Computer-Delivered Intervention for Individuals with Obesity and Elevated Anxiety Sensitivity

Study Protocol and Statistical Analysis Plan

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Study Protocol

Recruitment. Participants were recruited nationwide through advertisements and physician referrals. Recruitment techniques included electronic media (university listservs, Facebook, etc.) and flyers in community-based organizations (university settings, community health centers).

Procedures. Interested participants were directed to an online survey which included demographic and selected eligibility screening questions (e.g., height/weight to calculate BMI and ASI-3) that took approximately 10 minutes to complete. Individuals who were eligible at the pre-screen and willing to participate in the study were contacted and emailed an online baseline assessment, wherein full eligibility was assessed. During the baseline assessment, informed consent was obtained. The participant then completed an approximately 45-minute pre-intervention online survey that further evaluated eligibility criteria (i.e., re-evaluated height/weight and ASI-3) 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. Participants who met eligibility criteria were randomly assigned to complete either the (a) Anxiety sensitivity (AS) reduction program (AS Training [AST]) or (b) Health Information Control (HC); both took approximately 30 minutes to complete. Following the completion of the randomly assigned program, participants were redirected to a 5-minute post-intervention survey and asked to provide qualitative information regarding what they learned from the intervention. Participants were then compensated $20 in the form of an electronic gift card upon completing the baseline surveys and randomly assigned program. Participants were then emailed an online assessment to complete 1-week, 2-weeks, and 1-month post-intervention to assess relevant psychological and health-related constructs of interest. The post-intervention online assessments took approximately 45 minutes (each) to complete. Participants were compensated with $20 in electronic gift cards for completing each of the follow-up assessments for up to $80 in electronic gift cards for completing the entirety of the study.

Interventions:

AST. The AS training was adapted from Schmidt et al. (2007). The intervention provided descriptions on AS and the effects of AS on the body as well as obesity-related health behavior correlates. The intervention included both audio and visual aspects to portray the relevant information. The intervention first provided psychoeducational information on AS For example, participants were provided explanations as to what AS is and how it may manifest among individuals through a number of different scenarios. Participants were then provided psychoeducational information regarding relations between AS and obesity-related health behavior correlates (e.g., how AS influences eating behaviors and exercise avoidance). To illustrate, participants were provided information regarding how eating in response to AS may reinforce the belief that eating is an effective affect-regulatory strategy, further perpetuating this maladaptive behavior. As a result, this may lead to greater calories consumed and subsequent weight gain. Finally, concrete evidenced-based strategies to facilitate motivation and action steps for changing AS taken from previous work (i.e., interoceptive exposure; Schmidt et al., 2007; Schmidt & Trakowski, 2004) were incorporated into the intervention. Specifically, participants engaged in rapid breathing techniques (i.e., hyperventilating) in session and were encouraged to

practice multiple times and track their levels of distress. Participants were also provided information regarding additional interoceptive exposures they could practice outside of the intervention on their own time.

Control PFI. Participants assigned to the control group received a computer-delivered intervention for general health care that adapted materials from previous control conditions utilized in AS reduction trials (Marcus et al., 1999; Marcus et al., 2005; Smits et al., 2016). Specifically, the control condition received information on health-related care including, but not limited to, outdoor safety (e.g., wearing sunscreen, staying hydrated), improving communication with medical care providers, and regular attendance to doctor appointments. However, participants did not receive any recommendations or education on mood, dietary, or physical habits (e.g., exercise, physical activity).

Statistical Analysis Plan

The equivalence of the random assignment of groups regarding key baseline characteristics (e.g., demographics, baseline mental and physical health) and retention at each follow-up (i.e., 1-week, 2-week, 1-month; 0 = missed and 1 = completed) were assessed. Differences between key baseline characteristics were assessed for participants who completed all follow-ups (coded 0) versus participants who missed at least one follow-up (coded 1). Next, zero-order correlations among study variables were examined. Latent growth curve (LGC) analyses were conducted using Mplus version 8.2 using robust 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: (1) AS, (2) emotional eating, (3) expectancies of eating to manage negative affect, and (4) exercise self-efficacy. A conditional model was then specified to examine the impact of treatment (0 = HC, 1 = AST) on the slope factor for each of the stated outcome variables.

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 1-week and 2-week follow-up were freely estimated. The variances of the intercept and slope factors were also 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).