

Study Protocol and Statistical Analysis Plan  
For Research Project:

“Cluster-randomized Controlled Trial Examining the Effectiveness of Mindfulness-Based Cognitive Therapy for Anxiety and Stress Reduction within College Students”

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**“Cluster-randomized Controlled Trial Examining the Effectiveness of Mindfulness-Based Cognitive Therapy for Anxiety and Stress Reduction within College Students”**

**Abstract:** The objective of this project is to understand the potential effectiveness of a 4 week Mindfulness-Based Cognitive Therapy intervention delivered using a smartphone application for reducing anxiety and stress within college students. Although in-person mindfulness-based cognitive therapy approaches have been found effective for reducing anxiety and stress; given the pervasiveness of anxiety and stress in this population, there is a need to provide alternative and accessible interventions to improve students' mental health. 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. Accordingly, using a cluster-randomized controlled design, this intervention will assess the extent to which 4-weeks of using the Sanvello application was effective for reducing anxiety and stress within college students.

**Aims:**

- 1) To provide an assessment of the efficacy of the Sanvello application for reducing trait-level anxiety.
- 2) To provide an assessment of the efficacy of the Sanvello application for reducing chronic perceptions of stress.

**Number of subjects:** 314 individuals enrolled in a predominately freshman level college course.

**Design:** Cluster-randomized positive control Phase 2 clinical trial.

**Interventional Study Model:** Parallel — Participants are assigned to one of two groups in parallel for the duration of the study.

**Study Population:** The sample consisted of individuals ages 17 to 42 (inclusive) years of age enrolled in a predominately freshman level college course in the mid-Michigan, USA area.

**Eligibility Criteria:**

*Criteria for inclusion:* All individuals enrolled in the course that agreed to participate were enrolled. No individual was turned down due to sex, race, or ethnicity.

*Exclusion criteria:* The following exclusion criteria exist for all participants:

- a. Lack of consent.
- b. Complete inattendance in the college course during the pretest assessment and intervention period.

**Recruitment:** All participants in the course completed either the intervention or control as a course activity. Students had the ability to opt out of their data being used for research purposes.

**Protocol:** This investigation was approved by the Michigan State University Human Research Protection Program.

*Pretest:* Following consenting/opting out of their data being used for research purposes, students completed a series of questionnaires. Each section of students was randomly assigned using a serial stratification approach to either the active experimental group or the control experimental group.

*Experimental arm.* The active experimental group received a mindfulness based cognitive therapy through the Sanvello 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 1) Watch, 2) Read, 3) Listen, 4) Plan, 5) Listen – Mindfulness practice.

*Positive Control arm.* The control experimental group received training on the utilization of mindfulness-based stress reduction breathing techniques. 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 cultivate a non-judgmental attitude when confronted with potential distractions and 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.

*Intervention.* Participants were instructed to practice mindfulness daily using their instructed approaches for a period of 4 weeks.

*Posttest:* At the end of the 4 week study period, participants completed the same measures as were completed at the start of the study.

**Primary Measures:**

*State-Trait Anxiety Inventory:* Trait anxiety was assessed using the trait component of the Spielberger State-Trait Inventory (STAI) (Spielberger et al., 1970). The questionnaire comprised twenty statements assessing how individuals "generally feel." Participants rate their responses to each question on a 4-point Likert scale, with 1 corresponding to "not at all" and 4 indicating "very much so." Positively oriented questions that do not indicate anxiety, such as "I feel calm," are reverse scored. The possible trait anxiety scores range from 20 to 80, with scores above 45 reflecting high trait anxiety levels (Kayikcioglu et al., 2017).

*Perceived Stress Scale:* 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.

**Aims Assessment:**

- 1) *To provide an assessment of the efficacy of the Sanvello application for reducing trait-level anxiety.*

This aim was satisfied by examining intervention (active vs positive control) by time (pretest vs posttest) interactions for the Trait component of the Spielberger State-Trait Inventory.

- 2) *To provide an assessment of the efficacy of the Sanvello application for reducing chronic perceptions of stress.*

This aim was satisfied by examining intervention (active vs positive control) by time (pretest vs posttest) interactions for the *Perceived Stress Scale*.

**Statistical Analysis Plan:**

Data will be analyzed using multi-level modeling as this approach is robust to unbalanced data (i.e., missing observations if any occur) and accounts for a number of sources of variability. Analyses will be conducted with  $\alpha = 0.05$  and Benjamini-Hochberg false discovery rate control = 0.05 for post-hoc decompositions. Dependent variables from each primary outcome will be separately assessed using a 2 (Intervention: active, positive control)  $\times$  2 (Time: pre-test, post-test) univariate multi-level model including the random intercept for Participant, Cluster, and Participant by factor interactions if appropriate.