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Refinement and Examination of a Brief Anxiety Sensitivity Focused Intervention

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THE FLORIDA STATE UNIVERSITY
COLLEGE OF ARTS AND SCIENCES

REFINEMENT AND EXAMINATION OF A BRIEF ANXIETY SENSITIVITY FOCUSED
INTERVENTION

By
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This work is dedicated to my husband, parents and siblings. For it is through your unending patience, love and support, that I find the strength to pursue my personal and professional goals.

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ABSTRACT

Anxiety disorders are the most prevalent psychiatric disorders in the United States and result in substantial burden to the individual and society. While effective cognitive-behavioral treatments for anxiety disorders have been developed and well-studied, there has been substantially less focus on interventions aimed at the amelioration of risk factors related to the development of anxiety psychopathology. Anxiety sensitivity (AS) is a well-established, malleable risk factor for panic disorder and other psychopathology. Due to the risk that AS conveys, the development and validation of AS targeted interventions could substantially address the public health burden associated with anxiety psychopathology. The overall aim of the current investigation was to enhance the efficacy of AS treatment through the refinement of a previously validated intervention. This one-session intervention (ASERT) utilized psychoeducation and interoceptive exposure (IE) to target AS and was compared to a health-focused control intervention (PHET) among a sample ($N = 104$) of individuals with elevated AS. Results indicate that the ASERT group demonstrated significantly greater reductions in AS at posttreatment and across the one month study period than the PHET group. These treatment gains were seen across the physical, social, and cognitive ASI subscales. A month six follow-up assessment indicated that the ASERT group retained the majority of their AS reduction while the PHET group retained their elevated AS scores.

INTRODUCTION

Anxiety disorders represent the most prevalent form of psychopathology in the United States, and result in substantial disability and economic burden (Greenberg, et al., 1999; Kessler, et al., 2005). They are highly comorbid with other Axis I diagnoses and often follow a chronic and recurrent course if left untreated (APA, 2000). It has been suggested that much of the burden associated with anxiety disorders could be avoided through prevention and early intervention (Greenberg, et al., 1999). There are many well-established cognitive behavioral treatments for anxiety disorders (Chambless & Ollendick, 2001); however, research focused on amelioration of anxiety risk factors remains in a nascent stage (Feldner, Zvolensky, & Schmidt, 2004). Zvolensky and colleagues (2006) have suggested a translational framework to advance the risk factor treatment research. They emphasize the importance of utilizing basic research that has identified malleable anxiety risk factors in the development of efficacious treatments. A number of genetic, environmental and psychological factors have been investigated in relation to risk for anxiety psychopathology. Among those studied, very few have been found to be true risk factors in the development of anxiety symptomatology and disorders, and of those identified, an even smaller proportion have been identified as malleable.

The expectancy theory proposed by Reiss (1991) suggests that problems with anxiety develop from three fundamental sensitivities: anxiety sensitivity (AS), fear of negative evaluation (FNE) and injury/illness sensitivity (ISI). Individuals with elevated AS interpret physical sensations related to anxiety as an indication of impending illness, embarrassment, loss of control or other dire consequence. FNE is a fear of negative evaluation from others while ISI is a fear of developing an illness or being injured. These three sensitivities are said to be fundamental because all other fears and phobias are thought to develop from them. While FNE and ISI have not received a great deal of research focus, AS is well-established in the anxiety literature. Research has demonstrated that AS is distinct and unique from the two other fundamental sensitivities (Taylor, 1993), as well as from trait anxiety (Rapee & Medoro, 1994) and negative affect (Zvolensky, Kotov, Antipova, Leen-Feldner, & Schmidt, 2005). There has also been much work linking AS to the development of anxiety problems. Fearful responding to bodily sensations has been shown to be predicted by AS (Rabian, Embry, & MacIntyre, 1999; Zinbarg, Brown, Barlow, & Rapee, 2001; Zvolensky, Feldner, Eifert, & Stewart, 2001).

Individuals with preexisting panic disorder as well as other disorders report higher levels of AS than the general population (Kearney, Albano, Eisen, Allan, & Barlow, 1997; Rabian, et al., 1999; Taylor, Koch, & McNally, 1992). Among nonclinical samples, prospective studies indicate that AS predicts future occurrences of anxiety symptoms, spontaneous panic attacks and anxiety disorders, with some specificity for panic disorder (Hayward, Killen, Kraemer, & Taylor, 2000; Maller & Reiss, 1992; Schmidt, et al., 2010; Schmidt, Lerew, & Jackson, 1997, 1999; Schmidt, Zvolensky, & Maner, 2006; Weems, Silverman, & La Greca, 2000). Taken together these findings indicate that AS conveys a significant risk for the development of panic and anxiety. There is also an emerging line of research associating AS and substance use. Research indicates that AS is associated with the development of alcohol use disorders and relapse among smokers (Brown, Kahler, Zvolensky, Lejuez, & Ramsey, 2001; Schmidt, Buckner, & Keough, 2007; Zvolensky, et al., 2007). A separate line of evidence has revealed that AS is malleable through cognitive behavioral interventions. Several research investigations focused on panic disorder treatment have reported significant reductions in AS following treatment (Barlow, Craske, Cerny, & Klosko, 1989; Schmidt, et al., 2000; Telch, et al., 1993; Westling & Ost, 1999). The literature suggests that AS is a very well-established cognitive risk factor for anxiety and unlike many other risk factors (e.g., sex, genetics) it has been shown to be malleable. Thus, AS has been identified as a prime candidate for treatment development to reduce the public health burden associated with anxiety psychopathology (Zvolensky, et al., 2006).

Several studies have been reported that focus on the amelioration of AS. Gardenswartz and Craske (2001) compared a 1-day workshop to a waitlist condition among undergraduates at risk for developing panic disorder as indexed by the occurrence of a panic attack in the past 12 months and elevated AS (ASI (Reiss, Peterson, Gursky, & McNally, 1986) scores above 16). The five hour prevention workshop focused on interoceptive exposure (IE), psychoeducation, breathing retraining and cognitive restructuring. The workshop group did not report a significantly greater reduction in AS than those in the waitlist condition (43% vs. 35% reduction respectively) but those in the workshop condition were less likely to develop panic disorder in the six months following treatment.

Broman-Fulks and Storey (2008) evaluated the effect of a six-session exercise regimen on AS amelioration. Twenty-four undergraduates with elevated AS (ASI-R (Taylor & Cox, 1998) scores above 26) were randomly assigned to either 6-sessions of aerobic exercise or a no-

exercise condition in which participants came into the lab six times to complete self-report measures. The exercise regimen included a 20-minute walk or jog on a treadmill. The experimenter did not allow the participants distractions (e.g., talking, listening to music) during the exercise and monitored participants' heart rate to ensure that a range of 60 to 90% of their predicted heart rate was maintained. Individuals in the exercise condition reported a significant decrease in their AS levels (38% reduction), whereas the no-exercise group showed no reduction in AS levels (4% increase).

Feldner and colleagues (2008) conducted an investigation simultaneously targeting AS and smoking. Their sample included ninety-six individuals who had ASI scores at least one standard deviation above the mean and were daily smokers. Participants were assigned to a single two-hour group session that focused on either general health or on AS and smoking. The general health group received information regarding body weight, dietary habits and sleep hygiene. The AS and smoking group received information regarding anxiety/fear, panic disorder, AS, the smoking-stress link and smoking cessation. They were also taught and given the chance to practice three IE techniques that they were instructed to continue for homework. The AS-smoking group experienced a 34% reduction in AS which was significantly greater than the 22% reduction seen in the health control group.

To date the largest AS focused intervention was conducted by Schmidt and colleagues (2007). Participants ($N = 404$) with ASI scores 1.5 SD above the nonclinical mean (Schmidt & Joiner, 2002) were randomly assigned to either the ASAT (Anxiety Sensitivity Amelioration Training) condition or a health and nutrition based control condition. The ASAT condition consisted of a 30-minute computer presentation followed by 10 minutes with an experimenter. The presentation explored the following concepts: the nature of stress, AS, physiological arousal as uncomfortable but not dangerous, and IE. The ASAT group then spent 10 minutes with the experimenter who answered questions about the content of the presentation and provided instructions regarding IE homework. IE was not demonstrated nor practiced in the session. Those in the control group watched a 30-minute computer presentation focused on health and nutrition. They also spent 10 minutes with the experimenter who answered presentation questions and assigned readings relevant to the presentation for homework. Participants were followed for two years post-intervention.

Results indicate that both conditions produced a reduction in AS; however, the ASAT condition produced a significantly larger reduction in AS than the control condition (30% vs. 17%, respectively). The reduction in AS was primarily due to a reduction in the physical AS subfactor. The social subfactor showed a small but significant reduction whereas the cognitive subfactor did not. The immediate impact of the intervention was also demonstrated through a CO₂ challenge in which individuals breathed 20% CO₂ enriched air. The challenge was completed by individuals in both groups immediately following completion of the intervention. In response to the CO₂ challenge, those in the ASAT group reported significantly less subjective distress, physical symptoms and desire to flee the situation. Since the intervention was designed to specifically target AS, the specificity of the intervention was determined by examining the intervention's impact on the two other fundamental sensitivities (FNE and ISI). Results indicated ASAT had good specificity to AS as evidenced by no group differences on the FNE or ISI post-intervention. In terms of the development of psychopathology, those in the ASAT condition showed a lower incidence of Axis I diagnoses during the two year follow-up period.

The ASAT intervention resulted in significant gains across a number of different AS related outcomes, which is particularly noteworthy given the brevity of the intervention. While the experimenter in the ASAT condition provided instruction on IE, it was not demonstrated or practiced. Additionally there was no attempt to evaluate the extent to which participants utilized this technique on their own during follow-up. IE is thought to be an essential component of AS reduction among patients with panic disorder and involves repeated exposure to feared bodily sensations until habituation is achieved (Schmidt & Trakowski, 2004). Cognitive-behavioral treatments for panic-related disorders have indicated that IE plays a statistically and clinically significant role in achieving and maintaining therapeutic gains (Otto, Safren, & Pollack, 2004; Schmidt, et al., 2000). Without demonstration and practice of IE, there is a possibility that participants in the ASAT condition did not carry out the IE exercises as they were instructed and therefore the potency of this intervention was not maximized. That is, it is likely that participants may not have fully appreciated the gains that could be achieved through spinning in an office chair (dizziness) or breathing through a straw (shortness of breath). Indeed, they may have found these exercises too anxiety provoking to initiate for the first time on their own. Therefore, it is unknown whether the psychoeducational component alone resulted in the gains made by the ASAT group or if IE contributed to the effectiveness of this intervention.

With an aim to increase the potency of the ASAT intervention and more thoroughly investigate the role of IE, the current intervention sought to refine the ASAT program. The current study utilized a similar one treatment-session two condition design among a sample of individuals at elevated risk for developing anxiety disorders. The sample included individuals with ASI scores 1.5 SD above the mean as was the inclusion criteria used by Schmidt and colleagues (2007). Those randomized to the proposed AS intervention condition received psychoeducation based on the ASAT protocol. In this condition, therapists assessed individuals' anxiety on a number of different IE exercises (e.g., straw breathing, running in place, chair spinning). The most anxiety provoking exercise was practiced to the point of habituation with a study therapist to demonstrate the safety of the exercises and the rapid rate with which habituation can occur. Thus, IE exercises were tailored to address the AS fears of each participant. Additionally, participants were encouraged to practice IE during the follow-up interval, they received reminders for this practice, and the participants' compliance with daily IE homework over the follow-up period was monitored.

The somewhat active control condition from Schmidt and colleagues investigation (2007) was utilized as the model for the control condition. This provided a rigorous comparison group for the AS focused group because it was shown to reduce AS (Schmidt, Eggleston, et al., 2007) and includes a discussion of exercise which has been shown to decrease anxiety and AS (Broman-Fulks, Berman, Rabian, & Webster, 2004; Broman-Fulks & Storey, 2008; Manger & Motta, 2005; Stathopoulou, Powers, Berry, Smits, & Otto, 2006). While not an inactive or waitlist type control condition, the health focused control condition was still anticipated to have substantially less of an impact on AS than the AS focused condition. The ASAT intervention has already been shown to be more effective than the health focused control condition and unlike many of the exercise intervention studies, participants were not prescribed exercise for homework nor did they complete exercise during the intervention appointment.

The refined intervention was designed to increase the potency of ASAT while at the same time retaining its brevity and feasibility. Similar to the findings outlined above it was anticipated that the treatment group would show a greater reduction in AS in comparison to the control group, specifically this reduction in AS was anticipated for the ASI total score as well as the ASI-3 physical and social subfactors. Both measures of AS were employed because the ASI is the most commonly used measure and has received the most research validation; however, the

ASI was not designed to measure multidimensionality and therefore the ASI-3 which was designed for this purpose was used to examine the subfactors. We expected participants in the control condition to have a more fearful response to the CO₂ challenge than the treatment condition participants. In addition, it was anticipated that the treatment condition would show specificity to AS and not affect the two other expectancy sensitivities. Finally, secondary exploratory analyses were employed to examine whether a reduction in AS was associated with a reduction in alcohol and cigarette use and whether homework compliance was associated with treatment gains.

METHODS

2.1 Participants

Participants were first screened through the FSU introductory psychology subject pool mass screening that is conducted at the beginning of each semester. Individuals with a score of 1.5 SD above the mean on the ASI were invited via an e-mail notification to complete a screening appointment. Only those over the age of 18 were recruited for participation. During the screening appointment, participants completed a diagnostic interview and a general health questionnaire to ensure their eligibility for the study. Their ASI was also reassessed during this appointment. Individuals were included in the randomized sample if their score remained at or above a 20 on the ASI. Participants were compensated for their time with course credit. In addition, if they completed the month six follow-up appointment, they received \$10 compensation given that it was outside of the semester in which they were enrolled in introductory psychology.

The randomized sample was primarily female (83.7%) with an average age of 18.86 ($SD = 1.42$). The racial representation of the study participants was as follows, Caucasian (81.7%), African American/Black (8.7%), Asian (4.8%) and other (4.8%). A total of 11.5% of the sample identified as Hispanic or Latino.

2.2 Therapists

Study therapists were doctoral students in the clinical psychology Ph.D. program at FSU. Therapists were trained in the intervention protocol to ensure their familiarity with and adherence to the protocol. In addition, they were provided with detailed manuals to facilitate their presentation of the PowerPoint.

2.3 Assessments

2.3.1 Diagnostic Interview

Structured Clinical Interview for DSM-IV (SCID). Psychiatric diagnoses including substance use diagnoses were determined using the SCID-NP (non-patient version; (First, Spitzer, Gibbon, & Williams, 1994)). The SCID was administered by trained doctoral level therapists who completed an extensive training in SCID administration and scoring. The same training methods have been used in previous laboratory projects and resulted in high inter-rater

reliability for all Axis I diagnoses. SCIDs were presented and reviewed during weekly research meetings to ensure accurate diagnoses.

2.3.2 Self-report Measures

Acute Panic Inventory (API). The API is a commonly used inventory for assessing symptoms of arousal associated with panic attacks (Liebowitz, Gorman, Fyer, Dillon, & Klein, 1984). The API has been used extensively in panic provocation studies (Fyer, et al., 1987; Gorman, et al., 1994; Harrison, et al., 1989; Kotov, Schmidt, Lerew, Joiner, & Ialongo, 2005). Participants rate the severity of each symptom and their SUDS (subjective units of distress scale). The API was administered pre and post CO₂ challenge to assess subjective reactivity to this biological challenge.

Anxiety Sensitivity Index (ASI). The ASI (Reiss, et al., 1986) is the most widely used measure of the fear of bodily sensations associated with arousal, AS. Each of the 16 items consists of a possible negative consequence of anxiety symptoms. The measure has established good internal consistency (Peterson & Reiss, 1993). The ASI was assessed at screening to determine study inclusion and at each of the follow-up assessments to document changes in AS.

Anxiety Sensitivity Index - 3 (ASI-3). The ASI-3 (Taylor, et al., 2007) is an 18-item self-report measure of AS. This scale was developed to provide a more stable measure of the three most widely recognized AS subfactors (physical, social and cognitive concerns) than the original ASI provides. Each subfactor is represented by six items. The measure has shown good psychometric properties (Taylor, et al., 2007). The ASI-3 was utilized to assess changes in the AS subfactors following treatment intervention.

Beck Anxiety Inventory (BAI). The BAI is a measure of general anxiety symptomatology (Beck, Epstein, Brown, & Steer, 1988). Respondents rate the extent to which they have been bothered by the 21 anxiety symptoms (physical and cognitive) over the past week. The BAI has been widely used and shown to be both valid and reliable in clinical (coefficient alpha = .92) and nonclinical samples (coefficient alpha = .91; (Beck, Epstein, et al., 1988; Borden, Peterson, & Jackson, 1991). The BAI was utilized to insure that randomization to treatment condition was successful and that the two groups did not differ in baseline general anxiety.

Beck Depression Inventory (BDI). The BDI is a 21-item measure that assesses severity of depressive symptomatology (Beck, Steer, & Garbin, 1988). This measure has been shown to be valid and reliable among college and clinical samples (Beck, Steer, et al., 1988; Endler,

Rutherford, & Denisoff, 1999). The BDI has also attained high internal consistency among college students (Cronbach's alpha coefficients ranging from .82-.92) and demonstrated discriminative validity from the BAI (Creamer, Foran, & Bell, 1995). The BDI was utilized to insure that randomization to treatment condition was successful and that the two groups did not differ in baseline depression.

Demographic Questionnaire. This scale was created to collect data on the participants' gender, ethnicity, educational/occupational level, and current medications. It was administered during the screening appointment to ensure participant eligibility.

Fear of Negative Evaluation (FNE). The brief FNE is composed of 10-items that assess an individual's fear and expectations related to negative evaluations by others. The FNE is distinct from measures of other expectancy theory sensitivities such as the ASI and ISI (Taylor, 1993). This measure has been shown to have good internal consistency, validity and test-retest reliability (Leary, 1983). It was used to assess the specificity among the expectancy theory sensitivities of the treatment intervention on AS.

General Health Scale. This scale assesses an individual's general health including any current health related diagnoses or medication usage that would exclude their participation from the proposed study.

Injury Sensitivity Index (ISI). The 11-item ISI measures an individual's fear of injury and illness. The ISI is distinct from measures of other expectancy theory sensitivities such as the ASI and FNE (Taylor, 1993). It has shown adequate internal consistency (Taylor, 1993). It was used to assess the specificity among the expectancy theory sensitivities of the treatment intervention on AS.

Timeline Followback (TLFB). The TLFB (L. C. Sobell & Sobell, 1992) is a method to assess recent drug use. Participants are asked to retrospectively report on their consumption over the past 7 days to two years. For the current study participants were asked to separately report on the amount of alcohol and cigarettes consumed daily over the past month. This is a widely used measure to quantify substance use and has been validated for both alcohol and cigarettes (Fals-Stewart, O'Farrell, Freitas, McFarlin, & Rutigliano, 2000; Lewis-Esquerre, et al., 2005; L. C. Sobell, et al., 1996). The TLFB allowed for the exploratory analysis of whether reductions in AS were associated with a reduction in cigarette and alcohol consumption.

2.3.3 Homework Compliance

Homework Quantity Ratings. Participants returned their completed homework forms at the week one and month one follow-up appointments. Three separate ratings of homework quantity were calculated. First, participants received a point for each day in which they completed homework practice according to their returned forms. Second, included in the daily email reminder to complete the homework was a link to a website in which the participant was instructed to respond as to whether they had completed the homework that day. Third, the number of individual IE trials completed was calculated. The number of homework forms, check-ins and trials completed were calculated for both the week one and month one follow-up periods. These ratings were used to assess whether the amount of homework completed was associated with treatment gains.

Homework Quality Rating. The overall quality of completed IE homework was assessed for both the week one and month one follow-up periods utilizing five separate criteria: 1) whether a specific task was identified; 2) whether the task generated moderate levels of fear/distress (five or greater on a zero to ten point scale); 3) whether sensations experienced were identified; 4) whether thoughts were noted; 5) whether the task was repeated until the fear/distress was minimal (one or lower on a zero to ten point scale). Specifically, separate scores were calculated for the percentage of trials in which the interoceptive exercises completed were identified, the sensations were identified, the thoughts were identified as well as the percentage of days in which the initial fear reached a moderate level and the fear reduced to a minimal level. This ratings procedure is similar to one used previously that resulted in good inter-rater reliability (Schmidt & Woolaway-Bickel, 2000). The total ratings were used to assess whether the quality of homework completed was associated with treatment gains.

2.3.4 Physiological Assessment

CO₂ Challenge. CO₂ inhalation is a safe physiological challenge procedure commonly used in panic disorder research and treatment to provide a behavioral index of fear responding to a novel stimulus. In order to control for participants expectancies, all participants were told that there are several different physical sensations that may be experienced briefly after breathing CO₂ enriched air including: breathlessness, dizziness, chest discomfort and tachycardia. The experimenter filled a 4.8 liter venti-comp bag with 35% CO₂ enriched air directly from the

containment unit, using a Praxair industrial-grade switching valve (Model no 2123331). The participant, wearing a nostril clamp, exhaled all of the air in his/her lungs and then inhaled directly from the venti-comp bag via a sterile one-way disposable flow valve each of which was discarded after every use. Gas intake volume was indexed by subtracting the amount of gas inhaled by the participant during the provocation relative to the participant's vital capacity to ensure each subject inhaled a vital capacity breath.

Vital Capacity (VC). VC is measured in liters and constitutes the maximum amount of air that can be transported in and out of the lungs in a single breath. A Respirodyne II Plus respirometer and Respirodyne disposable flow sensor (Mircoro medical Limited, Kent, England) were used to measure each participant's VC. These measurements were used to ensure a consistent dosage of CO₂ across participants (i.e., 80% of VC was required or the inhalation procedure was repeated), simultaneously ensuring an adequate dose of CO₂ to produce the characteristic anxiogenic response.

CO₂ Intake Volume. CO₂ intake volume refers to the amount of CO₂ inhaled by the participant relative to VC. The amount of CO₂ remaining in a 4.8 liter venti-comp bag following the inhalation procedure was measured and subtracted from VC.

2.4 Procedure

2.4.1 Time Points

Sign-up. Participants signed up for the initial appointment via the psychology department's secure research participant registration website that briefly lists all department studies open to the undergraduate subject pool which is made up of all introductory psychology students who are required to complete seven hours of research participation.

Screening Appointment. Participants first read and signed an informed consent that ensured confidentiality, thoroughly outlined their proposed study involvement, and emphasized that they could discontinue their participation at any time, for any reason and at no penalty. They then completed the SCID and the general health scale. If the participant did not meet inclusionary criteria, they were debriefed, thanked for their time and awarded their research credits. Those who met inclusionary criteria were randomly assigned, based on a random numbers table, to one of the two intervention conditions (see description of experimental conditions). They were then scheduled for their intervention appointment.

Intervention Appointment. Participants first completed the self-report measures (see Table 1). After completion of the questionnaires, the participant completed the intervention with the study therapist. The post-intervention questionnaires were then completed. To provide a complementary biological index of the impact of the intervention, eligible participants then completed the CO₂ challenge. They were led to a comfortable recliner in a sound attenuated office. Participants completed an API following a five minute adaption period. They were then instructed to fully exhale, take a full and complete breath using the mouth piece, and hold the breath for five seconds. Following a practice of this procedure, the participant exhaled all of the air in their lungs, inhaled directly from the venti-comp bag and held their breath for five seconds. An API was completed immediately following the exhalation of the CO₂ enriched air. Following completion of the CO₂ challenge, the participant was scheduled for their week one follow-up appointment and given a reminder card for both that appointment and their midweek computer check-in.

Mid-Week Check-In. An e-mail was sent to the participant three days after their intervention appointment reminding them to complete the brief online check-in within the next 24-hour period. The e-mail also encouraged them to complete their assigned homework and reminded them of the time and location of their week one follow-up appointment. Participants were directed to a secure study website. The check-in was comprised solely of the ASI. Their study ID was used to identify their entry rather than their name or other identifiable information.

Week One Follow-up Appointment. Upon arrival at the laboratory offices, participants were directed to an individual testing room. Their homework forms were collected and they completed the self-report questionnaires. Then the CO₂ challenge was conducted using the same procedures as the intervention appointment. Finally, they were given a reminder sheet for their remaining check-in and appointment.

Mid-Month Check-In. An e-mail was sent to the participant two weeks after their intervention appointment reminding them to complete the brief online check-in within the next 24-hour period. The e-mail also encouraged them to complete their assigned homework and reminded them of the time and location of the month one follow-up appointment. Participants once again logged into the secure website and completed the ASI.

Month One Follow-up Appointment. A nearly identical procedure was employed in the month one follow-up as was used in the week one follow-up appointment. Participants were

directed to an individual testing room. Their completed homework forms were collected and they completed the self-report questionnaires. Following completion of the CO₂ challenge, they were debriefed and provided with the opportunity to ask any questions they had. They were then thanked and awarded their research credits.

Month Six Check-In. Participants received an e-mail inviting them to complete an additional online follow-up set of questionnaires. If willing, participants once again logged into the secure website and completed a brief set of questionnaires.

2.4.2 Description of Experimental Conditions

Anxiety Sensitivity Education and Reduction Training (ASERT). This training intervention was developed to closely model the educational and behavioral techniques that are commonly employed in the treatment of individuals with anxiety disorders. Specifically, the educational component of this condition was adapted from the AS intervention used by Schmidt and colleagues (2007). The therapist met individually with the participant for approximately 50 minutes. The therapist took the participant through a psychoeducational PowerPoint presentation that focused on the nature of stress and its effect on the body. The presentation sought to dispel myths regarding the immediate dangers of stress on the body. Participants were taught that the physiological arousal associated with stress is not dangerous and that they may have developed a conditioned fear to those arousal sensations which is indicated by their elevated AS score. IE exercises, designed to correct the conditioned fear to these bodily sensations, were explained. These exercises involve repeated exposure to a feared bodily sensation until the fear dissipated. After the psychoeducational training, the therapist completed a brief, standardized assessment of the participant's fear of different arousal sensations. In order to conduct this assessment, the therapist guided the participant through a number of brief exercises (e.g., breathe through a straw, spin in an office chair, etc.) and had them rate on a zero to ten point scale the level of fear/distress experienced during each exercise. The top fear producing exercise was selected to demonstrate the IE procedure. With the therapist's direction and assistance, the participant completed repeated trials of the selected exercise. The trials were repeated until fear/distress ratings reached a minimal level (0-2). If none of the assessment IE exercises generated substantial fear/distress, participants completed 10 repeated trials of straw breathing and 10 repeated trials of hyperventilation as these tend to be rated as the most challenging for patients with panic disorder (Schmidt & Trakowski, 2004). The participant was instructed how to

complete these exercises on their own for homework. They were given monitoring forms and told to complete one set of each of the exercises daily for the next month.

Physical Health Education Training (PHET). The other half of the participants were randomized to the PHET condition which was designed to control for effects of general education and time spent with a therapist in the ASERT condition. In the PHET condition, participants spent approximately 50 minutes with the therapist who guided the participants through a PowerPoint presentation regarding the importance and benefits of maintaining a healthy lifestyle as well as guidelines for achieving a healthy lifestyle. The presentation covered the following topics; diet, alcohol, water consumption, exercise and sleep. The therapist discussed with the client how to monitor their own daily health habits and daily monitoring forms were provided to the participant. To ensure the client understood how to complete the form, the therapist and participant jointly completed the form for the participant's behaviors the previous day. The participant was instructed to use the forms daily for the next month.

RESULTS

3.1 Sample and Preliminary Analyses

A total of 107 of the 129 individuals who came in for the screening appointment were determined to meet eligibility requirements. The vast majority were excluded due to their ASI score being below a 20. Three individuals declined to participate further or did not return for the intervention appointment. Thus, a total of 104 participants completed the intervention appointment with equal distribution between the ASERT and PHET conditions. A total of sixteen of these individuals did not complete the CO₂ challenges due to medical exclusionary criteria. All participants returned for the week one appointment and only one participant failed to return for the month one appointment. In terms of the online check-ins, 86% completed the mid-week check-in, 79% completed the mid-month check-in and 68% completed the month six check-in. Thus, the total size of the sample varies somewhat at the different time points.

Pretreatment data indicate that random assignment was successful. There were no differences between treatment conditions on the ASI ($\beta = -.03, p = .80$), BAI ($\beta = .06, p = .58$) or BDI ($\beta = -.06, p = .57$). There were also no differences between groups on current psychopathology diagnoses including: anxiety disorders ($\beta = -.08, p = .42$), mood disorders ($\beta = -.17, p = .09$), or any Axis I psychopathology ($\beta = -.14, p = .17$).

The diagnostic assessment indicated a current diagnosis in 45% of the sample with 36.5% meeting criteria for an anxiety disorder, 5.77% meeting criteria for a mood disorder and an additional 5.77% meeting criteria for another Axis I disorder (e.g., substance use disorder). This elevated rate of psychopathology is reflected in the global anxiety and mood self-report measures (BAI: $M = 15.12, SD = 9.70$, BDI: $M = 11.47, SD = 9.39$).

3.2 Main Study Hypotheses

3.2.1 AS Treatment Effects

The effect of treatment condition on posttreatment ASI scores was examined through the construction of four separate linear regression equations. In each equation, treatment condition served as the predictor and ASI (1) total, (2) physical, (3) social or (4) cognitive scores served as the dependent variable. Additionally, the pretreatment score for each of the dependent variables

was included as a covariate in its respective equation. As hypothesized, the ASERT group evidenced a greater reduction in ASI scores at posttreatment than the PHET group (total $\beta = -.29$, $p < .001$; physical $\beta = -.32$, $p < .001$; social $\beta = -.14$, $p < .01$; cognitive $\beta = -.17$, $p = .001$).

Next, the change from baseline to follow-up time points between the two conditions was examined. Following the same analytic strategy employed above, four linear regression equations were constructed for each follow-up time point (i.e., mid-week check-in, week one follow-up, mid-month check-in, month one follow-up and month six follow-up) with ASI scores serving as the dependent variable, treatment condition serving as the predictor and pretreatment ASI scores serving as a covariate. In line with study hypotheses, the ASERT group reported a greater reduction across the total and ASI subscale scores at each time point (see Table 2). Figures 1-4 present a graphical depiction ASI scores across the study period.

To more rigorously assess ASI scores over the homework/follow-up period, we repeated the above analyses controlling for posttreatment scores as opposed to pretreatment ASI scores. This allows for an examination of whether additional treatment gains were made between the two groups following the intervention appointment (see Table 2). The mid-week check-in scores indicate that a significant reduction was evidenced for the social subscale but not for the other ASI scores. At the week one follow-up appointment, the cognitive subscale evidenced a trend toward significant additional gains between groups whereas the other ASI scores evidenced a significant difference. Additionally, there was a significant difference between groups across all of the ASI scores at the mid-month check-in, month one follow-up, and month six follow-up.

In addition to ASI treatment gains among the ASERT group being significantly greater than the gains of the PHET group, the reduction in ASI scores among the ASERT group were sizable. As can be seen in Figure 1, while the PHET group maintained elevated scores across the study period, the ASERT group showed a substantial decrease in scores. The percentile decrease in total ASI scores for the ASERT group across the study period was as follows: 28% at posttreatment, 41% at mid-week, 45% at week one, 55% at mid-month, 58% at month one and 47% at month six. These results also indicate that the ASERT group maintained the vast majority of their treatment gains six months following the treatment. The percentile decrease in subscale scores for the physical subscale (37% at posttreatment, 49% at mid-week, 54% at week one, 64% at mid-month, 66% at month one and 52% at month six) and cognitive subscale (29% at

posttreatment, 46% at mid-week, 48% at week one, 66% at mid-month, 66% month one and 52% at month six) was greater than the social subscale (13% at posttreatment, 25% at mid-week, 29% at week one, 33% at mid-month, 42% at month one and 36% at month six); however, as Figures 2-4 graphically demonstrate, the pattern of results for each of the subscales mirrors that of the ASI total scores.

Given the high level of psychopathology within the sample, we next examined whether treatment condition had the same effect on ASI scores among those with and without an Axis I diagnosis. As would be expected, those with an Axis I diagnosis exhibited higher ASI scores than those without a diagnosis. It is possible that those with a current Axis I diagnosis may have shown a differential response to the intervention than those without a diagnosis. To examine the potential differential treatment response, we completed moderational analyses. A hierarchical linear regression was constructed with the month one ASI score serving as the dependent variable. Treatment condition and diagnostic status were entered into the first step as independent variables as well as pretreatment ASI as a covariate. The treatment condition and diagnostic status interaction term was entered into the second step along with all variables from the previous step. The treatment condition and diagnostic status were centered in order to reduce multicollinearity (Holmbeck, 2002). The simultaneous inclusion of the treatment condition and diagnostic status along with their interaction term in the second step of the regression equation ensured that any observed interaction was not attributable to the main effects of these variables (Cohen & Cohen, 1983). As would be anticipated based on the above results, treatment condition was associated with month one ASI scores ($\beta = -.54, p < .001$). However, neither diagnostic status ($\beta = .002, p = .98$) nor the interaction term ($\beta = -.03, p = .66$) was associated with the month one ASI score. These findings suggest that those with and without a current Axis I diagnosis evidenced the same pattern of results in response to the intervention (see Figures 5 and 6).

The ASI-3 was completed at the pretreatment, posttreatment, week one, and month one time points. When the ASI-3 was used in place of the ASI for the above sets of analyses, the same pattern of results emerged.

3.2.2 Specificity Analyses

In order to examine whether the ASERT intervention showed specificity to AS and did not affect the two other expectancy fears (fear of negative evaluation and injury sensitivity), two hierarchical regression equations were constructed. The posttreatment (1) FNE total score or (2) ISI total score served as the dependent variable while the pretreatment score for each of the dependent variables was included as the independent variable in the first step and experimental condition served as the independent variable in the second step. The analyses indicated that the two conditions did not differ in their posttreatment FNE scores ($\beta = -.02, p = .62$). Counter to the proposed hypothesis there was a slightly greater reduction in ISI scores ($\beta = -.08, p = .01$) among those in the ASERT group than those in the PHET group. Despite this significant treatment effect, there is a sizable relative difference in the effect sizes for posttreatment ISI ($R^2 = .06$) and ASI ($R^2 = .26$). To statistically test whether the effect for treatment condition on ASI was greater than that for ISI, a mixed model GLM was run. Treatment condition was entered as a fixed factor while the change in ASI and ISI were standardized and then included as repeated measures. Results indicated there was a significant interactive effect between treatment condition and the outcome measures ($F(1, 98) = 4.97, p = .03$). These results suggest that the effect of treatment condition on the change in ASI was statistically greater than that seen for the ISI.

3.2.3 General Scores of Depression and Anxiety

Given the difference in ASI scores between the treatment conditions following the interventions, we next conducted exploratory analyses to assess whether the treatment groups also demonstrated differential treatment effects for general levels of anxiety and depression at the follow-up time points. For each time point, a separate linear equation was constructed with treatment condition serving as the predictor and BDI or BAI serving as the dependent variable. Additionally, the pretreatment score for each of the dependent variables was included as a covariate in its respective equation. The BAI scores indicated no significant difference between groups at posttreatment ($\beta = .05, p = .30$) or week one ($\beta = -.15, p = .08$). The ASERT group did evidence a greater reduction in BAI scores at both the month one ($\beta = -.28, p < .01$) and month six ($\beta = -.40, p < .001$) time points. The BDI scores indicated no significant difference between groups at posttreatment ($\beta = -.04, p = .06$), the week one ($\beta = -.04, p = .32$), or month one ($\beta = -.09, p = .12$) time points. The difference between the two groups at the month six time point is

significant ($\beta = -.27, p < .01$) with the ASERT group reporting a greater reduction in BDI scores. See Table 3 for BAI and BDI scores across the study period.

It could be suggested that the reduction in ASI scores seen at the month one time point in the ASERT group was mediated by changes in anxiety symptoms. The analytic strategy proposed by Baron and Kenny (1986) was employed to examine this alternative hypothesis. First, a significant association between the independent variable (treatment condition) and the dependent variable (change in ASI score) is required. If the first step is satisfied, the second step requires a relationship between the proposed mediator (change in BAI) and the independent variable. The next step involves simultaneously regressing the dependent variable on both the independent variable and the proposed mediator.

As established in the previous section, the treatment condition was significantly associated with the change in ASI scores at month one ($\beta = -.65, p < .001$) and thus the first step was satisfied. Step two was satisfied as treatment condition was also associated with change in BAI scores at month one ($\beta = -.32, p < .01$). The next step involved simultaneously regressing the change in ASI scores on both the independent variable (treatment condition) and the proposed mediator (change in BAI). These analyses revealed a significant association between the change in BAI and the change in ASI ($\beta = .37, p < .001$). However, participant condition was still significantly associated with the change in ASI ($\beta = -.53, p < .001$) indicating that the results are consistent with a pattern of partial mediation. We used the Sobel test (Sobel, 1982) to further examine the significance of BAI's mediating role, which confirmed that the pattern of results were consistent with partial mediation ($z = -2.83, p < .01$).

We also tested the alternative model that changes in AS mediated the effect of treatment condition on BAI. The first two steps were satisfied above with treatment condition being significantly associated with both change in BAI and change in ASI. Next, the change in BAI was regressed on both the treatment condition and the change in ASI. These analyses indicated a significant relationship between changes in ASI and changes in BAI ($\beta = .58, p < .001$). The relationship between participant condition and change in BAI was no longer significant ($\beta = .06, p = .62$) which indicates that the results are consistent with a pattern of full mediation. The Sobel test further supported these results ($z = -4.47, p < .001$). With support for both models being found, definitive conclusions regarding the pattern of mediation cannot be drawn.

3.2.4 Physiological Challenge

Next, we examined the hypothesis that the ASERT group would show less reactivity to the CO₂ challenge than the PHET group. The API was completed both prior to and immediately following the CO₂ challenge. The pre-challenge API assessed participants' level of physiological symptoms and distress prior to engaging in the CO₂ challenge. The instructions for the post-challenge API directed participants to complete the form for their experience during the challenge. Utilizing a similar analytic strategy as outlined above, we constructed two linear regressions for each of the CO₂ challenge time points (i.e., posttreatment, week one follow-up, and month one follow-up) with experimental condition as the predictor and either the (1) API number of symptoms endorsed or (2) API SUDS score as the dependent variable. The pre-challenge score for each of the dependent variables was included as a covariate in its respective equation.

The results were mixed for the analyses focusing on the total number of API symptoms endorsed. These results indicated that the groups reported the same level of symptom reactivity at the posttreatment ($\beta = -.10, p = .30$) and week one follow-up ($\beta = -.04, p = .73$) time points; however, the ASERT group reported less symptom reactivity at the month one follow-up ($\beta = -.21, p = .05$). (See Figure 7.) While it was anticipated that the ASERT group would exhibit less symptom reactivity at each of the time points, the difference emerges at month one which is when the two group reported the largest divergence in ASI scores.

In contrast to our hypothesis, the API SUDS analyses indicated that the ASERT group reported a greater level of reactivity during the CO₂ challenge when controlling for pre-challenge SUDS (posttreatment $\beta = .44, p < .001$; week one $\beta = .62, p < .001$; month one $\beta = .50, p < .001$). However, Figure 8 seems to indicate a more nuanced pattern of results. The figure suggests that while the ASERT group seems to report lower pre-challenge SUDS at each time point, the post-challenge SUDS look to be remarkably similar across the two groups with the exception of the posttreatment time point. Analyses examining these graphical observations find support for them. First, the ASERT group reported a trend toward significantly lower pre-challenge SUDS at posttreatment ($\beta = -.18, p = .09$) while the difference was significant at week one ($\beta = -.31, p < .01$) and again trended toward significance at month one ($\beta = -.20, p = .06$). Second, the ASERT group showed a trend toward higher post-challenge scores at posttreatment

($\beta = .19, p = .07$) with the groups showing no difference at week one ($\beta = .05, p = .63$) or month one ($\beta = .001, p = .99$). These results indicate that the ASERT group reported greater SUDS reactivity to the CO₂ challenge; however, the two groups did not significantly differ in maximal level of SUDS reported in response to the challenge. Taken together these results are a bit puzzling because the two aspects of the API are presenting somewhat discordant results.

We conducted exploratory analyses to assess whether participants in the two groups would vary in their willingness to complete a second inhalation challenge during the treatment appointment. Analyses indicated that the two groups showed no difference ($\beta = -.08, p = .48$) in their reported willingness to complete a second inhalation challenge. Additionally, the two groups did not differ on their subjective report of whether or not they panicked during the challenge (posttreatment $\beta = .01, p = .95$; week one $\beta = .06, p = .57$; month one $\beta = -.07, p = .53$).

3.3 Exploratory Analyses

3.3.1 Substance Use

Given the previously documented association between AS and various substance use problems, we conducted exploratory secondary analyses to determine whether posttreatment AS scores were associated with posttreatment alcohol and cigarette consumption. To explore this association two linear regressions were constructed with ASI total score as the predictor and either the (1) total number of alcoholic drinks consumed or (2) or the total number of cigarettes consumed in the month following the intervention as the dependent variable. The one month total consumption of cigarettes or alcohol prior to the intervention was entered into its respective equation as a covariate as well as the pretreatment ASI total score. Results indicated that ASI scores at the month one follow-up were not associated with the total number of alcoholic drinks ($\beta = -.08, p = .29$) or with the total number of cigarettes ($\beta = .02, p = .55$) consumed over the one month study period.

We conducted additional analyses to more thoroughly examine these results since they ran counter to our hypotheses. First, including treatment group in the above analyses did not affect the pattern of results as treatment group was not associated with the total number of alcoholic drinks ($r = -.002, p = .98$) or with the total number of cigarettes consumed ($r = .022, p = .83$) during the one month study period. Next, we examined the relationship between

pretreatment ASI scores and pretreatment substance use and discovered that neither alcohol ($r = -.08, p = .45$) nor cigarette ($r = .14, p = .16$) consumption was associated with pretreatment ASI scores. In general, the vast majority of participants did not report regular consumption of either alcohol or cigarettes with participants reporting smoking an average of .16 ($SD = .82$) cigarettes and drinking an average of .48 ($SD = .81$) alcoholic beverages per day. Only two participants reported that they smoked an average of five or more cigarettes per day and seven participants reported that they drank an average of two or more alcoholic drinks per day.

3.3.2 Homework Compliance

Given that the IE homework that was assigned is thought to be skill based, it was anticipated that the more participants engaged in the homework the more gains they would likely experience. To examine the relationship between homework compliance in the ASERT condition and posttreatment AS, we examined both quantity and quality of homework completed. First, to examine whether the quantity of homework completed was associated with greater AS reductions posttreatment, three separate linear regression equations were constructed for each of the two follow-up time points (i.e., week one follow-up and month one follow-up). ASI total scores served as the dependent and pretreatment ASI total scores served as a covariate variable in each equation. The predictor in each equation was (1) the number of days homework was completed, (2) the number of homework trials completed or (3) the number of online homework check-ins completed. Results at the week one follow-up indicated that homework quantity as assessed by number of days ($\beta = .001, p = .99$), number of trials ($\beta = -.06, p = .54$) and number of online homework check-ins ($\beta = -.06, p = .59$) was not associated with AS scores. The month one follow-up appointment also indicated that the number of days ($\beta = -.02, p = .91$), number of trials ($\beta = .08, p = .52$) and number of online homework check-ins ($\beta = .09, p = .46$) were not associated with AS scores. On average, participants completed 111.13 ($SD = 58.39$) IE trials over 23.94 ($SD = 7.52$) completed homework days and completed the online homework check-in 14.15 ($SD = 8.44$) times.

To examine the quality of homework completed, five separate homework quality indices were calculated for both the week one and month one follow-up periods. Specifically, separate scores were calculated for the percentage of trials in which the interoceptive exercise completed

was identified, the sensations were identified, the thoughts were identified as well as the percentage of days in which the initial fear reached a moderate level and the fear reduced to a minimal level. To first broadly examine the association between these indices and the ASI scores at the two follow-up periods, partial correlations were calculated controlling in both sets of correlations for the pretreatment ASI score. As can be seen in Tables 4 and 5, there was no indication of a significant relationship between ASI scores and the homework quality indices. Thus, more fine grained analyses looking at these relationships were not conducted.

DISCUSSION

The primary aim of the current investigation was to increase the potency of previous AS amelioration interventions through a greater focus on IE. At the same time, we sought to maintain brevity and feasibility by utilizing a one-session computer assisted intervention based on the intervention employed by Schmidt et al. (2007). Results indicate that despite the PHET condition being a somewhat active control group, the ASERT group demonstrated significantly greater reductions in AS immediately following treatment. Further, participants in the ASERT group reported additional gains across the one month homework follow-up period. Based on the Schmidt et al. (2007) findings, we hypothesized that the ASERT intervention would result in significant reductions in the physical and social subscales but not the cognitive subscale; however, the current results demonstrate that this brief intervention significantly affected scores across all three subscales. To assess whether participants maintained the gains made during the study period, a month six follow-up was conducted. The scores from this time point indicate that both groups largely maintained their scores with the ASERT group retaining the majority of their AS reduction while the PHET group continued to report substantially elevated AS scores.

As noted, an aim of this investigation was to bolster previous AS amelioration interventions. While the reductions in AS seen among the ASERT group in the current investigation are quite sizable, direct comparisons across AS intervention trials are complicated by a host of factors including different follow-up time points, AS measures, levels of baseline AS, and length of treatment. Remaining cognizant of the imperfect nature of such a comparison, it is still useful to evaluate the efficacy of the current trial in light of AS intervention trials that have preceded it. For a more accurate comparison between trials, the percentile decrease in AS score was calculated at the time point in which the largest reduction was noted. The reduction in total AS scores seen in the current study at the month one follow-up (58%) is greater in magnitude than the 43% reduction reported by Gardenswartz and Craske (2001), the 34% reduction reported by Feldner et al. (2008), the 41% reduction reported by Broman-Fulks et al. (2008) and the 30% reduction reported by Schmidt et al. (2007). The current treatment results are well positioned among these previous AS amelioration trials and suggest that the ASERT intervention resulted in greater treatment effects than the previous interventions.

The current sample was drawn from an undergraduate population, yet the inclusionary criteria resulted in a sample with substantially elevated AS. As would be expected based on the elevated AS, the sample had a high rate of current Axis I psychopathology. While it could be hypothesized that current psychopathology would result in reduced responsiveness to the current intervention, those with and without an Axis I diagnosis showed the same pattern of AS treatment results. This suggests that the ASERT intervention is efficacious in reducing AS for both those who have current psychopathology and those at heightened risk for developing psychopathology. This speaks to ASERT's potential applications both in terms of prevention, as was seen in the Schmidt et al. (2007) investigation, and as a possible adjunct to assist therapists working with anxiety patients.

The treatment targeted AS with success but there was also a question of whether it would demonstrate specificity to AS among the two other expectancy fears (i.e., FNE and ISI). Based on the Schmidt et al. (2007) findings and the fact that the other two expectancy fears were not targeted in this intervention, it was expected that treatment condition would not differentially affect FNE or ISI. There was mixed support for this hypothesis. As anticipated, there was no difference between treatment groups on the FNE but there was a difference for the ISI. Although the ISI and ASI have been found to be distinct constructs (Taylor, 1993), there are conceptual similarities between the two. Elevated ISI is indicative of a heightened fear of developing an illness or being injured (Reiss, 1991). One aspect of the ASERT intervention sought to dispel myths often held by those with elevated AS regarding the perceived consequences of anxiety related sensations (e.g., a rapid heartbeat is an indication of an impending heart attack or lightheadedness will lead to passing out). For some participants, these myths may have overlapped with health/illness related concerns captured by ISI and thus would have also been addressed by the intervention. Despite there being a differential treatment effect for ISI, it is important to note that the effect size was substantially smaller than that seen for the ASI indicating the intervention did show specificity to AS among the expectancy fears with a more substantial effect on AS.

While the intervention targeted AS, the link between AS and general anxiety and to a lesser extent depression has been clearly established (e.g., Olatunji & Wolitzky-Taylor, 2009; Taylor, Koch, Woody, & McLean, 1996). Thus, it stands to reason that an intervention targeting AS would also affect symptoms of anxiety and depression. Results indicated that the ASERT

group reported a greater reduction in anxiety symptoms at the month one and month six time points but not at posttreatment or week one. A greater reduction in depression symptoms among the ASERT group emerged at the month six time point. At the month one time point, mediation analyses were consistent with changes in anxiety symptoms partially mediating the relationship between treatment group and changes in AS as well as changes in AS fully mediating the relationship between treatment group and changes in anxiety symptoms. With support for both models, it precludes our ability to draw definitive conclusions regarding the mediating role of these two factors. In addition, these analyses do not allow for causal conclusions because the mediational analyses drew variables from the same time point. However, given that the AS treatment effects emerged immediately following treatment and the effects for anxiety symptoms did not emerge until the month one time point, it is reasonable to conclude that changes in anxiety symptoms are not responsible for changes in AS at these early time points and perhaps more likely that the later changes in anxiety symptoms are due to changes in AS. Beyond the potential mediating effects, the significant reduction in symptoms of anxiety and depression among the ASERT group indicates that the intervention had more global effects on participants' well-being than solely reducing AS.

Although commonly used as a potential diagnostic marker, prospective predictor of panic or simply to evoke anxious responding, the Schmidt et al. (2007) investigation was the first to our knowledge to employ the CO₂ inhalation paradigm as an outcome measure following an AS intervention. Counter to our hypotheses and the results reported in the Schmidt et al. (2007) investigation, the ASERT group did not report less fearful reactivity in response to the CO₂ challenge than the PHET group. In contrast, the ASERT group reported greater SUDS reactivity yet comparable level of maximal SUDS in response to the challenge. When assessing symptom reactivity, the two groups reported the same level of symptom reactivity at the posttreatment and week one appointment with the ASERT group reporting less symptom reactivity at the month one appointment. Exploratory assessments inquiring as to whether the participants were willing to complete an additional CO₂ challenge during the treatment appointment did not yield a significant difference between the two groups. Additionally, the groups did not differ on their self-report of having panicked during the CO₂ challenge at any of the time points. It was anticipated that the ASERT group would demonstrate their treatment gains across these different assessment indices yet the only indices that came out in their favor was the symptom reactivity at

month one. With the exception of the SUDS reactivity, the other analyses indicated that the two groups did not differentially respond to the CO₂ challenge. Given the sizable difference in AS treatment effects reported between the two groups and the commonly cited link between AS and fearful responding to CO₂ inhalation (Zvolensky & Eifert, 2001), we were surprised that the ASERT group did not outperform the PHET group across these assessment indices.

However, previous investigations suggest that it is inaccurate to conceptualize AS as the sole determinant of differential responding to the CO₂ challenge or that this type of biological challenge is isomorphic with AS. In several previous investigations that reported an association between AS and fearful responding, closer examination indicated that fearful responding was associated with only an aspect of AS or that AS accounted for a very small proportion of variance explained (Rapee, Brown, Antony, & Barlow, 1992; Zinbarg, et al., 2001; Zvolensky, et al., 2001). Other investigations simply failed to find an association between AS and fearful responding (Koszycki & Bradwejn, 2001; Struzik, Vermani, Duffin, & Katzman, 2004). Additional examination of the Schmidt et al. (2007) data conceptualized CO₂–induced fear and AS as potential risk factors and found that the two factors had independent and synergistic effects in predicting anxiety symptomatology (Schmidt & Zvolensky, 2007). These previous findings suggest that while AS and reactivity to the CO₂ inhalation may be related, they are not synonymous. With both AS and CO₂–induced fear serving as potential risk factors in the development of anxiety symptomatology, an intervention that serves to reduce both could prove potent in anxiety prevention. Due to the discrepant findings, future research is needed to determine whether the type of intervention employed in the current investigation affects both factors, as was seen in the Schmidt et al. (2007) investigation, or whether the intervention needs to be augmented to more adequately address the CO₂–induced fear.

Supplementary analyses also investigated whether the reduction in AS resulted in a subsequent reduction in alcohol and cigarette use. Previous investigations have established a link between AS and substance use (e.g., Brown, et al., 2001; Schmidt, Buckner, et al., 2007; Zvolensky, et al., 2007) but results from the current sample did not support this association. Findings indicate that not only was substance use during the follow-up period not associated with reductions in AS but baseline AS scores were not associated with substance use in the month prior to treatment. Given that AS and substance use prior to study entry were not associated, it would be unexpected for the AS intervention to have affected substance use. The sample was not

selected based on rates of substance use and subsequently use across the sample was quite low with very few participants indicating a pattern of regular use. Thus, there was very little variance in the scores for the reduction in AS to affect. Future investigations with study samples composed of more regular or heavy substance users will be better positioned to determine whether reductions in AS affect substance use patterns.

The final supplementary analyses focused on whether homework compliance among the ASERT group affected reductions in AS over the one month homework period. While several of the previously noted AS amelioration studies assigned IE homework, none followed up on whether or not participants completed their homework and whether their rate of completion affected AS treatment gains (Feldner, et al., 2008; Gardenswartz & Craske, 2001; Schmidt, Eggleston, et al., 2007). Given that IE is thought to be a central component in the reduction of AS and that repeated practice of IE is thought to affect treatment gains (Craske & Barlow, 2007; Huppert, Ledley, & Foa, 2006; Schmidt & Trakowski, 2004), the current investigation sought to examine whether IE homework completion bolstered treatment effects. Counter to our hypotheses, indices of both homework quality and quantity were not associated with AS treatment gains. However, the pattern of AS scores across the study (see Figures 1-4) indicate that the reduction in AS scores was not limited to the intervention appointment but rather continued across the homework period with the lowest scores recorded at the end of this period. The only additional intervention during this time was the assigned IE homework which suggests that continued IE practice was at least partially responsible for these gains.

While the pattern of AS scores support this conclusion, the homework quality and quantity analyses do not. There are several possible explanations for this discrepancy in findings. First, the vast majority of participants reported completing a substantial amount of IE practice. There were very few participants that reported completing little to no homework. Therefore, it is possible that we did not have enough participants in this low range to fully test the benefits of IE homework. An alternative explanation is that despite our efforts to gain an accurate account of the amount of homework completed, some participants may have been dishonest in their recording. The completion of homework was incentivized with participants being told they would earn an additional research credit for completing 60% or more of the homework. This may have motivated some of the participants to complete the online check-ins and/or the homework sheets when they had not actually completed the corresponding IE trials.

Future research should continue to explore IE homework to determine whether it is necessary for improved treatment gains and if so how much is necessary to maximize gains. To investigate this more thoroughly, researchers could assign participants to complete no homework, one week of homework, etc. Guaranteeing accurate reporting of IE homework is more of a conundrum yet there are several possible ways to enhance accuracy. One is to have participants complete the homework forms on handheld computerized devices (e.g., palm pilots). This would disallow participants completing a stack of forms prior to arrival for follow-up appointments since the device would timestamp the forms. Participants could also be given a physiological monitoring device to wear during the exercise that would record their physiological reactivity and help to ensure they were actually engaging in the exercises when they reported they were doing so. In addition, incentives are likely to increase compliance with completing homework but it may be best not to incorporate this aspect into future intervention trials because it both increases the motivation to inaccurately report homework completion and also reduces the external validity of such trials since interventions outside of the research clinic are unlikely to incentivize homework.

This study should be considered in light of its limitations and opportunities for subsequent research. Beyond the limitations and future research noted above, the current sample had limited age and racial heterogeneity. While the sample was composed of a substantial proportion of individuals with current psychopathology and others at increased risk for psychopathology based both on their age and elevated AS, future investigations should employ a more diverse sample to ensure the intervention's generalizability.

Despite these limitations, this investigation provides important information regarding the amelioration of a well-established anxiety risk factor. As previously noted, anxiety disorders represent the most prevalent form of psychopathology in the United States and result in substantial disability and economic burden both to the individual and society (Greenberg, et al., 1999; Kessler, Chiu, Demler, & Walters, 2005). While there are many well-established psychological and pharmacological treatments for anxiety disorders (Chambless & Ollendick, 2001; Mitte, 2005), many individuals receive treatment after years of impairment or receive no treatment at all (Wang, Berglund, et al., 2005; Wang, Lane, et al., 2005). Among the primary factors that limit patient participation in treatment are access and cost (Schmidt & Keough, 2010). Weekly empirically supported individual therapy sessions with a highly trained therapist

remain the therapeutic gold standard but it is clear that this model is not sufficiently meeting society's profound need. Interventions such as the current one that are able to produce a sizable treatment effect in AS through a one hour computer assisted intervention have the potential to help address this intervention void by addressing both access and cost. Brief risk factor interventions such as the current intervention will not fully address these problems but they have the potential to fill a need in a stepped care process that does have the potential to more fully address the current inadequacies in our mental health system.

Table 1.
Schedule of Assessments.

Assessment	Screening Apt.	Intervention Apt.		Mid-Week Check-In	Week One Follow-up	Mid-Month Check-In	Month One Follow-up	Month Six Follow-up
		Pre TX	Post TX					
Diagnostic and Screening								
SCID-NP	X							
Anxiety Sensitivity Index	X	X	X	X	X	X	X	X
Demographic Questionnaire	X							
General Health Scale	X				X		X	
Anxiety & Panic Vulnerability								
Anxiety Sensitivity Index - 3		X	X		X		X	
Beck Anxiety Inventory		X	X		X		X	X
Beck Depression Inventory		X	X		X		X	X
Fear of Negative Evaluation		X	X					
Injury Sensitivity Index		X	X					
Physiological Reactivity								
CO ₂ Challenge			X		X		X	
Acute Panic Inventory (pre challenge)			X		X		X	
Acute Panic Inventory (post challenge)			X		X		X	
Homework Compliance								
HW Quantity Rating					X		X	
HW Quality Rating					X		X	
Substance Use								
Timeline Followback (alcohol and cigarettes)		X					X	

Table 2.

Beta Weights Examining Differences in ASI Scores Between the Two Participant Conditions Across the Follow-up Time Points.

	Time Points				
	Mid-week	Week One	Mid-Month	Month One	Month Six
Controlling for Baseline ASI					
ASI					
Total	-.37***	-.42***	-.47***	-.54***	-.51***
Physical	-.36***	-.41***	-.51***	-.54***	-.54***
Social	-.24**	-.32***	-.31***	-.44***	-.39***
Cognitive	-.24***	-.27***	-.31***	-.38***	-.33**
Controlling for Posttreatment ASI					
ASI					
Total	-.10	-.16**	-.26***	-.31***	-.32**
Physical	-.08	-.15**	-.28***	-.30***	-.33**
Social	-.14*	-.21***	-.21**	-.34***	-.35**
Cognitive	-.05	-.09	-.18**	-.22***	-.21*

*** $p < .001$

** $p < .01$

* $p < .05$

Table 3.
BDI and BAI Scores by Treatment Condition Across the Study Period.

Time Point	Condition	BDI <i>M</i> (SD)	BAI <i>M</i> (SD)
Pretreatment	ASERT	10.94 (9.14)	15.65 (10.31)
	PHET	12.00 (9.69)	14.60 (9.11)
Posttreatment	ASERT	10.26 (9.14)	15.33 (10.60)
	PHET	11.78 (9.76)	13.62 (8.80)
Week One	ASERT	8.87 (8.47)	10.50 (8.20)
	PHET	10.52 (9.77)	12.60 (9.70)
Month One	ASERT	8.06 (9.22)	7.83 (7.06)
	PHET	10.84 (11.13)	12.22 (10.35)
Month Six	ASERT	6.06 (7.79)	8.59 (8.95)
	PHET	11.86 (11.71)	15.39 (10.93)

ASERT = Anxiety Sensitivity Education and Reduction Training; PHET = Physical Health and Education Training; BDI = Beck Depression Inventory; BAI = Beck Anxiety Inventory.

Table 4.

Partial Correlations Between AS at the Week One Follow-up and Indices of Homework Quality Controlling for Pretreatment AS.

	Means (<i>SD</i>)	1	2	3	4	5	6
1. ASI	16.12 (10.41)	-					
2. Exercise Identified	.91 (.19)	-.05	-				
3. Sensations Identified	1.00 (.02)	-.02	-.11	-			
4. Thoughts Identified	.81 (.31)	-.04	-.24	.36*	-		
5. Moderate Fear	.43 (.37)	.04	.11	-.26	-.11	-	
6. Minimal Fear	.88 (.27)	.12	-.23	.05	-.10	-.37*	-

ASI = Anxiety Sensitivity Index; Exercise Identified = Percentage of trials in which IE exercise was identified; Sensations Identified = Percentage of trials in which sensations were identified; Thoughts Identified = Percentage of trials in which thoughts were identified; Moderate Fear = Percentage of days in which fear reached a five on a ten point scale; Minimal Fear = Percentage of days in which fear reached a 1 on a ten point scale.

* $p < .05$

Table 5.

Partial Correlations Between AS at the Month One Follow-up and Indices of Homework Quality Controlling for Posttreatment AS.

	Means (<i>SD</i>)	1	2	3	4	5	6
1. ASI	12.29 (9.38)	-					
2. Exercise Identified	.88 (.24)	-.22	-				
3. Sensations Identified	.98 (.12)	.10	-.10	-			
4. Thoughts Identified	.78 (.34)	.06	-.14	.25	-		
5. Moderate Fear	.34 (.30)	.15	.09	-.01	.02	-	
6. Minimal Fear	.87 (.25)	.02	.01	.21	-.19	-.15	-

Note: No correlations reached a level of significance.

ASI = Anxiety Sensitivity Index; Exercise Identified = Percentage of trials in which IE exercise was identified; Sensations Identified = Percentage of trials in which sensations were identified; Thoughts Identified = Percentage of trials in which thoughts were identified; Moderate Fear = Percentage of days in which fear reached a five on a ten point scale; Minimal Fear = Percentage of days in which fear reached a one on a ten point scale.

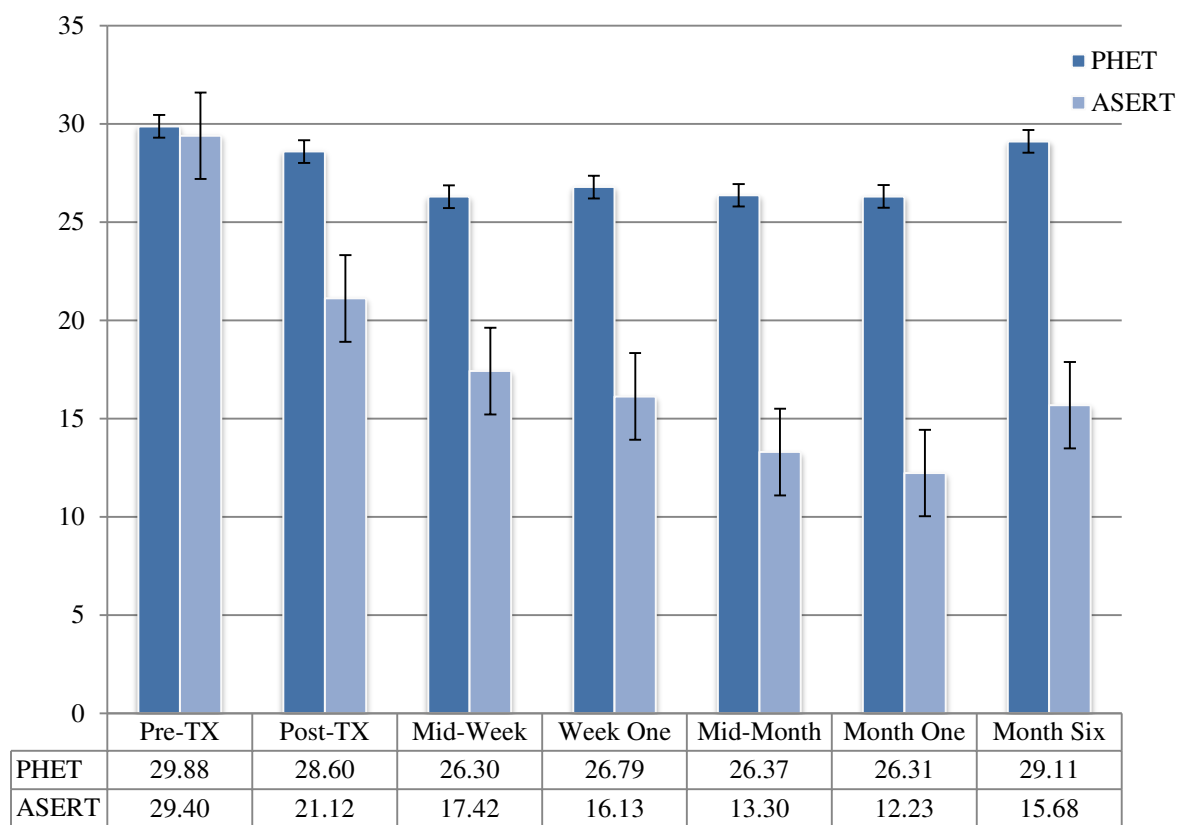


Figure 1.
ASI Total Scores by Treatment Condition Across the Study Period.

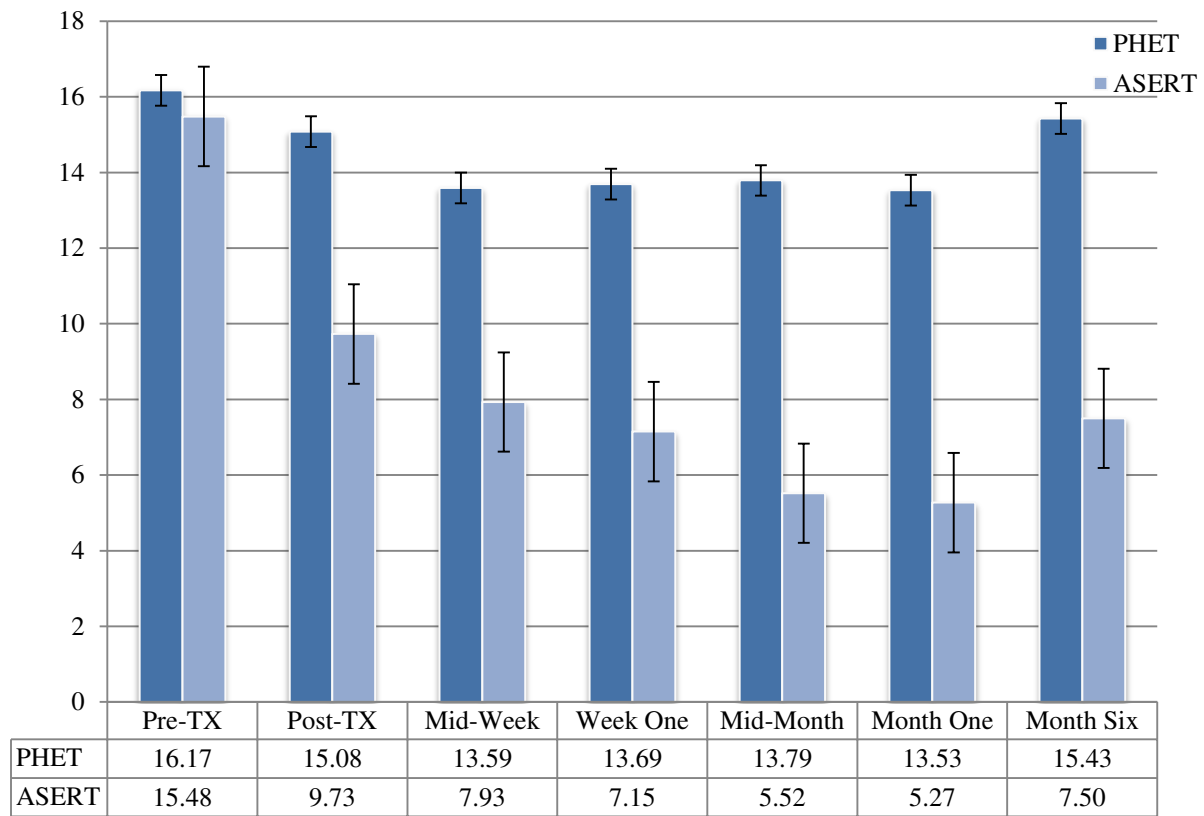


Figure 2.
ASI Physical Scores by Treatment Condition Across the Study Period.

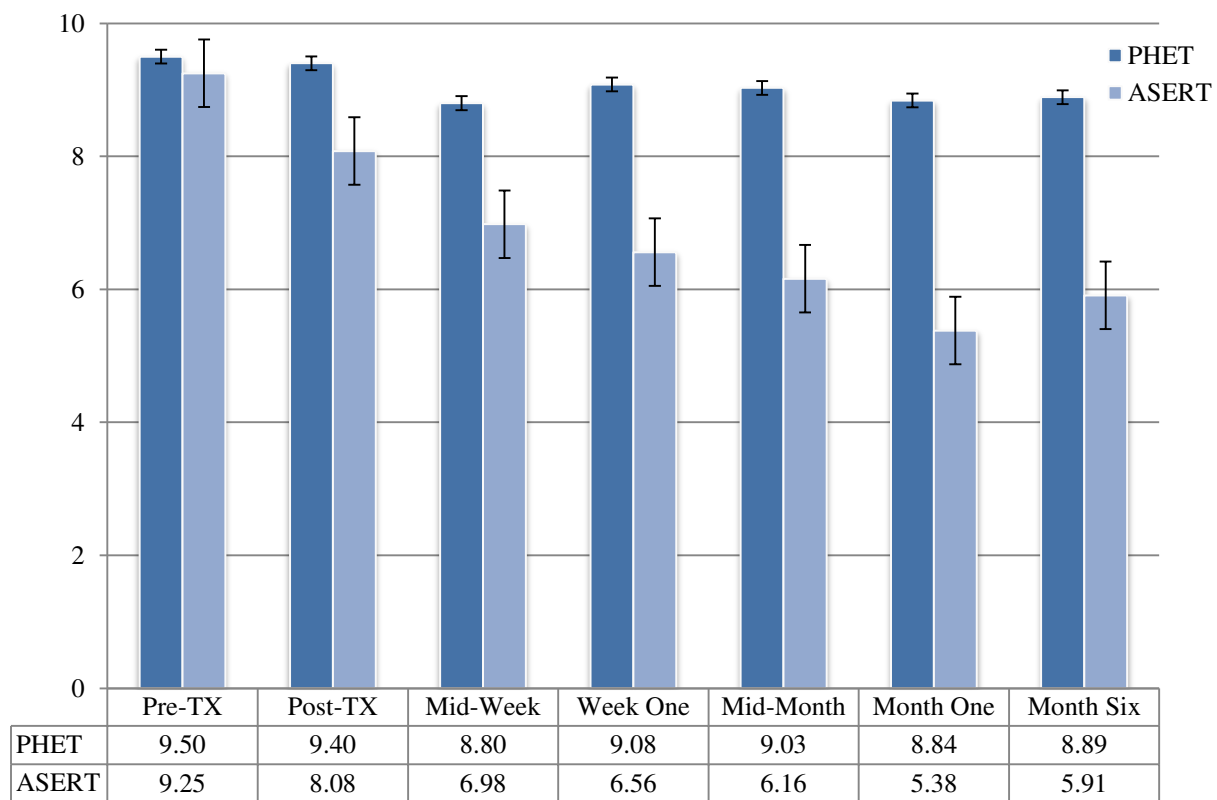


Figure 3.
ASI Social Scores by Treatment Condition Across the Study Period.

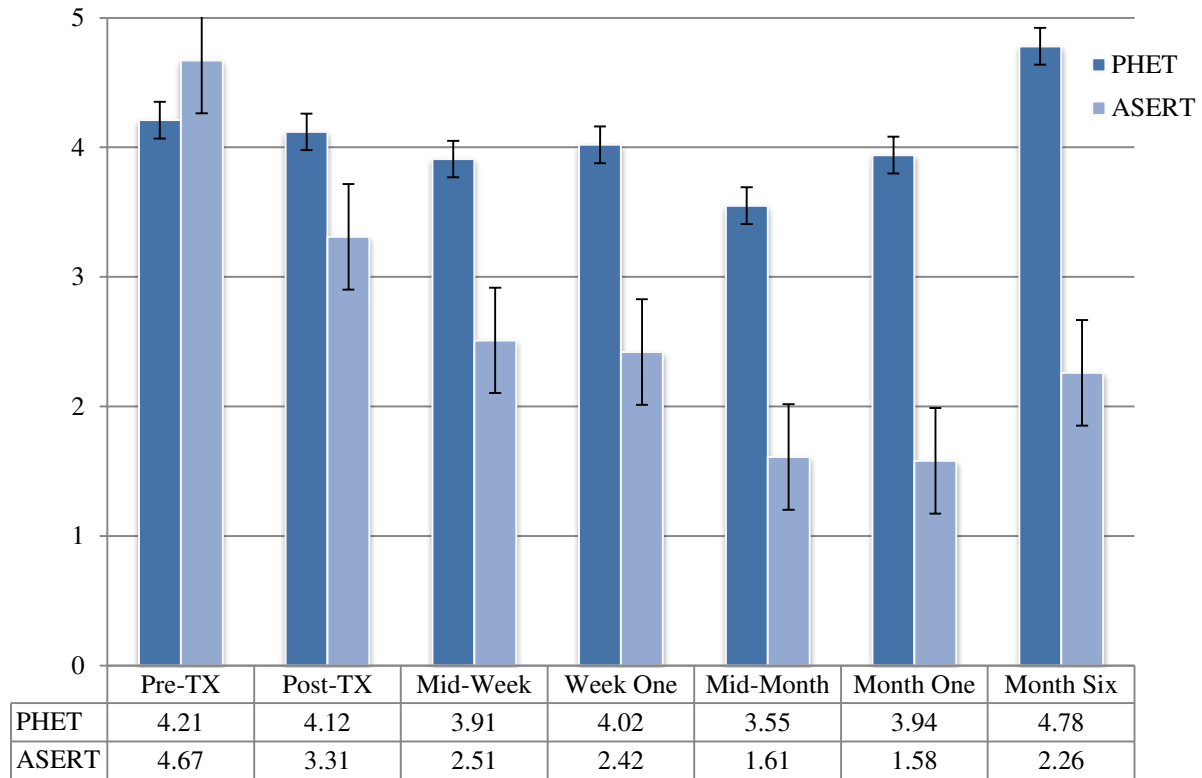


Figure 4.
ASI Cognitive Scores by Treatment Condition Across the Study Period.

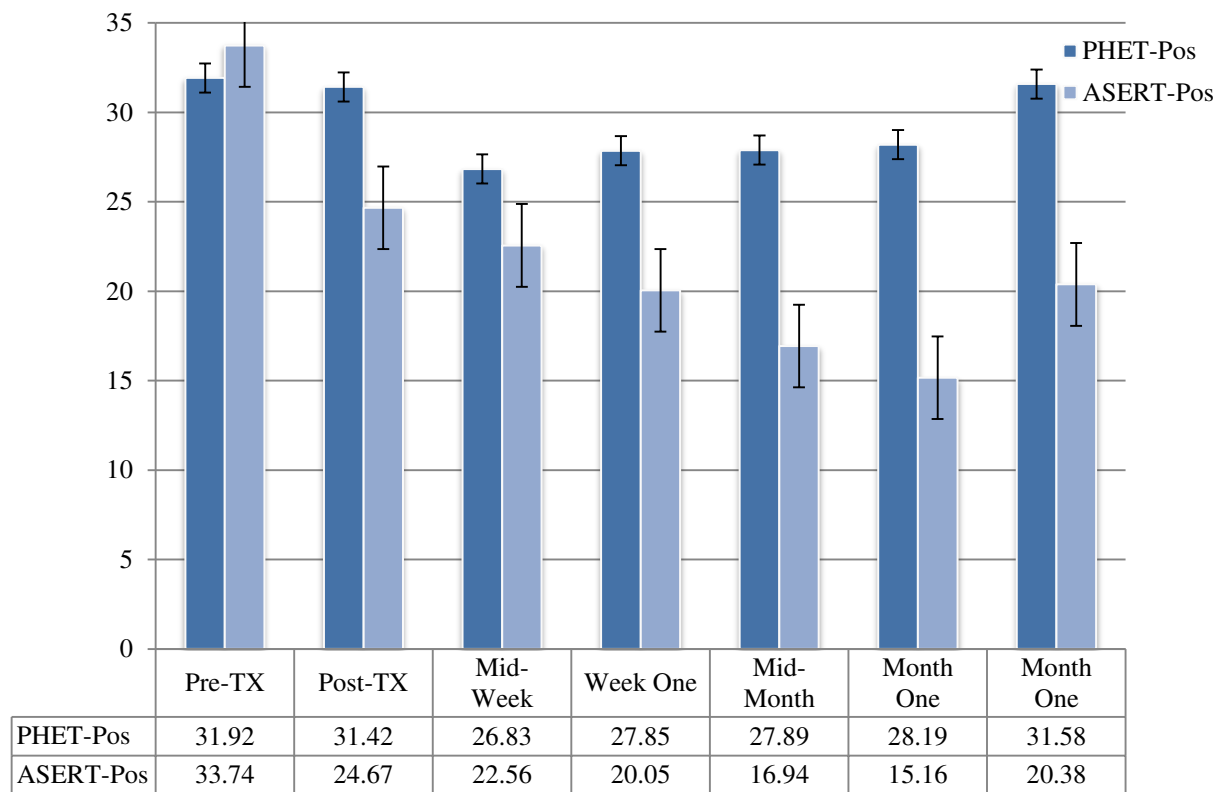


Figure 5.
ASI Total Scores by Treatment Condition Across the Study Period for Participants with an Axis I Diagnosis.

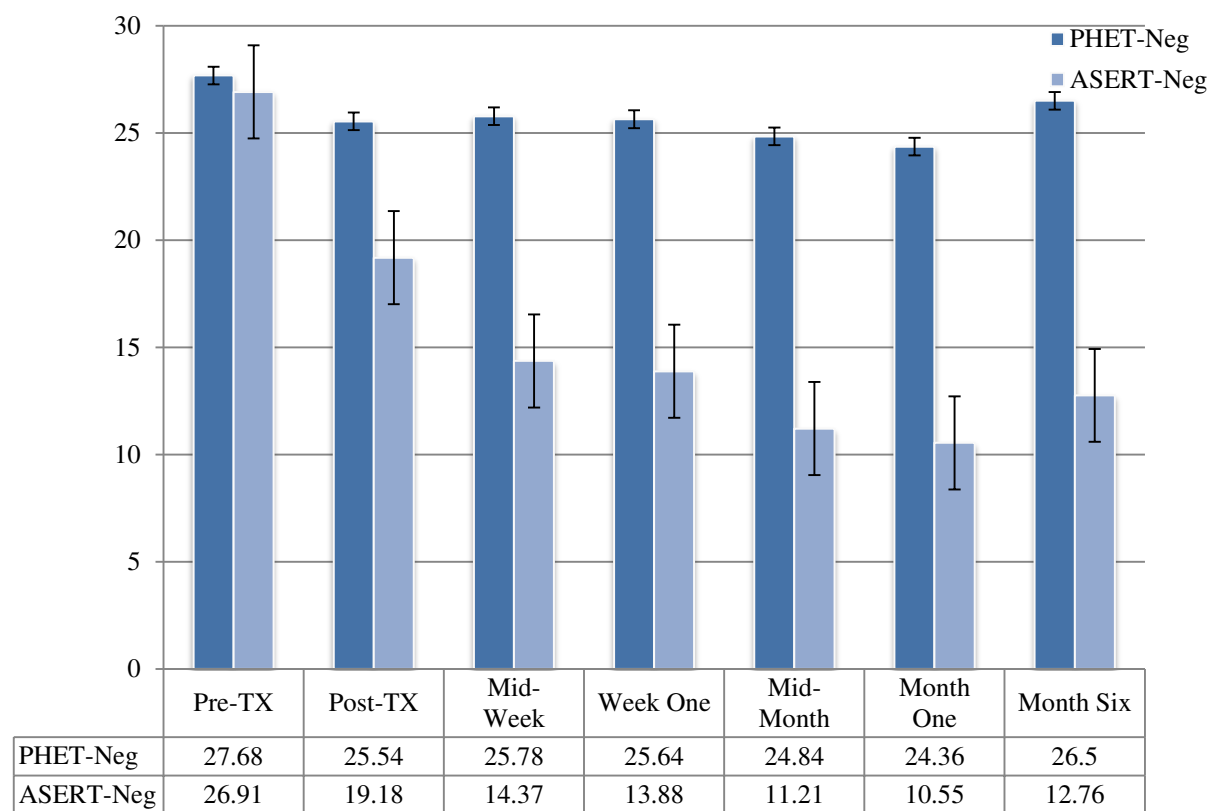


Figure 6.
ASI Total Scores by Treatment Condition Across the Study Period for Participants without an Axis I Diagnosis.

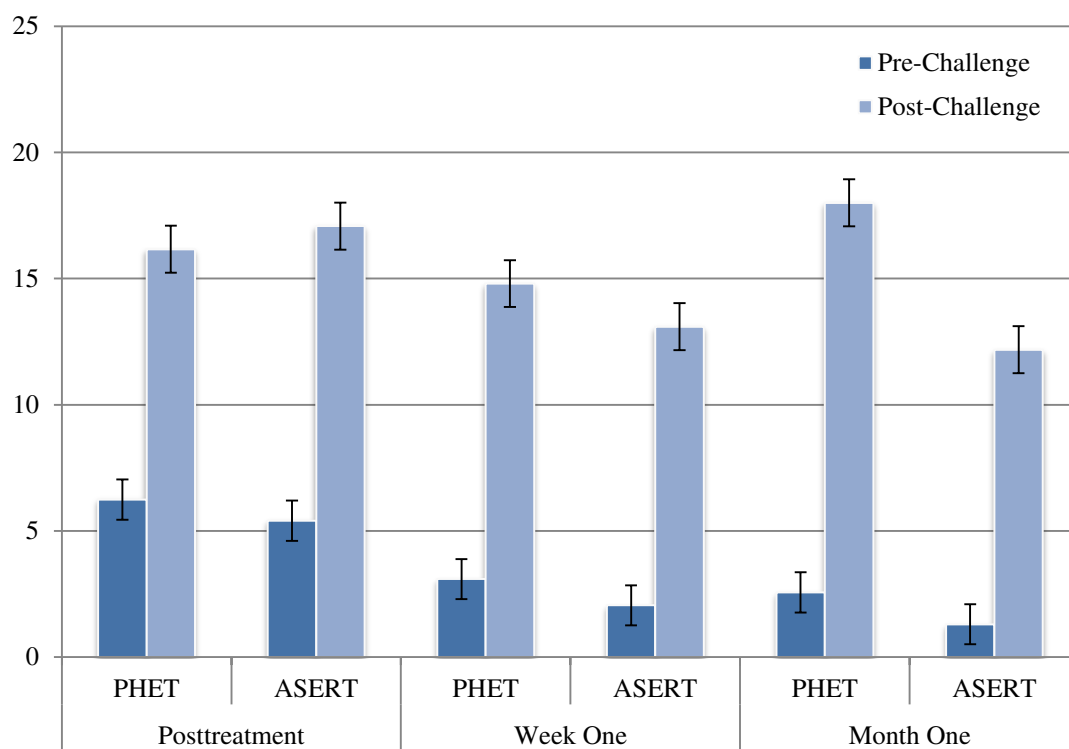


Figure 7.
Pre and Post CO₂ Challenge API Symptom Total Scores by Treatment Conditions.

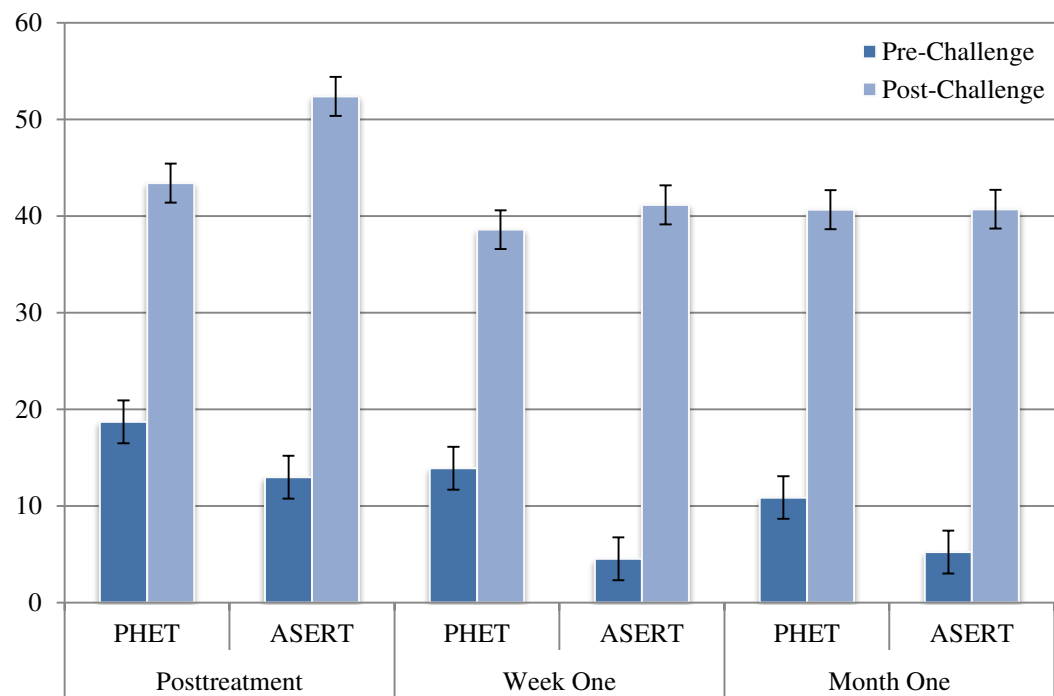


Figure 8.
Pre and Post CO₂ Challenge SUDS by Treatment Conditions.

APPENDIX A

“HUMAN SUBJECTS APPROVAL”

Office of the Vice President For Research Human Subjects Committee
Tallahassee, Florida 32306-2742
(850) 644-8673 · FAX (850) 644-4392

RE-APPROVAL MEMORANDUM

Date: 11/9/2009

To: Meghan Keough

Address: 4301
Dept.: PSYCHOLOGY DEPARTMENT

From: Thomas L. Jacobson, Chair

Re: Re-approval of Use of Human subjects in Research
Brief Health and Stress Focused Intervention for Anxiety (NRSA
grant title-under review)-Refinement and Examination of a Brief Anxiety
Sensitivity Focused Intervention

Your request to continue the research project listed above involving human subjects has been approved by the Human Subjects Committee. If your project has not been completed by 11/3/2010, you are must request renewed approval by the Committee.

If you submitted a proposed consent form with your renewal request, the approved stamped consent form is attached to this re-approval notice. Only the stamped version of the consent form may be used in recruiting of research subjects. You are reminded that any change in protocol for this project must be reviewed and approved by the Committee prior to implementation of the proposed change in the protocol. A protocol change/amendment form is required to be submitted for approval by the Committee. In addition, federal regulations require that the Principal Investigator promptly report in writing, any unanticipated problems or adverse events involving risks to research subjects or others.

By copy of this memorandum, the Chair of your department and/or your major professor are reminded of their responsibility for being informed concerning research projects involving human subjects in their department. They are advised to review the protocols as often as necessary to insure that the project is being conducted in compliance with our institution and with DHHS regulations.

Cc: Norman Schmidt, Advisor
HSC No. 2009.3454

APPENDIX B

“CONSENT FORM”

Florida State University Consent to Participate in a Research Study

Study Title: Brief Health and Stress Focused Intervention for Anxiety
Principal Investigator: Meghan E. Keough, M.S.
FSU Department: Psychology Department
Co-Investigator: Brad Schmidt, Ph.D.

What are some general things you should know about research studies?

You are being asked to take part in a research study. To join the study is voluntary. You may refuse to join, or you may withdraw your consent to be in the study, for any reason, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study. You should ask the researchers named above, or staff members who may assist them, any question you have about this study at any time.

What is the purpose of this study?

The purpose of the study, called the “Brief Health and Stress Focused Intervention for Anxiety,” is to evaluate different treatments designed to help people reduce their anxiety sensitivity, the extent to which individuals believe symptoms of anxiety are potentially harmful.

How long will your part in this study last?

The project consists of:

- 1 initial screening appointment which will last approximately 1.5 hours,
- 1 intervention appointment which will last approximately 2 hours,
- 2 follow-up appointments (2 weeks and 4 weeks post intervention appointment) which will each last approximately 1 hour, and
- 2 brief computer check-ins which will last approximately 15 minutes each.
- You may also be contacted at 6 months and 1 year following your initial appointments to complete brief computer check-ins.

What will happen if you take part in the study?

The current research study will include the following:

- *Initial Screening Appointment*

During this appointment you will be asked to complete a diagnostic interview with a member of the research team. We will also have you complete a series of questionnaires. The interview and questionnaires will determine whether the intervention is a good match for you. If the intervention is not a good match for you, then you will be issued your research credit and your participation in the study will be complete. If the intervention is a good match for you, then you will be randomized into either a health or stress focused intervention. Randomization refers to the process of assigning a participant into a study condition completely by chance-it functions very similar to flipping a coin. The health focused intervention will provide you with information about how to maintain or achieve a healthy lifestyle through eating, exercise and other health related behaviors. The stress focused condition will provide you with information about the nature of stress and anxiety as well as demonstrate techniques to minimize anxiety.

- *Intervention Appointment*

During this appointment, you will complete a series of questionnaires that assess anxiety, depression and emotional responding. You will meet with a study therapist who will review information with you about either health or stress. This appointment will also entail brief exposure to a fear-provoking stimulus. Specifically, you will take a single breath of 65% oxygen, 35% carbon dioxide mixture. This exposure may cause you to experience some physical sensation akin to anxiety; however, the sensations are momentary.

- *Mid-Week Check-In*

You will complete a brief set of questionnaire over the secure study website.

- *Week One Follow-up*

During this appointment, your homework forms will be collected, you will complete a series of questionnaires and you complete a single inhalation of the oxygen/carbon dioxide mixture.

- *Mid-Month Check-In*

You will complete a brief set of questionnaire over the secure study website.

- *Month One Follow-up*

During this appointment, your homework forms will be collected, you will complete a series of questionnaires and you complete a single inhalation of the oxygen/carbon dioxide mixture.

- *Month Six and Twelve Follow-ups*

If funding becomes available, you will be contacted at six months and twelve months after your initial appointment. You will be directed to the secure study website to complete a brief set of questionnaires.

What are the possible benefits from being in this study?

Research is designed to benefit society by gaining new knowledge. Based on the intervention, you may experience a reduction in anxiety, a reduction in distress and impairment, and potentially a reduction in related problems.

What are the possible risks or discomforts involved in participating in this study?

The risks to you in this study are minimal and involve no known risks to your health or well-being. Nevertheless, precautions will be taken to minimize any risks you may incur in the proposed study. Some individuals may experience slight discomfort describing their thoughts and behaviors. The inhalation of a single breath of 65% oxygen/35% carbon dioxide mixture can create a mild level of physical discomfort; however, any discomfort you may experience is completely temporary and will be only momentary. These activities should not be any more anxiety-provoking than situations commonly experienced in day-to-day life. If it is determined that there is an immediate need for assistance, you will be referred to clinicians with whom you may speak about your discomfort or distress. You furthermore have the right to refuse or discontinue participation at any time. You should report any problems to a member of the research team.

How will your privacy be protected?

Participants will not be identified in any report or publication about this study. Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, FSU will take steps allowable by law to protect the privacy of personal information. Careful measures will be taken to ensure your confidentiality as a participant in this study. Each participant will be assigned an Identification Code with which all questionnaires and behavioral observations will be labeled. The key associating Identification Codes with participant names will be kept separate from all assessment materials and consent forms in a secured file. The key associating Identification Codes with participant names will be destroyed following data collection. The de-identified data will be retained and may be used at a later time point to investigate the relationships between constructs included in the study.

The initial eligibility-determination interview and intervention appointments will be video recorded. These tapes will be used to ensure diagnostic reliability and treatment adherence. No participant will be identified in these tapes. After they have been reviewed by the research team, the tapes will be destroyed. The tapes will be destroyed on or before December 31, 2011. All other questionnaire data relevant to this project will be destroyed on or before December 31, 2018.

Will you receive anything for being in this study?

You will receive up to 7 research credits for your participation in this study. You will be compensated 1.5 research credits for the assessment appointment, 2 research credits for the intervention appointment, 1 research credit for each of the follow-up appointments and ½ research credit for the two check-in appointments. You will also receive 1 research credit for completing at least 60% of the follow-up homework. In addition, you can earn raffle tickets for completing the assigned homework. The raffle tickets will be entered into a drawing at the end of each semester for \$25 retail gift certificates. You will receive 1 ticket for completing 70%, 2 tickets for completing 80%, 3 tickets for completing 90% and 5 tickets for completing 100% of the homework. If you earn all 5 tickets, your chance of receiving a gift certificate will be approximately 10%.

If you are contacted and complete the six and twelve month follow-up assessments, you will be compensated ten dollars for each assessment.

Will it cost anything to be in this study?

There will be no costs for being in the study.

What if you have questions about this study?

You have the right to ask, and have answered, any questions you may have about this research. If you have questions, or concerns, you should contact the researchers listed on the first page of this form.

What if you have questions about your rights as a research participant?

All research on human volunteers is reviewed by a committee that works to protect your right and welfare. If you have questions or concerns about your rights as a research participant you may contact, anonymously if you wish, the Chair of the Human Subjects Committee, Institutional Review Board, through the Vice President for the Office of Research at (850) 644-8633.

Participant's Agreement:

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

Printed Name of Research Participant

Signature of Research Participant

Date

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BIOGRAPHICAL SKETCH

Meghan E. Keough completed her Bachelor of Science degree in psychology at the University of Washington. After completion of her degree, she worked at the University of Washington at Harborview Medical Center investigating depression and related psychological sequelae following traumatic brain injury. In 2005, she began her graduate training in clinical psychology at Florida State University where she completed extensive training in cognitive behavioral therapy for anxiety and mood disorders, served as the Associate Director and Research Coordinator for the Anxiety and Behavioral Health Clinic and established her own program of research. Meghan's research explores the risk and maintaining factors of panic and related anxiety disorders with an eye on improving the understanding, prevention, and treatment of these conditions. During graduate school, Meghan received awards from university as well as national and international organizations in recognition and support of her research. In fulfillment of her doctoral degree, Meghan completed a pre-doctoral internship at Massachusetts General Hospital/Harvard Medical School in the Cognitive Behavioral Therapy Program. Meghan is currently a T-32 Postdoctoral Senior Research Fellow in the Department of Psychiatry and Behavioral Sciences at University of Washington School of Medicine.