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Positive psychotherapy for smoking cessation enhanced with text messaging: Protocol for a randomized controlled trial

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ABSTRACT

Background: Despite reductions in cigarette smoking in the U.S., improvements in the efficacy of smoking cessation treatments are needed, as rates of sustained abstinence remain disappointingly low. Both low positive affect and high negative affect contribute to smoking relapse and constitute viable targets for smoking cessation interventions. Although some clinical trials have evaluated interventions to address depression as a smoking relapse risk factor, very few have focused on positive affect. Recently, we developed and conducted a preliminary clinical trial of a smoking cessation treatment that targets positive affect and cognitions by incorporating interventions rooted in positive psychology. The current randomized controlled trial will expand upon this preliminary trial to test whether this positive psychology-informed approach results in higher smoking cessation rates compared to a time-matched standard smoking cessation treatment control.

Methods: Three hundred and forty adult daily smokers will be randomly assigned to either positive psychotherapy for smoking cessation or standard behavioral smoking cessation counseling. Participants will meet weekly with a study counselor for 6 weeks and will receive transdermal nicotine patch and text messaging smoking cessation support. Additionally, text messaging in the positive psychotherapy condition will encourage engagement in positive psychology-specific strategies for boosting mood and staying smoke free. Smoking cessation outcomes will be measured at 12, 26, and 52 weeks following target quit date.

Conclusion: Results from this study will provide evidence on whether incorporating positive psychology interventions into smoking cessation treatment can improve smoking cessation outcomes relative to standard behavioral counseling with nicotine patch and text messaging.

1. Introduction/background

Only 15 to 25% of those involved in intensive smoking cessation treatments remain abstinent as long as one year [1–3]. Depression, high negative affect and low positive affect [4, 5], and cognitive factors, including hostility and alienation [6–10], have been implicated as contributors to poor smoking outcomes and may serve as targets for efforts to improve smoking cessation treatment. Mood management interventions have shown promise for improved smoking outcomes in those with elevated depressive symptoms or past major depressive disorder [11–13]; however, effect sizes for these interventions relative to standard counseling have been modest (OR = 1.41 to 1.47) with abstinence rates ranging from 13.0% for those with current depression to 20.1% for those with past depression [14]. Alternative approaches are needed that appeal to a broad range of smokers. Interventions derived from positive psychology—the scientific study of positive subjective experiences, individual traits, and institutions [15]—may be well-suited for this purpose. Positive psychology interventions (PPIs), which focus on cultivating positive affect (PA), cognition, and behavior, have been shown to enhance well-being and decrease depressive symptoms in clinical and non-clinical populations [16, 17], and can be readily integrated into smoking cessation counseling.

We recently developed [18] and pilot-tested the first smoking cessation treatment that incorporated positive psychology interventions, which we termed Positive Psychotherapy for Smoking Cessation (PPT-S) [19]. PPT-S focuses on accentuating and utilizing personal strengths

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as a means of enhancing self-efficacy, as well as on increasing attention to positive experiences and on increasing positive social interactions, which can serve as alternative reinforcers that maintain positive affect and reduce the relative attractiveness of smoking. In a pilot randomized controlled trial we assigned 60 participants to receive either a standard smoking cessation treatment control (ST) or PPT-S. Results indicated that PPT-S participants were significantly more likely to maintain smoking abstinence at follow-up than ST participants (OR = 2.75, 95% CI = 1.02, 7.42) [19]. Although there was no evidence of an effect of PPT-S on mood, increased engagement in strategies taught within PPT-S was associated with greater maintenance of smoking abstinence, suggesting that modifications to PPT-S to increase engagement with PPIs may improve its efficacy. Therefore, in the present trial, we will test the efficacy of an enhanced version of PPT-S—termed PPT-S + —that entails PPT-S plus a text messaging program to support smoking cessation and encourage engagement in PPIs. Text messaging interventions have been increasingly used in health promotion research [20, 21] and have shown promise in promoting greater adherence to medication regimens [22–25] as well as in smoking cessation [20, 26].

This randomized controlled trial will test the efficacy of PPT-S + compared to a time-matched ST control plus text messaging support for quitting (ST +). We hypothesize that participants in PPT-S + compared to ST + will display higher rates of biochemically-confirmed 7-day point-prevalence smoking abstinence across 12 months of follow-up. Additionally, we hypothesize that the effect of PPT-S + on smoking outcomes will be mediated by greater engagement in PPT-consistent quitting strategies, less residual attraction to smoking, and greater self-efficacy for smoking cessation.

2. Design

This randomized controlled trial will use a 2-group, between-subjects design with repeated measures to test the efficacy of PPT-S + versus ST + . We will randomize 340 smokers to either PPT-S + or ST + using urn randomization [27]. Both treatments will entail six individual counseling sessions over six weeks, with quit date scheduled for the third session (week 3). All participants will receive a time matched quit smoking program [19], with those in PPT-S + additionally receiving daily texts reminding them of their personal strengths, and prompts each evening to record positive experiences from the day. All participants will be provided with an eight week supply of nicotine patches with initial patch dosage based on their smoking rate at baseline. Smoking outcomes will be assessed at 12, 26, and 52 weeks after the scheduled quit date.

3. Methods

3.1. Study setting

All study procedures will take place at the Center for Alcohol and Addiction Studies in the Brown University School of Public Health in Providence, RI.

3.2. Participants

A total of 340 smokers will be enrolled in the study over an approximately 3-year period, which started in February 2017. To be included in the study, participants must meet the following criteria: 1) be at least 18 years of age; 2) smoke at least 5 cigarettes per day for longer than one year; 3) be willing to use the nicotine patch; 4) rate the importance of quitting smoking a 5 on a 0 to 10 scale (where 10 = *extremely important*); 5) have an active, text-capable cell phone and be willing to send and receive text messages for the duration of the intervention. Participants who do not have unlimited texting will be compensated an additional $20 to offset any additional costs on their cell phone bill. Participants will be excluded from the study, if they meet any of the following criteria: (1) are currently experiencing psychotic symptoms, affective disorder, or substance use disorder other than nicotine dependence; (2) are concomitantly using other pharmacotherapies for smoking cessation; (3) are pregnant or nursing, or (4) have any contraindications to the use of transdermal nicotine patch.

3.3. Outcome variables

3.3.1. Primary outcome measures

The primary outcome for testing intervention efficacy is biochemically verified 7-day point-prevalence abstinence at 12-, 26-, and 52-week follow-ups. We will also use the Timeline Followback [28, 29] to assess time to first lapse and relapse and continuous abstinence from smoking. Participants will provide breath samples for expired carbon monoxide (CO) analysis at baseline, each treatment session, and each follow-up interview. At 12-, 26-, and 52-week follow ups self-reported smoking abstinence with no other use of nicotine-containing products—including nicotine replacement therapy and electronic cigarettes—will be verified by both CO (cutoff value of < 4 ppm) [30] and saliva cotinine radioimmune assay analysis (cutoff value of ≤ 15 ng/ml) [31]. For those reporting smoking abstinence, but with past 7-day use of other nicotine containing products, abstinence will be verified only by CO. Continuous smoking abstinence will be defined as self-reporting no cigarettes smoked since quit date with abstinence biochemically confirmed at each follow-up or confirmed by collateral reports from significant others.

3.3.2. Secondary outcome measures and assessment points

The secondary outcome of this study is to determine if the effect of PPT-S + on smoking outcome is mediated by greater use of PPT-consistent strategies, reduced attraction to smoking, or greater smoking cessation self-efficacy. Participants will complete a Treatment Strategies Questionnaire at sessions 4–6 to assess frequency of general smoking cessation strategies usage, including planning for high-risk situations, and PPT-consistent strategies. PPT-consistent strategies are worded in a general way so that participants in each condition can rate how often they have done that activity; PPT-S consistent strategies include intentionally focusing on mental health benefits of quitting, using signature strengths, savoring positive experiences, and engaging in positive social interactions [19]. For those in PPT-S + , we also will have a record of how many PPT-S + interactive texts were responded to, which will be coded according to whether the exercise was completed. In both conditions, we will calculate a variable reflecting the percent of responses to interactive messages. Smoking cessation self-efficacy will be measured at each counseling session using a well-validated 9-item scale [32]. Residual attraction to smoking (e.g., “Does smoking have any attraction for you now?”) will be assessed at the end of the treatment (i.e. 4 weeks after quite date) with a validated 3-item scale [33].

3.3.3. Recruitment procedures

Participants will be recruited through advertisements localized to the greater Providence, Rhode Island region on public transportation, newspaper, radio, and local television. The advertisements give potential participants the information to call or text the study phone number or visit the study website for more information. Additionally, a social media campaign will be used including an interactive study website. Participants will have the opportunity to complete an online screener to determine eligibility.

3.4. Procedure overview

Prospective participants will be screened either by telephone or by an online web portal system according to the inclusion criteria. Participants meeting inclusion criteria will be invited to the Center for Alcohol and Addiction Studies at Brown University to complete a baseline interview to confirm eligibility. Eligible participants will be