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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

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The authors have no conflicts of interest to declare.

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.

Keywords

Positive psychology; positive psychotherapy; smoking; smoking cessation; 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 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 <4ppm) [30] and saliva cotinine radioimmune assay analysis (cutoff value of ö 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 randomized and start counseling within a week of the baseline interview. Quit date will be scheduled for all participants to coincide with their third session of counseling. Participants will be assessed on a variety of interview, self-report, and biochemical measures at baseline and each treatment session, and at 12, 26, and 52 weeks after quit date. Interviewers conducting follow-ups will not be aware of participants' assigned treatment condition. See Figure 1 for the CONSORT diagram of participant flow through the study.

3.5 Assessments

3.5.1 Baseline Assessment—At baseline, participants will complete written informed consent. They will then complete written questionnaires and interviews to determine eligibility for the study, including a medical history screen. A blood pressure reading will be taken to exclude participants who have elevated blood pressure that would require medical treatment. Because nicotine patch is contraindicated for nursing and pregnant women, all women of childbearing age will be administered a pregnancy test to ensure non-pregnant status. If pregnant, they will be referred to other treatment. Participants will be paid $20 for completing the baseline assessment.

3.5.2 Follow-up Interviews—Participants will return to the Center for Alcohol Addiction Studies to complete in-person follow-ups at 12, 26, and 52 weeks after their scheduled quit date. To increase retention, participants will be paid up to $120 for completing assessments according to the following schedule: $35 for 12-week follow-up (plus $20 for those without unlimited texting), $35 for the 26-week follow-up, and $50 for the 52-week follow-up. These payments are not contingent upon smoking status. When necessary, relatives or friends listed by participants as potential locators will provide information about participants' whereabouts. To encourage compliance with follow-up assessments among smokers who relapse, we will inform participants at baseline that the information they provide is extremely important regardless of their smoking cessation outcome.

3.6 Randomization procedures

After completing baseline appointment procedures, eligible participants will be randomized to either PPT-S+ or ST+ by the Project Coordinator, who is not involved in conducting assessments or providing treatment. The urn randomization technique[27] will be used to ensure that treatment groups are balanced on gender, PA, and level of cigarette dependence. Research assistants will not be informed of treatment condition assignment. The positive affect subscale of the Center for Epidemiologic Studies – Depression scale (CES-D PA) [34]

will be used to measure participants' PA over the past week; this scale has been shown to predict smoking outcome [4] and moderate the effect of PPT-S [19]. Participants' level of cigarette dependence will be measured via the Fagerström Test for Cigarette Dependence [35, 36]. Condition assignment will be placed in sealed folders, which the counselor will open when participants report to the study center for the initial session of counseling, at which point randomization is considered complete.

3.7 Details of the intervention and control

3.7.1 Behavioral Treatment Conditions—All participants will receive a common core of behavioral smoking cessation counseling which includes instructions for using the nicotine patch, a text messaging support program, and 6 weekly sessions of counseling. The first session of counseling lasts about 50 minutes with the remaining sessions lasting about 35 minutes. All participants have a target quit date set for session 3 (2 weeks post initial counseling session). Participants who relapse to smoking after session 3 may set a new quit date, but the initially scheduled quit date remains as the date on which other study procedures (e.g., follow-up visits) are based. See Figure 2 for the timeline of study procedures.

3.7.2 Counselor Qualifications, Training, and Supervision—Qualifications for study counselors are a master's degree or above with experience in behavioral health counseling. All counselors will conduct both PPT-S+ and ST+ sessions. Counselors will participate in approximately 20 hours of training prior to delivering interventions. Training will include an overview of PPT-S+ and ST+ protocols, review of manuals and handouts, and practice role-play exercises along with selected readings on treatment of tobacco use and positive psychology. Additionally, counselors will be asked to listen to several of the audiotape samples from the randomized controlled pilot study and will conduct mock sessions with one another.

Counselors will participate in weekly supervision sessions. All sessions will be audiotaped, and a session from every fifth case will be rated for adherence and competence. Counselors will be provided feedback on adherence to manual components, level of skill delivering components, use of appropriate structure and focus, empathy and facilitation of the therapeutic alliance. Counselors who deviate from the protocol will be monitored closely and may be asked to role-play protocols until their performance meets acceptable standards.

Treatment integrity for PPT-S+ and ST+ as described in the treatment protocols will be assessed with adherence checklists and global rating scales of competence. Ratings of treatment adherence will be conducted by a research assistant unaffiliated with treatment delivery using checklists containing each of the critical topics of the treatment session outlines in each condition. Checklists will be summed to indicate the proportion of intended topics that were covered in a treatment session. Session tapes will be rated only after participants' follow-ups are completed. A second research assistant will rate one-fifth of sessions as a reliability check. In our recent clinical trial, adherence was very high, at 95% or higher [19]. We will use a manualized protocol for rating counselor competence adapted from the Yale Adherence and Competence Scale Guidelines [37]. The protocol involves

rating frequency/extensiveness (adherence) and quality (competence) of counselor behaviors. Counselor competence ratings will be conducted by the principal investigator (CWK) and project director (PC).

3.7.3 Standard Treatment+ (ST+)—ST+ is based on clinical practice guidelines[38] and focuses on recognizing and problem solving potential causes of smoking relapse, providing support and reinforcement of success, and encouraging participants to seek support for smoking cessation outside of treatment[39]. When necessary, the counselor discusses strategies for managing relapses to smoking. The elements of the standard smoking cessation content in both interventions is shown in Table 1. In ST+, about 20 minutes of each session are dedicated to teaching progressive muscle relaxation, which is used to match contact time with PPT-S+ while keeping the amount of time focused on smoking in both PPT-S+ and ST+ similar. Relaxation training has not been shown to improve smoking abstinence[38]. Participants are instructed to use relaxation techniques to reduce stress in their day-to-day life as needed.

3.7.4 PPT-S+—Modeled after our previous pilot [19], the PPT-S+ condition shares the same fundamental smoking cessation components with ST+, but also integrates positive psychology concepts. Figure 3 shows the hypothesized mechanisms through which PPT-S+ is expected to enhance smoking outcomes. PPT-S+ focuses on accentuating individuals' strengths (e.g., humor, perseverance, kindness, spirituality) and linking them to behavior change, which is intended to enhance self-efficacy and development of a non-smoker identity, both potential key predictors of immediate and long-term smoking outcomes [33, 40]. PPT-S+ is also gained-framed [41, 42] to highlight that quitting smoking can be a rewarding challenge that enhances mental health [43–45]. Research has shown that positive self-affirmations [46] can reduce defensiveness about health information leading to increased behavioral intentions [47]. Finally, PPT-S+ focuses on increasing attention to the daily experience of positive events, as well as increasing positive social interactions and maintaining PA.

PA is distinct from negative affect both conceptually and empirically [48]. Some studies have suggested that low PA prior to smoking cessation treatment may have a unique association with poor smoking outcomes independent of depressive symptoms [4], although a recent study did not support this conclusion [49]. Both reductions in PA leading up to quit date and low PA after quitting have been implicated in smoking relapse [5, 50]. By focusing specifically on maintaining PA, PPT-S+ seeks to reduce the relative attractiveness of smoking as a mood enhancer and to enhance self-efficacy for remaining abstinent. Prior research has suggested that a behavioral activation approach to increasing positive reinforcement during smoking cessation has promise [13]. The PPT-S+ approach toward increasing positive reinforcement is distinct from that of behavioral activation, but both approaches may operate through similar mechanisms to affect smoking outcomes—providing alternatives for enhancing positive affect other than smoking.

The PPT-S+ model acknowledges that PPT-S+ may directly enhance positive affect, given prior research on positive psychology interventions. It also acknowledges that individuals with greater positive affect may find it easier to engage in PPT-S+ strategies. In our pilot

trial, the effect of PPT-S was, in fact, stronger among those with higher levels of positive affect prior to treatment[19]. However, results also suggested that it was use of PPT-S strategies that was more predictive of long-term outcome than positive affect itself.

The following intervention elements are unique to PPT-S+ (see Table 1 for timing of interventions):

PPT-S Model of Smoking Cessation.: PPT-S+ highlights that despite initial withdrawal symptoms, quitting smoking results in improved mental health and reduced stress [43, 45, 51–54]. The importance of attending to positive experiences and having positive social interactions when quitting is emphasized, noting that these experiences help people manage future obstacles. Counselors note that the exercises taught in PPT-S+ can be more difficult to complete during periods of stress or low mood, but that regular practice of the exercises has been shown to increase satisfaction with life and positive moods and reduce depression.

Positive Introductions.: PPT-S+ begins by introducing the concept of signature strengths and how those can be important in quitting smoking. Participants are provided feedback about their top five signature strengths based on the Values in Actions Survey [55], which assesses 24 signature personality strengths such as *Love of Learning*, *Kindness*, *Appreciation of Beauty*, and *Gratitude*. Participants are asked to share how they have demonstrated use of one of these strengths in a recent situation.

Using Signature Strengths.: Counselors highlight the role that signature strengths play in leading an engaged life and handling challenges. Throughout treatment, participants are asked to consider how they can employ their signature strengths to help them manage high-risk situations for smoking. For example, someone with high *Love of Learning* may be encouraged to seek out information on the health benefits of quitting smoking, whereas someone high in *Kindness* may be encouraged to use some of their money saved from not smoking to treat a friend to dinner.

Three Good Things.: At session 1, participants are instructed to record by text messaging three good things that happened each day. This exercise has been shown to have rapid and lasting effects on reducing depressive symptoms and increasing happiness [56]. This exercise is continued through session 3, at which point participants can choose whether to continue the exercise over the following weeks.

Savoring.: At session 2, counselors introduce the concept of savoring positive experiences, including sensory experiences (e.g., savoring chocolate rather than eating it in one bite), positive memories, and accomplishments. They assign participants to savor at least two experiences each day for two weeks and to record what they savored at the end of each day by text messaging. They continue this exercise through session 4.

Active/Constructive Responding.: At session 4, participants are instructed to listen carefully when people they care about report good events. They are instructed to go out of their way to respond actively and constructively to these events and to keep a record of these experiences through daily text messaging.

Savoring Acts of Kindness.: This exercise begins at session 5 and asks participants to become aware of when they exhibit kind behavior toward another person (or note others being kind) and to savor the kind behavior by noticing it and writing it down. Participants are asked to text the kind acts they did or witnessed each day. This exercise is based on a prior study showing that writing down one's acts of kindness enhanced well-being [57].

Maintenance Exercise.: In the final session, participants discuss their experiences with the PPT-S+ exercises and choose which exercise to continue over the next two weeks.

3.7.5 Text Messaging—Participants in both ST+ and PPT-S+ receive a core set of text messages to support smoking cessation, following the TXT-2-Quit (T2Q) program developed by Bock and colleagues [58]. The frequency of T2Q messages in PPT-S+ is reduced somewhat to accommodate the PPT-specific texts without creating unequal response burden between study arms. Participants will enroll in the program at baseline by responding to a text message. T2Q is an 8-week core program of daily texts tailored to the user's phase of quitting (e.g., preparing to quit, early weeks of active quitting, sustaining a recent quit, relapsed, preparing to make a second quit attempt). Message content includes behavioral (e.g. "Keep a stress ball handy to squeeze during times of intense craving."), motivational messages (e.g. "You decided to quit smoking and you're doing it. You're awesome") and information on dealing with nicotine dependence and withdrawal (e.g., "The worst of nicotine withdrawal is over in a few weeks, but breaking the smoking habit comes more slowly."). T2Q is flexible, allowing for special messages for each phase of quitting (e.g., recently quit, recently relapsed, maintaining abstinence, etc.) and allowing participants to set a unique quit date.

All participants will set a quit date to coincide with session 3 of counseling, but the program can accommodate those who need to set another quit date. Individuals who relapse are encouraged to make another attempt at cessation, and more intensive messaging is given to those recently quit or relapsed. Participants in ST+ receive 1 message per day leading up to a quit date, 4 messages per day in the 2 weeks immediately after quit date, and 2 messages per day in the four weeks after that. Those in PPT-S+ receive slightly fewer T2Q texts: 1 message per day leading up to a quit date and 2 messages per day in the 4 weeks after their quit date. Additional help is available on demand through automated motivational messages sent in response to a texted key word (e.g., "crave" or "slip") [58].

3.7.6 Text Messaging in PPT-S+—In addition to T2Q messages, participants in PPT-S + will receive daily texts intended to increase positive cognitions and engagement with exercises and to prompt participants to consider their signature strengths and how these can be used to facilitate quitting. Morning texts provide static messages relevant to a given exercise ("Notice what good things happen in other people's lives. Help them celebrate. It makes you both feel good!"), while afternoon/evening texts are interactive and ask for open-ended descriptions of what participants did to complete that day's exercise ("Did you find at least one chance today to respond actively and with enthusiasm to someone's good news?"), with a reminder sent after one hour if no response is received. These responses are tabulated for the smoking cessation counselor. Text messages specific to an exercise are initiated at the respective counseling session at which that exercise is introduced by texting a key word,

e.g., 'Savor,' to initiate the savoring texts. The exercise continues each day following the session until that exercise is replaced by a new exercise. At session 6, participants choose which exercise they want to continue and receive texts based on their choice for an additional two weeks. The texting protocol for PPT-S+ was developed and finalized based on pilot testing done with nine participants prior to initiating the randomized trial.

3.8 Masking/blinding

Participants will be randomized to ST+ or PPT-S+ after completing their baseline assessment by the Project Coordinator, who does not conduct outcome assessments. Due to the timing of the randomization procedures, project staff who conduct the baseline visit will have no way of knowing participants' study condition. Staff conducting follow-up outcome assessments will not be informed of condition assignment.

3.9 Timeline

Recruitment began in February 2017 and will continue until approximately April of 2020. Follow-ups will continue throughout this time and will be completed in mid-2021.

3.10 Sample size calculations

We estimated abstinence rates in PPT-S+ by roughly averaging and rounding the abstinence rates seen in our developmental trial [18] and pilot randomized controlled trial [19]. For PPT-S+, we estimated 45%, 30%, and 25% abstinence at 12, 26, and 52 weeks, with 20% continuously abstinent. Results of the pilot study suggested differences in abstinence rates between PPT-S and ST that ranged from roughly 12% to 15% [19]. Therefore, for ST+, we estimated 30%, 17.5%, and 12.5% abstinence at 12, 26, and 52 weeks, with 8% continuously abstinent; such effects would represent a clinically meaningful effect for PPT-S+.

For the analysis of point prevalence abstinence over time, we used a covariance matrix based on our past trial [19] and a program developed for power analysis for generalized estimating equations [59] and determined that a sample size of 272 participants would be needed to achieve power of .80 given our estimated abstinence rates. For the single measure of verified continuous abstinence, 298 participants are needed for power of .80. To allow for up to 10% of participants being lost to follow-up, however, we allowed for an initial sample of 340 in order to ensure adequate statistical power for our analyses.

3.11 Analysis Plan

Initial analyses will use chi-square tests to examine group differences in biochemically-validated, 7-day point prevalence smoking abstinence at each follow-up as well as continuous abstinence across follow-ups. The primary outcome analysis will utilize Generalized Estimating Equations [60, 61] to test the effect of treatment condition on abstinence at 12, 26, and 52 weeks post quit date. GEE is a method of repeated measures analyses for categorical and continuous outcomes that allows for appropriate modeling of covariance structures when observations are correlated across time [62]. The primary, between groups, independent variable in the analysis is treatment group assignment. ST+ will be used as the reference group in this model. The model will contain a linear effect of time as well as the variables included in the urn randomization—gender, cigarette

dependence, and CES-D PA—following clinical trial analysis recommendations [63]. A second step will test the interaction between treatment condition and time to determine whether relative effects of PPTS+ change over time.

We will also determine if intervention engagement, reduced attraction to smoking, or greater self-efficacy mediates the relationship between PPT-S+ and smoking behavior. A regression analysis will be performed predicting the mediators at session 6 (note that the self-report measures assess strategies used during the quit attempt retrospectively, while attraction and self-efficacy refer to the current moment). Additionally, we will run a second model which adds the mediators to the main effects generalized estimating equations model testing outlined in the previous paragraph. We will use the asymmetric products of coefficients method to calculate the significance of this indirect effect and its 95% confidence interval using the RMediate program [64, 65]. Mediators will be tested sequentially such that strategies will be entered first followed by reduced attraction to smoking and self-efficacy, which serve as more proximal mediators. Follow-up analyses will examine individually each of the four core PPT-S strategies to isolate whether either of these are more important to outcomes.

We will also test whether PA moderates the effect of PPT-S+ on smoking outcome. To do this, we will add to the model testing an interaction term between PA and PPT-S+. Given a significant interaction, follow-up analyses will establish whether there is a crossing point of PA level at which PPT-S+ is not likely to be more effective than ST+. Analyses will be repeated with the CES-D total score as the moderator.

4. Discussion

This randomized controlled trial will provide the first fully-powered test of the efficacy of PPT-S+ for smoking cessation. The study is innovative in several ways. First, although a handful of trials have been conducted using cognitive behavioral interventions to address affective factors in smoking cessation treatment, these studies have focused primarily on risk factors for poor smoking outcomes (e.g., negative affect and elevated depressive symptoms) and the amelioration of presumed deficits. Although these studies have yielded some promising results, benefits of depression and negative mood-focused treatments appear to be limited to those smokers with significant elevations in depressive symptoms or a history of recurrent major depressive disorder [12, 66]. PPT-S+ incorporates a positive psychology framework, which offers a shift from traditional psychopathology and deficit-focused models towards a focus on enhancing well-being and accentuating individual strengths [15, 67]. As such it may have appeal to a broad range of smokers and provides a novel alternative to existing approaches.

Smoking cessation programs, particularly those incorporating mood management interventions, have typically assumed that quitting smoking is likely to exacerbate negative mood and depression and therefore tend to focus on preventing that potential negative outcome. By contrast, PPT-S+ draws on evidence that successfully quitting smoking is likely to result in increased longer-term happiness [45, 51], reduced anxious arousal [52], and reduced depression compared to continued smoking [43, 53]. Indeed, a recent meta-analysis

concluded that the effect of quitting smoking on improved mental health is similar to the effect of antidepressant pharmacotherapy [54]. PPT-S+ gain-frames quitting smoking as part of an effort to increase both physical and mental health, while still acknowledging the challenges associated with acute negative moods encountered during quitting.

PPT-S+ extends our prior work in developing and piloting PPT-S by incorporating text messaging. For PPIs to be fully effective, it is important to ensure participants are maximally engaged in them, and results of our pilot studied showed that engagement in PPT-consistent strategies predicted better long-term smoking outcomes. We believe that incorporating text messaging will allow for such enhanced engagement. The text messaging program will provide both daily reminders to complete PPT-S+ exercises and the ability to record exercises each day without the need for paper and pencil. We believe that utilizing text messaging will help maximize the amount of engagement in PPT-S exercises, which will in turn result in higher rates of smoking abstinence. Mediational analyses will allow us to test whether this hypothesis is supported.

If efficacious, PPT-S+ should have high potential for implementation and population reach. PPIs have broad appeal given their emphasis on the universally attractive goal of enhancing happiness [68]. Such broad appeal could circumvent cultural barriers to behavioral treatment and be easily implemented with little adaptation for different populations. Secondly, PPT-S+ exercises do not require extensive staff training or treatment resources. The exercises are simple enough such that written directions for various PPIs can be integrated into myriad forms of counseling including individual, group, and web-based programs. Prior research has shown that clinicians are not required for administration of PPIs [56, 67, 69, 70]; in fact, a recent study found that completing PPIs by text messaging, without any clinical contact, was associated with greater reductions in depressive symptoms compared to control text messaging among those with elevated depressive symptoms [71]. Because text messaging is so widely available and because the clinical training and oversight needed to deliver PPT-S+ is quite modest, we believe the potential public health impact of PPT-S+ could be substantial if the results of this clinical trial show efficacy for smoking cessation.

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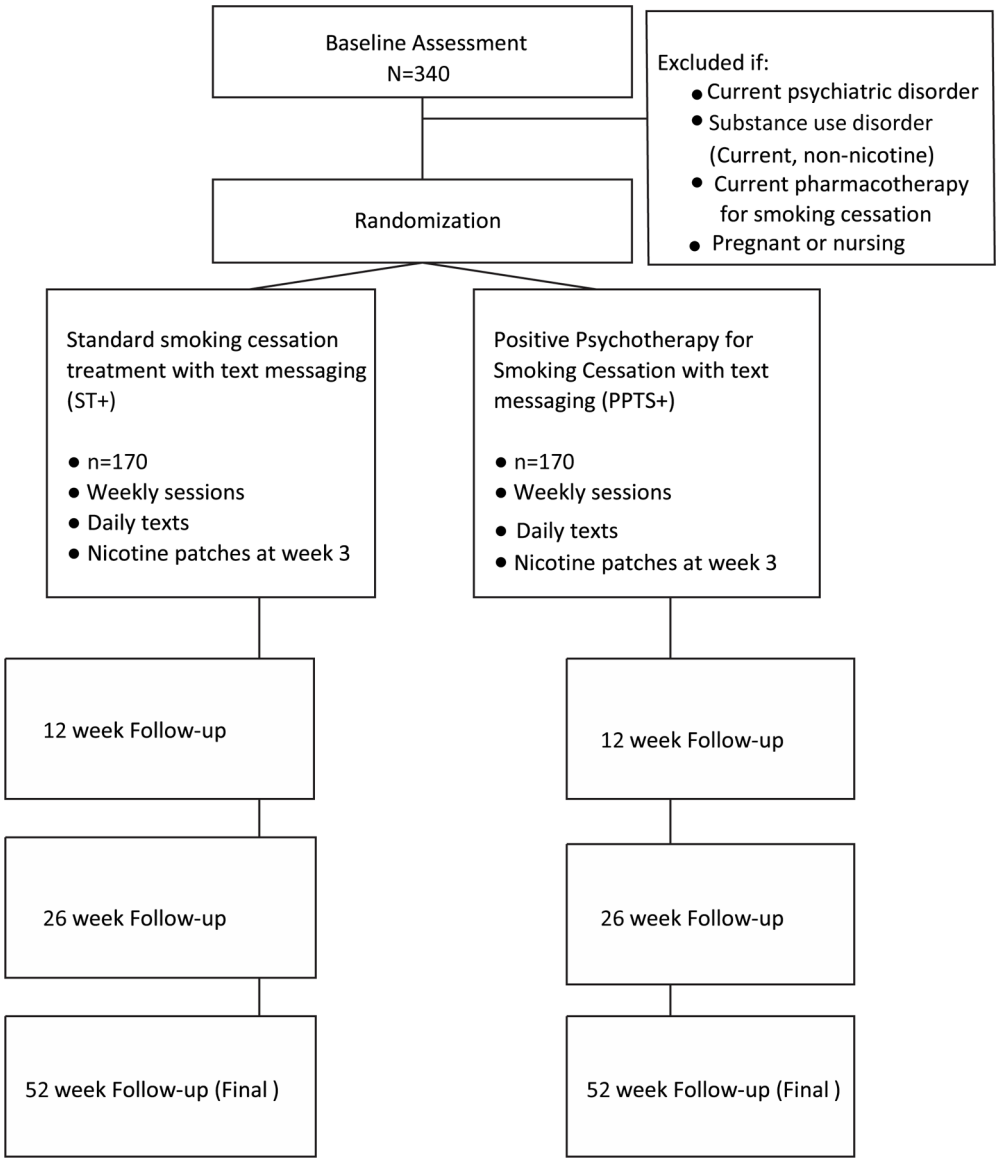

Figure 1.

CONSORT diagram showing participant flow. CONSORT = Consolidated Standards of Reporting Trials; PPT-S+ study design.

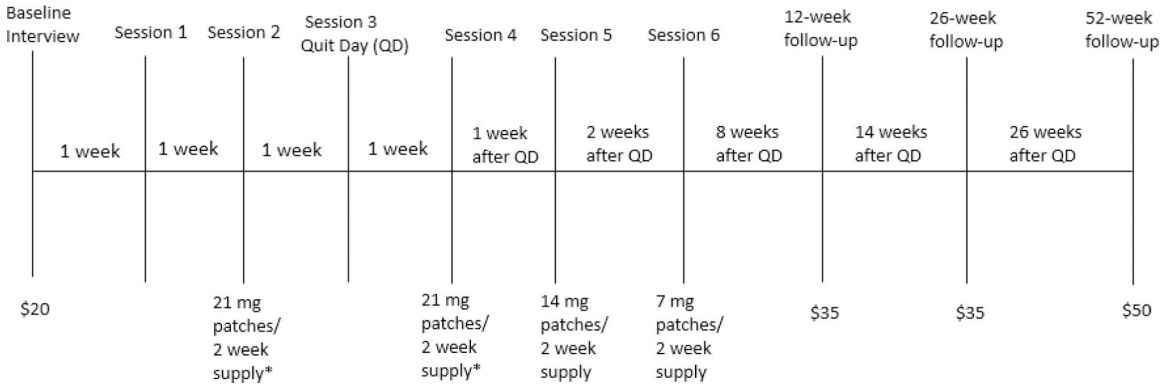

Figure 2.

Model showing participant session flow. Please note, if participant only smokes 5–10 cigarettes per day, they will start on 14 mg patches and will continue for 6 weeks tapering down to 7 mg nicotine patches.

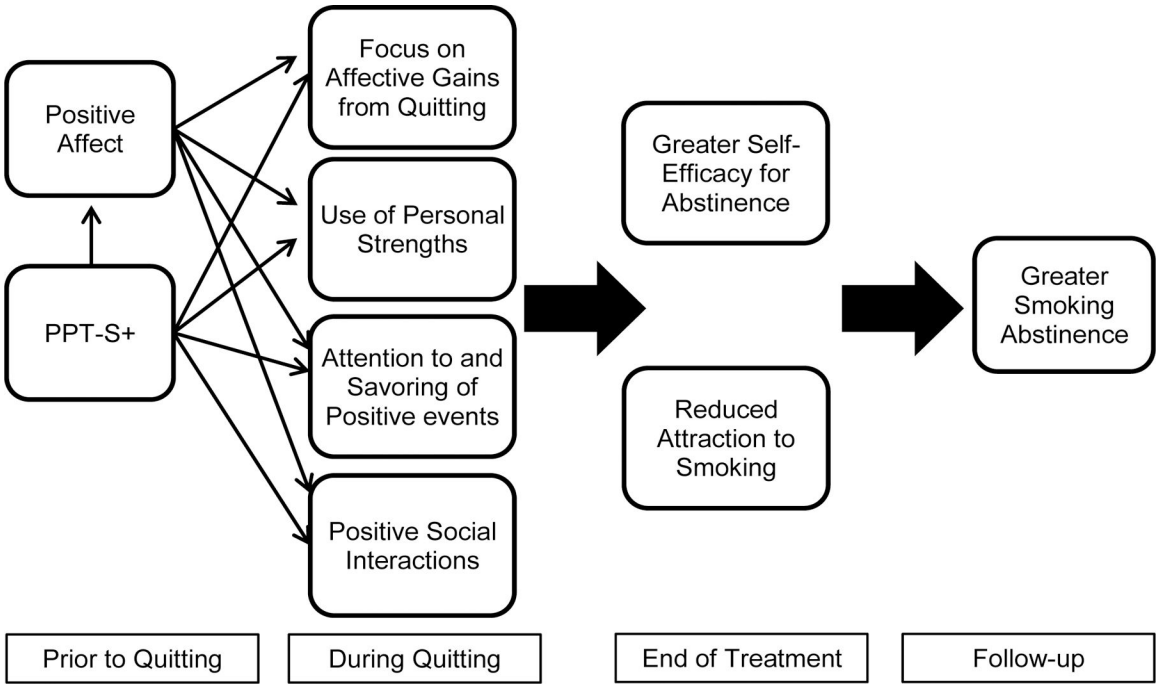

Figure 3.
Theoretical framework of the impact of PPTS+ intervention and affect on smoking cessation.

Table 1

Smoking cessation and PPT-S+ treatment components by session

Session #	Smoking Cessation Components	PPT-S+ Components
1	Reasons for quitting Smoking as physical addiction and habit Identifying high-risk situations	Positive Introductions PPT-S+ Model of Smoking Cessation 3 Good Things
2	Proper use of the nicotine patch Planning for high-risk situations Social support for quitting Preparing for quit date	3 Good Things Savoring Signature strengths in quitting smoking
3 (quit date)	Quit date review Starting nicotine patch Planning for high-risk situations	3 Good Things (optional) Savoring Signature strengths in quitting smoking
4	Managing smoking ‘slips’ Nicotine patch review Planning for high-risk situations	3 Good Things (optional) Active/Constructive Responding Signature strengths in quitting smoking
5	Benefits of quitting Managing smoking ‘slips’ Nicotine patch review Planning for high-risk situations	3 Good Things (optional) Savoring Acts of Kindness Signature strengths in quitting smoking
6	Benefits of quitting Managing smoking ‘slips’ Nicotine patch tapering Planning for high-risk situations	Review of PPT-S+ exercises Choosing PPT-S+ exercises to continue

Note. PPT-S+ = positive psychotherapy for smoking cessation plus text messaging