

EXAMINING EFFICACY, MECHANISMS, AND INTERVENTION FIDELITY OF  
MINDFULNESS-BASED COGNITIVE THERAPY FOR ANXIETY AND STRESS  
REDUCTION AMONG COLLEGE STUDENTS IN A RANDOMIZED CONTROLLED  
TRIAL

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## ABSTRACT

The prevalence of anxiety and stress among college students necessitates the investigation of potential alternative and accessible interventions that could be implemented into existing curricular and student-support programming to improve students' mental health. While mindfulness-based cognitive therapy (MBCT) smartphone applications have shown promising outcomes in alleviating anxiety and stress, it is essential to gain insight into the feasibility and efficacy of such an interventional approach in a collegiate population; as well as explore potential underlying mechanisms which could be better targeted to enhance the efficacy of future interventions for promoting mental health and well-being. The aim for this study was to assess the efficacy of a 4-week MBCT intervention using the Sanvello smartphone application in reducing trait-level anxiety and chronic stress in college-aged young adults ( $n = 150$ ) compared to a positive control group ( $n=139$ ). Participants completed assessments of trait anxiety, chronic stress, cognitive reappraisal, cognitive refocusing, distractive refocusing, and negative automatic thoughts at pretest and following 4 weeks of the interventions. Analysis of primary outcomes revealed greater reductions in trait anxiety and chronic stress for the MBCT group, relative to the positive control group with small to moderate effect sizes. The anxiolytic and stress-reducing effects of the MBCT intervention were observed to be mediated by changes in negative automatic thoughts but not by changes in cognitive reappraisal, constructive refocusing, or distractive refocusing. Given the efficacy of the Sanvello smartphone application and the overwhelmingly strong assessments of the appropriateness and feasibility of its use; student support initiatives may be well served by adopting such a platform within the context of first-line treatment and prevention of high anxiety and chronic stress within first year college students.

Keywords: Mindfulness-Based Cognitive Therapy, Cognitive Restructuring, Negative Automatic Thoughts

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## **CHAPTER 1: Introduction**

According to the American College Health Association (2019), over two-thirds of collegiate women and half of collegiate men experience a high prevalence of anxiety-related symptoms. Further, over half of students indicate moderate levels of chronic stress that adversely affects their daily functioning (Li et al., 2022). Compounding this, over the past several decades there has been a pervasive rise of violent incidents and mass shootings within US schools reducing student perceptions of well-being and exacerbating stress and anxiety (Fox & Fridel, 2018; Katsiyannis, Whitford, & Ennis, 2018; Levine & McKnight, 2020). These findings highlight the crucial need for effective interventions to address the heightened levels of anxiety and stress observed in college students. Although in-person mindfulness-based cognitive therapy approaches have been found effective for reducing anxiety and stress (Haller et al., 2021; Irving et al., 2009; Phang et al., 2016; Ozen et al., 2013; Kor et al., 2019); given the pervasiveness of anxiety and stress in this population existing support services are overwhelmed, thus there is a need to provide alternative and accessible interventions to improve students' mental health (Addis, Wade and Hatgis, 1999; Joyce et al., 2009; Newman et al., 2022). One such approach may be by leveraging existing tools such Sanvello — a free mindfulness-based cognitive therapy smartphone application — which could more easily be deployed across a broader population and potentially even implemented into existing curricular and student-support programming. However, prior to such implementation it is essential to gain insight into the feasibility and efficacy of such an interventional approach; as well as explore potential underlying mechanisms which could be targeted to enhance the efficacy of future interventions for promoting mental health and well-being.

Mindfulness-based interventions entail cultivating mindful awareness by attentively observing experiences, thoughts, and emotions (Lao et al., 2016; Gu et al., 2015). The most common and well-known interventions in this area are mindfulness-based stress reduction (MBSR) and mindfulness-based cognitive therapy (MBCT). MBSR encourages the development of self-management of stress and emotional distress by becoming more aware of thoughts and feelings regarding a particular stimulus or situation (Bishop, 2002). Although there is wide variation in the specific practices, a common implementation is through meditation and focused breathing exercises whereby the individual is taught to passively observe their thoughts and feelings without making judgements or assigning value to them as anything other than brief mental events. Further, individuals are encouraged to employ these meditation and focused breathing exercises when they experience times of stress or anxiety. Meta-analytic reviews have consistently observed beneficial effects of MBSR-based interventions in reducing trait anxiety (hedges  $g = 0.36$  to  $0.55$ ) and chronic perceptions of stress (hedges  $g = 0.83$  to  $1.0$ ) with similar effects regardless of the target population being students, healthcare professionals, or the general public (Grossman et al., 2004; Khoury et al., 2015; Questret et al., 2020). However, it is important to acknowledge persistent limitations within the extant literature on MBSR-based interventions relating to small sample sizes, non-random assignment, and the absence of control groups (Ludwig and Kabat-Zinn 2008; Philippot and Segal 2009). Indeed, Bohlmeiher and colleagues (2010) noted that the anxiolytic effects were reduced nearly in half when excluding lower-quality studies. MBCT interventions build upon the same core aspects of MBSR, but also integrate elements of cognitive therapy to help individuals recognize and interrupt negative thought patterns that can lead to perceptions of anxiety and stress (Kim et al., 2009). Meta-analytic comparison of MBCT against MBSR, in particular, has shown that interventions using

MBCT exert nearly twice as large of an anxiolytic effect than interventions using MBSR (Questret et al., 2020). Nevertheless, a key criticism of mindfulness-based interventions is that they are classically delivered through multiple one-to-two-hour sessions over the course of 8 weeks in an individual or small group format; representing a substantial constraint of both time and resources for the individual and clinical practitioners.

However, emerging evidence indicates that the anxiolytic and stress-reducing effects of mindfulness-based intervention programs manifest even when the intervention period is shortened. Specifically, Demarzo and colleagues (2017) observed similar effects of both 4-weeks ( $n=46$ ) and 8-weeks ( $n=51$ ) of a mindfulness-based intervention program, relative to a non-contact control group ( $n=49$ ) in reducing anxiety (Cohen's  $d = 0.45$  and  $0.57$ , respectively) with no statistical difference between intervention periods. Although the intervention programming implemented by Demarzo and colleagues (2017) still required 120-minute sessions each week with an experienced, certified mindfulness teacher; given the ubiquity of smartphones amongst college aged students, a promising potential approach is in utilizing smartphone-based applications to implement mindfulness-based cognitive therapy (MBCT) interventions.

While there are a wide-assortment of such applications, the present investigation specifically utilized the Sanvello application as it is a cost-free application that was compatible with a wide range of Apple and Android devices and thus represents a potential platform that could be used within broad segments of the college-student community. Further, there exists prior work specifically examining the efficacy of the application on both anxiety and stress. Specifically, Moberg and colleagues (2019) observed reductions in anxiety (Cohen's  $d = 0.4$ ) and stress (Cohen's  $d = 0.46$ ) in users of the Sanvello platform over the course of a 30-day intervention. However, it is critical to acknowledge the conflict-of-interest and self-serving

findings associated with Moberg and colleagues being cofounder/chief-executive-officer and on salary at Sanvello (formerly Pacifica Labs, Inc.). Further, the investigation specifically recruited individuals who were interested in using the Sanvello application or who were already existing users; which reflects a substantially different population and context than might be seen if deployed within the context of existing curricular and student-support programming in a collegiate population. Thus, while there is strong evidence that such implementation of MBCT can be effective, there remains an open question as to how feasible and effective such a brief smartphone-based interventional approach might be if implemented within a population that is not self-selecting to already use the application.

In contrast to the extensive body of literature examining the effects of mindfulness-based interventions, relatively few studies have examined the underlying causal mechanisms responsible for inducing changes in trait anxiety and chronic stress. Yet such an understanding is vital for providing insight into how to optimize and tailor interventional approaches to maximize their impact. Building from Beck's cognitive theory of anxiety and depression (1987), the crucial factor in the manifestation and alteration of negative psychological states such as anxiety and chronic stress is the emergence of negative thinking patterns. Negative thinking patterns encompass cognitive habits that lead individuals to perceive situations in a distorted manner. One prominent example of such a pattern is catastrophizing, when individuals tend to assume the most dire and pessimistic outcome in any given situation. From a construct-framework perspective, mindfulness-based cognitive therapy encourages the development of promoting awareness of and control over how an individual assesses a particular stimulus or situation (i.e., cognitive reappraisal), reframes/reinterprets the function and/or consequence of the event (i.e., constructive refocusing), and becomes accepting of experiences rather than exhibiting the

tendency to dissociate or avoid them (i.e., distractive refocusing) (Garnefski & Kraaij, 2006; Gross & John, 2003; Wolgast, Lundh, & Viborg, 2013). The fundamental premise of mindfulness-based cognitive therapy is that through the development of such core psychological constructs an individual may be better able to recognize and transform their negative automatic thoughts, beliefs, and behaviors (Sipe & Eisendrath, 2012). Accordingly, given such a framework, these core psychological constructs are presented as causally implicated in the effects of a MBCT intervention on trait anxiety and chronic stress. The present investigation sought to specifically examine these constructs as potential mediators of the anxiolytic and stress-reducing effects of MBCT.

Accordingly, the present study provides a novel contribution to the literature by addressing the following research questions: (1) What is the efficacy of a 4-week MBCT delivered through the Sanvello smartphone application for reducing trait-level anxiety and chronic stress, relative to control group, implemented within the context of a predominately first year-level collegiate course following a mass-shooting incident on campus. (2) To what extent do cognitive restructuring domains (cognitive reappraisal, constructive refocusing, and distractive refocusing) and negative automatic thoughts mediate the anxiolytic and stress reducing effects of the MBCT intervention. And (3) to what extent do intervention fidelity domains (implementation, dose, quality) moderate the efficacy of the 4-week MBCT for reducing trait-level anxiety and chronic stress. Based upon the extant literature, it was hypothesized that: (1) Engaging in the MBCT intervention would result in a greater reduction in trait anxiety and stress compared to the positive control group. Drawing upon Beck's cognitive theory of anxiety and depression (Beck, 1987) and the conceptualization of the construct-framework perspective, it was hypothesized that (2) greater changes in cognitive reappraisal, constructive refocusing, and



distractive refocusing would each mediate the changes in anxiety and stress induced by the MBCT intervention, with the strongest mediation effect observed for negative automatic thoughts. It was also hypothesized that (3) fidelity domains would exert a moderating influence on changes in anxiety and stress induced by the MBCT intervention.

## **CHAPTER 2: Review of Literature**

To gain a comprehensive understanding of the relationship between mindfulness practice and anxiety reduction, a review of the existing literature concerning both topics is necessary.

This chapter will provide insights into mindfulness practices and their potential mechanisms for reducing anxiety. The discussion will cover the following aspects: (1) the duration and frequency of mindfulness, (2) justification for online application, (3) the cognitive theory of anxiety and depression as a theoretical framework, and (4) the mechanism of cognitive restructuring.

### **Mindfulness**

In the past six decades, Buddhist traditions have taken root in the Western world (Fields, 1992; Bishop, 2004). Mindfulness, a contemplative practice, is based on the Buddhist belief in the impermanence of all things, the absence of an enduring self, and the concept of suffering caused by clinging to the illusion of a permanent self, also known as the "three marks of existence" (Bodhi, 2003). Mindfulness-based interventions differ from typical Western psychological assumptions in three main ways: 1) they focus on changing people's state of consciousness rather than the contents of consciousness, leading to reduced suffering; 2) they consider interpreting experiences in relation to the self-concept as detrimental; and 3) they emphasize the present moment as the only existing point in time, cautioning against attempts to overly orient oneself to the present (Rosch, 2007).

### **Mindfulness as a Technique**

Mindfulness techniques involve non-judgmental attention to the present moment, becoming aware of sensations, thoughts, and feelings without giving them undue significance. In the Buddhist concept of mindfulness, there are two components: concentration (samatha) and insight (vipassana). Samatha technique focuses on the object of meditation, while vipassana

involves observing impermanence, suffering, and not-self. Though often confused in psychological discussions on mindfulness, these two concepts have distinct implications for the outcomes of mindfulness practice. Empirical evidence and theory support the idea that mindfulness techniques lead to a lasting change in perspective and state of being (Brown & Ryan, 2003; Brown et al., 2007a, 2007b; Carmody et al., 2009; Gunaratana, 2011; Hollis-Walker & Colosimo, 2011; Kabat-Zinn, 1982; Leary et al., 2006).

#### Empirical Research on Mindfulness-Based Interventions

Various mindfulness-based interventions have been developed for incorporation into treatment plans tailored to individuals (Didonna, 2009). Due to their widespread utilization, it is crucial to conceptualize the possible mechanisms through which these therapies are effective when applied to various mental health disorders.

#### Mindfulness-Based Stress Reduction (MBSR)

In the early 1980s, Kabat-Zinn introduced the first mindfulness-based program, Mindfulness-Based Stress Reduction (MBSR), initially implemented in a pain clinic to help patients manage chronic pain. MBSR is a commonly used mindfulness training method, consisting of an 8-10 week course for groups of up to 30 individuals. The participants meet weekly to learn and practice mindfulness meditation skills, discuss stress and coping, and complete homework assignments. The program includes various mindfulness exercises such as body scan, sitting meditation, yoga, and mindfulness during everyday activities (Kabat-Zinn, 1982). Participants are encouraged to practice these skills for at least 45 minutes a day, six days a week, focusing on the present moment and observing things nonjudgmentally. The goal is to help individuals realize that sensations, thoughts, and emotions are transient and not to become absorbed in their content (Linehan, 1993b, p. 87).

The program involves teaching mindfulness meditation techniques that emphasize observing sensations and recognizing their impermanent nature. Kabat-Zinn posits that by shifting attention from reactivity to observation, individuals can uncouple the link between experiencing pain and the subsequent emotional reaction to it. He suggests that this suspension of normal reactions to internal events is a form of therapeutic exposure, leading to increased awareness of internal reactivity. However, Kabat-Zinn's explanation lacks a detailed description of the underlying psychological processes. A meta-analysis by Grossman et al. (2004), based on 20 studies, found that MBSR significantly improves mental and physical health, but it did not measure changes in mindfulness, indicating a need for further investigation into the underlying mechanisms.

In a study, Shapiro and colleagues (2006) proposed that the core psychological mechanism behind Mindfulness-Based Interventions is "reperceiving." They define reperceiving as a fundamental shift in perspective that occurs through the mindfulness components of intention, attention, and attitude. This shift enables individuals to distance themselves from their thoughts and emotions, viewing them as separate from their self. Shapiro et al. (2006) highlight that reperceiving leads to decreased identification with one's own thoughts and emotions, thereby reducing their power and impact. Negative thoughts may have a weaker link to depression, and negative emotions may be less persistent as a result. Additionally, reperceiving leads to a realization that the self is a constantly changing concept composed of memories, beliefs, sensations, and ideas. By practicing mindfulness, individuals can develop a less egocentric worldview and become less attached to the concept of self. This shift in perception can lead to increased compassion and concern for oneself and others. Furthermore, it may result in decreased distress when the concept of self is threatened, whether the threat is real or

perceived. Segal and colleagues developed Mindfulness-Based Cognitive Therapy (MBCT) in 2002 as a treatment for depression relapse (Segal et al., 2002). MBCT aims to train attention regulation by targeting a pattern of thinking known as "rumination," characterized by repetitive, negative thoughts about the causes and consequences of one's distress without resulting in problem-solving.

According to Segal et al.'s model of depression relapse, rumination is established and strengthened during the first depressive episode, and relapse occurs when a trigger reactivates rumination. The authors propose the concept of "modes of mind" to explain the problematic nature of rumination, specifically the distinction between the adaptive "doing" mode and the maladaptive "driven-doing" mode. In "driven-doing," the focus is on failing to be the person one wishes to be, generating negative feelings and making it difficult to let go of discrepancies in the internal arena, thereby perpetuating rumination. The authors suggest that the ruminative loop created in the "driven-doing" mode can be disrupted and terminated through learning to recognize when it is activated and relating to it with acceptance and nonreactivity while having the choice to redirect attention elsewhere. They propose that MBCT teaches skills to exit the "doing" mode and enter the "being" mode, using mindfulness meditation and psychoeducation. The program aims to improve the relationship with thoughts and feelings through decentering, teaching participants to view thoughts as transitory events and not giving them undue importance. This realization arises from observing thoughts and feelings nonjudgmentally and noting that they arise and pass away. The authors argue that the positive outcomes of MBCT are mediated by gains in mindfulness and self-compassion, as measured by the Self-Compassion Scale (Neff, 2003); However, the underlying mechanism by which self-compassion works needs to be adequately addressed (Kuyken et al., 2010).

The theory behind MBCT is that individuals who have experienced major depressive episodes are vulnerable to recurrences when they encounter mild dysphoric states, which can reactivate depressive thinking patterns. MBCT aims to prevent depressive relapse by teaching individuals to observe their thoughts and feelings nonjudgmentally and to view them as mental events that come and go rather than as aspects of themselves or as necessarily accurate reflections of reality (Segal et al., 2002). This attitude is believed to prevent the escalation of negative thoughts into ruminative patterns and promote mental well-being.

The National Institute of Clinical Excellence (NICE) recommends MBCT as a treatment for preventing relapse in depression, especially for those who have experienced depression three or more times (NICE, 2009). A study by Teasdale et al. (2000) found that MBCT halved the relapse rate in those who had previously experienced depression three or more times compared to treatment as usual. However, the study did not measure levels of mindfulness or its different traits in participants, leaving it unclear whether mindfulness is the mechanism of change and which aspect of mindfulness is responsible for the effects of the intervention.

In a study by Kim et al. (2009), the effectiveness of mindfulness-based cognitive therapy (MBCT) as an addition to medication in treating patients with panic disorder or generalized anxiety disorder (GAD) was investigated. The study included 46 participants who were randomly assigned to either an MBCT group or an anxiety disorder education (ADE) group. The MBCT group received eight weekly 2-hour sessions of MBCT, while the ADE group received eight weekly 2-hour sessions of education about anxiety disorders. The study results showed that the MBCT group had significantly more improvement than the ADE group in all anxiety and depression scale scores, as well as in the obsessive-compulsive and phobic subscales of the symptoms checklist. The MBCT group also showed improvements in quality of life and coping

skills. These findings suggest that MBCT may be an effective treatment for panic disorder and GAD in addition to medication, though more research is needed to confirm these findings.

The effectiveness of mindfulness interventions for reducing anxiety among individuals with anxiety disorders has yielded inconsistent findings in previous research (Hofmann et al., 2010; Khoury et al., 2015; Irving et al., 2009). Some studies have reported significant reductions in anxiety symptoms following mindfulness interventions, while others have not. Additionally, comparing mindfulness interventions to cognitive-behavioral therapy (CBT) interventions in terms of efficacy remains inconclusive (Goldin et al., 2016). However, recent studies suggest that mindfulness training can effectively reduce anxiety symptoms compared to other active treatments (Khoury et al., 2013). Specifically, Mindfulness-Based Stress Reduction (MBSR) has demonstrated efficacy in reducing anxiety symptoms, including anxiety in response to a laboratory social stress challenge task, when compared to an active stress-management education program group in individuals with generalized anxiety disorder (Hoge et al., 2013).

### Mindfulness and Anxiety

Studies examining the relationship between dispositional mindfulness and anxiety have shown promising results. Higher levels of dispositional mindfulness have been associated with lower levels of state anxiety, both in laboratory and class settings (Bellinger et al., 2015). Moreover, dispositional mindfulness has been found to mediate the effects of anxiety on academic performance, suggesting that individuals with higher dispositional mindfulness may experience relatively lower levels of anxiety and perform better on exams (Lopez-Navarro et al., 2020). Chen et al. (2013) demonstrated that even a brief one-week period of 30 minutes of mindfulness practice provided relief from anxiety in undergraduate students. Furthermore, a single bout of 3-minute mindfulness training has been shown to reduce anxiety two weeks post-

intervention (Lewis et al., 2021). Although these findings suggest promising dosage recommendations, further research is needed to explore mindfulness intervention dose-response relationships.

### Study Justification

The question of how much mindfulness intervention is needed to experience benefits has been a common inquiry. Current evidence suggests that even brief mindfulness interventions, such as 5-10-minute guided mindfulness inductions or 3-4 session mindfulness meditation training, can lead to immediate reductions in affective reactivity and impulsive behaviors, although the effects are generally small in magnitude. On the other hand, larger doses of mindfulness interventions, such as the 8-week MBSR program, have shown moderate-to-large overall effects pre-post training (Burgstahler & Stenson, 2019).

### Online Application Justification

A recent development in the mindfulness literature is the increasing use of internet and app-based mindfulness interventions. Smartphone applications for mental health interventions have been shown to reduce stigma around seeking treatment and increase access to care (Clough & Casey, 2015). While thousands of mental health apps are available, only a limited number have undergone rigorous scientific testing. Studies have found that mobile-delivered interventions for anxiety show small to moderate effect sizes, with potential improvements in study design and reporting of bias to strengthen further the evidence (Gee et al., 2015; Firth et al., 2017). Recent reviews also support the efficacy of mHealth apps for mental health, with increasing evidence of significant effects (Orsa-Duarte et al., 2021; Krusche et al., 2013).

### Sanvello: Anxiety and Depression (formally Pacifica)

Sanvello is a commercially available app designed for self-management of stress,



anxiety, and depression. The app, which is tailored for individuals with mild to moderate symptoms, is informed by the Cognitive Behavioral Therapy (CBT) model and provides psychoeducation, mood monitoring, identification of maladaptive thoughts, exposure and reappraisal activities, social support, self-care activities, and skills to target physical tension. At onboarding, users select up to 3 goals to work on, and the app prompts daily mood ratings and recommends activities to improve mood. There are also 35 days of Guided Paths with audio psychoeducational lessons and activities. Mober and colleagues (2019) conducted a study with 500 adults with mild-to-moderate anxiety or depression to evaluate the effectiveness of Sanvello. The study was conducted virtually with participants using the app for a month, with no level of use required, and compared to a waitlist group. Results showed significant improvement in depression, anxiety (0.47; CI 0.17 to 0.77;  $P=.002$ ), stress (2.09; CI 1.09 to 3.08;  $P<.001$ ) and self-efficacy in the active condition, with participants who completed more thought record exercises experiencing sustained improvement. The study found that individuals taking psychiatric medication benefitted less from the app, as measured by anxiety and stress symptoms.

#### Theoretical Justification

Beck's cognitive theory, formulated in 1987, posits that negative cognitive patterns are pivotal in the etiology and maintenance of anxiety and depression. This theoretical framework suggests that individuals experiencing these psychological disorders often exhibit automatic negative thoughts leading them to perceive nonexistent threats and interpret events in a pessimistic manner. Such negative cognitions arise from the establishment of negative belief patterns or schemas, which evolve over time through the influence of past experiences (Clark et al., 1996). The theory postulates that modifying these negative thoughts and schemas can

effectively alleviate symptoms of anxiety and depression. This forms the fundamental premise of Mindfulness-Based Cognitive Therapy (MBCT), an intervention that assists individuals in recognizing and transforming their negative thoughts, beliefs, and behaviors. Cognitive restructuring, a pivotal process within MBCT, involves identifying and challenging negative thoughts and beliefs, subsequently substituting them with more balanced and positive cognitive alternatives. The interpretation and construction of meaning are inherently shaped by an individual's subjective and personal schemas, which are in turn molded by their experiences and comprehension. When these schemas significantly deviate from reality, cognitive distortions and emotional disorders may ensue. The repetition of distressing events reinforces the strength of these schemas, amplifying the activation of maladaptive schemas and heightening the likelihood of psychopathological symptoms (Barlow, 2002). Beliefs, encompassing assumptions, fears, and evaluations, also play a prominent role in the cognitive model. Core beliefs, operating at the deepest level, exert a profound influence on an individual's self-concept, perceptions of others, and their worldview. Intermediary beliefs impact an individual's interpretation of specific situations, whereas automatic thoughts are idiosyncratic, context-specific cognitions that arise spontaneously. The content and orientation of automatic thoughts, as well as processing biases, exhibit variability across different emotional disorders, aligning with the content specificity hypothesis.

Huibers and colleagues (2021) put forth a hypothetical model aimed at addressing the existing criticism in current research regarding the lack of experimental designs to assess the causal effects of putative mechanisms on treatment outcomes. Their proposal focuses on evaluating common procedures used in cognitive-behavioral therapy (CBT) to determine which of these mechanisms directly or causally impact symptoms of anxiety and depression. Previous

studies have established a relationship between negative automatic thoughts and the occurrence of anxiety and depression, with a higher frequency of negative automatic thoughts being associated with greater severity of anxiety (Buchmann et al., 2018; Muris et al., 2009; Silk et al., 2019; Niles et al., 2021). According to Huibers and colleagues (2021), cognitive restructuring is the proposed mechanism through which the reduction in negative automatic thoughts contributes to the alleviation of symptoms related to anxiety and depression.

### Cognitive Restructuring

A potential way of decreasing negative automatic thoughts is by cognitive restructuring. cognitive restructuring is defined as structured, goal-directed, and collaborative intervention strategies that focus on the exploration, evaluation, and substitution of the maladaptive thoughts, appraisals, and beliefs that maintain psychological disturbance.

Cognitive Restructuring seek to alleviate psychological distress through altering what we think about as well as the way we interpret and think about our experiences or the situation we are in (Beck et al. 1979; Clark 1999). In cognitive restructuring, the individual must confront previously avoided or suppressed thoughts. The processes involved in cognitive restructuring, such as monitoring, stating, and challenging cognitions, serve as a form of exposure to the aversive material and require a willingness to experience it (Arch and Crask, 2008). Through this process, individuals learn to view their thoughts not as unchangeable truths, but rather as hypotheses to be evaluated logically and based on personal experience. Cognitive restructuring is seen as intervening early in the emotion generating process by altering how we interpret and evaluate the emotionally relevant circumstances, this perspective shares similarities with the concept of cognitive diffusion, as it creates a separation between the person and their thoughts, promoting greater awareness of present experiences (Hofmann and Asmundson, 2008).

Cognitive restructuring involves changing negative thoughts and emotions to more positive and productive ones(J. S. Beck & Beck, 2011).). This can be done through reappraising emotions, focusing on positive aspects, replacing irrational thoughts with rational ones, distraction, and distancing from negative thoughts (Gross, 1988; Barlow et al., 2011; Crake and Barlow 2007; Ellis, 1962, Fennel 1986; Beck, 1970; Amos, 2008). The process is seen in both clinical research and basic research and can be achieved through various techniques.

In a study conducted by Hofmann in 2004, a total of 90 individuals with social anxiety were randomly assigned to three different groups: group cognitive-behavioral therapy (CBT), exposure therapy without cognitive restructuring, or a wait list control. The results indicated that both the CBT and exposure therapy groups showed comparable improvement in symptoms immediately after treatment. However, only the CBT group displayed sustained symptom improvement even after the treatment had ended. This suggests that cognitive restructuring, which involves identifying and modifying maladaptive beliefs, may play a critical role in effectively treating social anxiety disorder. Furthermore, A study investigated the effectiveness of cognitive restructuring in reducing pain intensity and its association with demographic variables in cancer patients (Jan et al., 2022). Cognitive restructuring had a significant impact on reducing pain in cancer patients and could help alleviate pain-related issues. It is an appropriate intervention to address symptoms in cancer patients, indirectly impacting their cancer treatment. Wolgast and colleagues (2013) examined the concept of cognitive restructuring from well-established measures that aim to measure cognitive restructuring. The authors utilized cognitive emotion regulation questionnaire (CERQ) along with emotional regulation questionnaire (ERQ) to create distinct factors of cognitive restructuring specifically the three that are constructive refocusing, cognitive reappraisal and distractive refocusing.

Constructive Refocusing prompts clients to perceive their emotional experience as a singular moment in time, urging them to adopt a broader temporal perspective when assessing their current emotional state. By doing so, it enables clients not only to embrace the present moment rather than being preoccupied with the past or future, as emphasized in mindfulness cognitive therapy, but also to perceive the present as a mere fragment within the larger continuum of their lifespan. Constructive refocusing involves redirecting one's attention towards a positive active rather dwelling on the stressor. While cognitive reappraisal involves changing the way one think about a stressor in order to diminish the impact of the stressor. Typically, individuals would be asked to reframe the stressor as a challenge rather than a threat. Distractive refocusing involves taking one's mind off the stressor by focusing onto unrelated activity.

In light of Beck's cognitive theory of anxiety and depression, the present study seeks to delve into the potential mechanisms underlying the reduction of anxiety symptoms. While acknowledging the well-established link between the decrease in negative automatic thoughts and anxiety reduction, this research aims to go beyond this association and identify the precise components of cognitive restructuring that contribute to the alleviation of anxiety. By elucidating the specific aspects of cognitive restructuring that facilitate anxiety reduction, this investigation intends to enhance our understanding of the underlying processes and provide valuable insights for therapeutic interventions.

In conclusion, the effectiveness of mindfulness interventions for reducing anxiety among individuals with anxiety disorders remains a topic of ongoing research and debate. Previous studies have produced mixed results, with some demonstrating positive outcomes while others report limited efficacy, especially when compared to cognitive-behavioral therapy. However, recent research has shown promising results, particularly in relation to MBSR and MBCT.

Moreover, dosage and frequency of mindfulness interventions appear to play a significant role in their effectiveness, with larger doses and longer durations generally producing more substantial benefits. The rise of internet and app-based mindfulness interventions has also provided a novel avenue for anxiety management. Several studies support the effectiveness of mobile applications in reducing anxiety symptoms, and comparisons with in-person interventions have shown promising results. Among these apps, Sanvello stands out as a commercially available app that incorporates cognitive restructuring, which has been shown to play a crucial role in the reduction of anxiety symptoms.

Theoretical justification based on Beck's cognitive theory underscores the importance of cognitive restructuring in anxiety reduction. By modifying negative thoughts and beliefs, individuals can alleviate psychological distress and reduce anxiety. This process has shown promise in various studies, particularly when combined with mindfulness practices. While mindfulness interventions and cognitive restructuring hold great potential for anxiety reduction, more research is needed to understand the specific mechanisms underlying their effects. Further studies with larger sample sizes and more robust experimental designs are necessary to identify the optimal dosage and duration of mindfulness interventions and to establish their comparative effectiveness with other treatments. Overall, the field of mindfulness and anxiety is evolving, and the evidence suggests that these interventions hold promise in reducing anxiety symptoms. However, to fully harness their potential, continued research and refinement of these approaches are essential to provide individuals with effective and evidence-based strategies to manage anxiety and improve their overall well-being.

## **CHAPTER 3: Methodology**

### **Participants**

Analyses were conducted on a sample of 289 individuals enrolled in a predominately first year-level college course (17 to 42 years old, 59.9% female) in health-sciences at Michigan State University. This sample was drawn from the 314 individuals enrolled in the course, with 25 individuals excluded from analysis either as a result of complete in attendance in the course during the study period or opting out of their data being available for research use. See Fig.1 for CONSORT flow diagram of enrollment.

### **Study Design**

Data were collected during the Spring 2023 academic semester with the pretest assessments collected approximately 37 days following the February 13<sup>th</sup> mass-shooting incident at Michigan State University which resulted in the deaths of 3 students and the injury of 5 additional students. For context regarding the environmental trauma/stressor, during the 3-hour incident, students were instructed by campus authorities to shelter in place with a directive to “run, hide, fight” as the assailant went building-to-building across campus (Moran et al., 2023). During this time, reports of potential multiple assailants were being broadcast over publicly streamed police radio channels and no location on campus was deemed to be a safe location. Thus, mass confusion ensued as police entered buildings with weapons drawn and instructed students to vacate the premises and flee across campus to find another location to “run, hide, fight” (Moran et al., 2023). The experimental procedures used in this study adhered to the approved protocols of the Michigan State University Human Research Protection Program, ensuring compliance with relevant guidelines and regulations pertaining to the involvement of human subjects. Demographic data are provided in Table 1.

## Primary Outcomes

*State-Trait Anxiety Inventory:* Trait anxiety was assessed using the Trait scale of the Spielberger State-Trait Anxiety Inventory (STAI) (Spielberger et al., 1970). The questionnaire comprised twenty statements assessing how individuals "generally feel." The possible trait anxiety scores range from 20 to 80, with scores above 45 reflecting high anxiety levels (Kayikcioglu et al., 2017). The reliability and validity of the STAI have been well reported, with a Cronbach's alpha of 0.9 for reliability and a validity coefficient of 0.85 for Trait Anxiety (Vitasari et al., 2011). Meta-analytic findings indicate the test-retest reliability to be 0.9 for trait anxiety (Barnes et al., 2002).

*Perceived Stress Scale –4 Item version:* Chronic stress was assessed using the Perceived Stress Scale-4 (PSS-4) (Cohen et al., 1983). The questionnaire consisted of four items to capture the frequency of stress-related thoughts and feelings experienced over the past month. The possible scores range from 0 to 16, with higher scores indicating higher perceived chronic stress levels. The PSS-4 demonstrates sufficient internal consistency of  $\alpha = .72$  as a concise 4-item scale (Vallejo et al., 2018) and is considered as a reliable and valid instrument for assessing perceived chronic stress levels (Martoufzadeh et al., 2018; Lee, 2012).

## Secondary Outcomes Examined as Potential Mediators

*Emotion Regulation Questionnaire:* Cognitive reappraisal was assessed using the Emotion Regulation Questionnaire (ERQ-10) (Gross & John, 2003). The ERQ-10 is a 10-item scale that measures participants' tendency to regulate their emotions (e.g., "I control my emotions by changing the way I think about the situation I'm in"). Items are scored on a scale from 1 (strongly disagree) to 4 (neutral) to 7 (strongly agree) with a higher number indicating better cognitive reappraisal. The construct of cognitive reappraisal thus reflects traditional



cognitive behavioral therapy views related to changing the appraisals of the emotion-eliciting stimulus or situation. Cognitive reappraisal demonstrates adequate internal consistency in all studied samples (Cronbach's alpha: .82–.85) (Gross & John, 2003).

*Cognitive Emotional Regulation Questionnaire:* Constructive refocusing and distractive refocusing were assessed using the Cognitive Emotional Regulation Questionnaire (CERQ-18) which is designed to identify how individuals cope with adverse events through cognitive strategies (Garnefski & Kraaij, 2006). The construct of constructive refocusing reflects how the function or consequence of a situation are reframed/reinterpreted, as such this construct was quantified using the Refocus on Planning, Positive Reappraisal, and Putting into Perspective subscales of the Cognitive Emotional Regulation Questionnaire (Wolgast, Lundh, & Viborg, 2013). These subscales included prompts following the statement “when experiencing strong threatening or stressful life events, how often do you think in the following manner” such as “I think about how to change the situation”, “I think about a plan of what I can do best”, “I think I can learn something from the situation”, “I think that it hasn’t been too bad compared to other things.”

The construct of distractive refocusing reflects avoidance-related strategies to dissociate from the situation, as such this construct was quantified using the Positive Refocusing subscale of the Cognitive Emotional Regulation Questionnaire (Wolgast, Lundh, & Viborg, 2013). This subscale includes prompts following the statement “when experiencing strong threatening or stressful life events, how often do you think in the following manner” such as “I think of pleasant things that have nothing to do with it” and “I think of something nice instead of what has happened.” The reliability for constructive refocusing ranges from 0.82- 0.83 while distractive refocusing ranges from 0.73- 0.75 (Ceroni et al., 2022). The validity for constructive

refocusing ranges from 0.61-0.72 with distractive refocusing ranging from 0.55-0.76 (Dominiques et al., 2023).

*Autonomic Thoughts Questionnaire:* Negative automatic thoughts were assessed using the 8-item version of the Automatic Thoughts Questionnaire (ATQ-8) (Ruiz et al., 2020). The ATQ-8 employs a Likert-type scale (1 = not at all, 5 = all the time) to measure the frequency of negative thoughts (e.g., “I’m no good”, “I feel so helpless”) experienced during the past week, with higher scores indicating a higher frequency of negative automatic thoughts. The internal consistency across samples is adequate, with alpha and omega values of .89 (Ruiz et al., 2020).

#### Process Evaluation

*Training:* The course instructors received training materials, including a slide presentation and laboratory assignment, which described mindfulness and its benefits, and provided an example of a mindfulness breathing technique in all laboratory sessions. Additionally, the first author (OKE) and the course instructors met to discuss the weekly implementation of the mindfulness application in the classroom.

*Fidelity:* To evaluate the extent to which the intervention was delivered as intended, fidelity was assessed by the process evaluator (OKE). Fidelity was assessed based on NIH behavior change consortium guidelines (Bellg et al., 2004; Resnick et al., 2005) for reporting mindfulness-based intervention trials. A checklist comprising items targeting treatment components from design to enactment was used at the end of the intervention. The treatment fidelity for this study is provided in Table 3.

#### Process Evaluation Outcomes Examined as Potential Moderators

*Implementation:* The evaluation of implementation took place weekly during designated sessions of the course. Implementation was quantified by calculating the number of weeks in

which participants reported mindfulness practice, relative to the total four-week duration of the intervention.

*Dose:* The intervention dose received was calculated from self-report measures. Participants were asked weekly to report the number of minutes they spent engaging in mindfulness practice during the preceding week. Each week, participants were instructed to select a range corresponding to their practice duration. The options were as follows: 1-29 minutes, 30-59 minutes, 60-89 minutes, 90-119 minutes, 120-149 minutes, 150-199 minutes, and more than 200 minutes. To enhance reporting accuracy, participants in the MBCT group were provided with weekly instructions on determining the duration of their mindfulness practice using the Sanvello application. Dose was quantified as the mean weekly duration of mindfulness practice engaged in.

*Quality:* To evaluate the quality of the intervention we employed an assessment framework encompassing acceptability, appropriateness, and feasibility. At the conclusion of the intervention, these dimensions were assessed using a Likert type scale, ranging from 1 (Completely Disagree) to 5 (Completely Agree), with four items for each measure. Higher scores were indicative of greater acceptability, appropriateness, and feasibility of the intervention (Proctor et al., 2011). Despite the absence of established cut-off scores for interpretation, insight into qualifying participant's perceptions of the intervention was provided through the method of Weiner et al. (2017) who employed an approach wherein the weighted assignments were collapsed into intervals (e.g., Completely disagree is reflected by scores below 20%, Disagree is reflected by scores from 20 to 39%, Neither agree nor disagree is reflected by scores from 40 to 59%, Agree is reflected by scores from 60 to 79%, and Completely agree is reflected by scores above 79%). The Acceptability of the Intervention measure assessed how much the intervention

appealed to participants (e.g., “this intervention meets my approval”, “this intervention is appealing to me”, “I like the intervention”, “I welcome the intervention”). The Intervention Appropriateness measure evaluated the suitability of the intervention for the target population and environment (e.g., “this intervention is fitting”, “this intervention seems suitable”, “this intervention seems applicable”, “this intervention seems like a good match”). The Feasibility of the Intervention measure characterized the perceived ease of implementing the intervention (e.g., “this intervention seems implementable”, “this intervention seems possible”, “this intervention seems doable”, and “this intervention seems easy to use”).

### Procedure

Using a cluster-randomized positive control design, participants engaged in a 4-week mindfulness intervention as a part of a predominately first year level college course in the aftermath of a school-shooting. Each of the sections of the course were randomly assigned to either the MBCT group or positive control, which ran in parallel for the duration of the study. The MBCT group utilized Sanvello (Sanvello Health) — a free mindfulness-based cognitive therapy smartphone application. Participants were encouraged to practice mindfulness daily through the application program "Braving Anxiety," which consisted of 35 modules. The anxiety management program consists of the same 5 subdomains such as 1) Watch, 2) Read, 3) Listen, 4) Plan, 5) Listen – Mindfulness practice.

For example, the introductory day consisted of 1) *Watch* “How anxiety works”: Participants engaged in a brief visual presentation elucidates anxiety's intricacies. 2) *Read* “The anxiety loop” - which delves into the cyclic nature of anxiety and its impact on cognitive processes, emotions, and behaviors, highlighting their interdependent relationship. 3) *Listen* “Signs and Symptoms” - participants engaged in an auditory presentation that enhances their ability to identify prevalent

signs and symptoms associated with anxiety, providing a nuanced understanding of their potential occurrence. 4) *Plan* “Your anxiety goals” - through structured guidance, individuals were prompted to outline their anxiety goals within the designated space provided, incorporating the utilization of the SMART principle to optimize goal-setting efficacy. 5) *Listen* “Calming Breathing”- Participants were presented with an auditory resource guiding them through mindfulness practices, explicitly emphasizing the importance of integrating such techniques during moments of heightened anxiety.

Participants in the positive control group were instructed to engage in the utilization of the Mindfulness-Based Stress Reduction (MBSR) breathing technique. Participants were instructed to set a timer for 5 minutes in order to engage in mindfulness breathing. Comprehensive instructions were provided during the initial laboratory time, elucidating the method by which participants were to direct their attention towards their breath. Moreover, participants were encouraged to passively observe their thoughts and feelings without making judgements or assigning value to them as anything other than brief mental events, to subsequently redirect their focus back to their breathing. Participants were advised to integrate this technique into their daily lives as a means to alleviate anxiety and stress. In the subsequent weeks, participants were asked to report the frequency of their mindfulness practice over the past week.

All eight sections of the course (4 MBCT and 4 positive control) were provided with a presentation describing mindfulness and its role in health prior to receiving specific instruction on their assigned mindfulness practice. Prior to receiving training on mindfulness practices and again following the 4-week intervention period, participants completed the State-Trait Anxiety Inventory (Spielberger et al., 1970), the Perceived Stress Scale (Cohen et al., 1983), the Emotion

Regulation Questionnaire (Gross & John, 2003), the Cognitive Emotional Regulation Questionnaire (Garnefski & Kraaij, 2006), and the Automatic Thoughts Questionnaire (Ruiz et al., 2020). Intervention fidelity and quality were assessed in the MBCT group following the 4-week intervention period.

### Statistical Analysis

All data analyses were performed in R Version 4 (R Core Team, 2019) utilizing a familywise alpha level of  $p = 0.05$ . Analysis of the primary outcomes (trait anxiety and chronic stress) were conducted using a 2 (Group: MBCT, positive control)  $\times$  2 (Time: pre-test, posttest) univariate multi-level model including the random intercept for each participant to determine the efficacy of a 4-week MBCT (Aim 1). Additional random intercepts associated with cluster (course section), demographic characteristics, participant-by-mode, and participant-by-time interactions were considered but were not identified as statistically relevant (i.e.,  $p < 0.05$ ). Potential confounders were examined for inclusion in the multi-level modeling approach as additional random intercepts associated with cluster (course section), demographic characteristics, participant-by-mode, and participant-by-time interactions. However, as none of these were identified as statistically relevant (i.e.,  $p < 0.05$ ), they were excluded from the modeling approach. The multi-level model analyses were performed using the Rmimic (Pontifex, 2022) package which provides a standardized implementation wrapper and automated post-hoc decompositions utilizing the lme4 (Bates et al., 2015), lmerTest (Kuznetsova et al., 2017), and emmeans (Lenth et al., 2017) packages in R (R Core Team, 2019) with Kenward-Roger degrees of freedom approximations and Benjamini-Hochberg false discovery rate control = 0.05 for post-hoc decompositions. Cohen's  $f^2$  and  $d$  with 95% confidence intervals were computed as standardized measures of effect size, using appropriate variance corrections for within-subject

( $d_{rm}$ ) comparisons (Lakens, 2013). Given a sample size of 289 participants and beta of 0.20 (i.e., 80% power), the present research design theoretically had sufficient sensitivity to detect conventional t-test differences exceeding  $d = 0.16$  (with a two-sided alpha) as computed using G\*Power 3.1.2 (Faul et al., 2007).

Analysis of secondary outcomes (constructive refocusing, distractive refocusing, cognitive reappraisal, and negative automatic thoughts) as potential mediators for explaining the relationship between the changes in primary outcomes (trait anxiety and chronic stress) as a function of group were conducted separately using a two-step process. First hierarchical linear regression analyses were performed using a forward stepwise approach based upon Akaike Information Criterion (Akaike, 1974) to determine if any descriptive factors (i.e., age, biological sex, ethnicity, socioeconomic status, and years of education) should be included in the models. No descriptive characteristics improved the model fit between Group and the change in Trait Anxiety. Age was observed to improve the model fit between Group and the change in Chronic Stress and was thus included as a covariate. All variables and analyses residuals were screened for normality and homoscedasticity using histograms, Q–Q plots, Shapiro–Wilk tests (Shapiro & Wilk, 1965), and Studentized Breusch-Pagan tests (Koenker, 1981), and no data transformations were required or applied. Next, mediation analyses were performed using the Rmimic (Pontifex, 2022) package which provides a standardized implementation wrapper around the mediation (version 4.4.7; Tingley et al., 2014) package in R with unstandardized indirect effects computed using 1,000 nonparametric bootstrapped samples.

Analysis of intervention process evaluation outcomes (Implementation, Dose, Quality [acceptability, appropriateness, and feasibility]) as potential moderators for explaining the change in primary outcomes (trait anxiety and chronic stress) in response to the MBCT

intervention were conducted using correlation coefficients. This analysis was repeated, examining Implementation and Dose as intervention process evaluation outcomes as potential moderators for explaining the change in primary outcomes (trait anxiety and chronic stress) in response to the positive control intervention. Analyses were performed using the Rmimic (Pontifex, 2022) package which provides a standardized implementation wrapper around the WRS2 (Mair, Wilcox, & Patil, 2022) package in R to obtain bivariate robust 20.0%-bend correlation coefficients. This approach provides better estimates of the true association between variables by downweighting the potential impacts of pseudo-outliers and highly influential individual data points (Pernet, Wilcox, & Rousselet, 2013).



## CHAPTER 4: Results

Although there were no significant differences between the MBCT group and the positive control group with regard to socioeconomic status,  $p = 0.15$ ; the MBCT group was observed to be slightly older ( $19.9 \pm 2.4$  years) and have more education ( $13.9 \pm 1.0$  years) than the positive control group (age:  $19.4 \pm 1.6$ ; education:  $13.4 \pm 0.8$ ), Mann–Whitney  $U$ 's  $\geq 6963.0$ ,  $Z$ 's  $\geq 4.9$ ,  $p$ 's  $< 0.001$ ,  $r$ 's  $= 0.29$ . Demographic data are provided in Table 1.

Primary outcomes examining the efficacy of a 4-week MBCT intervention, relative to a positive control group

*Trait Anxiety:* Analysis revealed a main effect of Time,  $F(1, 251.6) = 13.2$ ,  $p < 0.001$ ,  $f^2 = 0.59$  [95% CI: 0.40 to 0.85], which was superseded by a Group  $\times$  Time interaction,  $F(1, 251.6) = 7.2$ ,  $p = 0.008$ ,  $f^2 = 0.32$  [95% CI: 0.19 to 0.49]. Post-hoc decomposition of the Group  $\times$  Time interaction was conducted by examining the effect of Time within each Group. For the MBCT group, the difference between posttest ( $45.5 \pm 5.1$ ) and pretest ( $47.4 \pm 4.5$ ) was statistically significant;  $t(242) = 4.7$ ,  $p < 0.001$ ,  $d_{rm} = 0.39$  [95% CI: 0.23 to 0.56]. However, no significant differences were observed between pretest ( $47.1 \pm 4.5$ ) and posttest ( $46.9 \pm 4.6$ );  $t(259) = 0.6$ ,  $p = 0.52$ ,  $d_{rm} = 0.06$  [95% CI: -0.12 to 0.24] for the positive control group. Secondary post-hoc decomposition of the Group  $\times$  Time interaction was conducted by examining the effect of Group within each Time. At pretest, no significant differences were observed between the positive control group and the MBCT group;  $t(413) = 0.3$ ,  $p = 0.7$ ,  $d_s = 0.04$  [95% CI: -0.19 to 0.27]. At posttest, the difference between the positive control group and the MBCT group was statistically significant;  $t(453) = 2.2$ ,  $p = 0.025$ ,  $d_s = 0.29$  [95% CI: 0.04 to 0.55]. See Figure 2a.

*Chronic Stress:* Analysis revealed a main effect of Time,  $F(1, 243.4) = 38.3$ ,  $p < 0.001$ ,  $f^2 = 0.77$  [95% CI: 0.54 to 1.09], which was superseded by a Group  $\times$  Time interaction,  $F(1, 243.4)$

$= 9.2, p = 0.003, f^2 = 0.19$  [95% CI: 0.09 to 0.30]. Post-hoc decomposition of the Group  $\times$  Time interaction was conducted by examining the effect of Time within each Group. For the MBCT group, the difference between pretest ( $8.6 \pm 2.6$ ) and posttest ( $7.5 \pm 2.4$ ) was statistically significant;  $t(236) = 6.9, p < 0.001, d_{rm} = 0.47$  [95% CI: 0.33 to 0.61]. The positive control group also exhibited a statistically significant, albeit smaller, difference between pretest ( $8.6 \pm 2.7$ ) and posttest ( $8.2 \pm 3.0$ );  $t(248) = 2.1, p = 0.036, d_{rm} = 0.15$  [95% CI: 0.01 to 0.29]. Secondary post-hoc decomposition of the Group  $\times$  Time interaction was conducted by examining the effect of Group within each Time. At pretest, no significant differences were observed between the positive control group and the MBCT group;  $t(365) = 0.1, p = 0.9, d_s = 0.01$  [95% CI: -0.22 to 0.24]. At posttest, the difference between the positive control group and the MBCT group was statistically significant;  $t(405) = 2.3, p = 0.022, d_s = 0.30$  [95% CI: 0.04 to 0.55]. See Figure 2b. Secondary outcomes examined as potential mediators of the anxiolytic and stress-reducing effects of the mindfulness-based cognitive therapy intervention

*Trait Anxiety and Cognitive Reappraisal:* Analysis observed that the relationship between Group (the positive control group vs the MBCT group) and changes in trait anxiety was not mediated by changes in cognitive reappraisal; *Proportion Mediated* = -2.9% [95% CI: -19.3% to 6.8%]; *Average Causal Mediation Effect* = 0.04 [95% CI: -0.05 to 0.15],  $p = 0.46$ ; *Average Direct Effect* = -1.26 [95% CI: -2.21 to -0.33],  $p = 0.006$ .

*Trait Anxiety and Constructive Refocusing:* Analysis observed that changes in constructive refocusing accounted for -12.9% [95% CI: -49.1% to -0.6%] of the relationship between Group and changes in trait anxiety; *Average Causal Mediation Effect* = 0.16 [95% CI: 0.01 to 0.35],  $p = 0.032$ ; *Average Direct Effect* = -1.39 [95% CI: -2.29 to -0.52],  $p < 0.001$ ). The directionality of the effects suggests that suppression may be occurring rather than mediation,

such that including changes in constructive refocusing within the model appears to increase the strength of the relationship between Group and changes in trait anxiety rather than eliminate it.

*Trait Anxiety and Distractive Refocusing:* Analysis observed that the relationship between Group and changes in trait anxiety was not mediated by changes in distractive refocusing; *Proportion Mediated* = -1.8% [95% CI: -17.4% to 12.6%]; *Average Causal Mediation Effect* = 0.02 [95% CI: -0.11 to 0.15],  $p = 0.7$ ; *Average Direct Effect* = -1.25 [95% CI: -2.16 to -0.34],  $p = 0.006$ .

*Trait Anxiety and Negative Automatic Thoughts:* Analysis observed that changes in negative automatic thoughts accounted for 28.0% [95% CI: 4% to 121.2%] of the relationship between Group and changes in trait anxiety; *Average Causal Mediation Effect* = -0.39 [95% CI: -0.89 to -0.07],  $p = 0.01$ ; *Average Direct Effect* = -0.99 [95% CI: -2.07 to 0.12],  $p = 0.092$  (see figure 3.iv.a).

*Chronic Stress and Cognitive Reappraisal:* Analysis observed that the relationship between Group and changes in chronic stress was not mediated by changes in cognitive reappraisal; *Proportion Mediated* = 8.7% [95% CI: -5.0% to 29.7%]; *Average Causal Mediation Effect* = -0.06 [95% CI: -0.17 to 0.03],  $p = 0.21$ ; *Average Direct Effect* = -0.58 [95% CI: -1.00 to -0.21],  $p = 0.002$ ), after controlling for the effects of Age.

*Chronic Stress and Constructive Refocusing:* Analysis observed that the relationship between Group and changes in chronic stress was not mediated by changes in constructive refocusing; *Proportion Mediated* = 7.7% [95% CI: -2.0% to 32.6%]; *Average Causal Mediation Effect* = -0.05 [95% CI: -0.16 to 0.01],  $p = 0.16$ ; *Average Direct Effect* = -0.59 [95% CI: -1.01 to -0.17],  $p = 0.01$ ), after controlling for the effects of Age.

*Chronic Stress and Distractive Refocusing:* Analysis observed that the relationship between Group and changes in chronic stress was not mediated by changes in distractive refocusing; *Proportion Mediated* = 9.5% [95% CI: -1.3% to 35.3%]; *Average Causal Mediation Effect* = -0.06 [95% CI: -0.15 to 0.00],  $p = 0.072$ ; *Average Direct Effect* = -0.58 [95% CI: -1.00 to -0.16],  $p = 0.014$ ), after controlling for the effects of Age.

*Chronic Stress and Negative Automatic Thoughts:* Analysis observed that changes in negative automatic thoughts accounted for 44.9% [95% CI: 18.0% to 133.1%] of the relationship between Group and changes in chronic stress; *Average Causal Mediation Effect* = -0.31 [95% CI: -0.53 to -0.12],  $p < 0.001$ ; *Average Direct Effect* = -0.38 [95% CI: -0.86 to 0.09],  $p = 0.12$ ), after controlling for the effects of Age (see figure 3.iv.b).

Process evaluation outcomes examined as potential moderators of the anxiolytic and stress-reducing effects of the MBCT intervention

*Fidelity:* This investigation ensured robustness in research design by grounding our intervention in the cognitive theory of anxiety and depression. Transparent communication was maintained among investigators, facilitators, and the first author. Facilitators were formally trained and received feedback to refine their delivery techniques. Participant engagement was monitored weekly through Qualtrics surveys and program quality was assessed from participant perspectives. Additionally, data on participants' daily mindfulness practices was collected to provide insight into the practical application of treatment-related skills. This allowed for assessment of engagement and practical use of learned techniques.

*Implementation:* The MBCT group exhibited greater implementation ( $79.2 \pm 25.0$  %) relative to the positive control group ( $64.3 \pm 28.3$  %),  $t(287) = 4.8$ ,  $p < 0.001$ ,  $d_s = 0.56$  [95% CI: 0.33 to 0.80].

*Dose:* The MBCT group exhibited a higher dose ( $20.5 \pm 24.5$  minutes) of the intervention than the positive control group ( $12.8 \pm 15.9$  minutes),  $t(257.6) = 3.2$ ,  $p = 0.002$ ,  $d_s = 0.38$  [95% CI: 0.14 to 0.61].

*Quality:* Perceptions of the acceptability of the intervention were skewed positively with 21.3% of the MBCT group completely agreeing and 70% of the MBCT group agreeing. Only 7.3% of the MBCT group was ambivalent and 1.3% completely disagreed with the acceptability of the intervention. Perceptions of the appropriateness of the intervention and the feasibility of the intervention indicated that 78.7% of the MBCT group completely agreeing and 20.7% agreeing. Only 0.7% of the MBCT group was ambivalent regarding the appropriateness and feasibility of the intervention.

*Trait Anxiety:* Correlational analysis of the change in trait anxiety with process evaluation outcomes in the MBCT group revealed a weak positive relationship for both intervention appropriateness,  $r = 0.21$  [95% CI: 0.06 to 0.37],  $p = 0.009$ , and intervention feasibility,  $r = 0.20$  [95% CI: 0.03 to 0.34],  $p = 0.017$ ; such that greater evaluation of appropriateness and feasibility of the MBCT intervention was associated with smaller reductions in trait anxiety. Correlational analysis of the change in trait anxiety with process evaluation outcomes in the positive control group revealed no significant relationships ( $|r's| < .019$ ,  $p's > 0.8$ ). See Table 2.

*Chronic Stress:* Correlational analysis of the change in chronic stress with process evaluation outcomes in the MBCT group revealed no significant relationships ( $|r's| < .06$ ,  $p's > 0.4$ ). Correlational analysis of the change in chronic stress with process evaluation outcomes in the positive control group revealed a weak positive relationship for dose,  $r = 0.24$  [95% CI: 0.08 to 0.39],  $p = 0.005$ , such that greater weekly duration was associated with smaller reductions in chronic stress. See Table 2.

## CHAPTER 5: Discussion

The primary aim of the present investigation was to determine the efficacy of a 4-week MBCT intervention delivered through the Sanvello smartphone application for reducing trait-level anxiety and chronic stress within the context of an entry-level collegiate course. To answer this question, trait anxiety and chronic stress were assessed prior to and following a 4-week intervention period where students were instructed to use either the Sanvello smartphone application or a MBSR-based breathing technique as a part of the course following a mass-shooting incident using a cluster-randomized approach. Results from the present investigation replicate the extant literature on MBCT-based interventions for reducing anxiety and in-particular, the findings by Moberg and colleagues (2019) who similarly assessed the effects of the Sanvello platform over the course of a 30-day intervention. Specifically, replicating Moberg et al.'s (2019) finding (cohen's  $d = 0.4$ ), the present investigation observed small to moderate reductions in trait anxiety (cohen's  $d_{\text{m}} = 0.39$  [95% CI: 0.23 to 0.56]) from pre- to posttest in individuals randomized to the MBCT-based group that used the Sanvello platform for a 4-week period. Thus, despite utilizing a more generalized sample of students enrolled in a predominately first year level college course, who may not necessarily have been motivated *a priori* to seek out MBCT-based therapy; the relative consistency of the findings is promising and is in-line with similar effect sizes observed in response to in-person mindfulness-based intervention programs (in-person standard MBCT approaches on reducing trait-level anxiety (hedges  $g = 0.466$ ) (Bamber and Morpeth, 2019).

The present investigation also replicated Moberg et al.'s (2019) finding of reductions in chronic stress (cohen's  $d = 0.46$ ). Specifically, following the 4-week intervention period individuals randomized to the MBCT-based group that used the Sanvello platform exhibited

moderate reductions in perceptions of chronic stress (cohen's  $d_{rm} = 0.47$  [95% CI: 0.33 to 0.61]) from pre- to posttest. Although, such a moderate effect size is somewhat smaller than meta-analytic findings from traditional mindfulness-based interventions (hedges  $g = 0.83$  [95% CI: 0.58 to 1.08]) (Khoury, Sharma, Rush, Fournier, 2015); it is important to note that the end of the 4-week intervention period in the present investigation coincided with the end of the academic term. Thus, it may be that the stress-reducing effects of the intervention were suppressed to some extent due to final exams.

From a programmatic perspective, it may also be that the smaller effect sizes for stress reduction resulting from the Sanvello platform — in comparison to traditional mindfulness-based interventions — were the result of the particular modules within the application that participants were instructed to complete. Within the present investigation, participants were asked to utilize the 35 modules associated with the application program "Braving Anxiety;" as such the specific content within the modules was oriented to target anxiety rather than chronic stress which may account for the relatively smaller effect sizes for the stress-reducing effects of the application. Further, of particular interest is that the positive control group also appear to have incurred reductions in chronic stress over the 4-week intervention (cohen's  $d_{rm} = 0.15$  [95% CI: 0.01 to 0.29]). While the positive control group did not engage in mindfulness-based stress reduction *per se*, the basic training provided to this group did employ a classic MBSR breathing technique and associated prompt. However, unlike the Sanvello smartphone application which provided recurring feedback and guidance; individuals in the positive control group did not receive repeated instruction over the course of the intervention period beyond encouragement to continue to practice the breathing technique and mindset. Nevertheless, it appears that even this approach was effective in incurring some small reductions in chronic stress.

It is also important to highlight the observation that the Sanvello smartphone application was associated with anxiolytic and stress reducing effects despite only 20.5 ( $\pm$  24.5) minutes of use per week. Accordingly, as two-hour in-person mindfulness-based intervention programs with experienced, certified mindfulness instructors appear to exhibit similar reductions in trait anxiety (Bamber and Morpeth, 2019) and only slightly more pronounced effects for chronic stress (Khoury, Sharma, Rush, Fournier, 2015); it would appear that the Sanvello smartphone application provides an alternative and accessible intervention that can more easily be deployed across a broader population and implemented into existing curricular and student-support programming. Such an approach may be well-positioned to reduce high levels of trait anxiety and chronic stress among collegiate students, while freeing up both time and resources for clinical practitioners to focus on those students with more dire/urgent needs.

#### Mechanisms

The secondary aim of the present study was to investigate cognitive restructuring domains (cognitive reappraisal, constructive refocusing, and distractive refocusing) and negative automatic thoughts as potential causal mechanisms responsible for the anxiolytic and stress reducing effects of the MBCT intervention. To answer this question, these constructs were assessed before and after the 4-week intervention period; the change in these constructs was examined as potential mediators of the relationship between the changes in trait anxiety and chronic stress as a function of the interventional groups (MBCT vs positive control). Despite the hypothesized causal pathway whereby MBCT interventions incur reductions in mental-health outcomes such as trait anxiety and chronic stress through alterations in cognitive reappraisal, constructive refocusing, and distractive refocusing, findings from the present investigation failed to observe a mediating effect of these constructs on either trait anxiety or chronic stress.



Despite such findings, it is important to highlight that this does not necessarily mean that cognitive reappraisal, constructive refocusing, and distractive refocusing are irrelevant in the context of mindfulness-based interventions inducing anxiolytic and stress-reducing effects. Rather, such a finding may be the result of the Sanvello application's primary emphasis on addressing negative automatic thoughts. While it does incorporate elements of cognitive restructuring, the consistency and intensity with which these are applied appear to be lesser than its focus on negative automatic thoughts. This design choice might explain why, despite our initial hypothesis that the Sanvello app would promote mental well-being through modifications in cognitive reappraisal, constructive refocusing, and distractive refocusing, our findings did not support this. Although considering changes in constructive refocusing as a covariate in the analysis served to increase the relationship between Group and changes in trait anxiety, the mediation analysis observed that constructive refocusing does not appear to be a mediator as it does not account for the effects of the intervention on changes in trait anxiety. Accordingly, these findings align with that of Foa and colleagues (2005), who observed that cognitive restructuring had limited effects on individuals with PTSD and their perceived levels of chronic stress. However, consistent with other investigations, negative automatic thoughts were found to account for nearly 28% of the effect of the intervention on trait anxiety and 45% of the effect of the intervention on chronic stress. Indeed, in their systematic review and meta-analysis, Gu and colleagues (2015) identified negative automatic thoughts as a mediator of the effects of MBCT interventions on depression, anxiety, and stress — yet cautioned their finding as the extant body of evidence lacked active control groups and failed to consider changes in the outcome. Accordingly, the present investigation addresses such limitations to provide further support for tailoring MBCT interventions to specifically target negative automatic thoughts to enhance their

potential anxiolytic and stress-reducing effects.

### Process Evaluation

The final aim of the present study was to determine the extent to which the anxiolytic and stress-reducing effects of the MBCT intervention delivered through the Sanvello platform were moderated by intervention fidelity domains (implementation dose, quality). To answer this question, analyses were conducted examining the relationship between intervention fidelity domains and the changes in trait anxiety and chronic stress within each interventional group. Findings from the present investigation observed no association between the dose or implementation of the MBCT-intervention and the change in trait anxiety. It is important to note that the present investigation relied upon self-reported measures of dose and implementation that were assessed on a weekly basis. Thus, the lack of an association may reflect inaccuracy within the self-report construct. Although such findings stand in contrast to meta-analytic findings by Parson et al. (2017), who observed a small yet positive relationship ( $r = 0.26$ ) between mindfulness dose and intervention outcomes in randomized controlled trials ( $n=28$ ). It's crucial to emphasize that the duration of our intervention might have limited the variability in intervention dosage and implementation, potentially leading to our null findings. Reliance on self-reported measures of usage can introduce biases, and using broad categorizations for dosage can mask nuanced differences.

Furthermore, potential clarification of our null findings is provided by Bamber and Morpeth (2019) who conducted a meta-analysis on college-aged samples. They sought to discern a relationship between mindfulness practice duration and its effect on anxiety. It was hypothesized that such a finding may be the result of the particular time constraints that college students experience; whereby spending greater time in mindfulness practice may exacerbate

perceptions of stress and anxiety as students are not working on other tasks (e.g., papers, projects, studying) (Bamber & Morpeth, 2019). Such an interpretation may also serve to explain why the positive control intervention observed that spending greater time on the MBSR-based breathing technique was associated with smaller reductions in chronic perceptions of stress. However, Bamber and Morpeth (2019) also observed that completing a greater number of total mindfulness sessions — regardless of the duration of the mindfulness session — was associated with a greater anxiolytic effect.

Future scholarly endeavors are requisite to delve into the relationship between the frequency of Sanvello platform usage and its potential efficacy in mitigating trait anxiety and chronic stress among collegiate populations, irrespective of the cumulative duration of the engagement. Simultaneously, the robustness and validity of findings would be greatly enhanced by adopting methodologies that extend beyond self-reported measures. Moreover, the brief duration of our current intervention could have led to a lack of variance in both the intervention dose and its implementation, which might explain a portion of the observed null findings. A critical area for subsequent research would be to evaluate the efficacy of the Sanvello smartphone application when used over a more extended period, such as an 8-to-16-week timeframe (with 16 weeks mirroring a typical collegiate semester). This extended engagement would provide a comparative perspective against our study's concise intervention duration and the traditional 8-week face-to-face intervention methodology.

In regard to intervention quality, the present investigation specifically characterized participant's perceptions of the intervention acceptability, appropriateness, and feasibility; and examined these factors as potential moderators of the anxiolytic and stress reducing effects of using the Sanvello smartphone application. Participants using the Sanvello smartphone

application overwhelmingly considered it to be an appropriate (suitable for the target population and environment) and feasible (perceived ease of use) intervention. Specifically, within the present investigation over 75% of participants rated the appropriateness and feasibility of the intervention above 80% (i.e., completely agree that the Sanvello smartphone application was suitable for the target population and environment and easy to use) and only a single participant rated the appropriateness and feasibility of the intervention below 60%. Perceptions of the intervention acceptability, were somewhat lower with 70% of participants rating the intervention between 60% and 80% acceptable (i.e., agree that the Sanvello smartphone application was appealing to use); and only 9% of participants rating the acceptability of the intervention below 60%.

Nevertheless, participant perceptions of the acceptability, appropriateness, and feasibility of using the Sanvello smartphone application were not found to be associated with the changes in chronic perceptions of stress. Interestingly, the more positively participants rated the appropriateness and feasibility of using the Sanvello smartphone application the smaller the reduction in trait anxiety ( $r \sim 0.2$ ). Speculatively, such a finding may be the result of participants more drawn to using the Sanvello smartphone application progressing further with MBCT-based treatment. The extant literature surrounding standard cognitive behavioral therapies indicates that individuals experience a gradual diminishment of negative automatic thoughts over the course of prolonged treatment, but that these thoughts exhibit a cyclic pattern of dissipation and re-emergence (Castonguay et al., 2010). As such, the efficacy of the intervention may be observed to follow such a similar pattern with individuals earlier in the treatment exhibiting more pronounced effects than those in later stages of treatment. Given the self-paced nature of the Sanvello smartphone application with distinct modules for completion, further insight may be

provided by future investigations specifically characterizing this pattern over the course of module completion. Some caution is warranted in the present finding, however, given the relatively small relationship and minimal variation in participant responding that could have contributed to spurious findings despite using a robust correlation approach. These findings stand in contrast to previous research which has observed an influence of participants' perception of treatment plausibility and expectancy of positive outcomes, indicating a small but significant impact on treatment outcomes in psychological therapies more broadly (Constantino et al., 2011). Nevertheless, the extent of such effects within the context of mindfulness-based interventions remains somewhat inconclusive (Crane et al., 2014; Snippe et al., 2015). Ultimately, the present findings highlight that participants in a predominately first year level collegiate course generally had high perceptions of the acceptability, appropriateness, and feasibility of utilizing the Sanvello smartphone application; even if such metrics of intervention quality did not translate to greater intervention efficacy.

Consistent with aims to improve reporting of mindfulness-based practices, the present investigation also qualified the mindfulness intervention used within the present investigation using the Mindfulness-Based Interventions, a fidelity tool developed by Bellg et al. (2004) and validated by Resnick et al. (2005). This fidelity tool consists of a comprehensive checklist, designed to ensure transparency and accuracy in evaluating the components of fidelity. The checklist encompasses various aspects, including the intervention's design and the training provided to instructors, which was conducted by the first author (OKE). With regard to the intervention design, the present investigation was largely consistent with the extant literature in detailing the treatment fidelity component of the study design (Ketcher et al., 2019). However, a strength of the present investigation was specifically considering a construct framework

perspective for assessing potential underlying mechanisms of the intervention efficacy. The use of the Sanvello smartphone application resulted in qualitatively different training than that employed by typical interventions that require extensive instructor training and recording to effectively deliver the intervention as intended. As such the instructor training was largely centered around application use; as the application has a user-centric interface and given the strong perceptions of usability from participants, it would appear that minimal training is necessary to ensure consistent mindfulness practice using this application. In regard to intervention delivery, the present investigation employed methods that are similar to the extant literature with active control groups ensuring equivalent feedback to both groups (Cherkin et al., 2016; Hoge et al., 2013; Shallcross et al., 2015; Williams et al., 2014; Kristeller et al., 2013). A benefit of the present design was the incorporation of the mindfulness-based intervention within the context of existing curricular programming. As such, the implementation of the intervention was particularly strong. Given the self-paced nature of the Sanvello smartphone application, the enactment of the intervention was characterized by the mean weekly duration of usage which is consistent with the extant literature reporting minutes per week of in-person or at home practice of mindfulness (Geschwind et al., 2012). Accordingly, the fidelity assessment suggests that interventional approach is consistent with that of the extant literature in this area and replicable for future investigations in this area.

## Limitations

Despite the relative strength of the present investigation, utilizing a large sample in a cluster-randomized design with a positive control group; it is important to highlight a number of limitations that represent deliberate choices and future directions. In particular, the present investigation restricted the study sample to only students enrolled in a single predominately

freshman-level college course. Although predominantly first year college-students have been found to exhibit higher levels of trait anxiety than their older and non-college aged peers (Naceanceno et al, 2021); further research is necessary to better understand the extent to which the feasibility and efficacy of using the Sanvello smartphone application may be altered with an older or more diverse sample of collegiate students. It is also important to acknowledge that the sample characteristics of the present investigation pertain to a specific population of college students who had experienced heightened anxiety and stress following the school shooting incident, potentially influencing our study outcomes but nevertheless reflecting a growing segment of school-aged children within the US. Additionally, as the cluster randomization approach assigned the intervention to students based upon their course enrollment (by section); it may be that pre-existing differences in sensitivity to mindfulness-based interventions or pre-exposure to mindfulness practices may have also related to course section enrollment. Although no differences between groups were observed for either trait anxiety or chronic stress at pretest, further research is necessary utilizing full randomization of participants to better account for this possibility.

While the present investigation did not include a follow-up assessment due to the end of the semester, it is worth noting that Morber and colleagues (2018), who utilized the same application, demonstrated that the treatment benefits were sustained for a period of two months following the conclusion of the one-month intervention. Accordingly, future studies may benefit by characterizing the longer-term effects of utilizing the Sanvello smartphone application. In particular, the nature of the application makes it such that individuals could presumably continue to use it well after formal training and monitoring of the intervention is completed with minimal additional burden. In this way, better metrics of the acceptability, appropriateness, and feasibility

of using the application could be assessed by examining the extent to which participants choose to continue to use the application when no longer explicitly assigned to do so. Furthermore, future studies could benefit from conducting longer follow-up assessments beyond the typical two-month period. Evaluating the sustained efficacy of brief MBCT interventions over extended timeframes will provide critical insights into the long-term impact and durability of these interventions. To bridge the gap between efficacy and effectiveness, it is paramount for research to explore the real-world implications of interventions, like the Sanvello app, in varied settings and across diverse populations. Doing so will not only refine our understanding of anxiety and stress interventions but also pave the way for more targeted and effective strategies for promoting mental well-being.

Collectively, the present investigation provides evidence that utilizing the Sanvello smartphone application within the context of existing curricular programming targeted towards predominately first year college students can be an effective means of reducing high levels of trait anxiety and chronic stress in this population. The cost-free platform and wide device compatibility of the Sanvello smartphone application renders it as a highly accessible alternative to traditional in-person MBCT-intervention approaches, enabling students to engage in mindfulness-practice when it best fits their needs and schedules while at the same time reducing potential burden on existing clinical services. Such findings are particularly relevant given evidence that many college counseling centers across the US are under-resourced and operate at total capacity during much of the year (Bailey et al., 2020). Although the Sanvello smartphone application was only perceived as moderately appealing to use — perhaps as a result of integrating it within the context of existing curricular programming; students overwhelmingly considered it to be an appropriate (suitable for the target population and environment) and



feasible (perceived ease of use) intervention. As such, the present findings suggest that student support initiatives to enhance mental health and well-being may be well served by adopting such a platform within the context of first-line treatment and prevention of anxiety and stress within first year college students. Further, by considering potential mechanisms which may underlie the efficacy of MBCT-based interventions; the present investigation highlighted the critical importance of interventions targeting negative automatic thoughts for optimizing their anxiolytic and stress-reducing effects. Student support initiatives seeking to enhance mental health and well-being through diverse programming should prioritize interventions that address negative automatic thoughts, as they play a key role in influencing both anxiety and stress outcomes. Overall, these findings provide valuable insights into the efficacy of utilizing the Sanvello smartphone application, potential mechanistic processes responsible for the efficacy, and insight into the relationship between intervention efficacy and fidelity. Such findings emphasize the importance of considering participants' perceptions and experiences in intervention design and implementation, even if they may not relate to greater intervention efficacy.

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## APPENDIX A: IRB Approval Letter

### **MICHIGAN STATE UNIVERSITY**

#### **EXEMPT DETERMINATION Revised Common Rule**

March 16, 2023

To: Matthew B Pontifex

Re: **MSU Study ID:** STUDY00008121  
**Principal Investigator:** Matthew B Pontifex  
**Category:** Exempt 1  
**Exempt Determination Date:** 3/16/2023  
**Limited IRB Review:** Not Required.

Title: Basic Instructional Program Mindfulness Pilot

This study has been determined to be exempt under 45 CFR 46.104(d) 1.

**Principal Investigator (PI) Responsibilities:** The PI assumes the responsibilities for the protection of human subjects in this study as outlined in Human Research Protection Program (HRPP) Manual Section 8-1, Exemptions.

**Continuing Review:** Exempt studies do not need to be renewed.

**Modifications:** In general, investigators are not required to submit changes to the Michigan State University (MSU) Institutional Review Board (IRB) once a research study is designated as exempt as long as those changes do not affect the exempt category or criteria for exempt determination (changing from exempt status to expedited or full review, changing exempt category) or that may substantially change the focus of the research study such as a change in hypothesis or study design. See HRPP Manual Section 8-1, Exemptions, for examples. If the study is modified to add additional sites for the research, please note that you may not begin the research at those sites until you receive the appropriate approvals/permissions from the sites.

Please contact the HRPP office if you have any questions about whether a change must be submitted for IRB review and approval.

**New Funding:** If new external funding is obtained for an active study that had been determined exempt, a new initial IRB submission will be required, with limited exceptions. If you are unsure if a new initial IRB submission is required, contact the HRPP office. IRB review of the new submission must be completed before new funds can be spent on human research activities, as the new funding source may have additional or different requirements.

**Reportable Events:** If issues should arise during the conduct of the research, such as unanticipated problems that may involve risks to subjects or others, or any



**Office of  
Regulatory  
Affairs  
Human Research  
Protection Program**

4000 Collins Road  
Suite 136  
Lansing, MI 48910

517-355-2180  
Fax: 517-432-4503  
Email: [irb@msu.edu](mailto:irb@msu.edu)  
[www.hrpp.msu.edu](http://www.hrpp.msu.edu)

problem that may increase the risk to the human subjects and change the category of review, notify the IRB office promptly. Any complaints from participants that may change the level of review from exempt to expedited or full review must be reported to the IRB. Please report new information through the study's workspace and contact the IRB office with any urgent events. Please visit the Human Research Protection Program (HRPP) website to obtain more information, including reporting timelines.

**Personnel Changes:** After determination of the exempt status, the PI is responsible for maintaining records of personnel changes and appropriate training. The PI is not required to notify the IRB of personnel changes on exempt research. However, he or she may wish to submit personnel changes to the IRB for recordkeeping purposes (e.g. communication with the Graduate School) and may submit such requests by submitting a Modification request. If there is a change in PI, the new PI must confirm acceptance of the PI Assurance form and the previous PI must submit the Supplemental Form to Change the Principal Investigator with the Modification request (available at <http://msu.edu>).

**Closure:** Investigators are not required to notify the IRB when the research study can be closed. However, the PI can choose to notify the IRB when the study can be closed and is especially recommended when the PI leaves the university. Closure indicates that research activities with human subjects are no longer ongoing, have stopped, and are complete. Human research activities are complete when investigators are no longer obtaining information or biospecimens about a living person through interaction or intervention with the individual, obtaining identifiable private information or identifiable biospecimens about a living person, and/or using, studying, analyzing, or generating identifiable private information or identifiable biospecimens about a living person.

**For More Information:** See HRPP Manual, including Section 8-1, Exemptions (available at <http://msu.edu>).

**Contact Information:** If we can be of further assistance or if you have questions, please contact us at 517-355-2180 or via email at [IRB@msu.edu](mailto:IRB@msu.edu). Please visit <http://msu.edu> to access the HRPP Manual, templates, etc.

**Exemption Category.** The full regulatory text from 45 CFR 46.104(d) for the exempt research categories is included below. <sup>1224</sup>

**Exempt 1.** Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

**Exempt 2.** Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview



procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

- (i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
- (ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
- (iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by 45 CFR 46.111(a)(7).

**Exempt 3.** (i) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

- (A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
- (B) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
- (C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by 45 CFR 46.111(a)(7).

(ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

(iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

**Exempt 4.** Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

- (i) The identifiable private information or identifiable biospecimens are publicly available;
- (ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;
- (iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or
- (iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

**Exempt 5.** Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or



authorities such as sections 1115 and 1115A of the Social Security Act, as amended. (i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

**Exempt 6.** Taste and food quality evaluation and consumer acceptance studies: (i) If wholesome foods without additives are consumed, or (ii) If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

**Exempt 7.** Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by 45 CFR 46.111(a)(8).

**Exempt 8.** Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:

- (i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with 45 CFR 46.116(a)(1) through (4), (a)(6), and (d);
- (ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with 45 CFR 46.117;
- (iii) An IRB conducts a limited IRB review and makes the determination required by 45 CFR 46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and
- (iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

<sup>1</sup>Exempt categories (1), (2), (3), (4), (5), (7), and (8) cannot be applied to activities that are FDA-regulated.

<sup>2</sup> Each of the exemptions at this section may be applied to research subject to subpart B (Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research) if the conditions of the exemption are met.

<sup>3</sup> The exemptions at this section do not apply to research subject to subpart C (Additional Protections for Research Involving Prisoners), except for research aimed at involving a broader subject population that only incidentally includes prisoners.

<sup>4</sup> Exemptions (1), (4), (5), (6), (7), and (8) of this section may be applied to research subject to subpart D (Additional Protections for Children Involved as Subjects in Research) if the conditions of the exemption are met. Exempt (2)(i) and (ii) only may apply to research subject to subpart D involving educational tests or the observation of public behavior when the investigator(s) do not participate in the activities being observed. Exempt (2)(iii) may not be applied to research subject to subpart D.

## **APPENDIX B: Dissertation Funding Source**

### **Dissertation Funding Source**

#### **1.Dissertation Completion Fellowship- 2022/2023**

The Graduate School, Michigan State University,

Funded- \$7,000

*Use: Teaching release to allow time for analysis, writing, and defense preparation*

Table 1. Participants demographic characteristics (mean  $\pm$  SD)

Measure	MBCT	Positive Control
N	150 (95 females)	139 (78 females)
Race	20% nonwhite	16.5% nonwhite
American Indian or Alaska Native	1	0
Asian	6	6
Black or African American	7	5
Native Hawaiian or other Pacific Islander	0	1
Hispanic or Latinx	3	4
White or Caucasian	120	116
Multiracial	13	7
Age (years)	19.4 $\pm$ 1.6	19.9 $\pm$ 2.4
Education (years)	13.9 $\pm$ 1.0	13.4 $\pm$ 0.8
Socioeconomic status	69.0 $\pm$ 15.5	66.6 $\pm$ 16.4
Implementation (% of weeks)	79.2 $\pm$ 25.0	64.3 $\pm$ 28.3
Dose (minutes)	20.5 $\pm$ 24.5	12.8 $\pm$ 15.9



Table 2. Bivariate robust 20.0%-bend correlation matrix for process evaluation outcomes (implementation, Dose, Quality [acceptability, appropriateness, and feasibility]) as potential moderators for explaining the change in primary outcomes (trait anxiety and chronic stress)

	Trait Anxiety	Chronic Stress	Implementation	Dose	Acceptability	Appropriateness
MBCT Intervention						
Trait Anxiety	---					
Chronic Stress	.130	---				
Implementation	-.042	.052	---			
Dose	.152	.015	.020	---		
Acceptability	.122	.067	-.289***	.122	---	
Appropriateness	.213**	-.048	-.210*	.200	.567***	---
Feasibility	.195*	-.046	-.213**	.033	.507***	.772***
Positive Control Intervention						
Trait Anxiety	---					
Chronic Stress	.002	---				
Implementation	-.012	.092	---			
Dose	.019	.239*	.287***	---		

Note: \* indicates  $p < 0.05$ . \*\* indicates  $p < 0.01$ . \*\*\* indicates  $p < 0.001$ .

Table 3. Treatment Fidelity Tool for Mindfulness Based Interventions

Fidelity Component	Item Checklist	Author Comments
<b>Design:</b> ensure a study can adequately test its hypotheses in relation to underlying theory and clinical processes	<ul style="list-style-type: none"> <li>Theoretical/substantive rationale for any adaptations from established MBI</li> <li>MBI and comparison program matched for dosage within and across conditions (e.g., number of sessions, hours per session, number of weeks, days per week)</li> <li>Plan for implementation setbacks (e.g., back-up facilitators)</li> </ul>	<p>1. Cognitive theory of anxiety and depression was utilized for theoretical rational of the study</p> <p>2. The positive control group met the same number of times compared to MBCT</p> <p>3. The execution of the study encountered obstacles arising from a tragic occurrence of a school shooting, which necessitated a strategic shift in order to mitigate the duration of the intervention.</p>
<b>Training:</b> ensure treatment providers are satisfactorily trained to deliver the intervention	<ul style="list-style-type: none"> <li>All facilitators received formal training.</li> <li>All facilitators were observed and received constructive feedback during initial phases</li> </ul>	<p>4. All facilitators met with the first author</p> <p>5. Facilitators were given feedback regularly</p>
<b>Delivery:</b> ensure intervention is delivered as intended	<ul style="list-style-type: none"> <li>All facilitators received ongoing, real-time constructive feedback, and inter-rater reliability assessments to minimize drift from curriculum and contamination between intervention groups</li> </ul>	<p>6. Throughout the duration of the semester, the primary author and facilitators maintained a continuous and unhindered channel of communication in order to ensure seamless operationality.</p>
<b>Receipt:</b> monitor and improve ability of participants to understand and perform treatment-related skills and strategies during delivery	<ul style="list-style-type: none"> <li>Participant attendance recorded.</li> <li>Measure of program acceptability collected.</li> </ul>	<p>7. Attendance data was collected by means of a weekly Qualtrics survey.</p> <p>8. Measure of program acceptability, feasibility, and acceptances was gathered at the end of the program both from participants and facilitators</p>
<b>Enactment:</b> monitor and improve the ability of participants to perform treatment-related skills and strategies in real-life settings	<ul style="list-style-type: none"> <li>Measure of practice collected (e.g., daily practice logs for minutes and types of practice used)</li> </ul>	<p>9. On a weekly basis, participants were requested to provide information regarding the total duration, measured in minutes, of their engagement for mindfulness</p>

Figure 1. CONSORT flowchart of the intervention

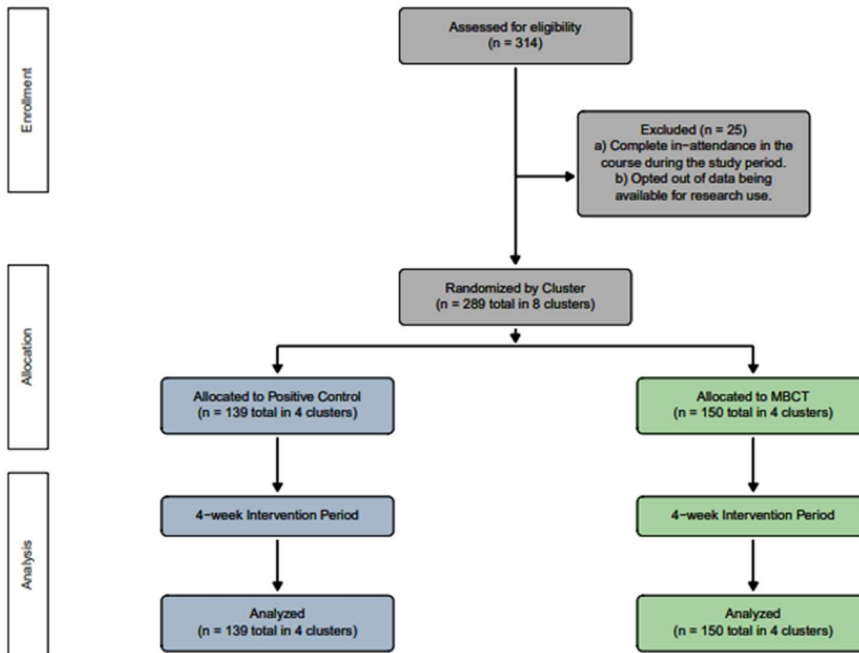


Figure 2. Primary Outcomes - Mean ( $\pm$  SE) trait anxiety (a) and chronic stress (b) at pre and posttest for the MBCT (solid green lines) and positive control (dashed blue lines) groups

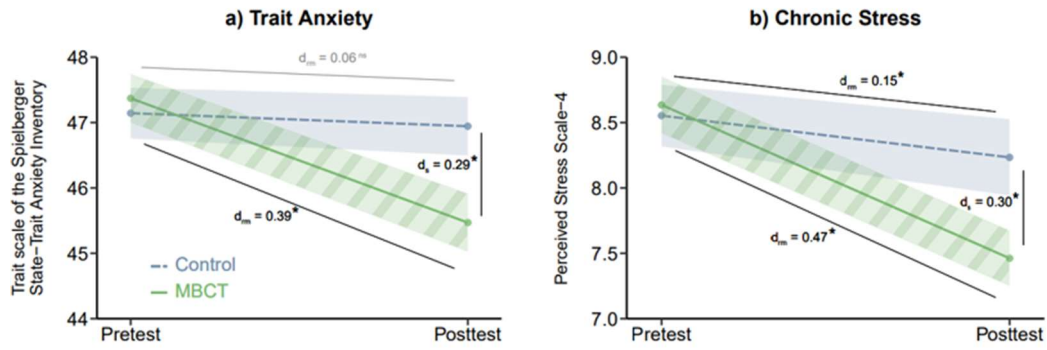


Figure 3. Scatterplots showing the relationship between changes in trait anxiety (a) and chronic stress (b) (posttest – pretest) and changes in secondary outcomes that were considered as mediators, for the MBCT (solid green circles/lines) and positive control (solid blue triangles/dashed blue lines) groups. Note: a small amount of random jitter was introduced for all scatterplots graphically representing the data to prevent overplotting

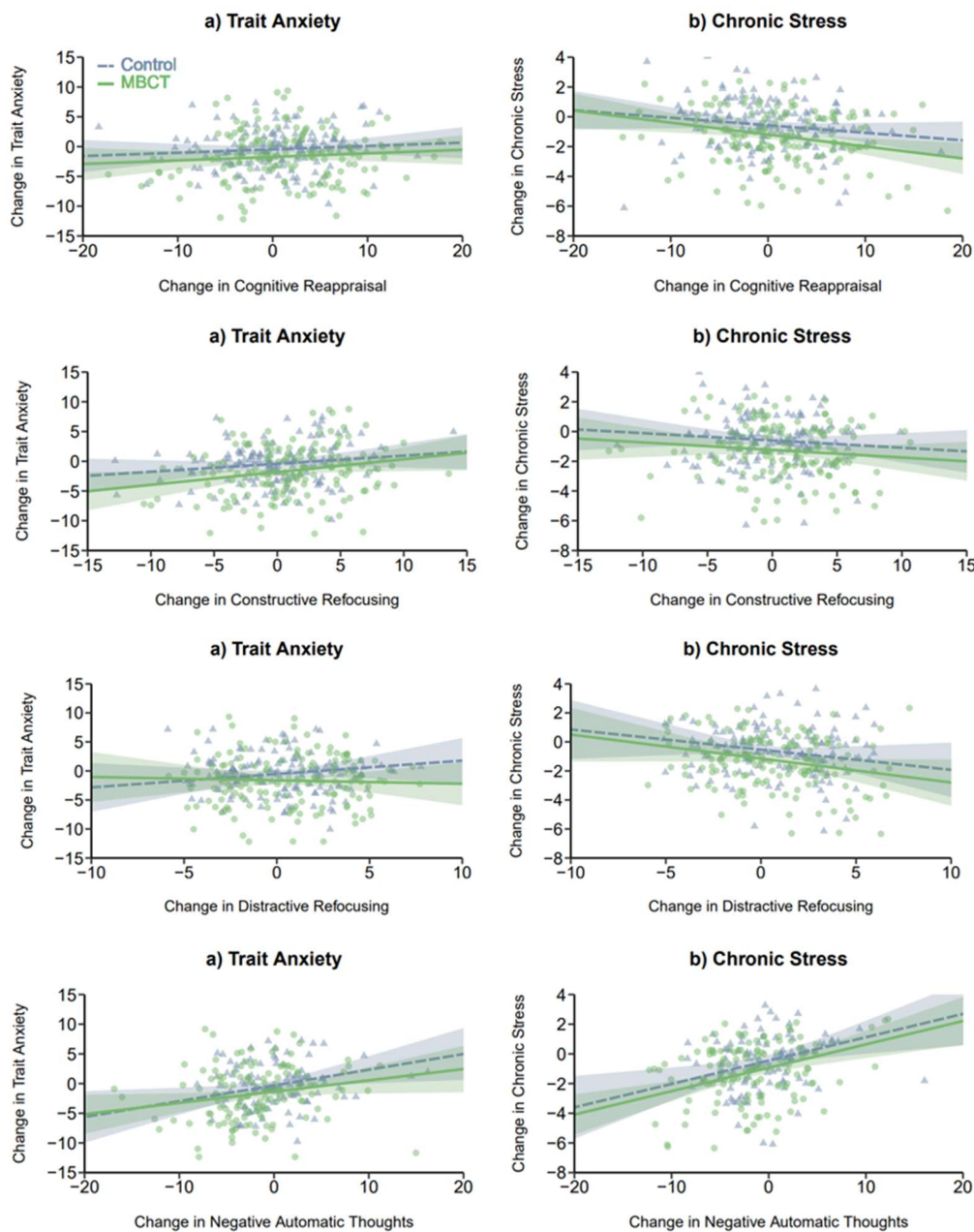


Figure 4. Scatterplots showing the relationship between changes in trait anxiety (a) and chronic stress (b) (posttest – pretest) and process evaluation outcomes examined as potential moderators, for the MBCT (solid green circles/lines) and positive control (solid blue triangles/dashed blue lines) groups. Note: a small amount of random jitter was introduced for all scatterplots graphically representing the data to present overplotting

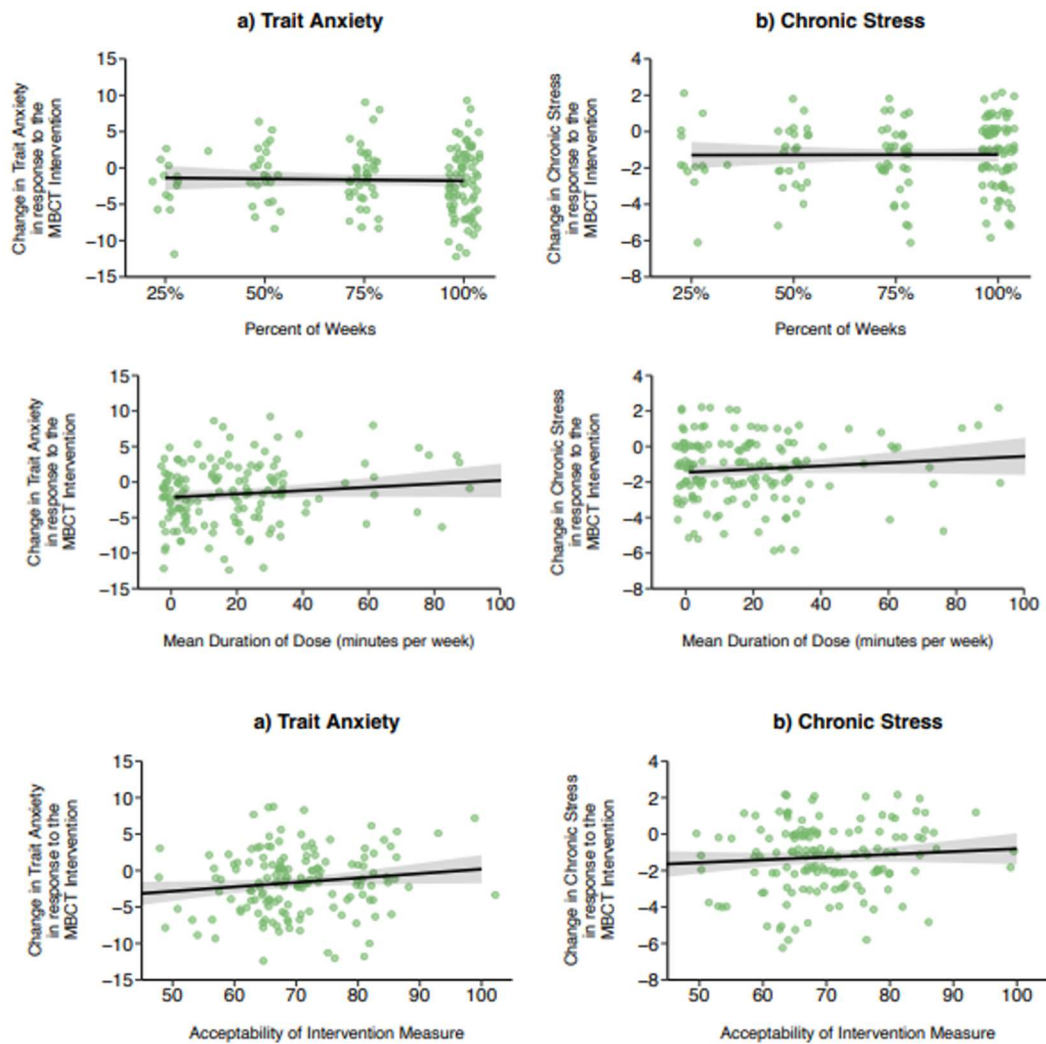


Figure 4. (cont'd)

