



Examining efficacy and potential mechanisms of mindfulness-based cognitive therapy for anxiety and stress reduction among college students in a cluster-randomized controlled trial

Oksana K. Ellison^a, Lauren E. Bullard^a, Gloria K. Lee^c, Spiridoula Vazou^a, Karin A. Pfeiffer^a, Shelby E. Baez^b, Matthew B. Pontifex^{a,*}

^a Department of Kinesiology, Michigan State University, 126 IM Sports Circle, East Lansing, MI 48824-1049, United States

^b Department of Exercise and Sport Science, University of North Carolina at Chapel Hill, United States

^c Department of Counseling, Educational Psychology & Special Education, Michigan State University, 620 Farm Ln, East Lansing, MI 48824, United States

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ABSTRACT

The pervasiveness of anxiety and stress among college students necessitates the investigation of potential alternative and accessible interventions which can be implemented into existing curricular and student-support programming to improve students' mental health. Mindfulness based cognitive therapy (MBCT) smartphone applications have shown promising outcomes in alleviating anxiety and stress. However, 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 aims for this study were (1) 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 ($n = 139$), and (2) to examine potential mediators of this effect. 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. Registered at ClinicalTrials.gov [number NCT06019299].

An assessment of mental health in college students, conducted by American College Health Association (2021), found a high prevalence of anxiety-related symptoms in over two-thirds of collegiate women and half of collegiate men. Over half of students indicate moderate levels of chronic stress that adversely affects their daily functioning (Beiter et al., 2015; Robotham, 2008). Although the prevalence of such mental health issues is higher amongst college students in North America, it nevertheless impacts a sizable portion of college students globally (Ahmed et al., 2023). These findings highlight the crucial need for effective interventions to ameliorate heightened levels of anxiety—a trait like

tendency to exhibit high baseline physiological arousal and assess situations as potentially threatening—and stress—the chronic perception of distress and loss of control—observed in college students. Although in-person mindfulness-based cognitive therapy approaches have been found effective for reducing anxiety and stress (Irving et al., 2009; Kor et al., 2021; Ozen et al., 2016; Phang et al., 2016) the pervasiveness of anxiety and stress in this population, has overwhelmed existing support services. Thus, there is a need to provide alternative and accessible interventions to improve students' mental health (Addis et al., 1999). One such approach could be by leveraging an existing and free tool, such as

* Corresponding author.

E-mail address: pontifex@msu.edu (M.B. Pontifex).

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the Sanvello mindfulness-based cognitive therapy smartphone application—which could more easily be deployed across a broad population and potentially could even be implemented into existing curricular and student-support programming. However, prior to implementation it is essential to assess the feasibility and preliminary efficacy of the interventional approach. Further, exploring potential underlying mechanisms could be targeted to enhance the efficacy of future interventions for promoting mental health and well-being.

Mindfulness-based interventions aim to cultivate mindful awareness, a process of attentively observing experiences, thoughts, and emotions (Bishop et al., 2004; 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 involves meditation and focused breathing exercises whereby the individual is taught to passively observe their thoughts and feelings without making judgments 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 heightened levels 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). 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 & Kabat-Zinn, 2008; Phillipot & Segal, 2009). Indeed, Bohlmeijer et al. (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 (Querstet 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 eight weeks in an individual or small group format. This approach represents a substantial constraint of both time and resources for the individual and clinical practitioners.

However, emerging evidence indicates that even when the intervention period is shortened, mindfulness-based intervention programs still elicit anxiolytic and stress-reducing effects. Specifically, Demarzo et al. (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. The intervention programming implemented by Demarzo et al. (2017) required 120-min 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 of shorter duration.

While there are a wide-assortment of smartphone-based applications, the present study specifically utilized the Sanvello application as it is cost-free and compatible with a wide range of Apple and Android devices, thus, represents a platform that could potentially be used within broad segments of the college-student community. Further, prior work exists in examining the efficacy of the application on both anxiety and stress. Specifically, Moberg et al. (2019) observed reductions in anxiety

(Cohen's $d = 0.40$) 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 associated with Moberg and colleagues as the cofounder/chief-executive-officer and on salary at Sanvello (formerly Pacifica Labs, Inc.). Further, the intervention specifically recruited individuals who were either interested in using the Sanvello application or were already existing users; therefore representing a substantially different population than the current study, which is instead assessing the possibility of using such an application within the context of existing curricular and student-support programming in a collegiate population. Thus, while there is strong evidence that implementation of MBCT in a variety of formats can be effective, an open question remains as it has yet to be explored how feasible and effective a brief smartphone-based interventional approach might be if implemented within a population that is not already aware of and self-selecting to use the MBCT 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 (1983) cognitive theory of anxiety and depression, 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. For example, a negative thinking pattern called catastrophizing explains the tendency for individuals to assume the most dire and pessimistic outcome in any given situation. From a skill-framework perspective, MBCT encourages the development of cognitive restructuring skills: how an individual (1) assesses a particular stimulus or situation (i.e., cognitive reappraisal), (2) reframes/reinterprets the function and/or consequence of the event (i.e., constructive refocusing), and (3) 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 et al., 2013). The fundamental premise of MBCT is that through the development of such core psychological skills 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 skills 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 skills 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 implemented during a first year-level collegiate course for reducing trait-level anxiety and chronic stress, relative to a control group? (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 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 (1983) cognitive theory of anxiety and depression and the conceptualization of the skills framework perspective, it was hypothesized that 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.

Method

Participants

Analyses were conducted on a sample of 289 individuals enrolled in a single 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 nonattendance 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. Demographic data are provided in Table 1.

Procedure

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. Although this investigation was a priori designed to investigate the effects of this interventional approach on anxiety and stress in a collegiate population, it is important to acknowledge that data were collected during the Spring 2023 academic semester with the pretest assessments collected approximately 37 days following the February 13th mass-shooting incident at Michigan State University which resulted in the deaths of

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

three students and the injury of five additional students. For context regarding the additional environmental trauma/stressor, during the 3-h 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 being deemed to be a safe location. Thus, mass confusion ensued as police entered buildings with weapons drawn and instructed students to vacate

i) CONSORT Flowchart

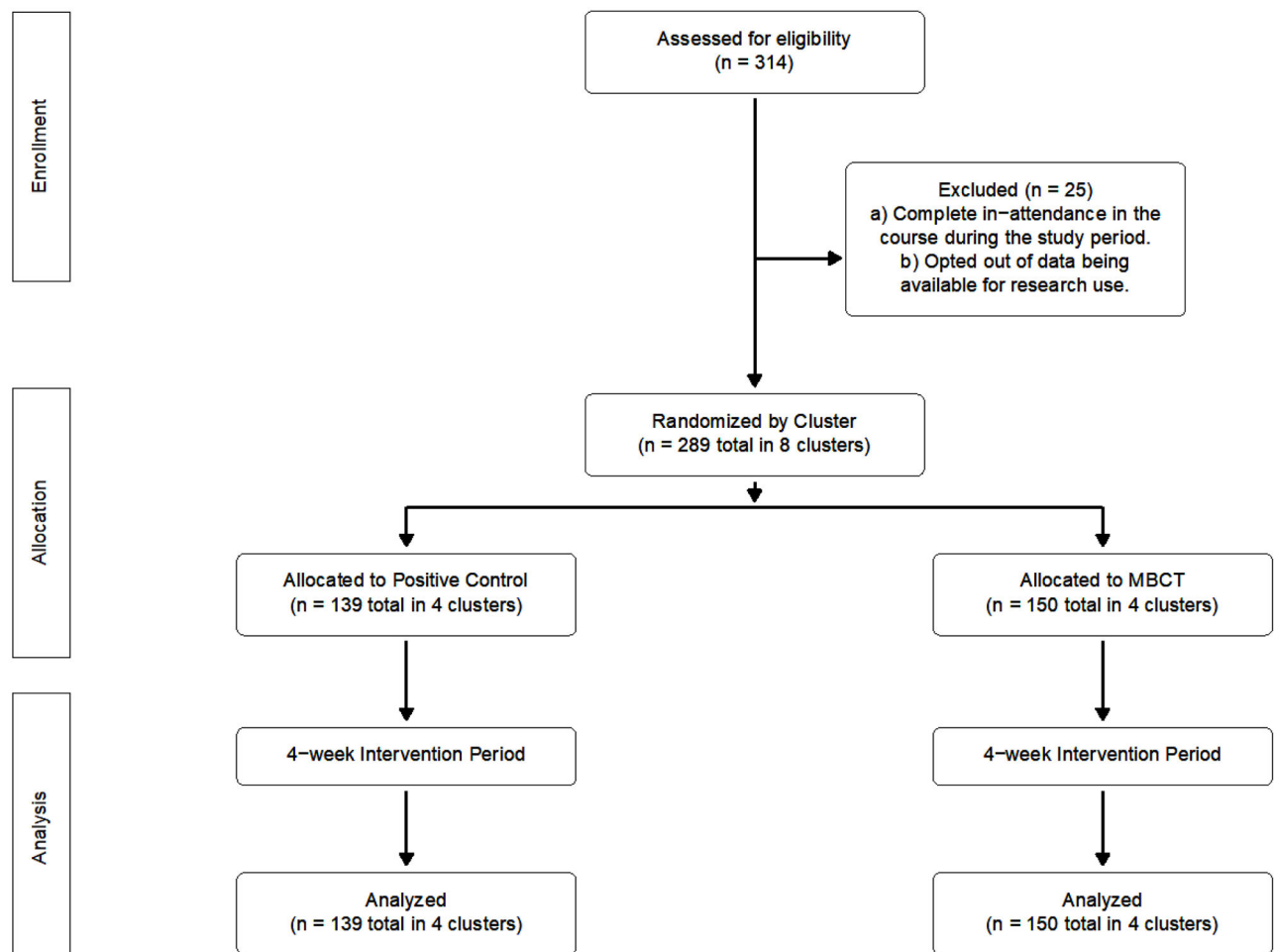


Fig. 1. CONSORT flowchart of the intervention.

the premises and flee across campus to find another location to “run, hide, fight” (Moran et al., 2023).

Once students returned to typical campus activities, the originally planned interventional approach to address anxiety and stress was implemented. Using a cluster-randomized positive control design, participants engaged in a 4-week mindfulness intervention as a part of a single predominately first year level college course. Each of the sections of the course were randomly assigned to either the MBCT group (experimental arm) or positive control (comparator arm), which ran in parallel for the duration of the study. Each week, participants in both groups were asked to report the frequency of their mindfulness practice over the past week.

Experimental arm

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 a 35 module anxiety management program in the format: 1) Watch, 2) Read, 3) Listen, 4) Plan, 5) Listen—Mindfulness practice.

For example, the first module 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, and 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.

Comparator arm

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 min in order to engage in mindfulness breathing. Comprehensive instructions were provided during the initial course meeting 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 judgments 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 to alleviate anxiety and stress.

All eight sections of the course (4 MBCT [experimental arm] and 4 positive control [comparator arm]) 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, 2012), 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 (Hollon & Kendall, 1980; Ruiz et al., 2020). Intervention fidelity and quality were assessed in the MBCT group following the 4-week intervention period. The protocol of this investigation is registered at ClinicalTrials.gov [number NCT06019299].

Process evaluation

Training

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 for reporting mindfulness-based intervention trials (Bellg et al., 2004). 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 2.

Table 2
Treatment fidelity tool for mindfulness based interventions.

Fidelity component	Item checklist	Author comments
Design: ensure a study can adequately test its hypotheses in relation to underlying theory and clinical processes	<ul style="list-style-type: none">• Theoretical/substantive rationale for any adaptations from established MBI• 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)• Plan for implementation setbacks (e.g., back-up facilitators)	1. Cognitive theory of anxiety and depression was utilized for theoretical rational of the study 2. The positive control group met the same number of times compared to MBCT 3. A robust and transparent communication channel was established, fostering effective collaboration and information exchange among the principal investigator, facilitators, and the first author.
Training: ensure treatment providers are satisfactorily trained to deliver the intervention	<ul style="list-style-type: none">• All facilitators received formal training.• All facilitators were observed and received constructive feedback during initial phases	4. All facilitators met with the first author 5. Facilitators were given feedback regularly
Delivery: ensure intervention is delivered as intended	<ul style="list-style-type: none">• All facilitators received ongoing, real-time constructive feedback, and inter-rater reliability assessments to minimize drift from curriculum and contamination between intervention groups	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 operability.
Receipt: monitor and improve ability of participants to understand and perform treatment-related skills and strategies during delivery	<ul style="list-style-type: none">• Participant attendance recorded.• Measure of program acceptability collected.	7. Attendance data was collected by means of a weekly Qualtrics survey. 8. Measure of program acceptability, feasibility, and acceptances was gathered at the end of the program both from participants and facilitators
Enactment: monitor and improve the ability of participants to perform treatment-related skills and strategies in real-life settings	<ul style="list-style-type: none">• Measure of practice collected (e.g., daily practice logs for minutes and types of practice used)	9. On a weekly basis, participants were requested to provide information regarding the total duration, measured in minutes, of their engagement for mindfulness

Implementation

Implementation was assessed weekly during designated sessions of the course. Implementation was then 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 outside of the classroom. Each week, participants were instructed to select a range corresponding to their practice duration. The options were as follows: 1–29 min, 30–59 min, 60–89 min, 90–119 min, 120–149 min, 150–199 min, and more than 200 min. 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, participants assessed the intervention on these dimensions 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").

Primary outcomes

State-trait anxiety inventory

Trait anxiety was assessed using the Trait scale of the Spielberger State-Trait Anxiety Inventory (STAI) (Spielberger, 2012). The questionnaire comprised of twenty items assessing how individuals "generally feel." The possible trait anxiety scores range from 20 to 80, with higher scores indicating greater levels of anxiety. The reliability of the STAI has been well reported, with a Cronbach's alpha of 0.9 for internal consistency (Balsamo et al., 2013) and test-retest reliability of 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 Cronbach's alpha = 0.72 as a concise 4-item scale (Vallejo et al., 2018) and has moderate convergent validity with the Short-Form Health Survey (Mitchell et al., 2008).

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"), with a higher rating indicating better cognitive reappraisal. The skill of cognitive reappraisal thus reflects traditional cognitive behavioral therapy aims of changing the appraisal of an emotion-eliciting stimulus or situation. Cognitive reappraisal demonstrates adequate internal consistency (Cronbach's alpha: 0.82–0.85) and test-retest reliability of 0.69 (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 skill of constructive refocusing reflects how the function or consequence of a situation are reframed/reinterpreted, as such this skill was quantified using the Refocus on Planning, Positive Reappraisal, and Putting into Perspective subscales of the Cognitive Emotional Regulation Questionnaire (Wolgast et al., 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 skill of distractive refocusing reflects avoidance-related strategies to dissociate from the situation, as such this skill was quantified using the Positive Refocusing subscale of the Cognitive Emotional Regulation Questionnaire (Wolgast et al., 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 internal consistency of the Cognitive Emotional Regulation Questionnaire has been observed to range from 0.68 to 0.81 (Cronbach's alpha) and has modest convergent validity with the Difficulties in Emotion Regulation Scale (Ireland et al., 2017).

Autonomic thoughts questionnaire

Negative automatic thoughts were assessed using the 8-item version of the Automatic Thoughts Questionnaire (ATQ-8) (Hollon & Kendall, 1980; Ruiz et al., 2020). The ATQ-8 assesses 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 (Cronbach's alpha: 0.89; Ruiz et al., 2020).

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). 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 (p 's > 0.05), they were excluded from the modeling approach. The multi-level model analyses were performed using the Rmimic (Pontifex, 2020) 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 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). All variables and analysis 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). Individual data points falling outside 2.5 times the median absolute deviation were replaced with the nearest value 2.5 times the median absolute deviation (Leys et al., 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 Group \times Time interactions exceeding an equivalent Cohen's $d = 0.1$ (with a two-sided alpha) as computed using the simr (Green & MacLeod, 2016) package in R. The power analysis was based on 100 simulations of the specified multi-level model using a parametric bootstrap approach to assess the sensitivity of detecting Group \times Time interactions in contrast to a main effect of Time.

Analyses 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 to determine if any demographic characteristics (i.e., age, biological sex, ethnicity, socioeconomic status, and years of education) should be included in the models. No demographic 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, and Studentized Breusch-Pagan tests, and no data transformations were required or applied. Next, mediation analyses were performed using the Rmimic (Pontifex, 2020) 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 1000 nonparametric bootstrapped samples.

Results

Sample characteristics: 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 and have more education (age: 19.9 ± 2.4 years; education: 13.9 ± 1.0 years) than the positive control group (age: 19.4 ± 1.6 years; education: 13.4 ± 0.8 years), Mann-Whitney U 's ≥ 6963.0 , Z 's ≥ 4.9 , p 's < 0.001 , r 's $= 0.29$. Demographic data are provided in Table 1.

Implementation: The MBCT group reported engaging in mindfulness practice on a greater number of weeks (79.2 ± 25.0 %) than the positive control group (64.3 ± 28.3 %), $t(287) = 4.8$, $p < 0.001$, $d_s = 0.56$ [95 % CI: 0.33 to 0.80].

Dose: The MBCT group reported a greater average minutes of mindfulness practice (20.5 ± 24.5 min) than the positive control group (12.8 ± 15.9 min), $t(257.6) = 3.2$, $p = 0.002$, $d_s = 0.38$ [95 % CI: 0.14 to 0.61].

Quality: Perceptions of the acceptability of the intervention were

skewed positively (80.4 ± 11.0 %) with 47.3 % of the MBCT group completely agreeing and 20 % of the MBCT group agreeing about its acceptability. Only 1.3 % of the MBCT group was ambivalent about the acceptability of the intervention. Perceptions of the appropriateness of the intervention (80.9 ± 10.5 %) and the feasibility of the intervention (81.9 ± 9.8 %) were highly similar with 53.3 % of the MBCT group completely agreeing and 15.3 % agreeing. Only 0.7 % of the MBCT group was ambivalent regarding the appropriateness and feasibility of the intervention.

Trait anxiety

Primary outcome

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 ± 5.1) and pretest (47.4 ± 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 ± 4.5) and posttest (46.9 ± 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 Fig. 2a.

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 100 %] 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 Fig. 3iv.a).

i) Primary Outcomes

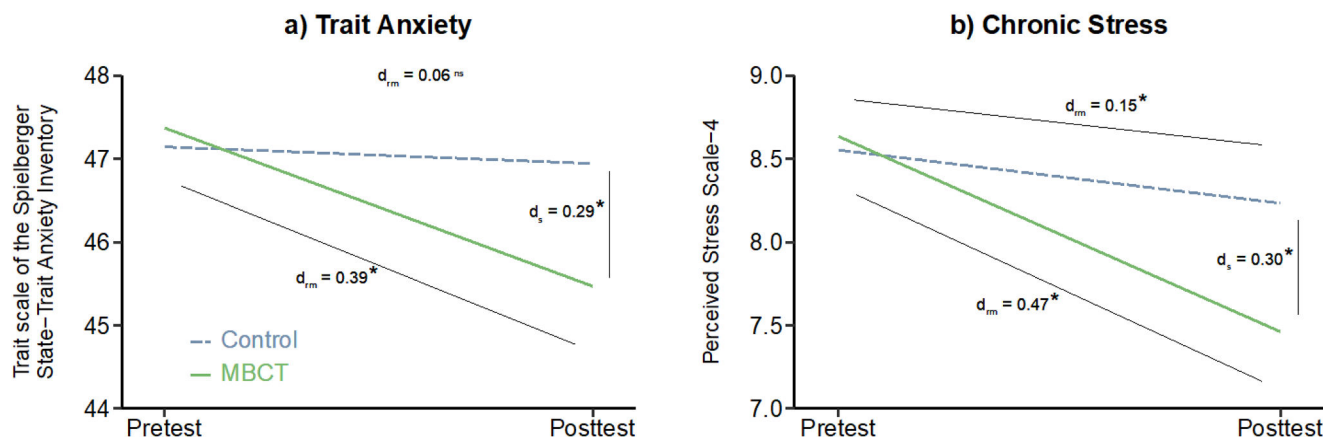


Fig. 2. Mean (\pm SE) trait anxiety (a) and chronic stress (b) at pre and posttest for the MBCT (solid green lines) and positive control (dashed blue lines) groups.

Chronic stress

Primary outcome

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 ± 2.6) and posttest (7.5 ± 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 ± 2.7) and posttest (8.2 ± 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 Fig. 2b.

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 100 %] 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 Fig. 3iv.b).

Discussion

Efficacy

The primary aim of the present study was to examine the efficacy of a 4-week MBCT intervention delivered through the Sanvello smartphone application for reducing trait anxiety and chronic stress among college students recruited from an entry-level health science course, using a cluster-randomized approach. 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 (intervention group) or a MBSR-based breathing technique (positive control group), as a part of the course. Results from this study replicate the extant literature on MBCT-based interventions for reducing anxiety and in-particular, the findings by Moberg et al. (2019) who similarly assessed the effects of the Sanvello platform over the course of a 30-day intervention. Specifically, replicating Moberg et al. (2019) finding (Cohen's $d = 0.4$), the present investigation observed small to moderate effect size in trait anxiety (Cohen's $d_{rm} = 0.39$ [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 reducing trait-level anxiety (Hedges' $g = 0.466$) (Bamber & Morpeth, 2019). Therefore, our findings support the utility and the efficiency of a shorter version of an MBCT intervention in the reduction of anxiety symptoms.

The present investigation also replicated Moberg et al. (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 the meta-analytic findings from

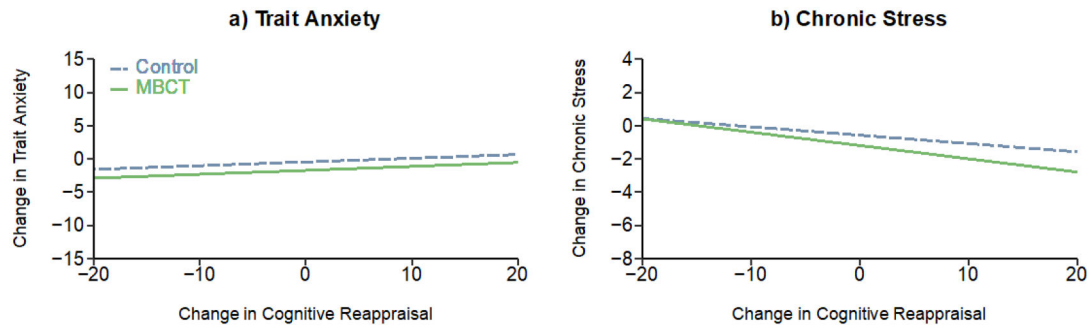
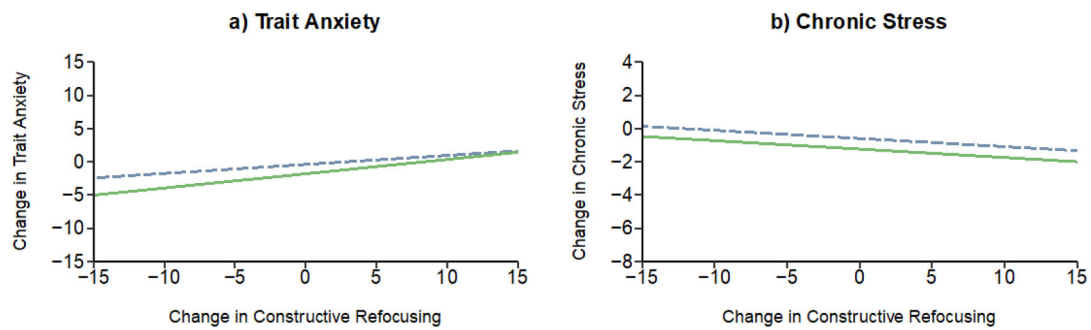
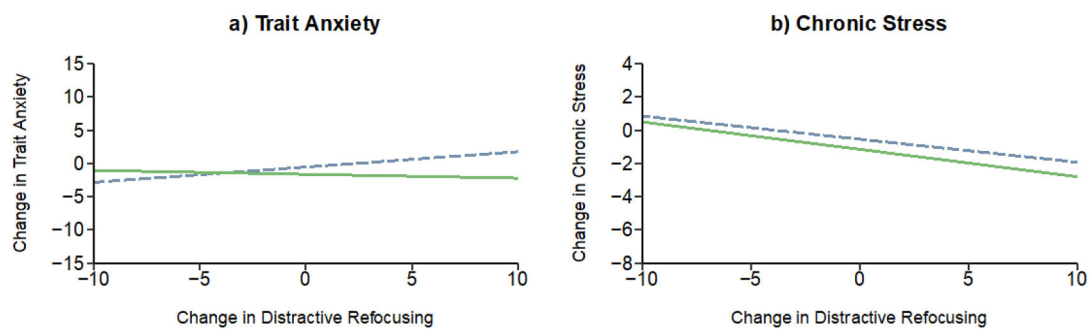
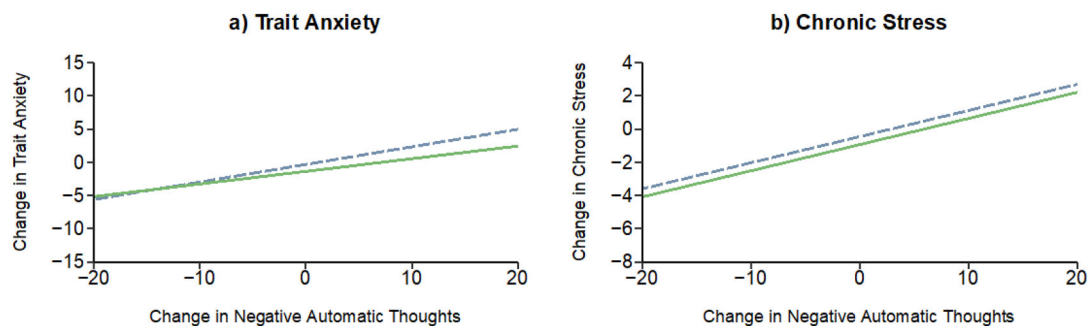
i) Cognitive Reappraisal**ii) Constructive Refocusing****iii) Distractive Refocusing****iv) Negative Automatic Thoughts**

Fig. 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.

traditional in-person mindfulness-based interventions (Hedges' $g = 0.83$ [95 % CI: 0.58 to 1.08]) (Khouri et al., 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 specific 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 (± 24.5) minutes of use on average per week. Traditional in-person mindfulness-based interventions which utilize two-hour long sessions with certified mindfulness instructors appear to exhibit similar reductions in trait anxiety (Bamber & Morpeth, 2019) and only slightly more pronounced effects for chronic stress (Khouri et al., 2015), as compared to the current intervention. Therefore, it appears 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 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 skills were assessed before and after the 4-week intervention period; and the change in these skills were 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 skills on either trait anxiety or chronic stress. However, consistent with other studies, negative automatic thoughts were found to account for 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 et al. (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.

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 (i.e., eliminate) the direct effects of the intervention on changes in trait anxiety.

Alternatively, it is important to note that the environmental context in which the intervention took place may have altered the potential for changes in cognitive restructuring to impact upon the primary outcomes. Specifically, although the present intervention was not *a priori* designed as a crisis interventional approach, it was implemented only a month after a mass-shooting event occurred on campus. Thus as Foa et al. (2005), observed that cognitive restructuring had limited effects on individuals with post-traumatic stress disorder (PTSD) and their perceived levels of chronic stress; it is important to acknowledge and consider the limitations this might introduce. Indeed, a limitation of the present investigation was the lack of inclusion of measures associated with more acute stress/anxiety and PTSD which may have been useful in further disentangling such relationships. Nevertheless, although the environmental context may have diminished the mechanistic impact of cognitive restructuring, it is important to acknowledge that the smartphone based MBCT-based intervention using the Sanvello application exhibited similar efficacy in such a crisis-related context as it did in non-crisis related contexts. However, given the pervasive rise of violent incidents and mass shootings within US schools over the past several decades which has contributed to reducing student perceptions of well-being and further exacerbating stress and anxiety (Fox & Fridel, 2018; Katsiyannis et al., 2018); further research in this area may benefit from including measures of PTSD, as secondary or 'shared' trauma may be more prevalent than commonly assumed potentially altering those target mechanisms for positively impacting stress and anxiety. Such measures may also contribute to a greater understanding of the intervention durations necessary to elicit changes given meta-analytic findings indicating that longer MBCT intervention exhibit greater efficacy in PTSD populations (Hopwood & Schutte, 2017).

Strengths, limitations, and future directions

In regard to intervention quality, the present investigation specifically characterized participant's perceptions of the intervention acceptability, appropriateness, and feasibility. Participants using the Sanvello smartphone application overwhelmingly considered it to be an acceptable (appealing to use), appropriate (suitable for the target population and environment), and feasible (perceived ease of use) intervention. Specifically, within the present investigation nearly 70 % of participants using the Sanvello smartphone application agreed or completely agreed that the Sanvello smartphone application was appealing to use, with only two participants being ambivalent over the

appeal of the intervention. Nearly 70 % of participants also agreed or completely agreed that the Sanvello smartphone application was suitable for the target population and environment and easy to use, with only a single participant being ambivalent over the appropriateness and feasibility of the intervention. Thus, despite integrating this intervention as a part of the course following a mass-shooting incident, 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.

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 (Phan et al., 2022). However, a strength of the present investigation was specifically considering a skill 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, 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). 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 intervention approach is consistent with that of the extant literature in this area and replicable for future investigations in this area.

Nevertheless, 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. Simultaneously, the robustness and validity of findings would be greatly enhanced by adopting methodologies that extend beyond self-reported measures such as by obtaining usage data directly from the application itself. 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.

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 a wider age range and a 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 [Moberg et al. \(2019\)](#), 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. 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.

Conclusion

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—even following a mass-shooting incident. 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 near total capacity throughout much of the year ([Bailey et al., 2021](#)). Students overwhelmingly considered the Sanvello smartphone application to be an appealing, 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, as well as potential mechanistic processes

responsible for the efficacy.

CRedit authorship contribution statement

Oksana K. Ellison: Conceptualization, Methodology, Formal analysis, Data curation, Writing – original draft, Writing – review & editing, Visualization, Resources. **Lauren E. Bullard:** Data curation, Investigation, Project administration. **Gloria K. Lee:** Methodology, Validation, Writing – review & editing. **Spiridoula Vazou:** Methodology, Validation, Writing – review & editing. **Karin A. Pfeiffer:** Methodology, Validation, Writing – review & editing. **Shelby E. Baez:** Methodology, Validation. **Matthew B. Pontifex:** Methodology, Software, Formal analysis, Data curation, Writing – review & editing, Visualization, Supervision.

Declaration of competing interest

The authors declare that they have no conflict of interest.

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References

- Addis, M. E., Wade, W. A., & Hatgis, C. (1999). Barriers to dissemination of evidence-based practices: Addressing practitioners' concerns about manual-based psychotherapies. *Clinical Psychology: Science and Practice*, 6(4), 430–441. <https://doi.org/10.1093/clipsy.6.4.430>
- Ahmed, I., Hazell, C. M., Edwards, B., Glazebrook, C., & Davies, E. B. (2023). A systematic review and meta-analysis of studies exploring prevalence of non-specific anxiety in undergraduate university students. *BMC Psychiatry*, 23(1), 240. <https://doi.org/10.1186/s12888-023-04645-8>
- American College Health Association. (2021). *American college health association-national college health assessment III: Undergraduate student reference group executive summary*. American College Health Association. https://www.acha.org/documents/ncha/ncha-iii_spring-2021_undergraduate_reference_group_executive_summary_updated.pdf
- Bailey, R. J., Erekson, D. M., Goates-Jones, M., Andes, R. M., & Snell, A. N. (2021). Busy therapists: Examining caseload as a potential factor in outcome. *Psychological Services*, 18(4), 574–583. <https://doi.org/10.1037/ser0000462>
- Balsamo, M., Romanelli, R., Innamorati, M., Ciccarese, G., Carlucci, L., & Saggino, A. (2013). The state-trait anxiety inventory: Shadows and lights on its construct validity. *Journal of Psychopathology and Behavioral Assessment*, 35(4), 475–486. <https://doi.org/10.1007/s10862-013-9354-5>
- Bamber, M. D., & Morpeth, E. (2019). Effects of mindfulness meditation on college student anxiety: A meta-analysis. *Mindfulness*, 10(2), 203–214. <https://doi.org/10.1007/s12671-018-0965-5>
- Barnes, L. L., Harp, D., & Jung, W. S. (2002). Reliability generalization of scores on the Spielberger state-trait anxiety inventory. *Educational and Psychological Measurement*, 62(4), 603–618.
- Bates, D., Mächler, M., Bolker, B., & Walker, S. (2015). Fitting linear mixed-effects models using lme4. *Journal of Statistical Software*, 67(1), 1–48. <https://doi.org/10.18637/jss.v067.i01>
- Beck, A. T. (1983). Cognitive therapy of depression: New perspectives. In P. J. Clayton, & J. E. Barrett (Eds.), *Treatment of depression: Old controversies and new approaches* (pp. 265–290). Raven Press.
- Beiter, R., Nash, R., McCrady, M., Rhoades, D., Linscomb, M., Clarahan, M., & Sammut, S. (2015). The prevalence and correlates of depression, anxiety, and stress in a sample of college students. *Journal of Affective Disorders*, 173, 90–96. <https://doi.org/10.1016/j.jad.2014.10.054>
- Bell, A. J., Borrelli, B., Resnick, B., Hecht, J., Minicucci, D. S., Ory, M., Ogedegbe, G., Orwig, D., Ernst, D., & Czajkowski, S. (2004). Enhancing treatment fidelity in health behavior change studies: Best practices and recommendations from the NIH behavior change consortium. *Health Psychology*, 23(5), 443–451. <https://doi.org/10.1037/0278-6133.23.5.443>
- Bishop, S. R. (2002). What do we really know about mindfulness-based stress reduction? *Psychosomatic Medicine*, 64(1), 71.
- Bishop, S. R., Lau, M., Shapiro, S., Carlson, L., Anderson, N. D., Carmody, J., Segal, Z. V., Abbey, S., Speca, M., & Velting, D. (2004). Mindfulness: A proposed operational definition. *Clinical Psychology: Science and Practice*, 11(3), 230.
- Bohlmeijer, E., Prenger, R., Taal, E., & Cuijpers, P. (2010). The effects of mindfulness-based stress reduction therapy on mental health of adults with a chronic medical disease: A meta-analysis. *Journal of Psychosomatic Research*, 68(6), 539–544. <https://doi.org/10.1016/j.jpsychores.2009.10.005>
- Cherkin, D. C., Sherman, K. J., Balderson, B. H., Cook, A. J., Anderson, M. L., Hawkes, R. J., Hansen, K. E., & Turner, J. A. (2016). Effect of mindfulness-based stress reduction vs cognitive behavioral therapy or usual care on back pain and functional limitations in adults with chronic low back pain: A randomized clinical trial. *JAMA*, 315(12), 1240–1249. <https://doi.org/10.1001/jama.2016.2323>
- Cohen, S., Kamarck, T., & Mermelstein, R. (1983). A global measure of perceived stress. *Journal of Health and Social Behavior*, 24(4), 385–396.
- Demarzo, M., Montero-Marin, J., Puebla-Guedea, M., Navarro-Gil, M., Herrera-Mercadal, P., Moreno-González, S., ... Garcia-Campayo, J. (2017). Efficacy of 8- and 4-session mindfulness-based interventions in a non-clinical population: A controlled study. *Frontiers in Psychology*, 8. <https://doi.org/10.3389/fpsyg.2017.01343>
- Foa, E. B., Hembree, E. A., Cahill, S. P., Rauch, S. A. M., Riggs, D. S., Feeny, N. C., & Yadin, E. (2005). Randomized trial of prolonged exposure for posttraumatic stress disorder with and without cognitive restructuring: Outcome at academic and community clinics. *Journal of Consulting and Clinical Psychology*, 73(5), 953–964. <https://doi.org/10.1037/0022-006X.73.5.953>
- Fox, J. A., & Fridel, E. E. (2018). The menace of school shootings in America. *The Wiley handbook on violence in education* (pp. 15–35). John Wiley & Sons, Ltd. <https://doi.org/10.1002/9781118966709.ch1>
- Garnefski, N., & Kraaij, V. (2006). Cognitive emotion regulation questionnaire—development of a short 18-item version (CERQ-short). *Personality and Individual Differences*, 41(6), 1045–1053. <https://doi.org/10.1016/j.paid.2006.04.010>
- Geschwind, N., Peeters, F., Huibers, M., van Os, J., & Wichers, M. (2012). Efficacy of mindfulness-based cognitive therapy in relation to prior history of depression: Randomised controlled trial. *The British Journal of Psychiatry*, 201(4), 320–325. <https://doi.org/10.1192/bjp.bp.111.104851>
- Green, P., & MacLeod, C. J. (2016). SIMR: An R package for power analysis of generalized linear mixed models by simulation. *Methods in Ecology and Evolution*, 7(4), 493–498. <https://doi.org/10.1111/2041-210X.12504>
- Gross, J. J., & John, O. P. (2003). Individual differences in two emotion regulation processes: Implications for affect, relationships, and well-being. *Journal of Personality and Social Psychology*, 85(2), 348–362. <https://doi.org/10.1037/0022-3514.85.2.348>
- Grossman, P., Niemann, L., Schmidt, S., & Walach, H. (2004). Mindfulness-based stress reduction and health benefits: A meta-analysis. *Journal of Psychosomatic Research*, 57(1), 35–43. [https://doi.org/10.1016/S0022-3999\(03\)00573-7](https://doi.org/10.1016/S0022-3999(03)00573-7)
- Gu, J., Strauss, C., Bond, R., & Cavanagh, K. (2015). How do mindfulness-based cognitive therapy and mindfulness-based stress reduction improve mental health and wellbeing? A systematic review and meta-analysis of mediation studies. *Clinical Psychology Review*, 37, 1–12. <https://doi.org/10.1016/j.cpr.2015.01.006>
- Hoge, E. A., Bui, E., Marques, L., Metcalf, C. A., Morris, L. K., Robinaugh, D. J., Worthington, J. J., Pollack, M. H., & Simon, N. M. (2013). Randomized controlled trial of mindfulness meditation for generalized anxiety disorder: effects on anxiety and stress reactivity. *The Journal of Clinical Psychiatry*, 74(8), 16662. <https://doi.org/10.4088/JCP.12m08083>
- Hollon, S. D., & Kendall, P. C. (1980). Cognitive self-statements in depression: Development of an automatic thoughts questionnaire. *Cognitive Therapy and Research*, 4(4), 383–395. <https://doi.org/10.1007/BF01178214>
- Hopwood, T. L., & Schutte, N. S. (2017). A meta-analytic investigation of the impact of mindfulness-based interventions on post traumatic stress. *Clinical Psychology Review*, 57, 12–20. <https://doi.org/10.1016/j.cpr.2017.08.002>
- Irving, J. A., Dobkin, P. L., & Park, J. (2009). Cultivating mindfulness in health care professionals: A review of empirical studies of mindfulness-based stress reduction (MBSR). *Complementary Therapies in Clinical Practice*, 15(2), 61–66. <https://doi.org/10.1016/j.ctcp.2009.01.002>
- Katsiyannis, A., Whitford, D. K., & Ennis, R. P. (2018). Historical examination of United States intentional mass school shootings in the 20th and 21st centuries: Implications for students, schools, and society. *Journal of Child and Family Studies*, 27(8), 2562–2573. <https://doi.org/10.1007/s10826-018-1096-2>
- Khouri, B., Sharma, M., Rush, S. E., & Fournier, C. (2015). Mindfulness-based stress reduction for healthy individuals: A meta-analysis. *Journal of Psychosomatic Research*, 78(6), 519–528. <https://doi.org/10.1016/j.jpsychores.2015.03.009>
- Kim, W., Lim, S.-K., Chung, E.-J., & Woo, J.-M. (2009). The effect of cognitive behavior therapy-based psychotherapy applied in a forest environment on physiological changes and remission of major depressive disorder. *Psychiatry Investigation*, 6(4), 245–254. <https://doi.org/10.4306/pi.2009.6.4.245>
- Koenker, R. (1981). A note on studentizing a test for heteroscedasticity. *Journal of Econometrics*, 17(1), 107–112. [https://doi.org/10.1016/0304-4076\(81\)90062-2](https://doi.org/10.1016/0304-4076(81)90062-2)
- Kor, P. P. K., Liu, J. Y. W., & Chien, W. T. (2021). Effects of a modified mindfulness-based cognitive therapy for family caregivers of people with Dementia: A randomized clinical trial. *The Gerontologist*, 61(6), 977–990. <https://doi.org/10.1093/geront/gnaa125>
- Kuznetsova, A., Brockhoff, P. B., & Christensen, R. H. B. (2017). lmerTest package: Tests in linear mixed effects models. *Journal of Statistical Software*, 82(13), 1–26. <https://doi.org/10.18637/jss.v082.i13>
- Lakens, D. (2013). Calculating and reporting effect sizes to facilitate cumulative science: A practical primer for t-tests and ANOVAs. *Frontiers in Psychology*, 4(863), 1–12. <https://doi.org/10.3389/fpsyg.2013.00863>
- Lenth, R., Love, J., & Herve, M. (2017). emmeans: Estimated marginal means, aka least-squares means. <https://github.com/rvnlenth/emmeans>
- Leys, C., Ley, C., Klein, O., Bernard, P., & Licata, L. (2013). Detecting outliers: Do not use standard deviation around the mean, use absolute deviation around the median. *Journal of Experimental Social Psychology*, 49(4), 764–766. <https://doi.org/10.1016/j.jesp.2013.03.013>
- Ludwig, D. S., & Kabat-Zinn, J. (2008). Mindfulness in medicine. *JAMA*, 300(11), 1350–1352. <https://doi.org/10.1001/jama.300.11.1350>

- Mitchell, A. M., Crane, P. A., & Kim, Y. (2008). Perceived stress in survivors of suicide: Psychometric properties of the Perceived Stress Scale. *Research in Nursing & Health*, 31(6), 576–585. <https://doi.org/10.1002/nur.20284>
- Moberg, C., Niles, A., & Beermann, D. (2019). Guided self-help works: Randomized waitlist controlled trial of Pacifica, a mobile app integrating cognitive behavioral therapy and mindfulness for stress, anxiety, and depression. *Journal of Medical Internet Research*, 21(6), e12556. <https://doi.org/10.2196/12556>
- Moran, D., Egan, P., Jesse, D., Lawler, E., & Sahouri, A. M. (2023). *Suspect dead, 3 killed, 5 injured in Michigan state shooting: What we know*. Detroit Free Press. <https://www.freep.com/story/news/local/michigan/2023/02/13/michigan-state-shooting-what-we-know-about-shots-fired-on-campus/69901251007/>.
- Naceanceno, K., Capps, S., Whittenburg, R., & Ortiz, A. (2021). A comparison of anxiety levels among college students. *Journal of Graduate Education Research*, 2, 25–31.
- Ozen, L. J., Dubois, S., Gibbons, C., Short, M. M., Maxwell, H., & Bédard, M. (2016). Mindfulness interventions improve depression symptoms after traumatic brain injury: Are individual changes clinically significant? *Mindfulness*, 7(6), 1356–1364. <https://doi.org/10.1007/s12671-016-0577-x>
- Phan, M. L., Renshaw, T. L., Caramanico, J., Greeson, J. M., MacKenzie, E., Atkinson-Diaz, Z., Doppelt, N., Tai, H., Mandell, D. S., & Nuske, H. J. (2022). Mindfulness-based school interventions: A systematic review of outcome evidence quality by study design. *Mindfulness*, 13(7), 1591–1613. <https://doi.org/10.1007/s12671-022-01885-9>
- Phang, C. K., Chiang, K. C., Ng, L. O., Keng, S.-L., & Oei, T. P. S. (2016). Effects of brief group mindfulness-based cognitive therapy for stress reduction among medical students in a Malaysian university. *Mindfulness*, 7(1), 189–197. <https://doi.org/10.1007/s12671-015-0399-2>
- Phillipot, P., & Segal, Z. (2009). Mindfulness based psychological interventions: Developing emotional awareness for better being. *Journal of Consciousness Studies*, 16(10–11), 285–306.
- Pontifex, M.B. (2020). *Rmimic: An R package that mimic outputs of popular commercial statistics software packages with effect sizes and confidence intervals*. (1.0) [Computer software]. <https://github.com/mattpontifex/Rmimic>.
- Proctor, E., Silmere, H., Raghavan, R., Hovmand, P., Aarons, G., Bunger, A., Griffey, R., & Hensley, M. (2011). Outcomes for implementation research: Conceptual distinctions, measurement challenges, and research agenda. *Administration and Policy in Mental Health and Mental Health Services Research*, 38(2), 65–76. <https://doi.org/10.1007/s10488-010-0319-7>
- Querstret, D., Morison, L., Dickinson, S., Cropley, M., & John, M. (2020). Mindfulness-based stress reduction and mindfulness-based cognitive therapy for psychological health and well-being in nonclinical samples: A systematic review and meta-analysis. *International Journal of Stress Management*, 27(4), 394–411. <https://doi.org/10.1037/str0000165>
- R Core Team. (2019). *R: A language and environment for statistical computing* (3.6.1) [Computer software]. <https://www.R-project.org/>.
- Robotham, D. (2008). Stress among higher education students: Towards a research agenda. *Higher Education*, 56(6), 735–746. <https://doi.org/10.1007/s10734-008-9137-1>
- Ruiz, F. J., Odriozola-González, P., & Suárez-Falcón, J. C. (2020). Psychometric properties of the automatic thoughts questionnaire-8 in two Spanish nonclinical samples. *PeerJ*, 8, e9747. <https://doi.org/10.7717/peerj.9747>
- Shallcross, A. J., Gross, J. J., Visvanathan, P. D., Kumar, N., Palfrey, A., Ford, B. Q., Dimidjian, S., Shirk, S., Holm-Denoma, J., Goode, K. M., Cox, E., Chaplin, W., & Mauss, I. B. (2015). Relapse prevention in major depressive disorder: Mindfulness-based cognitive therapy versus an active control condition. *Journal of Consulting and Clinical Psychology*, 83(5), 964–975. <https://doi.org/10.1037/ccp0000050>
- Shapiro, S. S., & Wilk, M. B. (1965). An analysis of variance test for normality (complete samples). *Biometrika*, 52(3–4), 591–611. <https://doi.org/10.1093/biomet/52.3-4.591>
- Sipe, W. E. B., & Eisendrath, S. J. (2012). Mindfulness-based cognitive therapy: Theory and practice. *The Canadian Journal of Psychiatry*, 57(2), 63–69. <https://doi.org/10.1177/070674371205700202>
- Spielberger, C. D. (2012). *State-trait anxiety inventory for adults*. The Meyers-Briggs Company - Consulting Psychologists Press.
- Tingley, D., Yamamoto, T., Hirose, K., Keele, L., & Imai, K. (2014). Mediation: R package for causal mediation analysis. *Journal of Statistical Software*, 59(5). <https://doi.org/10.18637/jss.v059.i05>
- Vallejo, M. A., Vallejo-Slocker, L., Fernández-Abascal, E. G., & Mañanes, G. (2018). Determining factors for stress perception assessed with the Perceived Stress Scale (PSS-4) in spanish and other european samples. *Frontiers in Psychology*, 9. <https://doi.org/10.3389/fpsyg.2018.00037>
- Weiner, B. J., Lewis, C. C., Stanick, C., Powell, B. J., Dorsey, C. N., Clary, A. S., Boynton, M. H., & Halko, H. (2017). Psychometric assessment of three newly developed implementation outcome measures. *Implementation Science*, 12(1), 108. <https://doi.org/10.1186/s13012-017-0635-3>
- Wolgast, M., Lundh, L.-G., & Viborg, G. (2013). Cognitive restructuring and acceptance: An empirically grounded conceptual analysis. *Cognitive Therapy and Research*, 37(2), 340–351. <https://doi.org/10.1007/s10608-012-9477-0>