% in persons who had never had a psychiatric disorder [43]. Smokers with PTSD are more likely to be dependent [11], to smoke heavily (>25 cigarettes per day [5]), to experience more severe withdrawal symptoms, and to relapse following a quit attempt [5]. Furthermore, the quit rate in smokers with PTSD is one of the lowest among groups defined by specific mental disorders [43]. The PTSD-smoking association observed in epidemiological surveys appears to reflect primarily the influence of pre-existing PTSD on the risk for subsequent smoking progression and transition to nicotine dependence [10,11,42]. Specific features of PTSD may contribute to smokers' progression to

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nicotine dependence and relapse including negative affect, fear, anxiety sensitivity, increased arousal, irritability, and anger. Thus, isolating the specific vulnerability mechanisms linking PTSD to smoking cessation problems may aid identification of possible therapeutic targets.

Some of the strongest and most consistent evidence contributing to tobacco use has been evident for anxiety sensitivity and distress intolerance [7]. These two constructs are conceptually and empirically distinct (i.e. sharing only 15–22% of variance with one another [7]), yet, they both are elevated among those with PTSD [7,46,60], can be targeted in treatment and changed [55] and tend to be related to cognitive-affective reactivity as well as emotional regulatory deficits of central theoretical and clinical relevance to smoking cessation [70]. Thus, they represent distinct mechanisms potentially underlying PTSD-smoking relations. These findings are consistent with contemporary theoretical models of smoking behavior [3].

As outlined above, improving cessation outcomes among individuals with PTSD may require reducing PTSD symptoms as well as anxiety sensitivity and distress intolerance that increase risk of relapse. Fear extinction-based treatments (i.e., prolonged exposure [PE], interoceptive exposure [IE]) have shown efficacy for reducing PTSD distress intolerance, and anxiety sensitivity [18,57,64] and therefore emerge as promising candidates to augment standard smoking cessation interventions for individuals with PTSD. Initial studies suggest a combined treatment approach for this population is worth further study. First, Felder, Smith, Monson, and Zvolensky [25] conducted a multiple-baseline study with six smokers with PTSD [25]. The intervention (12 50-minute sessions) included CBT for smoking and trauma-focused therapy for PTSD. Results showed small but significant reductions in PTSD symptoms, but only temporary reductions in smoking. Recommendations include a higher dose of PTSD/smoking treatment, adding more interoceptive exposure, and intent-to-treat analyses. Second, Gonzalez et al. [31] randomized 90 smokers with PTSD to smoking cessation alone or in combination with a trauma management program [31]. The trauma program (8 90-minute sessions) included interoceptive exposure, cognitive restructuring, and in-vivo exposure to trauma cues. Overall, results showed no significant difference between groups in PTSD symptom or smoking improvements. Recommendations include a higher dose of PTSD/smoking treatment. Also, this study did not include imaginal trauma exposure. The present study proposes to test an intervention that integrates PE and IE with standard cessation treatment among adults suffering from PTSD. More specifically, we will use a higher dose intervention (12 90-minute sessions), add imaginal trauma exposure, and add interoceptive exposure.

Drawing from basic research and stage-model treatment development work over the past decade, we have developed the Integrated PTSD and Smoking Treatment (IPST). IPST represents an integrated treatment that incorporates elements of intensive standard smoking cessation treatment with exposure-based procedures for reducing PTSD symptoms and associated AS, as well as enhancing tolerance to aversive internal sensations. The IPST protocol involves twelve weekly 90 minute sessions and was designed for use in conjunction with nicotine replacement therapy (NRT). In addition to PE for PTSD symptoms, aspects of IPST that uniquely focus on addressing fears of anxiety, bodily-related sensations, and affect-relevant withdrawal symptoms include: (1) interoceptive exposure (i.e., repeated exposure to feared bodily sensations) with (2) corrective information about anxiety and cognitive interventions designed to teach patients alternatives to catastrophic misinterpretations of the sensations and their feared consequences (“I will lose control”), as well as (3) continued use of situational exposure. Specifically, cognitive restructuring is aimed at eliminating catastrophic beliefs about the meaning and consequences of anxiety and PTSD symptoms as well as symptoms of withdrawal. Additionally, interoceptive exposure is employed to extinguish fears of aversive internal sensations regardless of their source, but with specific preparation for sensations that would be experienced as part of smoking discontinuation (withdrawal). The goal is not to attempt the

impossible task of eliminating anxiety or emotion-laden withdrawal sensations but rather to ensure that these internal cues are not interpreted fearfully, escalating bothersome sensations into debilitating panic and related negative affect symptoms. Exposure to such symptoms in advance of cessation should help to ensure that participants have practice with an alternative model of symptom management well before the characteristic symptoms of smoking discontinuation are encountered.

The primary aim of the proposed study is to obtain estimates of the relative efficacy of the integrated treatment for smokers with PTSD (IPST) compared to a smoking cessation only control condition (SC). The secondary aim is to perform an initial examination of the putative mechanisms underlying the hypothesized advantage of the integrated treatment. To this end, we will conduct a randomized controlled trial comparing the relative benefit of IPST over SC.

2. Methods

The Institutional Review Board of University of Texas at Austin approved this study and a Data Safety and Monitoring Board provides ongoing monitoring. This study is funded by the National Institutes of Health 1K01 grant number DA035930-01 and is registered on clinicaltrials.gov (ID: NCT01988935). This study is currently in the recruitment phase (year 3 of 5). The study is currently conducted at a single site at the University of Texas at Austin.

2.1. Specific aims & hypotheses

1. To compare, in a randomized clinical trial, the effects of IPST vs. SC on the following smoking cessation outcomes:
 - A. We expect that point prevalence abstinence (PPA) will be higher, both in the short- and long-term, in the IPST condition than in the SC condition. Similarly, we expect the rate of decline in abstinence over time to be smaller in the IPST condition than in the SC condition.
 - B. We expect mean time to first lapse and to relapse to be greater in the IPST condition than in the SC condition.
2. To compare, in a randomized clinical trial, the effect of IPST vs. SC on psychological symptoms, including PTSD symptoms, depressive symptoms, anxiety sensitivity, and distress tolerance:
 - A. We expect that psychological symptoms will be lower at post-treatment and follow-up in the IPST condition than in the SC condition.
 - B. We expect that treatment condition differences in psychological symptoms will mediate treatment condition differences in abstinence at both post-treatment and follow-up.
3. Exploratory aim: To determine if the advantage of IPST over SC on smoking outcomes is greater for those with greater baseline PTSD severity. PTSD severity is related to severity of depressive symptoms, distress tolerance, and anxiety sensitivity, and each of these is related to abstinence. Thus, individuals with low baseline PTSD severity are likely to have only modestly elevated levels of these psychological barriers to abstinence, and hence may benefit only minimally from the PTSD treatment in IPST. Those with high baseline PTSD severity, however, are likely to have significantly elevated levels of depressive symptoms, distress intolerance, and anxiety sensitivity, and hence can benefit greatly from IPST that is designed to reduce these symptoms.

2.2. Power analysis

Because we will have a sample size of 80, this application is not powered to detect small differences between treatment conditions.

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