Personalized Feedback for Distress Intolerant Smokers
Study Protocol and Statistical Analysis Plan
IRB Approval Date: 02/15/2019

Study Protocol

Recruitment. Participants will be recruited from the University of Houston (UH) and greater Houston area through advertisements and physician referrals. Recruitment techniques will include electronic media (e.g., university listservs, social media, etc.) and flyers in community-based organizations (e.g., UH campus, community health centers, etc.).

Pilot Procedure. Interested individuals will complete a phone pre-screen. Individuals who are eligible at the pre-screen and willing to participate in the study will be contacted and scheduled for an in-person baseline appointment at the Anxiety and Health Research Laboratory (AHRL) at the University of Houston, wherein full eligibility will be assessed, and informed consent will be completed. At the in-person baseline appointment, prospective participants will provide informed consent and complete additional eligibility screening including (1) a pre-intervention online eligibility survey (~45 minutes) and (2) and measures administered by a trained research assistant (e.g., CO assessment, breath holding tasks; ~15 minutes). Following completion of these tasks, a trained research assistant will determine the participant's eligibility. Subjects deemed ineligible will be unable to participate in the intervention, provided with resources, and compensated $10 for their time. Participants deemed eligible will complete a computer delivered intervention (~ 60 minutes) of the Active PFI intervention. Following the intervention, participants will complete a post-intervention online survey (~10 minutes) and tasks with a trained research assistant (~5 minutes). Additionally, the participant will complete an individual semi-structured interview with a trained researcher (~30 minutes). The semi-structured interview will include questions about the personalized feedback format and content, and suggestions to improve the feedback. The investigative team will review the feedback from the first 5 eligible participants and adapt/refine intervention content as needed. We will then present a revised version of the PFI to an additional 5 eligible participants individually, and complete the same feedback/evaluation process. Changes and suggestions elicited from the second round of participants will be integrated into the final PFI to be tested in Phase 2. The appointment will take approximately 2 hours and 45 minutes and participants will be compensated $40 for their time.

RCT Procedure. Interested individuals will complete a phone pre-screen. Individuals who are eligible at the pre-screen and willing to participate in the study will be contacted and scheduled for an in-person baseline appointment at the Anxiety and Health Research Laboratory (AHRL) at the University of Houston, wherein full eligibility will be assessed, and informed consent will be completed. At the in-person baseline appointment, prospective participants will provide informed consent and complete additional eligibility screening including (1) a pre-intervention online eligibility survey (~45 minutes) and (2) and measures administered by a trained research assistant (e.g., CO assessment, breath holding tasks; ~15 minutes). Following completion of these tasks, a trained research assistant will determine the participant's eligibility. Subjects deemed ineligible will be unable to participate in the intervention, provided with resources, and compensated $10 for their time. Participants deemed eligible will be randomized to either the (a) Active PFI or (b) Control PFI intervention (~60 minutes). Following the intervention, participants will complete a post-intervention online survey (~10 minutes), tasks with a trained research assistant (~5 minutes), and will be scheduled to return to the clinic for follow-up assessments at the AHRL-SUTC. Follow-up appointments, will consist of an online survey, breath holding task, CO collection, and Saliva Cotinine. The baseline appointment will take approximately 2 hours and 30 minutes and participants will be compensated $40 for their time.

Follow-ups will occur at 2- week and 1-month after the one-session intervention. Participants will return to the clinic for their follow-up assessments. Follow-up appointments will take approximately 30 minutes each and participants will be compensated $30 for each follow-up assessment.

Randomized Clinical Trial (RCT) Procedure:

Active PFI: The PFI will employ the feedback structure modeled from other work that has focused on substance use and negative mood symptoms. Participants' responses to questions measured at the baseline will be used to provide personalized feedback using algorithms comparing the individuals' response to population norms (matched and gender). The PFI will be interactive to facilitate participant engagement and memory retention; accurate responses are validated and inaccurate responses are provided feedback and corrective information. In general, the intervention has three a priori aims to provide: (1) personalized normative feedback about distress tolerance and its consequences (e.g., what low distress tolerance can lead to, such as worsened mental health); (2) psychoeducational information regarding relations between distress tolerance and smoking (e.g., how distress tolerance influences smoking); and (3) concrete evidenced-based strategies to facilitate motivation and action steps for changing distress tolerance taken from intensive distress tolerance treatments. The exact number of distress tolerance PFI components will be determined during the pilot phase. PFI components will include the smoking-based PFI (see Control PFI below) and may include additional distress tolerance elements such as distress tolerance levels; consequences of low distress tolerance (emphasizing the mental health risks); normative feedback contrasting one's own distress tolerance to their perceptions of others, and gender-matched norms; readiness to change (e.g., perceived barriers); protective behavioral strategies (e.g., mindfulness strategies) and evidenced-based treatment information (e.g., methods for increasing distress tolerance).

Control PFI: Participants assigned to the control group will receive the computerized PFI for tobacco. Specifically, the control condition will receive personalized feedback on smoking, but no distress tolerance personalized feedback. Thus, it will be possible to isolate the impact of distress tolerance feedback versus personalized smoking feedback. The Control PFI components include: smoking profiles (e.g., history of use, levels of nicotine dependence); consequences of smoking (emphasizing the health-related risks associated with the co-use of these behaviors); normative feedback contrasting one's own behavior with their perceptions of others for smoking, and gender-matched norms; readiness to change (e.g., perceived barriers); protective behavioral strategies (e.g., healthier stress reduction techniques instead of smoking); and evidenced-based treatment information (e.g., harm reduction techniques, methods for managing cravings).

Statistical Analysis Plan

Qualitative data will be analyzed using an iterative inductive analysis method consistent with the method of grounded theory. First, the semi-structured interviews will be transcribed. Second, two independent research assistants will draft a list of recurring (e.g., discussed by 2 or more participants) themes for PFI improvements that emerge from transcriptions. I will review all transcriptions and finalize the list of themes. Third, an independent research assistant and I will code the transcriptions across themes using Analysis Software for Word-Based Records. I will then examine the frequency of themes for the entire sample. Themes that are endorsed by at least 40% of the sample will be used to inform PFI revisions.

The equivalence of the random assignment of groups regarding key baseline characteristics will be assessed (e.g., cigarette dependence, education). Should groups differ on any characteristics, we will conduct analyses both with and without these variables as covariates to determine whether any potential randomization failures might impact results. The primary analysis strategy will consist of random effects multilevel modeling (i.e., generalized linear mixed modeling). Analyses will be conducted using Mplus. We will examine intervention effects on motivation, confidence, intention to quit, and perceived barriers for quitting smoking, as primary dependent variables. We hypothesize that participants randomized to the Active (relative to Control) PFI will report increased motivation, confidence, and intention to quit and greater decreases in perceived barriers for quitting smoking over time. Similarly, we will examine intervention effects on smoking rates, quit attempts lasting at least 24 hours, and coping-oriented smoking, as primary dependent variables. We hypothesize that participants in the Active (relative to control) PFI will report a greater decrease in smoking rate, increased number of quit attempts, and a greater decrease in coping-oriented smoking at the 2-week and 1-month follow-up. Finally, we will examine intervention effects on distress tolerance, anxiety/depressive symptoms, and willingness to use coping strategies as primary dependent variables. We hypothesize that smokers in the Active PFI, relative to Control, will report greater distress tolerance, greater reductions in anxiety/depressive symptoms, and increased willingness to use adaptive coping strategies at the 2-week and 1-month follow-up.

For these analyses, each participant will provide up to 3 repeated measures (i.e., baseline, 2-week, and 1-month). Intervention condition will be a dummy coded contrast. We will assess whether interventions are significantly different for outcomes at each follow-up point and if there are differences between the follow-ups. We will follow the procedures described by Preacher and colleagues to assess hypothesized (but exploratory) mediation effects of an increase in distress tolerance; whereby, path A is the effect of the predictor on the mediator, path B is the effect of the mediator on the outcome, path C is the effect of the predictor on the outcome, and path C' is the effect of the predictor on the outcome controlling of the mediator. Mediation analyses will be temporally ordered, such that mediators are assessed after the intervention (e.g., controlling for baseline levels of mediators) and outcomes will be assessed at a later point than the mediators (e.g., controlling for baseline levels of outcomes). Specifically, mediation will test indirect effects using percentile-corrected bootstrapped confidence intervals. As we have theoretically-informed multiple outcomes at multiple follow-ups, we will be sensitive to the effects of multiple testing on alpha inflation.