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A Qualitative Study of the Feasibility and Acceptability of a Smoking Cessation Program for People Living with HIV and Emotional Dysregulation

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Abstract

Despite high rates of co-occurring tobacco use and anxiety among persons living with HIV, evidence-based interventions for these individuals are limited. An existing cognitive-behavioral treatment protocol for smoking cessation and anxiety (Norton & Barrera, 2012) was modified to address transdiagnostic constructs, such as anxiety sensitivity, distress tolerance, and depressive symptomatology (Labbe et al., 2017). This study examines the feasibility and acceptability of the intervention as determined from qualitative data from structured exit interviews from 10 participants who completed treatment. Results demonstrated that participants were very motivated to quit smoking and enrolled in the program for health-related reasons and to be able to quit. Participants found nearly all the treatment components (i.e., psychoeducation, cognitive restructuring, behavioral experiments, homework) to be useful for reaching their smoking cessation goal and in managing emotional dysregulation. Last, all participants stated that they would strongly recommend the treatment program. This qualitative study provides initial evidence for the feasibility and acceptability of a modified smoking cessation treatment protocol for HIV+ individuals with anxiety and emotional dysregulation. Future research will focus on evaluating the efficacy of the protocol in a full-scale randomized controlled trial, as well as working to collect qualitative data from participants who discontinue treatment to better understand reasons for treatment attrition.

Keywords

HIV; smoking cessation; anxiety; emotional dysregulation; cognitive-behavioral therapy

Introduction

Cigarette smoking is the leading cause of preventable death and disability in the U.S., contributing to over 480,000 deaths each year (U.S. Department of Health and Human Services., 2014). People living with HIV/AIDS (PLWHA) are at an especially increased risk for developing medical complications as a result of cigarette smoking with rates of cigarette smoking among PLWHA up to at least three times that of the general population (Niaura et al., 2000; O’Cleirigh et al., 2014).

Anxiety disorders co-occur with smoking at rates that exceed those found in the general population (Ziedonis et al., 2008), and anxiety and depressive pathology significantly impair cessation success (Piper et al., 2010; Zvolensky et al., 2008; Leventhal & Zvolensky, 2015; Piper et al., 2011). Rates of current anxiety disorders among PLWHA have been estimated as high as 43% (Brandt et al., 2016; Johnson et al. 1995; Perkins et al., 1994; Sewell et al., 2000) and rates of depressive symptomatology are higher among PLWHA who smoke (Brandt et al., 2017; Chang et al., 2017; Lubetkin et al., 2018; O’Cleirigh et al., 2015).

Transdiagnostic treatment approaches seek to address the spectrum of an individual’s symptoms within a single model. Current evidence indicates that transdiagnostic treatments for anxiety and related disorders produce considerable symptom improvement, perform better than waitlist controls, yield improvements in depression, compare well to diagnosis-specific treatments, and are associated with high client satisfaction, therapeutic alliance, treatment expectations, and low dropout rates (Barlow et al., 2017; Norton & Hope, 2005; Schmidt et al., 2012);Norton, Hayes, & Springer, 2008); Schmidt et al., 2012). Accordingly, a transdiagnostic approach has the potential to confer similar advantages when integrated into a smoking cessation paradigm for PLWHA.

We modified an existing 8-week cognitive-behavioral treatment protocol for smoking cessation and anxiety (Norton & Barrera, 2012) to address transdiagnostic domains such as anxiety sensitivity, distress tolerance, and depressive symptomatology (Labbe et al., 2017). Here we report on the feasibility and acceptability of the intervention as determined by qualitative data from structured exit interviews of participants who completed the study protocol.

Method

Participants

Participants were recruited from the Infectious Disease Unit at a large medical center and a community health center in Boston, MA. Adults between the ages of 18–65 who smoked at least 10 cigarettes per day, had a State-Trait Anxiety Inventory (STAI-T; Spielberger, Gorsuch & Lushene, 1970) score > 39 at screening (i.e., clinically-relevant anxiety symptoms), and endorsed at least a moderate level of motivation (i.e., 50 out of 100 on a

Likert-type scale) to quit smoking were eligible to participate. All participants provided informed consent and all study procedures were approved by Institutional Review Board at the Massachusetts General Hospital.

Measures

Fagerstrom Test for Nicotine Dependence (FTND; Heatherton et al., 1991): The FTND was utilized as a measure of nicotine dependence at baseline. The FTND has shown good internal consistency, a single dimension factor structure, and positive relationships with the degree of nicotine intake as assessed by saliva cotinine (Heatherton et al., 1991).

Motivation Analog Scale: This is a single-item Likert-type scale that assessed a participant's motivation to quit smoking. Anchor points were 0 (not at all motivated to quit) to 100 (extremely motivated to quit).

State-Trait Anxiety Inventory (STAI; Spielberger, Gorsuch & Lushene, 1970): This is a 40-item self-report measure of state- and trait-level anxiety and has demonstrated good psychometric properties (Spielberger et al., 1983). In the present investigation, the 20 trait anxiety items were used as a screening measure.

Hospital Anxiety and Depression Scale (HADS; Zigmond & Snaith, 1983): This is a 14-item measure to determine levels of anxiety and depression. Seven items each relate to anxiety and depression. The HADS has is a reliable instrument for screening for clinically significant anxiety and depression among a medical population.

Procedures

After providing informed consent participants completed a two-hour baseline assessment, administered by pre- and post-doctoral clinical psychology fellows, to assess for psychiatric history and current depression and anxiety symptoms, as well as self-report measures. Eligible participants returned for an initial psychoeducation session, after which participants were randomly assigned to either the intervention (CBT) or enhanced treatment as usual (ETAU). All participants returned for individual follow-up assessments at one-, three-, and six-months post-treatment. Exit interviews were conducted with participants who were randomized to the intervention arm and completed the 6-month follow-up. Exit interviews lasted approximately 15 minutes and included open-ended questions about the following topics: (1) reasons for engaging in the program; (2) reasons for completing the program; (3) aspects of the program participants found helpful for quitting smoking and managing anxiety/emotion dysregulation; (4) aspects of the program participants did not find helpful for quitting smoking or managing anxiety/emotion dysregulation; (5) components of the program participants continue to utilize to help them stay quit and/or manage anxiety/emotion dysregulation; (6) components of the program participants found challenging; and (7) likelihood that participants would recommend this program to others. All interviews were conducted by research assistants and were audio recorded.

Treatment

Overview.—Treatment consisted of three main components: (1) CBT for smoking cessation based on the most recent clinical practice guidelines (U.S. Department of Health and Human Services, 2008); (2) nicotine replacement therapy (NRT), as it is recommended that smokers attempting to quit smoking receive pharmacotherapy (Fiore et al., 2000, 2008). The transdermal nicotine patch was utilized for this study because of the extensive empirical literature supporting its effectiveness and safety, its ease of use, and its relatively benign side effect profile. Dosage of the patches were 21mg, 14mg, and 7mg. Participants smoking 10+ cigarettes per day by Quit Day started at 21mg; participants smoking less than 10 cigarettes per day started at 14mg. Participants remained on the same dose for two weeks before stepping down to the next appropriate dose (i.e., 14mg, 7mg, or none). All patches were provided at no cost; and (3) CBT-based transdiagnostic intervention for emotion dysregulation. Six treatment modules, delivered across 10, 90-minute group or 60-minute individual therapy sessions, were designed to create a transdiagnostic treatment to simultaneously treat smoking and emotion dysregulation in PLWHA. “Quit Day” was session 7. The protocol was designed to be flexible and, generally, it was found that two sessions were needed to teach/practice behavioral exposure exercises, and two sessions were needed to teach/practice cognitive restructuring strategies. Individual attention was provided to troubleshoot problems in practicing skills and problem-solving around high-risk smoking situations. Below is a summary of the treatment.

Module 1: Education.—Participants received psychoeducation regarding the main components of treatment including the nature of anxiety and other mood symptoms, the relationship between mood symptoms and smoking, the cognitive-behavioral treatment model, and relapse prevention. Participants were provided psychoeducation about cigarettes and smoking, use and effectiveness of the patch, and the benefits of utilizing social supports to aid smoking cessation efforts.

Module 2: Treatment Rationale.—Participants were presented with the cognitive-behavioral model describing the co-occurrence and maintenance of smoking and emotion dysregulation. Procedures and rationale for each treatment module were described.

Module 3: Behavioral Experiments.—Participants were gradually exposed to situations in which their usual response was to smoke and practiced not smoking. Consequently, participants learned over time that they could manage withdrawal symptoms and associated distress.

Module 4: Cognitive Restructuring.—Participants were taught how to identify cognitive distortions that maintain their emotion dysregulation and cigarette smoking, and how to develop more helpful, rational responses.

Module 5: Problem Solving.—Participants were instructed on how to employ and practice problem-solving skills to approach high-risk smoking situations instead of avoiding them.

Module 6: Relapse Prevention and Termination.—Relapse prevention action plans were developed and reviewed weekly starting on Quit Day. The difference between a lapse and relapse was discussed and techniques for preventing relapse were presented. The final session was devoted to termination issues, identifying successes made in treatment, and encouragement of continued skills practice.

Data Analysis

Exit interviews were recorded, transcribed, and analyzed. The first author reviewed each transcript to identify common patterns and themes and to develop a coding framework. This iterative approach resulted in rationally-derived domains that best classify participants' responses. To establish validity and reliability of the domains, two additional raters (research assistants unrelated to this study) independently coded participants' responses into the best-fitting domains. Any disagreements between raters were reviewed and discussed until the discrepancy was resolved.

Results

One hundred and four individuals were assessed for eligibility, 72 were enrolled, and 53 were randomized, of which 26 were randomized to the treatment condition. Seventeen participants completed through session 7 (Quit Day), and 15 completed all treatment sessions. Thirteen participants completed through the 6-month follow-up of which ten participated in the exit interviews. Attrition was mostly due to loss of contact (N=10); three participants chose to discontinue participation, but data was not collected regarding reason. See Table 1 for descriptive statistics.

Expectations of the Treatment Program

Three domains captured participants' responses. Most responses fell into the "To Quit" category (n=7, 70%). Sample responses include, "I expected to quit smoking" and "For some solid tools to get myself to be able to step away from cigarettes." The next domain was "Not Sure" (n=2, 20%; "I really didn't know what it was"), followed by "Other" (n=2, 20%; "Just to learn more stuff").

Motivations to Initiate and Complete the Treatment Program

Three domains captured participants' responses. Most responses fell into the "Healthy" category (n=6, 60%; "I wanted to try and live a little longer" and "Because I am having a hard time breathing going up and down the stairs just to have a cigarette"). This was closely followed by "To Quit" (n=5, 50%; "I've wanted to quit for a long time but never got past day one") and "Other" (n=4, 40%; "Because your medications can stop working by you smoking and I never knew that").

Five domains captured participants' responses regarding why they completed the treatment program. Participants' responses were varied, with several participants providing multiple motivating factors. "Health" (e.g., "Because it was for my benefit - for my healthcare"), "Finishing What I Started" (e.g., "I always finish what I start"), and "Wanting to Quit" (e.g., "My sole desire to stop smoking") each received the same number of responses (n=3, 30%),

“Saving Money” (e.g., “Because I owe all this money”) was another motivating reason to complete the program (n=2). “Other” garnered the most responses (n=4); however, these motivating factors were idiosyncratic and did not fall into any other domains. Examples include, “I just wanted to be honest with myself” and “They [cigarettes] really smelled bad.”

Helpful Aspects of the Treatment Program

Six domains best captured participants’ responses regarding aspects of the treatment program they found helpful in quitting smoking. Participants’ typically provided more than one response to this question. “Homework/Wrap Sheets”, “Handouts”, and “Cognitive Restructuring” each received the same number of responses (n=3). “Behavioral Experiments” and “The Patch” each received two responses. “Other” received the most responses (n=6); however, these responses were specific to each individual participant. Examples include, “Nothing stands out” and “Just, like, the contact and, like, the touching base.”

Responses regarding aspects of the treatment participants found helpful in managing psychological distress fell into three domains. “Tracking/Awareness” (e.g., “Being able to log it [stress levels] and keep track of it made it easier”) and “Other” (e.g., “Helping me quell the anxiety around quitting and around not smoking”) each received three responses. “None” received two responses.

Aspects of the treatment program that were not helpful

Three domains captured participants’ responses to aspects of the treatment program they did not find helpful for quitting smoking. Most of the responses (n=7) fell into the category “Nothing.” Sample responses include, “The whole program was helpful from day one” and “No. No. Everything helped”. “Homework/Wrap Sheets” (e.g., “I knew I smoked a lot. I didn’t need to see it on paper”) received two responses and “Other” received one response, which was in reference to doing an in-session behavioral experiment (“I just didn’t like going outside to [smoke] a cigarette...It was just a waste, to me, of the time”).

Only one domain was created to capture participants’ responses regarding aspects of the treatment program they did not find helpful for addressing symptoms of psychological distress. All responses fell into the “Nothing” category. Sample responses include “No” and “No. It was all helpful.”

Continued Use of Intervention Components

Five participants (50%) reported they were still using pieces of the intervention to help them remain quit, four participants (40%) reported they were not, and one participant (10%) reported that he was only using “some parts.” Of the five participants that endorsed continuing to use pieces of the treatment, they were asked which pieces they used. Specific responses included: cognitive restructuring (e.g., “Don’t beat yourself up”), behavioral activation (e.g., “Using the chart of activities”), use of the patch, and removing oneself from high-risk smoking situations.

Four participants (40%) reported that they continued to use pieces of the intervention to help manage psychological distress and six participants (60%) reported that they did not. Pieces of the intervention that the participants reported they continued to use included prayer (e.g., “I pray on certain things”), behavioral activation (e.g., “Don’t take away your daily things that you have to do”), and meditation.

Challenging Aspects of the Treatment Program

Seven participants (70%) reported they believed parts of the intervention were challenging. Aspects of the intervention participants found challenging varied. Responses included: having to remember to use the patch (e.g., “Remembering the patch and, you know, like I went back and forth between patches a few times”), remembering to do homework (e.g., “Just kind of remembering to, you know, to fill in the little assignments and homework”), difficulties with aspects of the behavioral experiments (e.g., delaying smoking a cigarette, difficulties with riding out a craving, practicing tolerating distress), and disliking the group setting (e.g., “I don’t like to talk in groups...It’s not enough time in just one hour, one and a half hour, to have a group of four to get specialized with every single person with the topic”). Despite these challenges, participants reported that it was helpful that they faced these challenges because it made them “feel accomplished”, helped them “manage cravings”, and helped them “achieve a goal.”

Recommendation to Others

Eight participants (80%) responded that they were “highly/completely confident” in recommending the program to friends experiencing similar problems (e.g., “I do recommend it very highly - 100%”), and two participants (20%) responded that they were “pretty confident.”

Discussion

The aim of this current study was to utilize qualitative data from exit interviews conducted with study completers to examine the feasibility and acceptability of an integrated transdiagnostic treatment protocol addressing smoking cessation and anxiety symptoms/emotional dysregulation among PLWHA smokers. The data from this qualitative study revealed that, overall, participants found the treatment to be very helpful in their smoking cessation efforts. Nearly all participants reported that all aspects of the treatment were useful for helping quit smoking as well as managing their anxiety and distress. Further, all participants stated they would recommend this treatment program to others. Accordingly, the results from these qualitative data indicate acceptability of the treatment approach.

The feasibility of administration and uptake of the modified treatment protocol was also evaluated via examination of the qualitative data. Results demonstrated that not only did participants find the materials and skills helpful, but also that they were able to learn and practice the skills to help them quit smoking. Taken together, results from the exit interviews illustrate that this newly developed treatment approach was generally well-received and useful in attaining participants’ treatment goals.

This study has strengths and limitations that need to be considered. One strength is that the exit interviews were conducted by study staff who did not conduct the intervention sessions. Therefore, study participants may have felt freer to share their honest opinions about the treatment and responses were less likely to be influenced by social desirability. Another strength is that participants were diverse with regards to their distress tolerance, smoking histories, and demographic backgrounds. For example, some participants met diagnostic criteria for various anxiety disorders while others were only sub-threshold. Similarly, some participants were smoking 40 cigarettes per day at baseline while others were smoking 10 or less per day. Despite these ranges, participants demonstrated similar responses with regards to acceptability and feasibility. This is important because it shows this treatment has the potential to be more broadly disseminated in community settings where the patient population is more diverse than a traditional randomized controlled trial setting. One limitation is that results of this study may not generalize to younger adults, women, or patients from different geographical areas. Second, this study had a small sample size. Though it may be likely that some responses would be similar amongst a larger sample, a larger sample size may have also broadened the response categories and provided additional insights into participants' experiences. Nevertheless, given the narrow range of responses provided by the current sample, the data seem to indicate rather stable response categories. Third, interviews were conducted with study completers. As such, data from the interviews do not inform why people dropped out of the treatment. Future research should focus on collecting information from participants who choose to discontinue to understand better reasons for discontinuation and ways to improve the program.

Overall, results from this qualitative study indicate that the newly developed transdiagnostic treatment for smoking cessation for PLWHA and emotional dysregulation is feasible with regards to uptake/engagement among participants, and that the treatment was acceptable and well-liked. Future research will focus on quantitatively examining the outcome data from this study to determine the preliminary efficacy of the treatment. Given that this study is one of the first of its kind aiming to establish efficacy of a transdiagnostic smoking-anxiety treatment that addresses the unique needs of smokers with HIV, a larger-scale study is necessary in order replicate the initial findings. Once initial efficacy has been established, the treatment approach will be further explored and evaluated in broader dissemination models and larger-scale efficacy studies with regards to examining long-term abstinence from cigarettes, predictors of abstinence, and clinically-meaningful reductions in depression and anxiety.

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Table 1.

Descriptive statistics of the study sample (N=10)

	Mean (SD)	N (%)
Age	50.20 (6.2)	--
Gender		
Male	--	9 (90%)
Female	--	1 (10%)
Race		
Black	--	5 (50%)
White	--	4 (40%)
Other	--	1 (10%)
Education		
Less than high school	--	2 (20%)
High school	--	1 (10%)
Partial college	--	4 (40%)
College	--	3 (30%)
Employment		
Unemployed	--	2 (20%)
Disability	--	4 (40%)
Part-time work	--	1 (10%)
Full-timework	--	3 (30%)
Relationship status		
Married	--	1 (10%)
Single	--	9 (90%)
Sexual orientation		
Exclusively homosexual	--	3 (30%)
Homosexual with some heterosexual experience	--	3 (30%)
Bisexual	--	1 (10%)
Exclusively heterosexual	--	3 (30%)
Motivation to quit smoking	81.4 (23.8)	--
Cigarettes smoked per day	10.75 (9.34)	--
Hospital Anxiety and Depression Scale (HADS)		
Anxiety	3.9 (2.3)	--
Depression	2.9 (3.4)	--

* Scores <8 on the HADS indicates mild anxiety/depression symptomatology