Personalized Feedback for Distress Intolerant Smokers
Study Protocol and Statistical Analysis Plan
NCT03918031
IRB Approval Date: 02/15/2019

Study Protocol

Recruitment. Participants were recruited nationwide through advertisements and physician referrals. Specifically, recruitment techniques included electronic media (e.g., university listservs, social media, websites, craigslist) and flyers in community-based organizations (e.g., campus, community health centers).

Pilot Procedure. Interested individuals completed a phone pre-screen. Individuals who were eligible at the pre-screen and willing to participate in the study were contacted and scheduled for an in-person baseline appointment at the laboratory, wherein full eligibility was assessed, and informed consent was completed. At the in-person baseline appointment, participants were provided informed consent and completed additional eligibility screening, including (1) a pre-intervention online eligibility survey (~90 minutes) and (2) and measures administered by a trained research assistant (e.g., CO assessment, breath holding tasks; ~20 minutes). Following completion of these tasks, a trained research assistant determined the participant's eligibility. Subjects deemed ineligible were unable to participate in the intervention, provided with resources, and compensated $10 for their time. Participants deemed eligible completed a computer delivered intervention (~ 90 minutes) of the Active personalized feedback intervention (PFI). Following the intervention, participants completed a post-intervention online survey (~15 minutes) and tasks with a trained research assistant (~5 minutes). Additionally, participants completed an individual semi-structured interview with a trained researcher (~10 minutes). The semi-structured interview included questions about the personalized feedback format and content, and suggestions to improve the feedback. The investigative team reviewed the feedback from the first 5 eligible participants and adapted/refined the intervention content as needed. We then present a revised version of the PFI to an additional 5 eligible participants individually, and completed the same feedback/evaluation process. Changes and suggestions elicited from the second round of participants were integrated into the final PFI to be tested in the RCT phase. Participants were compensated $60 for their time.

RCT Procedure. Interested participants were instructed to contact the research lab. Participants who expressed interested were sent a unique link to an online survey which included demographic and selected eligibility screening questions (e.g., cigarettes smoked per day, distress tolerance) that took approximately 10 minutes to complete. Each unique link could only be used one time. Individuals who were eligible at the pre-screen and willing to participate in the study were provided an additional unique link to complete an online baseline assessment. During the baseline assessment, informed consent was obtained electronically. The participant then completed an approximately 90-minute pre-intervention online survey that further evaluated eligibility criteria (i.e., re-evaluated distress tolerance) as well as assessed psychological and health-related constructs of interests. Participants who did not meet eligibility criteria were provided with referrals and compensated $10 in the form of an electronic gift card. To ensure quality responses, speeding checks were included and IP addresses and coordinates were checked to prevent multiple attempts to complete the survey by the same respondent. Moreover, unique links to participate were created for each participant at every stage of the study. Participants who met eligibility criteria were randomly assigned to complete either the (a) Active PFI (60-minutes) or (b) Control PFI (30-minutes). Following the completion of the program, participants were redirected to complete a post-intervention online survey (~15-minutes) to gather qualitative feedback and assess for treatment satisfaction. Eligible participants were compensated $60 in the form of an electronic gift card upon completing all portions of the

baseline (e.g., pre-intervention survey, randomly assigned intervention, and post-intervention survey). Participants were then emailed a unique link to complete an online assessment at 2-weeks and 1-month post-intervention to assess relevant psychological and health-related constructs of interest. The post-intervention online assessments took approximately 30-minutes (each) to complete. Participants were compensated with $30 in electronic gift cards for completing each of the follow-up assessments for up to $120 in electronic gift cards for completing the entirety of the study.

Randomized Clinical Trial (RCT) Procedure:

Control PFI Condition: The Control PFI included personalized feedback on motivation to change smoking, behavior through eliciting responses regarding importance, confidence, and readiness to quit smoking. Next participants were shown graphics depicting their perceptions of smoking behaviors (e.g., percentage of sex-matched adults who they believe currently smoke) and attitudes (e.g., percentage of individuals who they believe smoke that would like to quit) in comparison to normative values in the US. Participants were then guided through a variety of financial and health-related costs of smoking personalized to their smoking behavior (e.g., amount they spend on cigarettes, impact on life expectancy) as well as psychoeducation on dangerous chemicals currently used in cigarettes. Participants were also provided with various health benefits of quitting smoking. Finally, quit tactics were reviewed with participants (e.g., gradual reduction, nicotine replacement therapy) as well as the 5 D's (i.e., Delay, Distract, Deep breaths, Drink water, and Discuss). The intervention included a racial/ethnic and sex-matched digital avatar that guided participants through the intervention. The Control PFI also provided audio and visual aspects to portray the relevant information and interactive games and activities to foster engagement.

Active PFI Condition: The Active PFI included all of the components of the Control PFI as well as the addition of distress tolerance components. Distress tolerance components included personalized normative feedback about distress tolerance and its consequences. For example, participants were provided psychoeducation on what low distress tolerance is, what it can lead to (e.g., worsened mental health), and how their distress tolerance level compares to normative averages. Next, participants were provided psychoeducational information regarding relations between distress tolerance and smoking behavior (e.g., how distress tolerance influences smoking behavior). Finally, concrete evidenced-based strategies to encourage motivation and action steps for changing distress tolerance taken from intensive distress tolerance treatments were incorporated. Specifically, participants engaged in imaginal activities aimed at building tolerance for distress such as imagining a recent stressful event and imagining being around cigarette smoke. Participants were encouraged to continue to practice imaginal activities in order to build tolerance to distress.

Statistical Analysis Plan

The equivalence of the random assignment of groups regarding key baseline characteristics (e.g., demographics) and retention (i.e., 2-week, 1-month; 0 = completed and 1 = missed) were assessed. Differences between key baseline characteristics were also assessed for participants who completed all follow-ups (coded 0) versus participants who missed at least one follow-up (coded 1). Then, paired t-tests were conducted to assess change in credibility and expectancy between baseline and post-intervention. Latent growth curve (LGC) analyses were then conducted using Mplus version 8.6 using maximum likelihood. Multiple imputation using

1,000 imputed datasets calculated in Mplus were used to handle missing data. LGC modeling was used to evaluate the overall trajectories across time of smoking related variables: (1) increased motivation, confidence, and intention to quit, (2) fewer perceived barriers for quitting smoking, and (3) reduced smoking rate. A conditional model was then specified to examine the impact of treatment (0 = Control PFI, 1 = Active PFI) on the slope factor for each of the stated outcome variables. Similar procedures were utilized for mood-related outcomes: (1) greater distress tolerance, (2) reductions in anxiety/depressive symptoms, and (3) increased willingness to use adaptive coping strategies.

For all analyses, shape factors were set for the slope to be centered at the baseline assessment and the 1-month follow-up was fixed at 1.0. The 2-week follow-up was freely estimated. LGC analysis model fit was evaluated with the following fit indices: root-mean-square (RMSEA; Steiger, 1990) and standardized root-mean-square residual (SRMR; Jöreskog & Sörbom, 1996) with values below .08 indicating acceptable fit (Little, 2013), Tucker-Lewis index (TLI; Tucker & Lewis, 1973) and comparative fit index (CFI; Bentler, 1990) with values at .90 or above indicating acceptable fit (Little, 2013). Effect sizes were interpreted in the Cohen's *d* metric (i.e., small = 0.2, medium = 0.5, and large = 0.8) utilizing the partially standardized path coefficient.