Study Protocol

Positive Psychotherapy for Smoking Cessation Enhanced With Text Messaging: A Randomized Controlled Trial

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Study Aims

This randomized controlled trial will test the efficacy of Positive Psychotherapy for Smoking Cessation plus Text Messaging (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.

Method

Note regarding response to Covid pandemic

The procedures below describe the protocol as implemented prior to March 2020. With social distancing and closure to in-person activities, procedures were modified to accomodata remote enrollment, assessment, and intervention. Those modification are noted as "AFTER MARCH 2020"

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 or at the Massachusetts General Hospital in Boston, MA. AFTER MARCH 2020: All procedures happened online or by telephone only.

Participants

A total of 340 participants will be enrolled in the study over an approximately 3-year period, which started in February 2017. 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.

AFTER MARCH 2020: To confirm smoking status at baseline, participants were sent a NicAlert test strip for saliva testing of cotinine and completed the test while being observed during a Zoom call with a research assistant. A test positive for cotinine was required for enrollment. The limit of detection for the NicAlert strip is 30 ng/mL

Outcome Variables

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 [3, 4] 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) [5] and saliva cotinine radioimmune assay analysis (cutoff value of $\leq$ 15 ng/ml) [6]. 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.

AFTER MARCH 2020: Self-reported abstinence was biochemically confirmed with a NicAlert test which was sent to the participants how and self-administered while being observed by the research assistant on Zoom.

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 [2]. 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 [7]. 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 [8].

Recruitment Procedures

Participants will be recruited through advertisements localized to the greater Providence, RI and Boston, MA 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.

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 study sites 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.

AFTER MARCH 2020: All assessments and counseling occurred by telephone or Zoom videoconferencing.

Assessments

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.

AFTER MARCH 2020: No blood pressure readings or pregnancy tests were done.

Follow-up Interviews

Participants will return to the study sites 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.

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[1] 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) [9] 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 [10, 11]. 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.

Details of the intervention and control

Nicotine Replacement Therapy

All participants will be provided an eight week supply of transdermal nicotine patch with initial patch dosage (7mg, 14mg, or 21mg) based on their smoking rate at baseline following the product recommendations.

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.

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. 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.

Standard Treatment+ (ST+)

ST+ is based on clinical practice guidelines[12] 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[13]. 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[12]. Participants are instructed to use relaxation techniques to reduce stress in their day-to-day life as needed.

PPT-S+

Modeled after our previous pilot [2], the PPT-S+ condition shares the same fundamental smoking cessation components with ST+, but also integrates positive psychology concepts. 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 [8, 14]. PPT-S+ is also gained-framed [15, 16] to highlight that quitting smoking can be a rewarding challenge that enhances mental health [17-19]. Research has shown that positive self-affirmations [20] can reduce defensiveness about health information leading to increased behavioral intentions [21]. 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 [22]. 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 [23], although a recent study did not support this conclusion [24]. Both reductions in PA leading up to quit date and low PA after quitting have been implicated in smoking relapse [25, 26]. 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 [27]. 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 [17, 19, 28-31]. 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 [32], 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 [33]. 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 [34].

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.

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

[35]. 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") [35].

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.

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.

4.9 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.

AFTER MARCH 2020: Given that recruitment had not yet reached its final goal, we restarted enrollment of new participants in June of 2020 and continue to enroll new participants through September 2020 with all follow-ups completed by December 2021.

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 [36] 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.

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Table 1

Smoking cessation and PPT-S+ treatment components by session

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

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