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THE STATE UNIVERSITY
OF NEW JERSEY

STUDY INFORMATION

Title of Project: Persist to Quit: Telehealth Counseling for Smokers with Serious Mental Illness

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1.0 Research Introduction

1.1 Purpose/Specific Aims

This study will test the feasibility and acceptability of a telehealth-delivered treatment designed to help smokers with serious mental illness to quit using a therapy approach focused on increasing task persistence.

A. Objectives

We will test the feasibility, acceptability, and initial efficacy of our PTSC-S intervention when delivered via telehealth.

B. Hypotheses / Research Question(s)

1. We hypothesize that the PTSC-S intervention will be acceptable to participants, and the study will be feasible to conduct.

2. As compared to baseline, participants will report greater task persistence as evidenced by reduced scores on the Thoughts About Smoking Questionnaire (TASQ).

3. As compared to baseline, participants will report smoking fewer cigarettes per day at 1- and 3-month follow-up.

1.2 Research Significance (Briefly describe the following in 500 words or less):

We created a treatment manual designed to help smokers with serious mental illness to quit smoking, in part, by targeting deficits in the tendency to persist in difficult or frustrating tasks (i.e., "task persistence"). While several measures of task persistence were not found to be significantly changed in the study, we detected a significant change (in the hypothesized direction) on a measure of thoughts likely to dampen task persistence as it relates to. Specifically, as hypothesized, scores on the Thoughts About Smoking Questionnaire (TASQ) showed significant decreases from baseline to the target quit date, $t(16) = 7.753$, $p < 0.001$, and maintained those significant decreases from baseline to end-of-treatment, $t(19) = 4.537$, $p < 0.001$.

In addition, we found that the intervention was feasible and understandable. Once we began providing transportation to our research participants, attendance exceeded our goal of 65% of participants attending at least 6 of 8 treatment sessions. We also found that in response to the statement, "Overall, this treatment was easy to understand," 68.8% of participants endorsed "7: Totally Agree" with an additional 18.8% endorsing "6: Agree very much" for a total of 87.6% endorsing at least a 6 out of 7. In response to the statement, "Overall, this treatment was helpful," 56.3% of participants endorsed "Totally Agree" with an additional 25% endorsing "Agree very much" for a total of 81.3% endorsing at least a 6 of 7.

1.3 Research Design and Methods

Overview: We will evaluate the feasibility and acceptability of our intervention (Persistence Targeted Smoking Cessation for Serious Mental Illness; PTSC-S) when delivered via telehealth in a single group, within-subjects design.. The purpose of this trial is to test the feasibility, acceptability, and initial efficacy of our PTSC-S intervention.

A. *Participant Recruiting and Screening:* The project will take place remotely via telehealth to reduce patient burden and travel difficulties. Our Rutgers offices in New Brunswick, NJ, are located in the building next to a large University Behavioral Health Care outpatient clinic that serves clients with serious and persistent mental illness. We will recruit New Jersey resident smokers from Rutgers University Behavioral Health Care, from the community via our website, social media, and local flyers, via Rutgers listservs, local

agencies or organizations who serve mental health consumers (i.e. CHOICES; Serv Behavioral Health Systems, Inc.; George J. Otlowski, Sr. Center for Mental Health Care, Hunterdon Behavioral Health Care), and ElevateU's Study Recruitment Platform (more detailed information listed below under "ElevateU Recruitment"). We will use IRB approved language from recruitment advertisements for electronic communication (i.e. listservs, newsletters, ect.) with approved study sites. Potential participants will call our offices for a telephone pre-screen or fill out an interest form on Qualtrics that would be followed by a telephone pre-screen. If potentially eligible, they will be offered a more in-depth telehealth phone or video assisted screening after providing informed consent. If all inclusion criteria are met, they will be invited to participate. This is an urban area with a large low-income population and therefore a greater proportion of smokers than the average of 14.8% in the state of New Jersey. Previous studies have given us the necessary experience with Rutgers listservs, websites, Craigslist, and use of flyers and brochures to maximize recruitment.

ElevateU. ElevateU is a pilot recruitment platform funded by the National Institute on Drug Abuse. The purpose of the online platform is to match individuals with substance use disorders who wish to participate in research with researchers doing relevant substance use research. The recruitment platform is currently in a pilot phase and there is therefore no fee or contractual agreement related to using this National Institute on Drug Abuse funded platform.

Access to ElevateU's recruitment platform https://moshemu.com/ is provided to researchers at no cost. Researchers may register and create an entry describing their research study on the Moshemu website for potentially interested individuals to view. ElevateU advertises online, at no cost to the research teams for research studies. Potential research participants who see the advertisement may choose to click on the advertisement link which will take them to a description of the study. If interested in that study, the potential research participant can "sign up" to be contacted by the research team via email and/or phone numbers.

ElevateU, as part of this registration process, potential research participants may choose to voluntarily provide information related to health behaviors so they can be contacted in the future if they match with other relevant research studies. Providing this information is voluntary. The ElevateU platform is seen as providing minimal risk to participants who wish to enroll in studies because the website and registration/data storage process is similar to methods currently being used in people's day to day lives. For example, people typically register on Facebook, Reddit, and online patient communities such as "Patients Like Me," where they provide information about their health either through free text conversations and/or responses to questions. This website will be using similar methods and therefore seen as minimal risk to participants.

Furthermore, the primary method of identification will not be through name but through email address. Participants have the ability to create a new email address by creating a free email through tools such as gmail.com. Overall, we believe these methods involve minimal risk and have been used in a variety of IRB-approved studies by our team (e.g., UCLA and UC Irvine researchers) in the past.

All information collected via ElevateU's platform will be stored in an encrypted database. Two copies of the encryptions will be created with a passkey for each user (participant on the online recruitment platform) and for each study that the user enrolls in. If the user opts into the study, a copy of their data becomes encrypted with a passkey of the study. It is therefore will only ever be accessible to the user themselves and to the manager of any study they enroll in.

Recruitment using ElevateU. ElevateU will advertise, at no cost to us, for the IRB approved study, Persist to Quit: Telehealth Counseling for Smokers with Serious Mental Illness. Information about our IRB approved study will only be described in language consistent with already IRB approved study flyers. As noted above, potential participants who see the advertisement will have the option to click the link on the ad, read about the study, and opt-in to being contacted by IRB approved research staff if they are interested in participating or learning more about our study.

When a potential participant actively opts-in to being contacted, Dr. Steinberg's Moshemu account will be notified. The research team will then have access to the contact information the potential participant chose to provide. Dr. Steinberg's team will be able to download a CSV file with the contact information and Dr. Steinberg will store this file on the secure HIPAA compliant Rutgers OneDrive folder.

Study Procedures: A trained research assistant (who will receive weekly and as-needed supervision from the principal investigator) will pre-screen potential participants on the phone, followed by a pre-baseline tutorial regarding the required technology and assist with any troubleshooting needs. A research assistant will meet with participants via telephone or telehealth video platform, obtain informed consent via a HIPAA compatible survey platform (i.e., Red Cap or Qualtrics), and administer the baseline assessment battery (see Assessment Measures table below). We will divide the baseline assessment battery into two sessions to minimize participant fatigue if necessary. Each baseline assessment session will last approximately 90 minutes.

The research coordinator (who will receive weekly and as-needed supervision from the principal investigator) will screen participants at baseline using the SCID-RV for suicide risk exclusion criteria. If any participant indicates high levels of depression or suicidality, we will provide phone numbers and a recommendation to contact Rutgers University Behavioral Health Care or the Rutgers RWJMS Department of Psychiatry outpatient practice. In case of imminent suicide risk, a research staff member will call Acute Psychiatric Services (APS) at 855-515-5700 with the research participant and the principal investigator will be contacted immediately.

Questionnaires that are commonly used in tobacco dependence treatment studies will be used in the current study. Women of childbearing age will confirm in writing that they are not pregnant or nursing, not planning on becoming pregnant in the next three months, and that they are using effective birth control if they are sexually active. Carbon monoxide (CO) levels (also commonly collected in tobacco dependence treatment studies) will be assessed with a personal carbon monoxide monitor that connects to one's mobile device and CO reading in parts per million (ppm) will be recorded.

Study Intervention: We will provide free, weekly individual telehealth video counseling sessions for 8 weeks and 10-weeks' worth of the nicotine transdermal patch (an FDA-approved smoking cessation product available over the counter). All sessions will be video recorded for treatment integrity and supervision.

HIPAA compatible video platform: We will use Microsoft Teams for all assessment and telehealth counseling appointments. If there are any problems connecting to Microsoft Teams, we will use Doxy.me or Zoom as a backup. Both Microsoft Teams, Doxy.me, and zoom are HIPAA compatible platforms for telehealth services. A trained research assistant will meet with each participant via Microsoft Teams (or via telephone) if participant is unable to use the technology without any assistance

to review technology, telehealth application, and assist with any technology issues prior to the beginning of assessment or counseling.

In the event we are unable to meet with a patient using telehealth video services (e.g. because of internet connectivity issues), we will provide counseling using the telephone. There is a strong literature supporting tobacco "QuitLines", proactive telephone counseling and we would therefore still be providing treatment via an empirically supported format. We expect this will in the best interest of the patient as abruptly stopping treatment would be unethical.

Emails: We may create a Google account email with a complex password for each research participant using their assigned ID number and short title of our study "ptscs" (i.e. ID#ptscs@gmail.com) if a participant does not have an email address to use. We will store this information using the HIPAA compliant Microsoft OneDrive cloud storage system and may assist participants with their email as needed. No PHI will be transmitted via this email account. This email will be used to set up the Smokerlyzer application for the iCO Smokerlyzer device, as the application requires an email to be sent to our research team with the results of their breath test. We will ask our participants to not use this email account for communication outside of the research study to protect their confidentiality. See section 1.7.2 for more on the iCO Smokerlyzer device.

B. *Data Points:* We will collect data at baseline, at the end of treatment, and at follow up at 3-months post quit date.

C. *Duration:* Participants will be active in the study for approximately 4 months. We anticipate completing data collection activities within 32 months.

D. Primary study endpoints include baseline, at the end of treatment, and at follow up at 3-months post quit date. We will assess AEs on a rolling basis and report them at DSMB meetings. We will conduct an interim analysis after 50% of the target enrollment has completed followup assessment.

1.4 Preliminary Data

Our pilot study (N=26) examining the PTSC-S intervention demonstrated that we could successfully follow-up this population (20 of 26 participants were reached at end-of-treatment). In addition, we demonstrated that our intervention engaged our target mechanism (i.e., task persistence). While there was no change in persistence on multiple measures, we did find that as hypothesized, scores on the Thoughts About Smoking Questionnaire (TASQ) showed significant decreases from baseline to the target quit date, $t(16) = 7.753$, $p < 0.001$, and maintained those significant decreases from baseline to end-of-treatment, $t(19) = 4.537$, $p < 0.001$. These data indicate that our PTSC-S intervention positively influenced cognitive aspects of our target mechanism, thus meeting milestone 1. More specifically, our intervention was able to positively influence cognitions likely to dampen task persistence.

We also found that 57.7% of participants met our target of attending at least 6 of 8 sessions. Importantly, early in the study, we noticed that patients were having difficulty with transportation and therefore were missing many sessions. We therefore instituted a protocol in which we were able to provide transportation to the participants and this has increased participant attendance in treatment. When excluding the first 5 patients from the equation (those who did not have the benefit of transportation provided to them), we find that 66.7% of participants attended at least 6 of 8 of their PTSC-S treatment sessions.

Finally, participants found the intervention to be easy to understand and helpful. In response to the statement, "Overall, this treatment was easy to understand," 68.8% of participants endorsed "7: Totally Agree" with an additional 18.8% endorsing "6: Agree very much" for a total of 87.6% endorsing at least a 6 out of 7In response to

the statement, "Overall, this treatment was helpful," 56.3% of participants endorsed "Totally Agree" with an additional 25% endorsing "Agree very much" for a total of 81.3% endorsing at least a 6 of 8.

1.5 Sample Size Justification

Based on data from the R21 phase of the study, we can expect a large effect (Cohen's dz = 1.28) of the intervention on task persistence as measured by the Thoughts About Smoking Questionnaire (TASQ). We detected a change in mean(SD) scores, in the predicted direction, from 4.371(1.0) at baseline to 3.218(1.1) at follow-up. An effect of dz = 1.28 setting power at 80% and alpha at 0.05 suggests we need N = 6 participants in the within-subjects analysis to detect an effect (see Figure 1 below).

Because effect sizes may be unstable at smaller sample sizes, we will be much more conservative and assume an effect size of Cohen's dz = 0.5 (consistent with a medium, rather than a very large effect size). Given a medium effect size, while setting power at 80% and alpha at 0.05, we will require N = 27 participants for this within-subjects design (see Figure 2 below). While we will impute baseline data where follow-up data are missing (i.e., assuming no improvement), we will also recruit additional participants to account for the possibility of up to 20% loss to follow-up (i.e., 80% retention rate). We will therefore aim to recruit 34 additional participants to have N = 27 with complete data at follow-up after making the protocol changes described within this document.

1.6 Study Variables

A. Independent Variables, Interventions, or Predictor Variables

We will provide 8-weeks of free telehealth counseling to participants and 10 weeks of nicotine transdermal patch (an FDA-approved, over-the-counter medication).

"Persistence-Targeted Smoking Cessation in those with Serious Mental Illness (PTSC-S)" is an 8-session, individual, smoking cessation counseling strategy that focuses heavily on using cognitive behavioral therapy targeted at disputing automatic thoughts that may reduce task persistence for smokers with serious mental illness. While disputing automatic thoughts will be the focus of each session, skill building and support will also be included. Participants will be asked to complete homework assignments between sessions – including keeping a daily thought record to monitor automatic thoughts that may put them at risk for smoking. A daily thought record is a commonly used cognitive behavioral therapy homework assignment in which participants practice identifying and evaluating their thoughts. Participants will also track their daily cigarette use and nicotine patch use for homework.

We will give participants a 10-week supply of the nicotine transdermal patch (an FDA-approved, over-the-counter medication) to be used starting two weeks prior to their Quit Date. Although the nicotine patch is commercially available without a doctor's prescription, Co-I Dr. Jill Williams (an addiction psychiatrist) will provide medical monitoring during this study. Consistent with the product insert, participants will be instructed to use one nicotine patch daily, and to apply it upon awakening at about the same time each day. Subjects will be instructed to vary the site of application of the patch daily to minimize any skin irritation. They will use the 21mg patch for the first 8-weeks, then 2-weeks of the 14mg patch.

B. Dependent Variables or Outcome Measures

Primary Outcome measures

- We will measure prolonged abstinence with a 2-week grace period following the target quit date until end-of-treatment and 3-months post quit-date

- We will measure feasibility using a scale regarding how "useful" the intervention was, how acceptable the length of each session was, and how acceptable the number of counseling sessions offered was (with higher scores reflecting ratings of more useful and more acceptable).
- Follow-up rates of at least 80% at the 3-month follow-up
- Rates of missing/unusable data will be < 10% of all data collected

Secondary Outcome measures:

- 7-day point prevalence abstinence at end-of-treatment and 3-months post quit-date
- Percent abstinence days between the target quit-date and end-of-treatment and 3-months post quit-date.
- Task Persistence
- Treatment attendance

1.7 Drugs/Devices/Biologics

1) *Nicotine replacement therapy.* The nicotine transdermal patch is an accepted, FDA approved treatment for nicotine dependence. Nicotine patches are available over-the-counter (OTC) without a prescription. Study participants will be provided with information by a research therapist describing the proper use of the nicotine patch, including a description of common side effects.

A. Drug Accountability and Storage Methods

- *Storage and accountability.* We will store any existing nicotine replacement therapy (NRT) in original packaging (box containing 2-week supply) in locked cabinets in a room with locked doors at 317 George Street; Suite 105; New Brunswick, NJ. We will document temperature of the room weekly using a min/max thermometer. All future NRT orders will be directly shipped to participants.
  - *Back Up Storage Site*: In the event the storage room reaches a temperature near the maximum or minimum allowed temperature range, we will temporarily store the medication at the Rutgers RWJMS Research Pharmacy located in the East Tower, 8th Floor, 125 Paterson Street in New Brunswick, NJ. We will continue to store the medication at the Research Pharmacy until our storage room temperature returns to the allowed range.

    Any time there is a transfer of medication between the research pharmacy and Addiction Psychiatry office, a trained research assistant will contact the pharmacy and arrange to drop off/pick up the medication. We will document the transfer in the in the medication log. The research assistant will document their name, the date of the transfer, and the number of boxes transferred.

    If the medication is stored at the pharmacy and the research therapist needs to dispense the medication to a research participant, the research therapist will arrange with a research assistant to pick up the medication within the same day of the appointment and document this in the medication log as described above.
- *Inventory.* A trained research assistant will use an NRT inventory log to document the Lot # and Expiration date of each box of NRT. After receiving the nicotine patch shipment, a research assistant will meet with the participant using telehealth video platform, asking the patient to show each nicotine box's expiration date and lot number. This information will be documented in the inventory log.

- *Dispensing NRT.* We will purchase the 10-week supply and ship the nicotine patches directly to each participant. We anticipate directly sending our participants the nicotine patches will reduce patient burden and travel difficulties. We will monitor the package tracking number for delivery and confirm with participants via phone or telehealth service they have received the package. To protect the confidentiality of our participants, there will be no indication on the package that the participant is enrolled in a research study. After receiving the nicotine patch shipment, a research assistant will meet with the participant using telehealth video platform, asking the patient to show each nicotine box's expiration date and lot number. This information will be documented in the dispensing log. The research therapist with meet with the participants who will be instructed to store unused nicotine patches at room temperature consistent with the packaging instructions. Consistent with the product insert, participants will be instructed to use one nicotine patch daily, and to apply it upon awakening at about the same time each day. Participants will be instructed to vary the site of application of the patch daily to minimize any skin irritation. They will use the 21mg patch for the first 8-weeks, then 2-weeks of the 14mg patch. We will not collect unused portions of the NRT because it is not common practice to specify a time limit by which participants are required to use the NRT. Patients will receive large stickers with the label "21mg" or "14mg". A research assistant will watch patients put the correct sticker over the seal of the appropriate nicotine patch box to minimize chances that patients will open the wrong box.

2) *Carbon Monoxide Monitor.* We will use the iCO™ Smokerlyzer to measure carbon monoxide (CO). The iCO Smokerlyzer has an FDA regulatory classification of a General Wellness Device (GWD) and therefore does not have a 510(k) number. The iCO™ Smokerlyzer® allows you to measure your breath CO levels to encourage the user to make an informed decision about cutting down or stopping smoking to promote better general health, which is in line with the definition and intended use of a General Wellness Device (GWD).

The iCO Smokerlyzer works with iOS or android smartphone or tablet and in conjunction with their Smokerlyzer®App (available on Apple App Store & Google Play Store). Each participant will receive an iCO Smokerlyzer and a computer tablet with the app loaded to the device. The iCO Smokerlyzer provides biofeedback in the form of a personal CO level immediately from a simple breath test.

The patient is asked to hold their breath for a 15 second countdown. This is displayed on the screen of the device. At the end of the breath hold, the patient blows gently into the ICO Smokerlyzer expiring as much of the breath in their lungs as possible. The reading on the device shall rise until the peak reading is held on the display. After completing the breath test, participants will send our research team the results, which are date and time stamped, from an email account we set up for them. The data itself are stored on the participants' own mobile device and the data transmitted via email will not contain any PHI. For more information about participant's email accounts please reference 1.3.A.

A. Device Accountability and Storage Methods

- *Storage and accountability.* We will store the iCO Smokerlyzer devices with the study coordinator or Principal Investigator. We will document when each iCO Smokerlyzer devices are provided to participants.
- A research assistant will provide instructions on how to use the iCO Smokerlyzer. The study PI is accountable for the devices.

1.8 Primary Specimen Collection

N/A

1.9 Interviews, Focus Groups, or Surveys

We will conduct a semi-structured interview (SCID-RV for DSM 5 - Modules A, B, C, and D; Suicidal Ideation and Suicide Attempt) as part of the baseline assessment. This semi-structured interview is widely recognized as the gold standard for determining psychiatric diagnoses.

If any participant indicates high levels of depression or suicidality, we will provide phone numbers and a recommendation to contact Rutgers University Behavioral Health Care or the Rutgers RWJMS Department of Psychiatry outpatient practice. In case of emergent suicidality a research staff member will call Acute Psychiatric Services (APS) at 855-515-5700 with the research participant.

A. Administration

Participants will meet with a research assistant for a "pre-baseline" appointment technology tutorial for assistance with any troubleshooting needs. Participants will then meet with a research assistant to provide electronic informed consent through HIPAA compatible survey platform, RedCap or Qualtrics. Following consent, participants will complete a questionnaire battery that does not include PHI online via Qualtrics.

- **Timing and Frequency**

We will divide the baseline assessment battery into two sessions to minimize participant fatigue if necessary. Each baseline assessment session will last approximately 90 minutes. We will then provide free, weekly individual counseling sessions for 8 weeks. Participants will complete an end of treatment assessment and a 3-month post quit date assessment, each will last approximately 60 minutes.

- **Location**

Participants will complete questionnaires and counseling sessions using a HIPAA compatible telehealth platform (e.g. Microsoft Teams, Doxy.me, or zoom)

- **Procedures for Audio and Visual Recording**

Participants will be asked permission to allow study staff to video record their intervention as part of the research study, by signing an addendum to the informed consent form. The recording(s) will be used for clinical supervision, to validate the integrity of the counseling intervention, and potentially to later examine the relationship between what is said during the sessions and various clinical outcomes. The recording(s) will include the participant ID number and date of the research appointment and will automatically be stored within the Microsoft Teams environment (i.e., Microsoft Streams). If we were forced to use Doxy.me or zoom as a backup, recordings would be stored on password protected local computers, and the files would then be encrypted and moved to a HIPAA compatible network storage. The files themselves will be password protected and encrypted using the Advanced Encryption Standard 256 method (AES-256). Files will be linked with each participant's ID number. Files will be destroyed 6 years after the protocol is closed.

B. Study Instruments

Concept	Measure	B/L	Week 4	Week 8	3-mo. Post QD	Weekly
DEMOGRAPHICS	Demographics Questionnaire (includes National Health and Nutrition Examination Survey (NHANES) items)	X				
TOBACCO/SUBSTANCE USE	Fagerström Test for Nicotine Dependence (Heatherton et al., 1991)	X				
	Timeline Followback (TLFB; Sobell & Sobell, 2000)			X	X	X
	Current Tobacco Use	X		X	X	X
	Expired Breath Carbon Monoxide (CO)	X		X	X	X

	Smoking History (Allen et al., 2019; NHANES)	X		X	X	
	Medicinal Cannabis	X		X	X	
	AUDIT-C	X				
	DAST-10	X				
	Brief WISDM (Smith et al., 2010)	X				
CRAVING AND WITHDRAWAL	Wisconsin Smoking Withdrawal Scale (Welsch et al., 1999)	X		X	X	
MOTIVATION TO QUIT SMOKING	ICT – Change Measure (includes self-efficacy) (Miller & Johnson, 2008)	X		X		
	Quitting Fatigue			X	X	
	Commitment to Quitting Smoking Scale (CQSS) (Kahler et al., 2007)	X		X		
TASK PERSISTENCE						
	Breath-holding	X		X	X	
	Temperament and Character Inventory—Persistence Scale (TCI-P) (Cloninger, Przybeck, Svrakic, & Wetzel, 1994)	X		X	X	
	2-item Task Persistence Measure (Steinberg et al., 2007)	X		X	X	
	Distress Tolerance Scale (DTS) (Simons & Gaher, 2005)	X		X	X	
	Discomfort Intolerance Scale (Schmidt, 2006)	x		x	x	
	Thoughts About Smoking Questionnaire	X		X	X	
MENTAL HEALTH SYMPTOMS	Brief Experiential Avoidance Questionnaire	X		x	x	
	Brief Symptom Inventory (BSI) (Derogatis & Melisaratos, 1983)	X		X	X	
	Mental Health and Smoking	X		X		
	SCID-RV for DSM 5 - Modules A, B, C, D, and Suicidal Ideation and Behavior (First et al., 2015)	X				
MEDICAL HISTORY	Medical History Form[a]	X				
	Pregnancy Form	X				
	Baseline Medical Problems	X				
ADVERSE EVENTS	Adverse Event Tracking			x	x	x
	Adverse Event Specifics Log			x	x	x
COVID-19	COVID-19 Questionnaire	X				
SLEEP	The Pittsburgh Sleep Quality Index (PSQI; Buysse, 1989).	X		X	X	
TECHNOLOGY	Technical Glitches Questionnaire					X
TELEHEALTH	Post-counseling questionnaire			x		
FEASIBILITY AND ACCEPTABILITY	Working Alliance Inventory – Short Revised (WAI-SR; Munder et al., 2010)		X			
	Patient Satisfaction Survey					X
	Final Exit Interview			X		
	Weekly Exit Interview					X

[a] Participants answering "yes" to any item listed under cardiovascular disorder on the "Medical History Form" will be reviewed by an Addiction Psychiatrist for follow-up and approval for the study. The Addiction Psychiatrist will review this assessment and will be documented in the patient chart. The addiction psychiatrist will review any other items listed as "yes" on the "Medical History Form", determine if follow up is needed, and will be documented in the patient chart.

Online Measures (Qualtrics)

Demographics Questionnaire. This questionnaire includes primarily items from the National Health and Nutrition Examination Survey (NHANES; (United States Department of Health and Human Services & Disease Control and Prevention, 2010) including items about age, race, and income.

Smoking History. This questionnaire includes primarily items from the National Health and Nutrition Examination Survey (NHANES; (United States Department of Health and Human Services & Disease Control and Prevention, 2010). This self-report asks whether a participant relights cigarettes (Yes/No); if subjects responded "Yes," a follow-up question was asked to determine the number of cigarettes that were relit (Allen et al., 2019).

Fagerström Test for Cigarette Dependence (FTCD; Heatherton, Kozlowski, Frecker, & Fagerström, 1991). The FTCD is a commonly used, 6-item questionnaire designed to measure dependence upon cigarettes.

Brief Wisconsin Inventory of Smoking Dependence Motives (WISDM; Smith et al., 2010). The Brief WISDM is a 37-item, theoretically derived measure of tobacco dependence measuring a variety of smoking motives. Respondents rate each item on a scale ranging from ranging from 1 = Not true of me at all to 7 = Extremely true of me.

Wisconsin Smoking Withdrawal Scale (WSWS; (Welsch et al., 1999). The WSWS is a 28-item scale developed to contain reliable subscales tapping the major symptom elements of the nicotine withdrawal syndrome. There are 7 subscales: anger, anxiety, sadness, concentration, sleep, hunger, and craving. Respondents rate each statement on a scale ranging from 0 (strong disagree) to 4 (strongly agree).

ICT – Change Measure (Miller & Johnson, 2008). This measure asks participants to rate their perception of importance of quitting and confidence in quitting on a 10-point Likert-type scale from 0=Definitely Not to 10 = Definitely.

Quitting Fatigue. Quitting fatigue will be measured with a single Likert-scale item ranging from 0 (Not true of me at all) to 10 (Extremely true of me) in response to the statement, "I am tired of trying to quit smoking."

Commitment to Quitting Smoking Scale (CQSS; Kahler et al., 2007). The CQSS measures motivation, or "commitment" to quitting smoking with eight Likert scale items with response options ranging from 1 = strongly disagree to 5 = strongly agree.

Thoughts About Smoking Questionnaire. The Thoughts About Smoking Questionnaire is a 14-item scale that was developed by the PI to examine cognitions related to smoking that were likely to decrease persistence towards the goal of quitting. Respondents rate items from 1-7 (Totally Disagree to Totally Agree).

Temperament and Character Inventory—Persistence Scale (TCI-P; Cloninger, Przybeck, Svrakic, & Wetzel, 1994). This subscale examines the trait of task persistence in 8 True/False items.

2-item Task Persistence Measure (Steinberg et al., 2007). This 2-item scale measures task persistence via a 4-choice Likert scale (Very True to Very Untrue)

Distress Tolerance Scale (DTS; Simons & Gaher, 2005). 15-item scale used to assess participants' perception of their ability to tolerate mental distress. Items (e.g. "I can't handle feeling distressed or upset") answered on 5-point Likert-type scales ranging from (1) strongly agree to (5) strongly disagree evaluate participants' ability to experience and endure negative emotional states and includes scales that assess appraisal, tolerance, absorption, and regulation. This scale contains good psychometric properties, including high internal consistency. Because six of these items are included in the DII, below, this measure will be comprised of nine items.

Distress Intolerance Scale (DIS; Schmidt, 2006). 5-item measure on which participants indicate, on a 7-point Likert-type scale (0 = not at all like me to 6 = extremely like me), the degree of agreement towards statements related to their tolerance of discomfort

COVID-19 Questionnaire. This questionnaire includes questions from the Coronavirus Stressor Survey (McLean & Cloitre, 2020) and relationship between the coronavirus and smoking.

Brief Symptom Inventory (BSI; Derogatis & Melisaratos, 1983). The BSI is a self-report instrument assessing severity of psychiatric symptoms.

Breath-holding. We will document time in seconds that participants can hold their breath as a measure of task persistence. Participants will raise their hand when the experience begins to become uncomfortable and the total persistence score will be the time (in seconds) bewteen when they indicate discomfort and when they release their breath.

Medical History Form. We developed this form to collect brief medical information to assist in confirming eligibility for this study.

Inclusion Exclusion Criteria Form. We developed this form to confirm eligibility for this study. Part one includes criteria from the initial phone screen. Part two includes risk assessment information from the baseline assessment.

Technical Glitches Questionnaire. We developed this form to collect brief feedback about any technology issues related to telehealth. This brief questionnaire is completed by therapists, rather than participants to assess intervention feasibility.

The Pittsburgh Sleep Quality Index (PSQI; Buysse, 1989). Measure the quality and patterns of sleep. It differentiates "poor" from "good" sleep by measuring seven domains: subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleep medication, and daytime dysfunction over the last month. The client self-reports each of these seven areas of sleep on a 0 to 3 scale, whereby 3 reflects the negative extreme on the Likert Scale. A global sum of "5"or greater indicates a "poor" sleeper.

Post-counseling questionnaire. We developed this form to collect feedback from participants based on their experience with telehealth counseling.

Working Alliance Inventory – Short Revised (WAI-SR; Munder et al., 2010). The Working Alliance Inventory-Short Revised (WAI-SR) is a 12-item measure for the assessment of the therapeutic alliance

Patient Satisfaction Survey. We developed this form to collect feedback from participants regarding satisfaction with the intervention and delivery via telehealth.

Final Exit Interview. We developed this form to collect feedback from participants based on their overall experience with this treatment and rating of usefulness.

Weekly Exit Interview. We developed this form to collect feedback from patients from participants based on their experience and ratings of usefulness.

Medicinal Cannabis. We developed this form to assess medicinal cannabis use.

Mental Health and Smoking. Indicates patient's belief about the influence of their mental health and quitting smoking.

Alcohol Use Disorders Identification Test, AUDIT-C. 3-item alcohol screen that can help identify persons who are hazardous drinkers or have active alcohol use disorders.

Drug Abuse Screen Test, DAST-10. Screen that can help identify persons with problematic substance use.

Electronic Measures Forms

Timeline Followback (TLFB; Sobell & Sobell, 1992). The TLFB method is a strategy for assessing substance use requires participants to retrospectively estimate their daily substance and alcohol use.

Expired Breath Carbon Monoxide (CO). Participants will provide expired breath carbon monoxide by blowing into the iCO smokerlyzer. CO levels will be documented on this form in parts per million (ppm). The iCO Smokerlyzer works with iOS or android smartphone or tablet and in conjunction with their Smokerlyzer®App (available on Apple App Store & Google Play Store). Each participant will receive an ICO Smokerlyzer and a computer tablet with cellular service with the app loaded to the device. The iCO Smokerlyzer provides biofeedback in the form of a personal CO level immediately from a simple breath test. After completing the breath test, participants will email our research team the results, which are date and time stamped, from an email account we set up for them. The data itself are stored locally on the mobile device and the data transmitted via email will not contain any PHI.

Pregnancy Form. Using this form, women will state in writing that they are not pregnant or nursing, not planning on becoming pregnant in the next two months, and that they are using effective birth control if sexually active. Although we will request this attestation from all female participants, it should be noted that the nicotine patch is available over-the-counter, and although the package insert states that "the risks to your child from this medicine are not fully known" observational and intervention studies do not find harmful effects on the fetus or on the pregnancy as compared to placebo in human studies (Bar-Zeev et al., 2018). We therefore expect the risks continue to be minimal to our female population and are outweighed by benefits by participation in this study.

SCID-RV for DSM 5 - Modules A, B, C, D, and Suicidal Ideation and Behavior (First, Williams, Karg, & Spitzer, 2015). This semi-structured interview is widely accepted as the gold standard for determining psychiatric diagnoses.

Baseline Medical Problems. We developed this form to summarize any medical problems existing before the study started to help differentiate pre-existing conditions from new adverse events occurring once the participant engages in treatment.

Adverse Event Tracking. We developed this form to monitor adverse events at each weekly appointment.

Adverse Event Specifics Log. We developed this form to monitor details for adverse events.

Treatment Form. We developed this form to monitor report weekly carbon monoxide and current tobacco use. This form will be used by the research therapists at weekly appointments. This form includes a table for research therapists to monitor participant's dispensed nicotine patch progress.

1.10 Timetable/Schedule of Events

	2018	2019	2020	2021	2022
Rutgers / UBHC project meeting	x	x	x	x	x
Train study therapist and research asst.	x	x	x	x	x
Recruit participants (N=90; 30/yr; 3/month)	x	x	x	x	
Complete follow up assessments		x	x	x	x
Data Analysis				x	x

2.0 Project Management

2.1 Research Staff and Qualifications

Marc Steinberg, Ph.D. (PI) is a licensed clinical psychologist, a faculty member in the Rutgers RWJMS Department of Psychiatry, and director of the Tobacco Research & Intervention lab. His research focuses on tobacco dependence treatment, including tobacco dependence treatment development and tobacco use in vulnerable populations such as those with psychiatric comorbidity and lower socioeconomic status. Dr. Steinberg has been PI or Co-I for multiple randomized clinical trials of tobacco dependence treatments for high-risk smokers including RCTs of motivational interviewing, behavioral therapy, and of nicotine nasal spray for smokers with serious mental illness, of persistence-targeted smoking cessation in low SES smokers, and of varenicline for smokers not yet ready to quit.

Jill Williams, MD (Co-I) is Professor and Director, Division of Addiction Psychiatry, Rutgers Robert Wood Johnson Medical School. Dr. Williams' research focuses on smokers with mental illness comorbidity and she has extensive experience in randomized clinical trials for tobacco dependence treatment with R01 grant support from NIDA and NIMH. Dr. Williams and Dr. Steinberg are both housed in the Division of Addiction Psychiatry with one office door separating them. They meet regularly to discuss clinical research issues.

Patricia Dooley-Budsock M.A, LPC, NCTTP (Research Therapist). Ms. Dooley has almost 20 years experience in working with serious mental illness and cognitive behavioral therapy.

Shou-En Lu, Ph.D. (Biostatistician) is an Associate Professor in the Department of Biostatics in the Rutgers School of Public Health who specializes in multivariate survival analysis, clustered data analysis and cohort case-control and case-cohort designs.

Graduate Students:
Benjamin Billingsley
Rachel Rosen

Doctoral Psychology Interns and Graduate students have completed coursework and didactics in substance use treatment, cognitive behavioral therapy, and motivational interviewing. Students also have prior experience treating individuals with psychosocial impairment in the surrounding area. All graduate students have also interfaced with members of the community to facilitate completion of research projects focused on nicotine use. This includes, but is not limited to, structured clinical interviewing of research subjects and administration of behavioral tasks.

All graduate students have also completed online coursework on ethical research practices (e.g., HIPAA compliance).

Undergraduate Students:
Drashya Shah
Sara Diras
Sanjana Thaper
Daniella Burnett

Other research staff:
Anagha Babu

Undergraduate students have completed coursework in psychology have completed online coursework on ethical research practices (e.g., HIPAA compliance).

2.2 Resources Available

Facilities- Participants will be daily smokers from New Jersey. Participants will attend treatment remotely using an online telehealth HIPAA compatible platform. Participants will be in the state of New Jersey during any counseling sessions though they may be outside of New Jersey (e.g., if they are traveling) for follow-up research assessment appointments.

Medical Or Psychological Resources- Dr. Steinberg is a licensed clinical psychologist in that state of New Jersey and will assist in training study staff in the management of crisis intervention. In addition, they will be available 24/7 to field any questions/concerns study staff have regarding how to proceed in the event that participants experience unanticipated psychiatric distress during the course of the study.

Research Staff Training- All graduate students and research assistants will complete intensive training with Dr. Steinberg, including proper administration of each intervention condition and proper administration and management of nicotine replacement therapies. All graduate students will also complete weekly supervision with Dr. Steinberg.

2.3 Research Sites

Research activities will occur remotely or at the offices of Rutgers RWJMS Division of Addiction Psychiatry. We may temporarily store nicotine patches at Rutgers RWJMS Research Pharmacy located at the East Tower, 8th Floor, 125 Paterson Street, New Brunswick, NJ 08901.

3.0 Multi-Site Research Communication & Coordination

N/A

3.1 Outside Research

N/A

4.0 Research Data Source/s

4.1 Primary Data-Subjects and Specimens

Research participants will be 61 daily cigarette smokers with schizophrenia, schizoaffective disorder, or bipolar disorder. We will collect questionnaire data and expired breath carbon monoxide. We will provide 8-weeks of free counseling to participants and 10 weeks of nicotine transdermal patch (an FDA-approved, over-the-counter medication).

4.2 Subject Selection and Enrollment Considerations

A. Recruitment Details

Research assistants will post flyers at UBHC and will work with staff for help in connecting with potential participants. Research assistants will post flyers and place leaflets in local areas.

B. Source of Subjects

We will recruit smokers from Rutgers University Behavioral Health Care, from the community via our website and local flyers, via social media, via Rutgers listservs, local agencies or organizations who serve mental health consumers (i.e. CHOICES, SERV Behavioral Health Systems, Inc.; George J. Otlowski, Sr. Center for Mental Health Care, Hunterdon Behavioral Health Care), and ElevateU's Study Recruitment Platform (explained above in section 1.3 1.3 Research Design and Methods).

C. Method to Identify Potential Subjects

Participants responding to flyers or otherwise referred will complete a telephone screen to determine likely eligibility. If potentially eligible, they will be offered a more in-depth telehealth appointment screening after providing informed consent. If all inclusion criteria are met, they will be invited to participate.

D. Subject Screening

Interested participants will complete a brief telephone screening where they will be assessed by trained study personnel who will determine initial eligibility.

Inclusion Criteria

- Must be between 18 – 70 years old
- Must indicate willingness to make a quit attempt in the next 30 days
- Must report being a daily smoker (including those labeled "little cigars") for past month
- Must have a diagnosis of Schizophrenia, Schizoaffective Disorder, or Bipolar Disorder on SCID-5-RV
- Psychiatric illness must be stable, as indicated by no hospitalizations in previous 8 weeks, and a stable psychotropic medication regimen for 8 weeks

- Must have a smartphone, tablet, or computer with ability to download apps
- Must currently receive mental health treatment
- Must sign release of information for current mental health treatment providers

Exclusion Criteria

- Must not currently (in past 10 days) be taking varenicline (Chantix),
- Must not currently (in past 10 days) be taking bupropion (Zyban/Wellbutrin) to quit smoking.
- Must not be taking any nicotine preparations (gum, lozenge, patch, spray, inhaler) daily over the last 10 days
- Must not be currently receiving tobacco dependence treatment counseling.
- Must not report myocardial infarction, unstable angina pectoris, or significant cardiac arrhythmia (including atrial fibrillation) in the past 30 days.
- Women must not be pregnant, nursing, or planning on becoming pregnant in the next three months. Women who can become pregnant may be included if using effective birth control.
- Must not have pending legal matters with potential to result in jail time
- Must not be planning on moving outside of New Jersey in next 3-months
- Problematic substance use in the past 3 months (AUDIT-C score ≥5 for men and ≥4 for women, DAST-10 score of ≥4)
- Must not have suicidal ideation in the past week with intent, plan, or access to method; must not have attempted suicide in the past year (as assessed on the SCID-RV)

E. Recruitment Materials

We will rely upon flyers and consumer letters. We will also give UBHC staff a handout to use for reference when making referrals. Please see attachments. We additionally anticipate recruitment of participants via word-of-mouth.

F. Lead Site Recruitment Methods

N/A

4.3 Subject Randomization

N/A

4.4 Secondary Subjects

N/A

4.5 Number of Subjects

A. Total Number of Subjects

N=120

B. Total Number of Subjects If Multicenter Study

N/A

C. Require Number of Subjects to Complete Research

N=61

D. Feasibility of Recruiting

We anticipate enrolling 3 participants monthly over the course of 3 years. Based on previous research conducted by the principal investigators this should be feasible. This is an urban area with a large low-income population and therefore a greater proportion of smokers than the average of 14.8% in the state of New Jersey. Previous studies have given us the necessary experience with Rutgers listservs, websites, Craigslist, and use of flyers and brochures to maximize recruitment.

4.6 Consent Procedures

A. Consent

- **Documenting Consent**

All participants will provide electronically signed informed consent using the HIPAA compatible survey platform, RedCap or Qualtrics after being given the opportunity to read the consent form in full and to ask questions about the research. A research assistant will also electronically sign the consent form as a witness.

- **Waiver or Alteration of Consent Process**

N/A

B. Consent Process

- **Location of Consent Process**

Verbal consent will be obtained for the initial phone screen. The PI or RA will first explain the purpose of the phone screen and limits of confidentiality and provide an overview of the study. If potential participants remain interested, they must verbally agree to phone screen completion.

During the initial telehealth meeting, study personnel will verbally go over the consent form including details regarding the procedure, time commitment, payment, risks/benefits, and option to discontinue at any time without penalty, and ask the participant questions to ensure they understand.

- **Ongoing Consent**

N/A

- **Individual Roles for Researchers Involved in Consent**

A trained research assistant (who will receive weekly and as-needed supervision from the principal investigator) will pre-screen potential participants on the phone, followed by obtaining informed consent and administering the baseline assessment battery.

1. Consent Discussion Duration

Staff will go over details regarding the procedure, time commitment, payment, risks/benefits, and option to discontinue the study at any time without penalty. We anticipate that it will take participants 5 minutes to read the consent and up to an addition 5 for staff to review relevant information.

2. Coercion or Undue Influence

Potential participants will explicitly be told in the consent form that the study is completely voluntary and that they may withdraw without penalty at any time. We will inform participants who wish to withdraw, who do not wish to participate, and who do not meet inclusion criteria about alternative cessation treatment options.

3. Subject Understanding

Participants will read a consent form or will have the consent form read to them before signing it. Trained research staff will proactively ask participants to describe the research

study to them in their own words to ensure that participants understand the consent form. If there is any doubt of competence to consent, the individual will not be enrolled. In addition to providing written informed consent, participants must verbally indicate that they understand the study procedures and that they have no further questions.

4.7 Special Consent/Populations
N/A

4.8 Economic Burden and/or Compensation for Subjects

A. Expenses
N/A

B. Compensation/Incentives
Participants will be paid $100 through the duration of the study. They will receive $35 at the initial assessment, $30 at the post-counseling assessment (after session 8), and $35 at the 3-months post-quit date assessment. Participants will be paid via the Rutgers ClinCard system.

B.1 We may divide the baseline assessment battery into two sessions to minimize participant fatigue if necessary.

C. Compensation Documentation
We will maintain a full accounting of funds using the Rutgers ClinCard system.

4.9 Risks to Subjects

A. Description of Subject Risk
There is a risk of discomfort associated with nicotine withdrawal for patients who are quitting smoking. The nicotine patch (an FDA-approved medication) is well tolerated; however, there are potential side effects that may arise when using the patch. Potential side effects include dizziness, headache, nausea, vomiting, diarrhea, or redness or swelling at the patch site. Each patient will discuss these side effects with their therapist. If questions arise as a result of the patch, one of the study co-investigators is an Addiction Psychiatrist who will be available to provide patients with information regarding their side effects.

The overall risk of AEs in this study is expected to be low because both the counseling sessions and the use of over-the-counter nicotine replacement products are low risk and similar to established treatments to help smokers quit. We will monitor patients for AEs at every session, however, and any AEs that are deemed to be moderate to severe will be reviewed by addiction psychiatrist, Dr. Williams and discussed at the weekly research meetings. The team will document the recommended actions with input from Dr. Williams. AEs will be followed until they resolve or until participant study completion. The AE Tracking Form and AE specifics log will also be completed.

There is a risk that participants' confidentiality could be violated. To reduce the risk of violating confidentiality, several steps will be taken. Only IRB approved members of the research team will have access to the data. All computers used by research staff with be password protected with complex passwords. The participants google email account will only include their participant ID number and we will ask that participants do not use this account for communication outside of the research study to protect their confidentiality. Data will only be accessed when coded, entered, or audited. The PI will maintain responsibility for safe data storage. All data will be stored in locked cabinets within locked rooms. We will use a telehealth platform that is HIPAA compatible (e.g. Microsoft Teams, Doxy.me, or zoom). Based on these procedures, we anticipate that the risk to confidentiality is very low.

B. Procedures for Risks to Embryo, Fetus, and/or Pregnant Subjects
N/A

C. Risks to Non-Subjects
N/A

D. Assessment of Social Behavior Considerations
Study risks are minimal and include a small, temporary increase in distress as a result of the assessments; however, the methodologies employed have been utilized in many labs and clinical settings with hundreds of participants suffering from a range of psychopathology, and approved by as many IRBs.

- **Reasonably Foreseeable Risks**
  Study risks are minimal and include a small, temporary increase in distress as a result of the assessments. Participants who quit may experience at least mild nicotine withdrawal symptoms even with counseling and nicotine replacement therapy.

- **Risk Of Imposing An Intervention On Subject With Existing Condition**
  N/A

- **Other Foreseeable Risks**
  Our research team employs standard procedures to ensure confidential information about study participation is not disclosed. All data are linked to an arbitrary 3-digit study ID unrelated to personal information. The file linking participants to their study ID will be stored in a password-protected file, located within a password-protected database on an encrypted computer. Only select trained laboratory personnel will have access to the file. All computer files or printed data used for analysis also will be de-identified. Informed consent collected remotely will be stored in HIPAA compatible survey platform, RedCap. Physical consent forms and payment forms will be stored in a locked file cabinet separate from data in an office that is locked when not occupied. Participants' confidentiality also is protected by never associating a participant's name with results in any published or otherwise publicly presented report. Demographic information, including information about participants' age, ethnicity, education, marital status and employment status, will be reported using averages and percentages computed over multiple participants and never reported at the level of individual participants.

- **Observation And Sensitive Information**
  N/A

E. Minimizing Risks
Participants will be instructed to call 911 if they experience a medical emergency and Acute Psychiatric Services (APS) at 855-515-5700 if they experience a psychiatric emergency. Patient will be counseled and provided with appropriate emergency contact information in the event a research assistant or study therapist determines that emergency care is warranted.

Our research team employs standard procedures to ensure confidential information about study participation is not disclosed. All data are linked to an arbitrary 3-digit study ID unrelated to personal information. The file linking participants to their study ID will be stored in a password-protected file, located within a password-protected database on an encrypted computer. Only select trained laboratory personnel

will have access to the file. All computer files or printed data used for analysis also will be de-identified. Informed consent collected remotely will be stored in HIPAA compatible survey platform, RedCap. Physical consent forms and payment forms will be stored in a locked file cabinet separate from data in an office that is locked when not occupied. Participants' confidentiality also is protected by never associating a participant's name with results in any published or otherwise publicly presented report. Demographic information, including information about participants' age, ethnicity, education, marital status and employment status, will be reported using averages and percentages computed over multiple participants and never reported at the level of individual participants.

All technology platforms handling PHI will be HIPAA compatible and our team is well trained in HIPAA compliance.

F. Certificate of Confidentiality
We have obtained a Certificate of Confidentiality from the National Institutes of Drug Abuse.

G. Potential Benefits to Subjects
The benefits of taking part in this study include access to high-quality, smoking cessation treatment based on empirically supported psychosocial approaches. If participants quit smoking, they will experience health benefits; however, they may receive no direct benefit from taking part in this study.

H. Provisions to Protect the Privacy Interests of Subjects
Our research team employs standard procedures to ensure confidential information about study participation is not disclosed. All data are linked to an arbitrary 3-digit study ID unrelated to personal information. The file linking participants to their study ID will be stored in a password-protected file, located within a password-protected database on an encrypted computer. Only select trained laboratory personnel will have access to the file. All computer files or printed data used for analysis also will be de-identified. Informed consent collected remotely will be stored in HIPAA compatible survey platform, RedCap. Physical consent forms and payment forms will be stored in a locked file cabinet separate from data in an office that is locked when not occupied. Participants' confidentiality also is protected by never associating a participant's name with results in any published or otherwise publicly presented report. Demographic information, including information about participants' age, ethnicity, education, marital status and employment status, will be reported using averages and percentages computed over multiple participants and never reported at the level of individual participants.

I. Research Team Access to Subject Data
Only IRB approved staff will have access to participant data. All data will be coded by arbitrary study number to ensure confidentiality and will be stored in a locked filing cabinet or stored on the lab server where access will be password-protected. Data collected online will be de-identified (e.g., associated with an arbitrary study ID number) and only accessible to trained study personnel. Informed consent collected remotely will be stored in HIPAA compatible survey platform, RedCap. Physical consent forms with identifying information (names) will be filed separately from actual study data in a separate locked filing cabinet. This cabinet the office in which it is kept will ensure that it is also double-locked.

4.10 Secondary Data – Records/Chart Reviews/Databases/Tissue Banks/etc.
N/A

4.11 Chart/Record Review Selection
N/A

4.12 Secondary Specimen Collection
N/A

5.0 Special Considerations

5.1 Health Insurance Portability and Accountability Act (HIPAA)
We will be obtaining and/or disclosing individually identifiable health information associated with a HIPAA-covered component or entity. See attachments for release of information and request of information forms.

Informed consent, release of information , and request for information collected remotely will be stored in HIPAA compatible survey platform, RedCap. All technology platforms handling PHI will be HIPAA compatible and our team is well trained in HIPAA compliance.

5.2 Family Educational Rights and Privacy Act (FERPA)
N/A

5.3 NJ Access to Medical Research Act
N/A

5.4 Code of Federal Regulations Title 45 Part 46 (Vulnerable Populations)
N/A

6.0 Research Data Protection and Reporting

6.1 Data Management and Confidentiality

A. Hypothesis 1: The PTSC-S intervention will be acceptable to participants, and the study will be feasible to conduct as evidenced by:

a. At least 80% of participants will provide at least a 5 on a 1 – 7 scale regarding how "useful" the intervention was, how acceptable the length of each session was, and how acceptable the number of counseling sessions offered was (with higher scores reflecting ratings of more useful and more acceptable). Analysis 1a: Descriptive statistics will be reported.
b. We will achieve follow-up rates of at least 80% at the 3-month follow-up. Analysis 1b: Descriptive statistics will be reported.
c. Rates of missing/unusable data will be < 10% of all data collected. Analysis 1c: Descriptive statistics will be reported.

Hypothesis 2: As compared to baseline, participants will report greater task persistence as evidenced by reduced scores on the Thoughts About Smoking Questionnaire (TASQ). Analysis 2: One-tailed, paired sample t-tests will be used to examine decreases in scores on the TASQ at each timepoint.

Hypothesis 3: As compared to baseline, participants will report smoking fewer cigarettes per day at 1- and 3-month follow-up. Analysis 3: One-tailed, paired sample t-tests will be used to examine decreases in cigarettes smoked per day on the TASQ at each timepoint.

B. We determined the sample size based on data from the R21 phase of the study, we can expect a large effect (Cohen's dz = 1.28) of the intervention on task persistence as measured by the Thoughts About Smoking Questionnaire (TASQ). We detected a change in mean(SD) scores, in the predicted direction, from 4.371(1.0) at baseline to 3.218(1.1) at follow-up. An effect of dz = 1.28 setting power at 80% and alpha at 0.05 suggests we need N = 6 participants in the within-subjects analysis to detect an effect (see Figure 1 below).

Because effect sizes may be unstable at smaller sample sizes, we will be much more conservative and assume an effect size of Cohen's dz = 0.5 (consistent with a medium, rather than a very large effect size). Given a medium effect size, while setting power at 80% and alpha at 0.05, we will require N = 27 participants for this within-subjects design (see Figure 2 below). While we will impute baseline data where follow-up data are missing (i.e., assuming no improvement), we will also recruit additional participants to account for the possibility of up to 20% loss to follow-up (i.e., 80% retention rate). We will therefore aim to recruit 34 additional participants to have N = 27 with complete data at follow-up after making the protocol changes described within this document.

C. Data Handling: Only IRB approved members of the research team will have access to the data. The research staff collecting the data will bring the data to the PI within 24 hours of it being collected. Data will only be accessed when coded, entered, or audited. The PI will maintain responsibility for safe data storage. All data will be stored in locked cabinets within locked rooms.

Data collection: The data will be collected through telehealth video interview using HIPAA compliant platform (e.g. Microsoft Teams, Doxy.me, or zoom). If telehealth video appointments are unable to be done because of internet connectivity, we will conduct telephone interviews. Data will be stored at the Division of Addiction Psychiatry; 317 George Street; Suite 105; New Brunswick, NJ 08901. Only the IRB-approved research team will have access to the research data.

Data entry, editing and management, including handling of data collection forms, different versions of data, and data storage and disposition: Data will only be accessed and handled by IRB approved study personnel and kept in password protected databases. Dr. Steinberg is ultimately responsible for the receipt and transmission of all data. Informed consent collected remotely will be stored in HIPAA compatible survey platform, RedCap. Paper copies of data (e.g., names on consent forms) will be stored immediately in Rutgers offices where they will be locked in a cabinet housed behind a locked door (of Division of Addiction Psychiatry, 317 George Street, Suite 105, New Brunswick).

All computer files will be kept on computers requiring login and complex passwords for entry, and all files with identifying information will have the extra protection of a password to open that individual file. The individual participant's personal information, including name and contact numbers, will be kept separate from their study data and linked only by a study number assigned by the PI. The master link between the study number and patient contact information will be destroyed once all data is collected and checked for accuracy. The confidential binder containing telephone screen forms will be shredded and properly discarded after 12 months of study completion. Participant names will not be used in any publications or papers derived from this study.

Additionally, we have obtained a Certificate of Confidentiality from the NIH.

D. Qualtrics and Excel databases will be created in such a way as to not allow for out of range data.

E. Data (described in section 1.6 B) will only be accessed and handled by IRB approved study personnel and kept in password protected databases. Dr. Steinberg is ultimately responsible for the receipt and transmission of all data. Paper copies of data (e.g., names on consent forms) collected at the UBHC will be brought immediately to Rutgers offices where they will be locked in a cabinet housed behind a locked door (of Division of Addiction Psychiatry, 317 George Street, Suite 105, New Brunswick).

6.2 Data Security

Our research team employs standard procedures to ensure confidential information about study participation is not disclosed. All data are linked to an arbitrary 3-digit study ID unrelated to personal information. The file linking participants to their study ID will be stored in a password-protected file, located within a password-protected database on an encrypted computer. Only select trained laboratory personnel will have access to the file. All computer files or printed data used for analysis also will be de-identified. Informed consent collected remotely will be stored in HIPAA compatible survey platform, RedCap. Physical consent forms or other forms with identifiable information be stored in a locked file cabinet separate from data in an office that is locked when not occupied.

All technology platforms handling PHI will be HIPAA compatible and our team is well trained in HIPAA compliance.

6.3 Data and Safety Monitoring

A. Periodic Data Evaluation

A Data Safety Monitoring Board will meet quarterly to evaluate safety data and other study issues.

B. Type of Data Evaluated

Safety data will be reviewed quarterly. Efficacy data will be evaluated after 50% of participants have completed follow-up data collection.

C. Collection of Safety Information

We will use case report forms to document adverse events at each telehealth patient contact.

D. Frequency of Data Collection

We will document adverse events at each telehealth patient contact.

E. Reviewer of Data

A Data Safety Monitoring Board will meet quarterly to evaluate safety data and other study issues. The PI (Dr. Steinberg) and medical monitor (Co: Dr. Williams) will review safety data as it is collected.

F. Schedule of Review of Cumulative Data

Safety data will be reviewed every 6-months.

G. Tests for Safety Data

Independent t-tests will be used to examine differences between treatment groups with respect to number of adverse events reported.

H. Suspension of Research

We do not expect any adverse events in this trial that would indicate stopping the trial because we are providing established treatments to smokers trying to quit. We will monitor adverse events, however, and stop the trial if our DSMB determines that it is warranted in response to adverse events.

In addition, we will stop the trial if the DSMB concludes that interim analysis at the halfway point of the trial provided overwhelming evidence that PTSC-S intervention was more efficacious than the control intervention.

6.4 Reporting Results

A. Sharing of Results with Subjects
Participants will not be provided with individual study results.

B. Individual Results
Participants will not be provided with individual study results.

C. Aggregate Results
Aggregate results such as average number of sessions attended, proportion of participants obtaining abstinence from smoking, and cigarettes smoked per day may be reported in peer reviewed scientific conference presentations, peer-reviewed scientific publications, or peer-reviewed NIH grant applications.

D. Professional Reporting
Study results may be presented to the scientific community via peer reviewed manuscripts and presentations at scientific conferences. They will also be included in peer-reviewed NIH grant applications.

E. ClinicalTrials.Gov Registration and Data Reporting
The trial will be registered with ClinicalTrials.gov within the first three months of receiving the grant funds and will reflect the procedures and primary/secondary outcomes outlines in this protocol.

6.5 Data Sharing
N/A

7.0 Data and/or Specimen Banking
N/A

8.0 Other Approvals/Authorizations
N/A

9.0 Bibliography

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